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UNIVERSIDAD PERUANA
CAYETANO HEREDIA

ACCESS TO ESSENTIAL DIAGNOSTICS IN PERU

FIND Report

Final Report 2021

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ABBREVIATIONS

Abbreviation	Name in Spanish	Translation used
ADM	Dispositivos Médicos Activos	Active medical devices
ADEX	Asociación de exportadores	Association of Exporters
ANM	Autoridad Nacional de Productos farmacéuticos, insumos médicos y productos sanitarios	National Authority for Pharmaceutical Products, Medical Devices and Sanitary Products (DIGEMID)
ANS	Autoridad Nacional de Salud	National Health Authority - Ministry of Health of Peru
ADIFAN	Asociación de Industrias Farmacéuticas Nacionales	National Pharmaceutical Industries Association
ALAFAL	Asociación de Laboratorios Farmacéuticos Latinoamericanos	Association of Latin American Pharmaceutical Laboratories
ALFARPE	Asociación Nacional de Laboratorios Farmacéuticos	National Association of Pharmaceutical Laboratories
ANCAB	Asociación National de Cadenas de Boticas	National Association of Chains of Boticas
AIDESEP	Asociación Interétnica de Desarrollo de la Selva Peruana	Inter-Ethnic Association for the Development of the Peruvian Jungle
APESEG	Asociación Peruana de Empresas de Seguros	Peruvian Association of Insurance Companies
APEPS	Asociación Peruana de Entidades Prestadoras de Salud	Peruvian Association of Healthcare Providers
CNCC	Centro Nacional de Control de Calidad (del INS)	Center for Quality Control from the INS
CCL	Cámara de comercio de Lima	Lima Chamber of Commerce
CONFIEP	Confederación Nacional de Instituciones Empresariales Privadas	National Confederation of Private Business Institutions
CONOSCE	Sistema de Inteligencia de Negocios del OSCE	Business Intelligence System of the OSCE
COMSALUD	Comité o rama de Salud de la CCL (CCL)	Healthcare committee/branch of the Lima Chamber of Commerce (CCL)
CUBSO	Catálogo Único de Bienes, Servicios y Obras del SEACE	Unique Catalogue of Goods, Services and Works of the SEACE
DGA	Dirección General de Abastecimiento	General Directorate of Supply
DGIESP	Dirección General de Intervenciones Estratégicas en Salud	General Directorate of Strategic Health Interventions
DGOS	Dirección General de Operaciones en Salud	General Directorate of Health Operations
DIGEMID	Dirección General de Medicamentos, Insumos y Drogas	General Directorate of Medications, Supplies and Drugs
DIRESA/GERESA	Dirección Regional de Salud/Gerencia Regional de Salud	Regional Directorate of Health
DIRIS	Dirección de redes integradas de salud (en Lima)	Directorate of Integrated Networks of Health (Lima), equivalent to the DIRESAS for the regions
EDL	Listado de pruebas diagnósticas esenciales	Essential diagnostics list
EPS	Empresas Prestadoras de Salud	Health providing companies
EPP	Equipos de Protección Personal	Personal protective equipment
ESN	Estrategias Sanitarias Nacionales	National Health Strategies
EsSalud	Seguro Social de Salud del Perú	Social Security System
FFAA	Fuerzas armadas	Armed forces
FOSMAR FOSFAP FOSPEME SaludPol	Fondos de aseguramiento de la marina, fuerzas armadas, ejército y policía respectivamente	Insurance funds for the navy, air force, army, and police force, respectively

Abbreviation	Name in Spanish	Translation used
FP	Fuerzas Policiales	National Police
GDP	PBI-Producto Bruto Interno	Gross domestic product
GHTF	-	Global Harmonization Task Force
HIV	Virus de la inmunodeficiencia humana	Human immunodeficiency virus
HPV	Virus del papiloma humano	Human papillomavirus
IAFA	Institución Administradora de Fondos de Aseguramiento en Salud	Administrative Institution of Health Insurance Funds
IETSI	Instituto de Evaluación de Tecnologías en Salud e investigación	Institute for Health Technology and Research
IMDRF	-	International Medical Device Regulators Forum
INDECOPI	Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual	National Institute for the Defense of Competition and the Protection of Intellectual Property
INEI	Instituto Nacional de Estadística e Informática	National Institute of Statistics and Informatics
INS	Instituto Nacional de Salud	National Institute of Health
IPRESS	Institución Prestadora de Servicios de Salud	Institution Provider of Health Services
IVD	Pruebas de diagnóstico in vitro	In vitro diagnostic
LA	Latino América	Latin America
LMIC	Países de ingresos medios bajos	Low- and middle-income country
MEF	Ministerio de Economía y Finanzas	Ministry of Economy and Finances
MD	Dispositivos médicos	Medical devices
MINDEF	Ministerio de Defensa	Ministry of Defense
MININTER	Ministerio del Interior	Ministry of the Interior
MINSA	Ministerio de Salud	Ministry of Health
NCD	Enfermedades no transmisibles	Non-communicable disease
OECD	Organización para la Cooperación Económica y EL Desarrollo	Organization for Economic Cooperation and Development
OGA	Oficina General de Administración	General Office of Administration
OOP	Gasto de Bolsillo	Out-of-pocket expenditure
OSCE	Organismo Supervisor de las Contrataciones del Estado	Supervisory Agency for State Procurement
PAHO	Organización Panamericana de la salud	Pan American Health Organization
PEAS	Plan Esencial de Aseguramiento en Salud	Essential Health Insurance Plan
PNP	Policía Nacional	National Police
PNUDME	Petitorio Nacional Único de Dispositivos Médicos	National list of essential medical devices
PP	Productos farmacéuticos	Pharmaceutical products
RES	Recursos Estratégicos en Salud	Strategic Health Resources
RNP	Registro Nacional de Proveedores	National Registry of Suppliers
RUC	Registro Único de Contribuyente	Unique Taxpayer Registry
SDG	Objetivos de Desarrollo Sostenible	Sustainable Development Goal
SEACE	Sistema electrónico de contrataciones del estado	Electronic state contracting system
SIGA-MEF	Sistema Integrado de Gestión Administrativa	Integrated Administrative Management System
SISOL-SALUD	Sistema Metropolitano de la Solidaridad	Metropolitan System of Solidarity
SIS	Seguro Integral de Salud	Comprehensive health insurance

Abbreviation	Name in Spanish	Translation used
SOAT	Seguro Obligatorio de Accidentes de Tránsito	Compulsory Traffic Accident Insurance
SNA	Sistema Nacional de Abastecimiento	National Supply System
SP	Productos Sanitarios	Sanitary products
SUNAT	Superintendencia Nacional de Aduanas y de Administración Tributaria	National Superintendency of Customs and Tax Administration
SUSALUD	Superintendencia Nacional de Salud	National Health Superintendency
UNICEF	Fondo de las Naciones Unidas para la Infancia	United Nations International Children's Emergency Fund
UNFPA	Fondo de Población de las Naciones Unidas	United Nations Population Fund
UPCH	Universidad Peruana Cayetano Heredia	Peruvian University Cayetano Heredia
WHA	Asamblea Mundial de salud	World Health Assembly
WHO	Organización Mundial de la Salud	World Health Organization

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I

INTRODUCTION

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> **Access to good quality, affordable, and appropriate health products is indispensable to advance universal health coverage (UHC), address health emergencies, and promote healthier populations.**
>
> WHO, Medical Devices website[1]

Background

Medicine is rapidly evolving, and there is increased recognition for the importance of healthcare tools such as health products/health technologies, pharmaceuticals and medical devices as enablers of more effective medical interventions. While there have been major developments and improvements in access to pharmaceuticals in recent decades, similar advances in relation to medical devices, and especially in vitro diagnostics (IVD), have lagged, with access to these products in low- and middle-income countries (LMICs) representing a particular challenge.

The World Health Organization (WHO), in the sixtieth World Health Assembly (WHA) of 2007 and through the Resolution WHA60.29, defined the term "health technologies" as "*the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives*". This resolution urges member states to collect, verify, update and exchange information on health technologies (in particular medical devices), as an aid to their prioritization of needs and resources. This would also allow these countries to formulate appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement, and management of health technologies (in particular medical devices), in collaboration with personnel involved in health technology assessment and biomedical engineering.[2]

There are millions of different types of medical devices on the world market, which have been categorized into more than 7000 generic groups. The WHO defines a medical device as "*any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose*". In 2012, The Global Harmonization Task Force (GHTF), a voluntary group of representatives from the medical device regulatory authorities and the medical device industry, modified the definition of "medical device" and provided definitions for the terms "in vitro diagnostic (IVD) medical device", "accessory to a medical device" and "accessory to an IVD medical device". However, not all countries have adopted these definitions.[3]

The term "in vitro" means "in glass"; IVD tests are typically conducted in test tubes and similar equipment, as opposed to "in vivo" tests, which are conducted in a living organism. IVD tests may be performed in laboratories, healthcare facilities or even at home. The tests themselves can be performed using a variety of instruments ranging from small, handheld kits to complex laboratory instruments.

WHO recognizes the importance of IVD tests for the prevention, diagnosis and treatment of infectious and non-infectious diseases. In 2018, WHO committed to provide a model as a standardized reference of measurement, and to improve their diagnostic services for all countries, by producing the first Essential Diagnostic List (EDL).[4]

The first version of the EDL (2018) included 113 IVD tests, of which 58 were general laboratory tests, and 55 were specific to diseases of public health importance, both infectious and non-infectious.[5] The EDL is reviewed and updated each year by a panel of WHO experts. In early 2021, WHO published the third version of the EDL.[6] A total of 172 IVD tests are listed in this report, which can be classified into:

1. General IVD tests intended for routine care, detection, and diagnosis of a wide range of diseases.
2. IVD tests for the detection, diagnosis, and monitoring of specific diseases, including human immunodeficiency virus (HIV), tuberculosis (TB), malaria, hepatitis B and C, syphilis, and human papillomavirus (HPV).
3. IVD tests intended for the detection of specific diseases required to perform before a blood donation process.

Access to quality IVD tests forms a part of universal

health coverage, a fundamental pillar of renewed primary healthcare, supported by the United Nations Sustainable Development Goals (SDGs) that member countries have committed to achieving by 2030.[4,7,8] It is estimated that in LMICs, approximately 8 million people die annually due to conditions associated with problems in the healthcare system.[9] Improving the healthcare system in these countries implies ensuring universal access to a high-quality healthcare system, including access to essential medicines and diagnostics.

The use of syndromic management has often proven to be ineffective[4] when utilized in countries with limited resources. Healthcare decisions must be supported by diagnostic tests in at least 70% of cases. However, global data indicate that just 3 to 5% of healthcare budgets are allocated to diagnostic tests.[10] It is essential that LMICs increase the access to, coverage and quality of diagnostics in their healthcare systems. Countries such as India and regions such as sub-Saharan Africa have begun to develop national EDLs for the implementation of their diagnostic services; however, they report that the access to and quality of such diagnostic services remain low.[5]

In Peru, the healthcare system is fragmented, which makes universal healthcare and access to IVD tests even more difficult. This report allows us to get closer to understanding the ecosystem and the market for IVD tests in Peru, through analysis and comparisons of primary data and from the perspective and experience of key relevant actors.

Objectives and methodology

The main objective of this report was to characterize the healthcare ecosystem and the market for IVD tests in Peru. This was achieved through collection, consolidation, description and analysis of data obtained through a bibliographical revision and interviews with key actors.

In addition, the follow specific objectives were included:

1. Describe and analyse the regulatory framework/ laws on the access to IVD tests in Peru,
2. Conduct a market analysis of IVD tests available in Peru,
3. Gather market data, trend analysis and knowledge of IVD test acquisition, pricing, supply chain and market access mechanisms for new IVD tests in Peru.

The methodology used in this report was that of a mixed study (quantitative-qualitative), in which three phases were included.

Phase 1: Review of standards and available data regarding markets associated with IVD tests

An exhaustive review of primary sources was carried out, with the objective of understanding and documenting the regulatory pathways for approval of IVD tests in Peru and the selection process for IVD tests used or that could be used in Peru, from both normative and legislative perspectives. This was achieved by performing a detailed review of the norms, rules, directives, recommendations, legal and other pertinent frameworks that ensure the financing, acquisition, surveillance, control and distribution of essential IVD tests. Additionally, we had access to publicly available data relating to the purchasing process for IVD tests in Peru: budgets, investments, and market size. All of the information was collated and organized in a database, which has been included as part of the appendix.

Phase 2: In-depth interviews with key actors

A total of 21 interviews were conducted with key actors, via Zoom, which allowed us to explore factors related to the entire process of access to essential IVD tests in Peru. For these interviews, an interview guide was created as a result of the reviewed literature and in accordance with the thematic axes we planned to explore. The interviews lasted on average 40 minutes. There were 874 minutes of recordings from interviewees who permitted their interview to be recorded.

Key actors interviewed included stakeholders from the public and private sectors who have worked for at least one year in the processes and/or activities involved in accessing essential IVD tests. The following thematic axes were explored in relation to the context of access to essential IVD tests in Peru:(i) control and surveillance, (ii) selection, (iii) programming, (iv) acquisition, (v) storage, (vi) distribution, (vii) users, (viii) financing, and (ix) information systems.

Phase 3: Analysis

Based on the information collected in phases 1 and 2, we wrote this report about the IVD test ecosystem in Peru, including regulatory, procurement and market issues, as well as an analysis of the gaps and challenges in accessing IVD tests in Peru. Potential key stakeholders have been identified, and who will be presented with the Foundation for Innovative New Diagnostics (FIND) virtual marketplace.

This study was reviewed and approved by the ethics committee of the Universidad Peruana Cayetano Heredia (UPCH). All participants received an information sheet prior to providing verbal informed consent.

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II

THE PERUVIAN HEALTH SYSTEM

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Introduction

Peru is a Latin American middle-income country comprising approximately 33 million inhabitants.[11] It is highly centralized, politically, and economically, in its capital city, Lima, which accounts for around one third of the total population and 46% of the national gross domestic product (GDP).[12] Similarly to other Latin American countries, Peru is predominantly urban, with only around 20.7% of the population classified as living in rural areas.[13]

Decentralization has long been on the political agenda in Peru, but it was only in March 2001 that the congress approved a constitutional reform for decentralization, which granted regional governments political and administrative autonomy. This reform organized the country into regions, departments, provinces, and districts. Peru has 25 regions (including Lima), each with their own directorate of health (DIRESAS/GERESAS). In the case of the health sector, the transfer of responsibilities was only completed in 2010.

Throughout the past two decades, Peru has undergone a period of sustained economic growth along with improvements in the healthcare of the general population. Indeed, indicators such as child and neonatal mortality,[14] prevalence of anaemia, chronic malnutrition, maternal mortality, poverty, and extreme poverty have decreased. Other indicators have increased, such as the number of doctors per citizen, life expectancy, vaccine coverage, use of family planning, antenatal care coverage, and access to water and sewage systems.[15]

It is important to note, however, that socio-economic, regional, and ethnic inequalities in access to healthcare persist.[16,17] Chronic child malnutrition and iron-deficiency anaemia disproportionately affect the poorest and more rural populations, while the probability of attending a medical consultation is also related to an individual's level of income.[18] Additionally, non-communicable diseases (NCDs) are becoming increasingly relevant, being responsible for the greatest numbers of premature deaths and disabilities throughout the past decade.[19]

Due to the Odebrecht corruption scandals[20] in Latin America and the prosecution of former presidents and politicians, political turmoil has consistently undermined policy throughout the past five years. This instability in Peru is evidenced by four attempted presidential impeachments, one successful impeachment, one presidential resignation and a dissolution of congress. As a result, Peru has seen five different presidents (constitutional and unconstitutional) in 5 years, countless motions of censure against the executive branch, and 11 ministers of health during the same timeframe. In general, the tenure of a health minister is just a few months, slowing reforms and the development of important public policies.

Although the Peruvian health system shares a similar structure and characteristics with those of other Latin American countries, it possesses important nuances and unique specificities that should be highlighted to allow a more complete understanding.[21]

Structure of the Peruvian health system

The Peruvian health system is divided into sub-sectors: public and private. Each of these operates independently and autonomously, with its funding, and (theoretically) attends different segments of the population.[22] Providers, however, frequently work with both sectors, public and private. Each sub-sector and its corresponding institutions, centres and agencies manage different databases and information systems, leading to the complete atomization of information relating to the population's health. These information systems tend to be poorly managed, and vertical integration of information, when existent, is highly deficient. In other words, Peru has a fragmented health system, characterized by its segmentation and poor horizontal integration with regards to the definition of sectorial obligations, information and procuremnet systems, and the provision of healthcare services.[23]

The public sector comprises four sub-sectors: The Ministry of Health (MINSA) health establishments, the social security system (EsSalud) and the health establishments of the armed forces and the national police. The private sector is composed of a constellation of private health establishments and providers. The General Law on Healthcare (Law 26842)[24] states that the governing body and national authority responsible for the implementation and design of regulations and public policies in the health sector is the MINSA, with a jurisdiction spanning both private and public sectors and their corresponding sub-sectors. (Figure 2.1)

Figure 2.1: The Peruvian health system

	Public Sector			Private Sector
Institution	Ministry of Health (MINSA)	Ministry of Labor	Ministry of defense/ Homeland Ministry	Private networks & providers
Provider	Ministry of Health (MINSA) Regional Governments	ESSALUD	Health Facilities from Armed Forces	Private networks & providers
Health Facilities	Primary Health Care centers (PHC): 7874 Secondary/tertiary centers (H): 175	PHC: 220 H: 69	PHC: 134 H: 7	PHC*: 6533 H: 270
Financing	Direct Gov transfers, SIS, OOP	Compulsory contributions, OOP	Direct Gov, transfers, OOP	Private insurers, OOP
Insurer	Comprehensive Health Insurance (SIS)	ESSALUD	FOSMAR FOSFAP FOSPEME SALUDPOL	Private insurers
Users	Poor, uninsured, all	Formal workers and dependents	Armed forces, police and dependents	Population willing to pay
% Peruvian population affiliated	**61%**	**29%**	**2%**	**8%**

SIS, Comprehensive Health Insurance (SIS, Spanish acronym); OOP: out-of-pocket expenditure
* Includes medical offices with one health provider or different types of providers

MINSA and regional governments

Service delivery is divided across Peru according to the region. The MINSA oversees service delivery in the metropolitan area of Lima, while due to the decentralization laws, public hospitals and health facilities in the rest of the country are managed locally by each regional government. The government offers the MINSA's healthcare services to the general uninsured population via the Comprehensive Health Insurance scheme (Seguro Integral de Salud or SIS, the acronym in Spanish), which subsidizes the provision of health services and supplies for the poorest portion of the population. Financing for the SIS is derived from the national budget, controlled by the Ministry of Economy and Finances (MEF), and is debated and voted on each year in the legislature. However, the SIS represents only about 15% of the budget of the MINSA health establishments. The remaining budget for health facilities, supplies and human resources is funded by the MEF, through MINSA for Lima and through the regional governments for the rest of the country.

Despite being subject to broader MINSA regulations and programmes, regional governments have autonomy over their budget and allocate funds according to their individual priorities. Regional governments are still institutionally weak, with deficient management of budget and public spending, and local authorities that receive funding tend to be selected for political affinity and camaraderie rather than for their technical capacities. Consequently, governance at a local level tends to be poor and the health provision of regional and local services, suboptimal.

Since the decentralization and regionalization of public healthcare, the MINSA has been unable to adequately organize the distribution of medical supplies, especially outside of Lima. The regional health authorities lack the logistical capability to control the flow of supplies that are subsequently deposited in medical storehouses. The absence of automated alert systems to detect expiration dates and maintain adequate storage standards have resulted in the loss of important quantities of medical supplies. Each region has a regional public health laboratory but in general, outside of Lima, most of these laboratories have limited capabilities and are underfunded.

The urgent decree DU-017-2019 of 2019 declared the universality of health coverage, by automatically affiliating every citizen to the SIS regardless of their socio-economic status. This automatically enrolled more than 2.28 million Peruvians into the SIS. From the second trimester of 2019 to the third trimester of 2020, more than 3.55 million newly insured citizens were added to the SIS, resulting in a total of 20.9 million Peruvians insured with the SIS.[25] However, this extension of universal health coverage has not been accompanied by increases in funding or improvements in the management of the funds available for the SIS.

EsSalud, the armed forces, and the national police

The social security system known as EsSalud is an organization that is dependent on the Ministry of Labor, which provides healthcare services to workers in the formal labour market and their dependents through its own network of health centres and institutions. These health services are funded through a direct, contributory regime, which is based on the contributions from employers, independent formal workers and, complementarily, the state. Formal payroll workers are automatically enrolled in the social security system. Businesses are obligated to enrol their workers in EsSalud and pay social security on their behalf, which amounts to 9% of a worker's gross income.[26]

EsSalud's network of health centres and hospitals are not as widely distributed throughout the national territory as the MINSA network but tends to have better and more specialized equipment in tertiary hospitals. Most of EsSalud's network covers important urban centres and regional capitals, concentrating on secondary and tertiary levels of care. For example, 95% of patients who require dialysis and almost 100% of patients who receive heart, liver and bone marrow transplants are seen and treated by EsSalud, which focuses on patients with high-cost and chronic diseases.[27]

EsSalud functions independently from the MINSA, and coordination between the SIS network and EsSalud is limited. In the regions and remote localities, health centres tend to be under-utilized, under-equipped and understaffed, in both MINSA and EsSalud establishments. In localities where only one provider is present, individuals affiliated to the other system have no option other than paying out-of-pocket (OOP) to access their services.

Healthcare networks of the armed forces (FFAA) and national police (PNP) function independently of the other sub-sectors. The FFAA networks are dependent on the Ministry of Defense (MINDEF) and include additional sub-sectors and distinct providers for its three branches, the navy, air force and army. The PNP network is dependent on the Homeland Ministry (MININTER) and functions autonomously, with its own facilities and funding. Each of these institutions possesses its own insurers: FOSMAR for the navy, FOSFAP for the air force, FOSPEME for the army and SaludPol for the national police.

The facilities and insurers for the FFAA and the PNP only provide services and reimbursements to their members (members of the military and police) and their immediate relatives and to their workers. They have their own health establishments, hospitals, networks, and internal administrations, which conform to the broader national regulations but do not partake in programmes piloted from the MINSA. Despite functioning as independent health insurers, the armed forces, and national police IAFAs (Spanish acronym for Administrative Institution of Health Insurance Funds) do not control their own funding or budgets and depend on financing from the Public Treasury as well as co-payments from the direct relatives of the insured population.[22]

The private healthcare sector

The private healthcare sector comprises a plethora of private healthcare providing entities, private insurance companies, clinics, hospitals, and civil society organizations.[28] These are divided between lucrative and non-lucrative private services. The former includes private Healthcare Providing Companies (EPS), private insurance companies, private clinics (specialized and non-specialized), medical and polyclinical centres, private laboratories, and image-based diagnostic services. The latter, non-lucrative private sector is small in Peru and includes services provided by civil society institutions such as The Red Cross Peru, religious organizations, churches, local and international non-governmental organizations. These associations are usually financed by external co-operations or private and governmental donations and have a restricted area of influence.

The private healthcare sector is highly fragmented, as it comprises a constellation of atomized entities of varying sizes and responsibilities (from private individual health provider offices and individual diagnostic services to hospitals and private insurance networks). Vertical integration and coordination between different private entities and levels of care, where they exist, are minimal. The costs and quality of services are highly variable depending on the type of private establishment, the location of the facility (rich or poor area) and are entirely financed by OOP spending.[i] Although most users of private healthcare services tend to be uninsured by other types of public health insurance, users of other insurance plans may be referred or may decide to use private health facilities, in cases where specialized treatments and operations are required.

Employers and independent individuals can purchase private insurance by affiliating with private health companies that possess healthcare networks through linkages with other individual entities (hospitals, clinics, etc). Likewise, some hospitals and private clinics possess and offer their own insurance programmes.

In addition to public and private healthcare services, the Metropolitan System of Solidarity (SISOL-SALUD), a public–private service, offers primary healthcare services in the Lima Metropolitan Area through its "Solidarity Clinics". It has been relatively successful due to its specific nature that

[o] With the exception of EsSalud services outsourced to EPSs.

is better adapted to urban centres, presenting users with specialized doctors directly at the first level of healthcare.[29] It is characterized by a public–private model, in which health services are provided by private medical micro-businesses while the Municipality of Lima is responsible for its administration. Despite being a decentralized organ of the Municipality of Lima, its budget is self-funded through reduced fees. However, there have been complaints about the quality of the services and continuum of care provided by the SISOL-SALUD, and it is not overseen by the MINSA.

Peruvians and insurance coverage

According to the National Institute of Statistics and Informatics (INEI), in 2020, 76.7% of the population of Peru possessed at least one type of health insurance.[30] However, the National Health Superintendency (SUSALUD) counted 31.37 million affiliates to health insurance schemes representing a coverage of 96.2% of the population.[25] As established in the legislative decree No. 1158, health insurance schemes are provided by Administrative Institution of Health Insurance Funds (IAFAs), which can be public, private or a mixture of the two.

IAFAs include the SIS; EsSalud; FOSMAR, FOSFAP and FOSPEME (armed forces); SaludPol (national police); private Healthcare Providing Entities (EPS); private insurance companies; the Association of Regional and Provincial Funds against Traffic Accidents (AFOCAT); healthcare entities that offer pre-paid healthcare services; car insurance schemes; and health funds. In total, in the third trimester of 2020, 95 different IAFAs existed.

As shown in Table 2.1, according to SUSALUD (31), the majority of the Peruvian population (92%) is covered by a public health insurance scheme under the public health system. Most affiliates belong to the SIS (61%), with the second main insurer being the social security system (29%). Private health insurance systems and funds account for the remaining 8%.

Figure 2.1: The proportion of the Peruvian population affiliated to various health insurance schemes in 2020

IAFAs	Number of affiliates	%
SIS	20,925,019	61
EsSalud	9,830,937	29
EPS	846,519	2
FFAA and PNP	607,835	2
Car insurance and health funds	83,218	0
Pre-paid healthcare services	924,241	3
Insurance companies	1,031,463	3
Total	**34,249,232**	**100**

Levels of healthcare

Regardless of their public or private nature, each system and sub-sector operates separately through its own healthcare-providing institutions and centres (Institution Provider of Health Services, or its acronym in Spanish, IPRESS). Healthcare centres are organized into three categories (primary, secondary, and tertiary), each of which comprise complementary sub-categories. Primary healthcare encompasses the most generalized and basic health services, which cover most medical needs required by individuals throughout their lives.[32] Secondary healthcare refers to specialized medical services, while tertiary healthcare focuses on services that usually require specialized equipment, expertise and hospitalization.

In Peru, primary healthcare services tend to comprise health posts, health centres and medical offices, whereas secondary healthcare services include general and specialized hospitals and clinics. Tertiary services refer to more specialized hospitals and specialized institutes (see Figure 2.1). Peru has a National Registry of health providing institutions and centres; however, many services are not categorized, especially in the private sector.[31]

Primary healthcare services tend to be poorly funded despite being the largest category of healthcare service providers; they lack supplies and equipment and have underused human resources.[33] The healthcare networks are dysfunctional and coordination between different levels of the system is deficient. Due to the under-use of primary healthcare facilities, government funding is usually directed towards the secondary and tertiary levels of healthcare, exacerbating the initial problem and resulting in subpar financing for primary healthcare institutions, which inevitably affects the quality of healthcare delivered. As a result, the primary healthcare level has become a *"system which derives patients, (…) it should resolve 80% of cases, and only refer 20% [to other levels of care]"*.

According to the interviews we conducted, the COVID-19 pandemic may have a substantial impact on future policies. The Peruvian government has the opportunity to generate normative and structural changes, to allow more attention to be paid to healthcare provision and greater levels of health technology provision in the first level of healthcare (e.g. telemedicine). These types of establishments should be endowed with portable equipment and easy-access healthcare technologies.

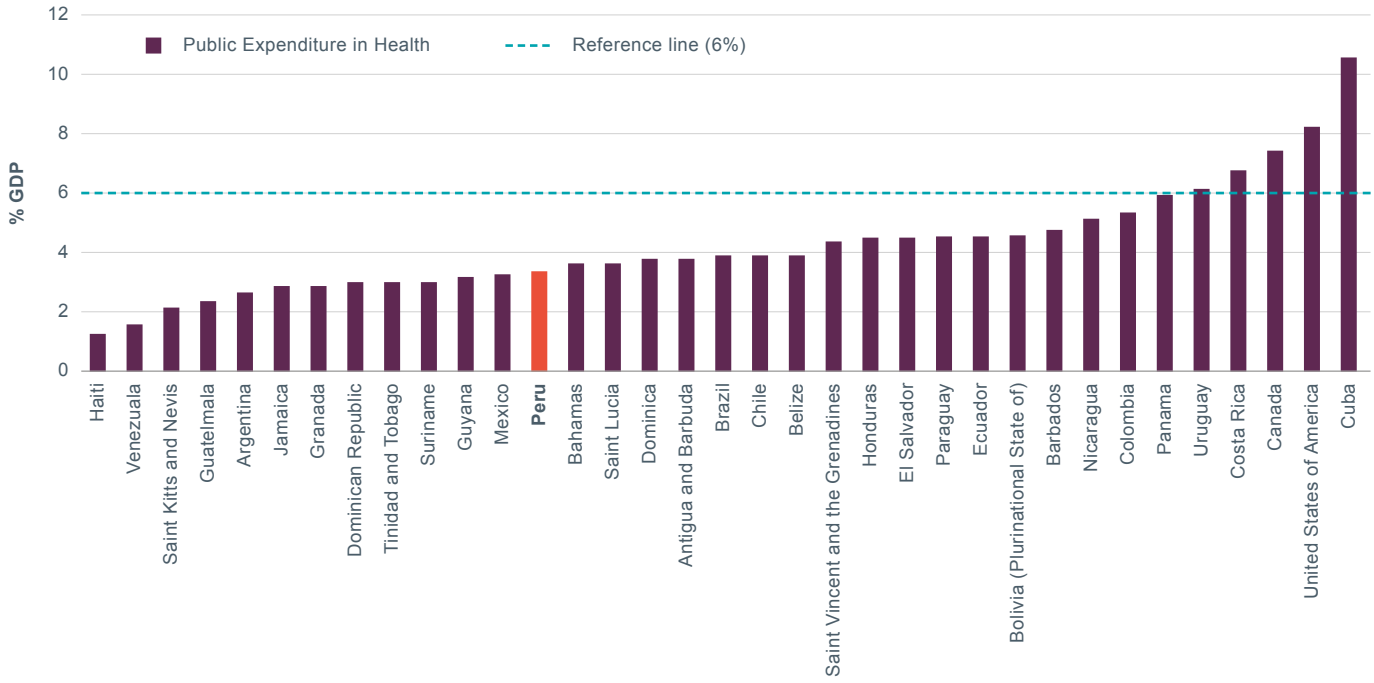
Interviewees have also signalled the importance of including pharmacies and "*boticas*" (drugstores not owned by pharmacists) to promote better public health, since most Peruvians seek healthcare advice and services in these types of establishments. Currently, these establishments are not allowed to sell IVD tests, except for pregnancy tests and glucose strips when medically indicated.

Financing

Despite an increase in public investment in healthcare throughout recent decades, Peru lags behind the rest of the Pan-American region, ranking 23rd out of 35 countries in terms of percentage of GDP spent on health. With public spending on health in Peru of approximately 3.5% of its GDP, this is less than the 6% Latin American regional average and considerably less than the Organization for Economic Cooperation and Development (OECD) average of 8.8%.[34]

Total health expenditure (including both private and public) represented around 5% of the GDP of Peru in 2017. (35) This mainly comes from three sources: government budget (31%), compulsory contributory health insurance schemes (31%) and private OOP expenditure (35%).[21] Levels of OOP as part of the total healthcare expenditure have remained high, at around 30 to 40%, throughout the past 20 years.[35] Despite steady decreases since 2008, OOP in Peru remains considerably higher than in other OECD and developed countries. This phenomenon is common to other Latin American countries, such as Mexico and Venezuela, where the accrued importance of informal healthcare provision and a lack of basic healthcare coverage for broad sections of the population result in considerable OOP expenditure.[21] In Peru, a large informal sector, which is not located in the lower quintile of income distribution, typically purchases healthcare services through OOP. Moreover, despite their higher costs and acute fragmentation, private health services remain in high demand, primarily due to the general opinion that their services are qualitatively superior to publicly provided healthcare, further increasing OOP expenditure.

Figure 2.2: Public expenditure on health in Latin American countries during 2017 (percentage of GDP)



Source: OPS (2017). Salud en las Américas+. Resumen: panorama regional y perfiles de país. Washington D.C

Conclusion

The Peruvian health system is fragmented into a myriad of different healthcare providers. The private and public sectors are divided into sub-sectors, each of which functions using a different network of providers, funders and information systems and targets different strata of the population. Despite the intention of transitioning to a system of universal health coverage and affiliating most citizens to the SIS, in practice, both financial and human resources have not been sufficiently increased to meet the increased demand associated with universal healthcare. Additionally, the fragmentation of governing authorities due to political instability and a lack of inter-operability further hinders the institutional consolidation of a universal healthcare system in Peru. Despite being the major provider of healthcare, the public sector's inefficiency and poor quality of service has driven large sections of the population towards OOP expenditure for health services. Additionaly, this situation is further exacerbated with a low level of public spending, normalized privatisation of health services and with the legality of medical oligopolies.

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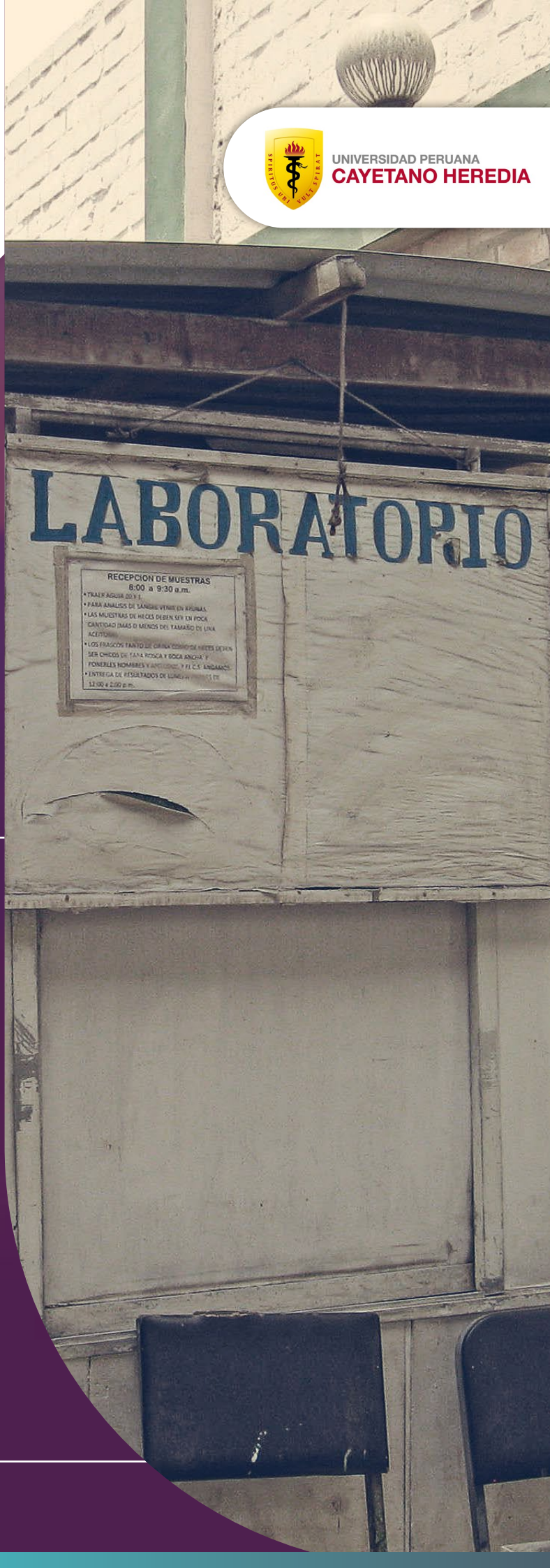


III

REGULATORY ISSUES RELATED TO MEDICAL DEVICES AND IN VITRO DIAGNOSTICS IN PERU

III

REGULATORY ISSUES RELATED TO MEDICAL DEVICES AND IN VITRO DIAGNOSTICS IN PERU

In April 1990, the Peruvian Ministry of Health created the General Directorate of Medications, Supplies and Drugs (DIGEMID) as the national technical body in charge of ensuring the rational use of and access to safe and effective quality medicines.[36,37]

DIGEMID is also known as the National Authority for Pharmaceutical Products, Medical Devices and Sanitary Products (ANM, acronym in Spanish). DIGEMID collaborates with other directions/institutions within the MINSA, other ministries and other public and private institutions to implement activities related to the regulation, authorization, registration, technical and scientific evaluation of medicines for human use, collectively referred to as pharmacovigilance. It has also evolved to be responsible for the registration and regulation of cosmetics and medical devices.

DIGEMID does not have its own laboratories to analyse the quality of products, be they medications, medical devices or IVDs. When necessary, products are sent to be analysed at the Centre for Quality Control (CNCC) of the Peruvian National Institute of Health (INS), which in turn subcontracts other private laboratories if they are unable to perform the required analyses.

In 1997, the General Health Law No. 26842 and its corresponding rule (Supreme Decree DS 010-97-SA) were instituted to regulate general medical devices. The Supreme Decree DS 010-97-SA makes no specific mention of IVDs, although *"reagents for clinical diagnosis"* were included under medical–surgical and dental supplies, as the category "M" (diagnostic agents).[38] The approval process for medical devices could take no more than seven days and was mainly based on complying with documentation, so it was largely unregulated.[39]

There was also an automatic free pass that allowed IVDs to be brought into the country if DIGEMID offices did not comply with the review and provide results within seven days. As a result, many IVDs of unknown quality entered the country. In July 2001, a Supreme Decree DS 020-2001-SA added an additional category, "Ñ", to the classification of devices, for *"others not included in the previous categories"*. It also added that *"diagnostic reagents had to include the specificity and sensitivity in the labelling when pertinent"*.

In November 2009, the Peruvian government approved the Law of Pharmaceutical Products, Medical Devices and Sanitary products Law No. 29459, replacing Chapter III of the General Health Law No. 26842. (24) This new law established the requirement to request the sanitary registration (*registro sanitario*) of pharmaceutical products necessary to guarantee their effectiveness, safety, and quality; it also included the timeframes necessary for such evaluation.

Law 29459 defines the principles, criteria and basic requirements for drugs, equipment, supplies, and other resources used in health facilities to provide health services; it includes three chapters specifically about the access and rational use of pharmaceutical products (PP), medical devices (MD) and sanitary products (SP), as well as a chapter focused on current research.[40] This law considered the entire lifecycle of devices: manufacturing, importation, storage, distribution, marketing, promotion, advertising, prescription, sale, use and destination. It also increased the administrative periods, fees, and technical and scientific documentation required for the registration and approval for the commercialization of medical devices in Peru. The rule was published in July 2011, as the Supreme Decree DS 016-2011-SA.[41] Although this new regulation improved the definition of the categories of products included, it did not have a specific chapter related to IVDs. The three categories of products included in the rule are:

a. ***Pharmaceutical products (PP):*** including drugs, preparations of known composition and chemical compounds used for the prevention, diagnosis, treatment or cure of a disease. These products are classified as: i) medicines, ii) herbal medicines, iii) diet products and sweeteners, iv) biological products and v) galenic products.

b. ***Sanitary products (SP):*** including cosmetic products, household hygiene products, absorbent personal hygiene products and items for baby-care. These products are used for, among other things, cleaning, caretaking, personal or domestic protection. They are classified as: i) cosmetic products, ii) sanitary articles and iii) household cleaning articles.

c. ***Medical devices (MD):*** including those *"… instruments, appliances, machines, in vitro reagents or calibrators, software applications, materials, or other similar articles, intended by the manufacturer to be used in humans or in combination for one or more of the following specific purposes:*

- *Diagnosis, prevention, monitoring, treatment, or alleviation of a disease.*
- *Diagnosis, prevention, monitoring, treatment, or compensation of an injury.*
- *Investigation, replacement, modification, or support of a person's anatomy or physiological process.*
- *Support or maintenance of life.*
- *Birth control.*
- *Disinfection of medical devices."*

Nonetheless, it was not until 2012 that a new regulatory document was published that modified some articles of the previous regulatory document.[41] This new regulation, the Supreme Decree DS 001-2012-SA,[42] among other changes, established in its First Transitory Complementary Provision article that IVDs remain governed by the provisions of the regulation approved by Supreme Decree DS 010-97-SA. (38) Therefore, the process of approval for IVDs reverted to the old regulations of 1997, which only required compliance with a few documents (see Box 3.1).

Box 3.1: Requirements to obtain sanitary registration for IVDs* in Peru, Supreme Decree DS 010-97-SA article 113

Present a document (simple affidavit declaration) that includes the following:

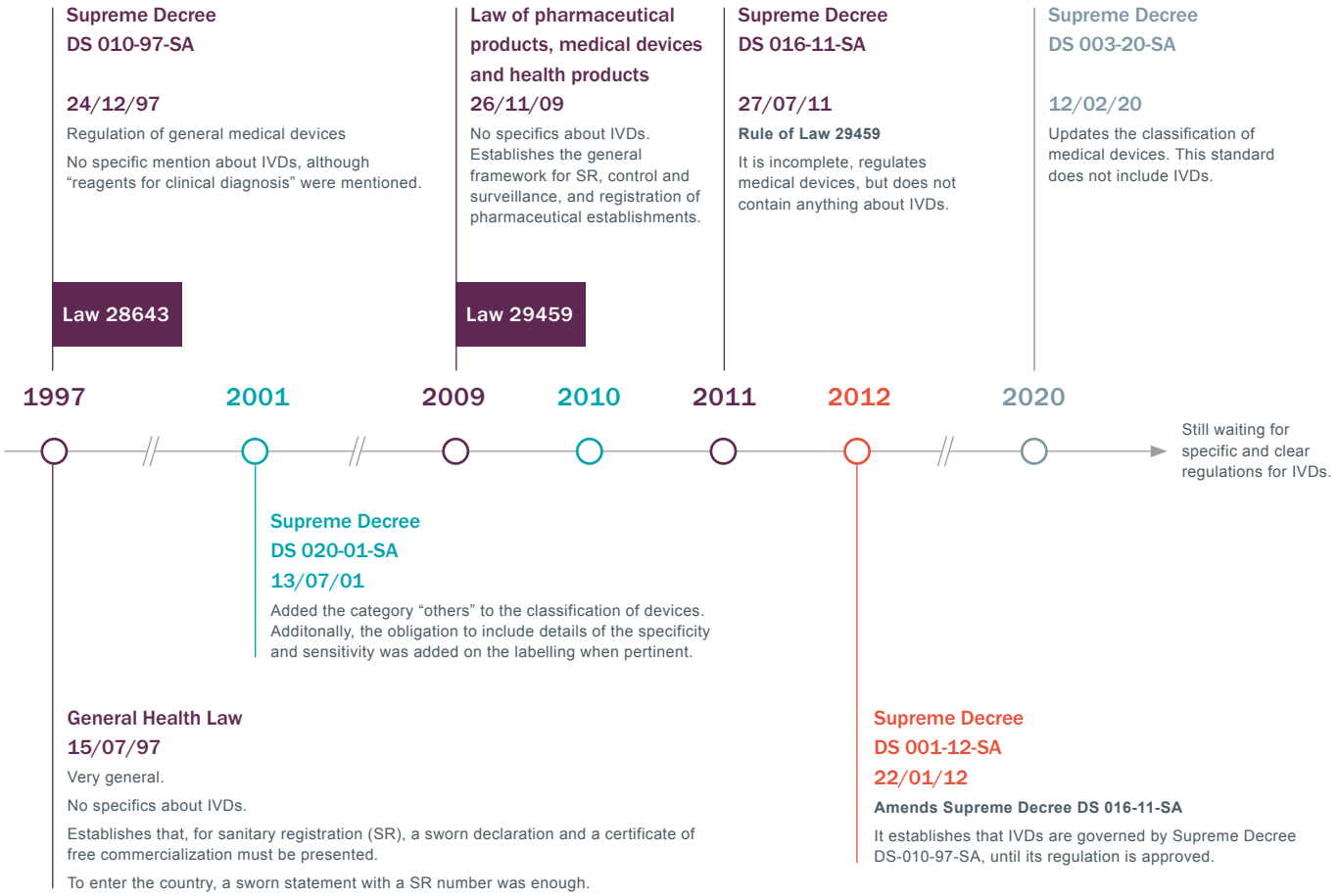
1. Reason for the request (requesting sanitary registration of an IVD)
2. Name of the IVD
3. Form of presentation
4. Type of packaging materials (mediate and immediate)
5. Name and country of the laboratory or manufacturer
6. Name, business name and address of the registrant
7. Analytic methodology (for supplies) and technical specifications for equipment
8. Formula and complete contents (for odontology supplies)
9. Package insert and/or instruction manual in Spanish

*The requirements are the same as for the sanitary registration of medicinal plants for traditional use (either for their therapeutic, diagnostic or preventive properties), as well as for homeopathic products and IVD tests.

However, reverting to the 1997 regulations was counterproductive, as they do not contain specific definitions or guidelines for IVDs or their components: reagents, calibrators, control materials, specimen receptacles, software, related instruments or apparatus and other articles that might be crucial for their use. A timeline summary of the regulations related to medical devices and IVDs is shown in Figure 3.1.

In practice, there is lack of clarity in the requirements for sanitary registrations and re-registrations of IVDs. Similarly, it is not possible to control their quality, safety and effectiveness on the national market, and, depending on the specific case (especially for kits or IVDs with readers), the evaluation or requirements often depend on the "evaluators". This situation has been going on for nearly 10 years and specific regulations for IVDs have still not been issued.

Figure 3.1: Timeline of regulations related to medical devices and IVDs in Peru



Definition of an IVD test according to DIGEMID

IVD tests have not been defined in any of the Peruvian regulatory documents. However, DIGEMID has published a definition on its website (box 3.2).[40]

Box 3.2: The DIGEMID definition of an IVD test (from their website)

IN VITRO MEDICAL DIAGNOSTIC DEVICE (IVD)

- Products intended by the manufacturer for the examination of samples derived from the human body, used alone or in combination for the in vitro examination of samples primarily to:
- Provide information on a physiological or pathological state or congenital anomaly.
- Monitor or determine the safety and compatibility with a potential receiver.
- Supervision of the therapeutic measures applied.

Classification of medical devices

The Supreme Decree DS 016-2011-SA classifies medical devices into four categories according to their level of risk for humans:

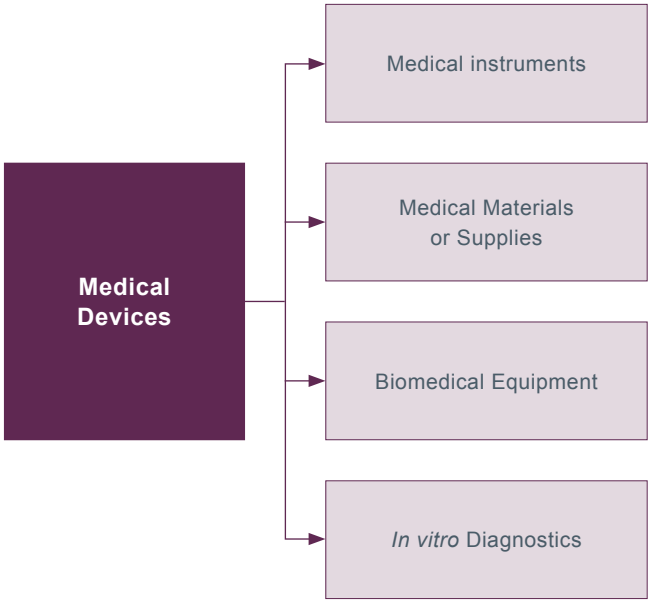
i) Low risk – Class I
ii) Moderate risk – Class II
iii) High risk – Class III
iv) Critical risk – Class IV

This classification was ratified in 2020 with the Supreme Decree DS 003-2020-SA,[43] as part of the Peruvian state's need to adopt rules and essential principles of security and performance, taking as a reference the current updated documents of the Global Harmonization Task Force (GHTF), as adopted by the International Medical Device Regulators Forum (IMDRF). It lists a device as an "active medical device" (AMD) when the device depends on an energy source, such as electricity. Medical software is included as an AMD. A further definition is that of AMDs for diagnostics (AMDDs): any AMD that is used for the screening, diagnosis or monitoring of disease. However,

there was no mention of IVDs in this Supreme Decree, thus the picture in relation to IVDs remains unclear, although according to the regulators, everything regarding IVDs is covered by the 1997 regulations.

In addition to the previously mentioned classification, DIGEMID has a further categorization for medical devices, which appears on their website.[40] This includes four categories: i) medical instruments, ii) medical materials or supplies, iii) biomedical equipment and iv) in vitro diagnostics (Fig 3.2).

Figure 3.2: DIGEMID classification of medical devices[40]



Pharmaceutical establishments

Peru's regulation, Supreme Decree DS-014-2011 (44), defines pharmaceutical establishments as those in charge of the manufacture, importation, exportation, storage, marketing, distribution, dispensing and/or sale of pharmaceutical products, health products or medical devices and classifies them as follows:

a) **Pharmaceutical offices:** Pharmacies or boticas (pharmacies not owned by pharmacists). These establishments dispense pharmaceutical products, medical devices (except biomedical equipment and controlled technology) and sanitary products to the final consumers. They operate under the responsibility and administration of a professional pharmaceutical chemist. They must possess a certificate of good pharmaceutical office practices, which includes compliance with good storage practices (BPA), good dispensing practices, good pharmacovigilance practices, and if applicable, good distribution and transportation practices (BPDT) and good pharmaco-therapeutic follow-up practices.

b) **Pharmacies belonging to health establishments:** These establishments provide services for the management and dispensing of pharmaceutical products and/or medical devices (except biomedical and controlled technology equipment). They also offer pharmaco-therapy and clinical pharmacy services. They must be certified in good practices for the dispensing, storage, distribution and transport, pharmacovigilance and, if applicable, pharmaco-therapeutic monitoring. They are under the technical direction of a professional pharmaceutical chemist, who is responsible for supervising and controlling the activities carried out by the pharmacy.

c) **Medicine cabinets (*botiquines*):** These establishments dispense pharmaceutical products, medical devices and sanitary products included on a restricted list approved by DIGEMID. They must be certified in good storage practices and other complementary standards. They are under the technical direction of a professional pharmaceutical chemist.

d) **Distributors (*droguerias o distribuidores*):** These establishments are dedicated to the import, export, marketing, storage, quality control and/or distribution of pharmaceutical products, medical devices and sanitary products, including IVD tests. They either possess their own or have outsourced warehouses. In the latter case, the outsourced warehouses must be certified in good storage practices. They are under the technical direction of a professional pharmaceutical chemist. Distributors must be a Peruvian business (or a Peruvian subsidiary of an international company that is registered as a Peruvian business).

e) **Specialized warehouses:** These are facilities for the storage and distribution of pharmaceutical products, medical devices (except biomedical and controlled technology equipment) and/or sanitary products. They must be certified in good storage and good distribution and transportation practices. They are under the technical direction of a professional pharmaceutical chemist.

f) **Laboratories (Medical devices/Pharmaceuticals):** These are facilities dedicated to the manufacturing, assembly, fractioning, conditioning, or reconditioning, quality control or export of pharmaceutical products, medical devices, and health products, as well as the importation of supplies for the manufacture of medical devices. They can also market their products to other health establishments. They must be certified in good manufacturing, good storage, good distribution and transportation, and good pharmacovigilance practices. They are under the technical direction of a professional pharmaceutical chemist.

Table 3.2 shows the prerequisites for obtaining a sanitary authorization for pharmaceutical establishments. Sanitary authorizations are provided by the DIGEMID in the case of laboratories and distributors (in the Lima Metropolitan Area), whereas regional health authorities provide authorizations to establishments outside of the Lima Metropolitan Area. These authorities issue the sanitary authorization or a rejection within 30 days of receiving the application.

Table 3.2: Requirements for laboratories and distributors to obtain sanitary authorization

#	Documents / Reports	Laboratory	Distributor
1	Affidavit authorization request with the following data: 1. Names and surnames or business name, address, Unique Taxpayer Registry (RUC). 2. Name of the legal representative. 3. Commercial name and address of the establishment, production and warehouse storage areas. 4. Name and registration of the Technical Director. 5. Names and registration numbers of the professionals in charge, including the heads of production, quality control and quality assurance areas that work in the establishment in the case of laboratories, or assistant pharmaceutical chemical professionals in the case of distributors (drugstores). 6. Hours of operation of the establishment and working hours of the professionals in charge or their assistants.	x	x
2	A map of the establishment's location.	x	x
3	A sketch showing the distribution of laboratory areas, indicating useful storage volume.	x	
4	Sketches of the internal distribution of the establishment and specialized warehouse, indicating the maximum useful storage volume for each area and the areas for products or devices that require special storage conditions, as appropriate.		x
5	Flow diagram of production processes, indicating quality control measures for each stage of the process.	x	
6	Sketch of critical support systems.	x	
7	List of critical equipment for production and quality control.	x	
8	Copy of the zoning licence.	x	
9	Copy of the third-party service contract, if applicable.	x	
10	Copies of certificates of professional qualifications of the technical director and other staff responsible for quality assurance, production and quality control areas, and pharmaceutical chemical professional's assistants in the case of distributors (drugstores).	x	x

Good practices required by DIGEMID for pharmaceutical establishments

Each of the following types of good practice requirements is directed towards pharmaceutical products, medical devices and sanitary products.

Good manufacturing practices (BPM)

Good manufacturing practices (BPMs) seek to guarantee the manufacturing of health supplies that are safe for use in the healthcare services provided to patients. BPMs are necessary for any type of health supplies, including IVDs. Through an administrative decree,[45] the ANM has regulated the procedure of BPM certification for laboratories dedicated to the fabrication of IVD tests at the national and international level. Laboratories and distributors must present files requesting the certification of BPMs directly or through a legal representative. If the laboratory is located outside of Peru, it must present its application through an authorized representative who resides in Peru. The certification for BPMs takes a maximum time-period of 90 days. The ANM accepts a BPM certificate, or its equivalent, issued by a competent authority in a country with a high level of sanitary surveillance. It also accepts certificates issued by competent authorities of other countries that have subscribed to mutual recognition conventions. A BPM certificate is valid for five years.

Good storage practices (BPA)

Good storage practices (BPAs) are required to guarantee the preservation of the properties and characteristics of an IVD test, through adequate storage and considering the particularities of each product. The requirements and operational procedures that are mandatory for establishments that manufacture, import, export, store, market or distribute IVD tests are regulated in a technical document.[46] A BPA certificate is valid for 3 years.

Good distribution and transportation practices (BPDT)

Good distribution and transportation practices (BPDTs) are required to regulate the distribution and transport of IVD tests and are regulated in a technical document approved by the Peruvian state.[47] This set of standards require that the distribution, handling, and transport of IVD tests be carried out under adequate conditions, in such a way that the properties and characteristics of IVD tests and medical devices in general are preserved.

A BPDT certificate is valid for 3 years. BPDT certification is mandatory for warehouses and drug stores that transport and distribute medical devices that require cold temperatures (refrigerated or frozen), nationwide.

Sanitary registration for pharmaceutical products, sanitary products, and medical devices

In Peru, pharmaceutical products, sanitary products, and medical devices (including IVD tests) must have a sanitary registration (registro sanitario), which allows manufacture, import, storage, distribution, commercialization, promotion, deployment and use of the products. As explained previously, in the section on regulations, medical devices are regulated through Law No. 29459 and follow various rules and Supreme Decrees (DS 016-2011-SA and modifications, including DS 003-2020-SA). IVD tests are regulated by Supreme Decree DS 010-97-SA. These regulations are still incomplete, causing confusion.

Health registrations are only granted to entities possessing sanitary authorization, such as laboratories or distributors, and are issued solely by DIGEMID. Sanitary registrations are temporary, having a validity of 5 years, with the possibility of renewal for another five-year period. DIGEMID can deny, suspend, modify, or cancel sanitary registrations whenever a diagnostic test is found to not comply with specifications and characteristics that it was accredited for during its registration.

Box 3.3: A description of the need for foreign laboratories or distributors to partner with local laboratories or distributors for the sanitary registration of products

The laboratories or distributors constituted in Peru or in a foreign country must follow the same procedures and present same documents for the inscription of a new diagnostic test within DIGEMID's national sanitary registration. However, in the case of foreign companies, these must partner with a local laboratory and/or distributor, which will follow the procedures required for a sanitary registration of the product. Another possibility would be the constitution of a local subsidiary in Peru, which could manage the registration of the diagnostic test.

DIGEMID has a "Directorate of Control and Surveillance"; one of the roles of this office is to supervise the post-registration quality of medical devices, and in theory could immobilize, suspend, or cancel sanitary registrations, depending on the severity of their findings reports could be used to improve future national purchases.

Prerequisites for the application or reapplication of the sanitary registration of medical devices

The process to apply for the sanitary registration of a medical device is summarized in Box 3.4. Table 3.3 shows the requirements for the application and reapplication of a sanitary registration, considering the level of risk of the medical device, as established by DS 016-2011-SA.

Box 3.4: Process for applying for sanitary registration of a medical device

1. Prepare a file with all the documents required for sanitary registration according to the risk level of the device (DS 016-2011-SA, see Table 3.4)
2. Upload the file to the Foreign Trade Single Window (VUCE) (www.vuce.gob.pe); an administrative fee is paid for this process.
3. The document review period varies according to the risk level of the medical device.
4. If there are any changes required, these must be corrected within 30 days. The usual changes include that a free sale certificate does not endorse the medical device or that there are inconsistencies based on the name of the medical device.
5. After corrections, the application is approved or denied.

From our interviews, it was noted that the "regular" time for this process to be conducted by DIGEMID takes from 2 to 3 months. However, interviewees also commented that the entry of a new medical device to the market could take 7 to 13 months through the private sector, 3 to 6 months through the EsSalud, and 6 to 18 months through the MINSA, for internal approval reasons.

In the case of IVD tests, in theory and according to the regulators, the prerequisites that should be included in an application are the specific product details and those established in DS 010-97-SA:

1. Application submitted as a sworn statement
2. Copy of the Certificate of Free Marketing or Certificate of Use
3. Copy of the BPM certificate or other document that certifies its compliance, issued by a competent authority (this usually comes in the Free Sale Certificates (CLV abbreviation in Spanish), or ISO 13485.

However, both for medical devices in general and IVD tests specifically, some interviewees mentioned situations that constitute constitute barriers to obtain the sanitary registration.

Interviewees expressed that DIGEMID should carry out procedures and processes more rapidly. The current procedures are time consuming and cumbersome because there are no specific regulations for the registration of IVD tests, meaning that many evaluations are somewhat subjective. The interviewees agreed that the main reason for these delays is the use of a regulatory system that is intended for pharmaceutical products and thus requires information and documentation that in many cases does not apply to medical devices and diagnostic equipment.

The interviewees also mentioned that some companies attempt to impede the market entry of their competitors when handling and blocking procedures in DIGEMID. Precautionary measures or judicial processes are presented between companies or directly towards DIGEMID, ordering DIGEMID not to register a certain product. However, any company that believes its patents are being violated can request INDECOPI to pronounce itself and inform DIGEMID, which can, in some cases, retract a registration. It is possible that a patent may have expired, but the company that held the previous patent has filed a new patent application for any other manufacturing process. Thus, a monopoly is generated, affecting the population's access to medical devices and specifically IVD tests.

The interviewees noted some improvements in DIGEMID. The regulatory and approval work for medical devices has been separated. The Functional Unit for Medical Devices has increased its staff to 40, of whom 12 evaluate the files received, while the remainder produce the final reports. The interviewees suggested that if a diagnostic test or medical device is approved in a country that has a high level of surveillance (such as the US or a country in Europe), then delays should be reduced. This also occurs in neighbouring countries, such as Chile and Colombia.

Table 3.3: Prerequisites for the application or reapplication for the sanitary registration of medical devices[41,42]

#	Documents / medical device classification (Class)	Class I Low risk	Class II Moderate risk	Class III High risk	Class IV Critical risk
1	Application with an Affidavit Authorization	x	x	x	x
2	Free marketing certificate issued by the competent authority in the country, or if applicable, letter from the manufacturer	x			
3	Free marketing certificate issued by the competent authority of the country or origin or exporter, or if applicable, letter from the manufacturer		x	x	x
4	BPM certificate issued by the national or foreign manufacturer, issued by the ANM or document that certifies compliance with quality standards specific to the type of medical device (for example: CE Certificate of the European Community, current ISO 13485 Standards, FDA or others)	x		x	x
5	Certificate or proof of compliance of the equipment with international quality standards issued by the competent authority or national or international accredited entity, defined as such by the ANM.		x		
6	Technical Report of the medical device, according to the article 130 of DS 016-2011-SALUD	x	x	x	x
7	Technical studies and analytical verifications	x	x	x	x

#	Documents / medical device classification (Class)	Class I Low risk	Class II Moderate risk	Class III High risk	Class IV Critical risk
8	Copy of validation reports of the sterilization or calibration process, in the case of sterile medical devices or with a measurement function	x	x	x	x
9	Disposal method, where applicable	x	x	x	x
10	Labeling project for urgent packaging and immediate packaging, as appropriate	x	x	x	x
11	Contents in the Manual instructions or insert in Spanish language. In the case of imported devices, it is required to present the documentation in the original language with a simple Spanish translation	x	x	x	x
12	Risk analysis Management Report, according to the specific ISO standard in force.		x	x	x
13	Technical information supporting the essential conditions of safety and efficacy of the medical device		x		
14	Quality parameters, according to current ISO and safety standards, established by the FDA or the European Community, or another internationally recognized document		x	x	x
15	Clinical trials demonstrating the safety and efficacy of the medical device			x	x
16	List of countries where the medical device is commercialized for imported products.			x	x
17	Submit a post-marketing surveillance program of the medical device by the manufacturer.			x	x
18	Certificate showing biological safety, in the case of devices manufactured fro tissues and their human or animal derivatives.				x

Deadlines for application or reapplication for medical device sanitary registration

Table 3.4 shows the deadlines established for the ANM to evaluate the application or reapplication for the registration of medical devices, which range from 60 to 120 days depending on the level of risk. However, from the interviews carried out, it was determined that these deadlines are rarely met, representing one of the difficulties and barriers that companies face when introducing new medical devices to the market.

Table 3.4: Deadlines for the application or reapplication for the registration of medical devices[41]

Medical device classification	Deadline for evaluation	Fee*
Low risk – Class I	Up to 60 days	S/. 1348.50 (362.99 USD)
Moderate risk – Class II	Up to 90 days	S/. 1558.50 (419.52 USD)
High risk – Class III	Up to 120 days	S/. 1811.10 (487.51 USD)
Critical risk – Class IV	Up to 120 days	S/. 2051.00 (552.09 USD)

*The fee varies each year according to the USD exchange rate and other considerations

Certificate of sanitary registration

DIGEMID also issues certificates of sanitary registration, which allows a distributor other than the owner of the registry to import IVD tests, assuming the same responsibilities and obligations as the owner. This certificate is issued within 15 days.

These certificates of sanitary registration were created to generate greater accessibility. Once a company has obtained a sanitary registration, any other importer can request the right to import the same product, for which they no longer must present sanitary registration requirements. They are only asked for a copy of the certificate of sanitary registration, which will allow them to import the same product, albeit subject to any changes that the holder of the sanitary registration makes.

According to the interviewees, to obtain this certificate one does not need permission from the holder if the original sanitary registration is valid. In other words, once the registration has been granted to one importer, other importers benefit from this and do not need to reapply. However, if the primary holder makes any changes to the product that has the sanitary registration, the other importers will need to do the same (for example, changes in the insert).

Special authorizations

Special authorizations and exemptions for IVD test usage also exist. In the following cases, DIGEMID has the faculty of provisionally authorizing the importation, fabrication and use of diagnostic tests without a sanitary registration, through the prior presentation of documents indicated in the Supreme Decrees DS 016-2011-SA and DS 016-2013-SA (48):

- Situations of urgency or declared emergency
- Exclusive research purposes
- Exclusive training purposes
- Prevention and individual treatment
- Public health situations in which the need and non-availability of the medical device in the national market is demonstrated.

Requirements for the import of medical devices

Once medical devices have been granted sanitary registration, if they are produced outside of the country, in addition to the sanitary registration, a series of authorizations are required for their importation and distribution. This process must be carried out by the owner of the registration and is regulated by Supreme Decree DS 016-2011-SA. The documents that are required are listed in Box 3.5.

Box 3.5: Requirements for the import of medical devices

- Copy of the resolution of the sanitary registration or certificate of sanitary registration of the medical device
- Identification of the shipment by manufacturing batch and medical device expiration date
- Copy of the medical device's certificate or protocol of batch analysis on entry
- Certificate or analysis protocol of the incoming batch, according to the type of medical device
- Copy of the current manufacturer's (BPM) certificate issued by the ANM*.

* If the medical device comes from a highly vigilant country, the BPM certificates issued by those countries will be accepted. A document that certifies compliance with good practices, specific to the type of device and according to the level of risk, issued by the competent authority of the country of origin is also acceptable.

Additionally, the interviewees mentioned that, as part of the import and distribution process, the customs department takes between 1 and 2 weeks to release cargo. Only after this can medical devices be removed from their warehouses, which can result in cost overruns. The interviewees also pointed out that these delays do not occur in neighbouring countries, such as Chile.

Comments from interviewees and conclusions

Currently, the regulatory system in Peru is impacted by the absence of specific regulations related to IVD tests and confusion between the regulations for medical devices and pharmaceutical products. Through the interviews, it has been found that although there are several regulatory documents, there is a lack of trust in relation to the objectivity of the regulatory process. Stakeholder confidence in governmental regulation and the regulatory entity is mixed. DIGEMID is acknowledged by all stakeholders as the sole national regulatory authority responsible for evaluating the quality of diagnostic devices through the sanitary registration approval process. However, the informants expressed concerns surrounding the subjectivity of the process due to a lack of technical, legal, and scientific expertise among evaluators, combined with the *"stringent adherence to the letter of the law which has several mis-definitions and gaps"*. Some stakeholders commented that the DIGEMID is unable to perform consistent evaluations of the same medical or diagnostic device, especially in the case of innovative technologies such as diagnostic kits. However, some IVD tests enter the country with very simple requirements and only require quality control evaluation once they are in Peru, but the process involved in such evaluation is not clear. They also stated that product approval depends on the specific DIGEMID evaluator involved and that the time taken for evaluations varied.

No clear signs of harmonization within the regulatory processes in Peru

We were given examples related to the lack of harmonization within the regulatory processes in Peru. Many companies use an international symbol signifying *"manufactured by"*, which is accepted in most countries. However, DIGEMID requires the use of the words "manufactured by" (*fabricado por*) for a product to be approved. Unfortunately, transnational companies that distribute to different regions may not find it profitable to make such a modification just for Peru, especially considering the relatively small quantities of IVD tests imported into the country. Also, although the regulations do not require results from regional studies, national data are sometimes requested for the evaluation files, even if there are sufficient data from other countries. These factors act as disincentives for companies wanting to introduce their products in the Peruvian market, as it impacts on market profits.

Lack of infrastructure,[ii] human capacity and investment hinders efficient regulatory processes

Law No. 29459 contains more stringent regulations for medical devices, but the lack of infrastructure and financial investment in the regulatory process in Peru impedes the evaluation of medical devices, particularly in terms of quality control. The regulations state that the first lot to be commercialized in Peru requires evaluation by the Peruvian National Institute of Health Center for Quality Control. However, without adequately trained technical staff and crucial infrastructure, such as serum banks, the Center for Quality Control is unable to evaluate IVD tests.

Inability to facilitate entry of innovative medical devices and unclear pathways for IVD tests

The complexities with medical devices and the inability to define IVD tests introduces multiple barriers for their commercialization, which increases the financial, human and time investments that both regulators and distributors must make. Beyond the already considerable barriers to entry in the market due to global competition[iii] and high start-up costs, the lack of specific IVD test regulations in Peru adds an additional level of uncertainty for both sides, especially for innovative devices. When companies are unsure of how to classify innovative medical devices or IVD tests, they may request a consultation with DIGEMID to evaluate their case during pre-market approval; however, such appointments may be delayed for several months.

Peru's 2009 Law of Pharmaceutical Products, Medical Devices, and Sanitary Products was intended to align Peruvian regulations with recommendations made by the GHTF. However, IVD tests were not included in this law, and they remain "regulated" by the 1997 Supreme Decree DS 010-97-SA,[38] which includes several inaccuracies and gaps that must be addressed to achieve an effective regulatory framework for IVD tests in Peru. This lack of specific recognition and requirements for IVD tests is an issue that requires close attention.

Ultimately, the approval of a law that increased regulatory requirements for medical device commercialization in Peru, but did not apply the concept of harmonization and lacked adequate adjustments of the institutions (e.g. human resources and infrastructure needed), has resulted in confusion for manufacturers as well as regulatory and public health agencies, thus not fulfilling the main goal of providing Peruvians with better quality medical devices.

[ii] The lack of DIGEMID infrastructure, such as premises and laboratories.
[iii] This refers to the fact that, being a small market, the Peruvian IVD test market is not attractive to foreign distributors and, due to the small quantities purchased, economies of scale are limited. Competition from countries with a larger market make it comparatively less profitable to enter the smaller Peruvian market.

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IV

THE DIAGNOSTICS SUPPLY CHAIN IN THE PUBLIC SECTOR

IV
THE DIAGNOSTICS SUPPLY CHAIN IN THE PUBLIC SECTOR

The public sector

The Peruvian state did not, until recently, have a national policy for the strategic supply of centralized purchases, with its inherent benefits including economies of scale, better maintenance, and evaluations of quality. Over many decades, each sector has established their own supply mechanisms, according to their individual needs.

The National Supply System

In 2018, the Peruvian state established the National Supply System (SNA) through legislative decree 1439 (49), which set out the principles, definitions, composition, standards, and procedures to ensure an effective and efficient public sector supply chain so that products could reach the final consumer.

The SNA comprises the following entities:

i) The General Directorate of Supply (DGA) in the Ministry of Economy and Finance. This is the governing body of the SNA and regulates the management of movable and unmovable goods. It is also obligated to implement the unique catalogue of goods and services. Additionally, it oversees the functions of the SNA: OSCE, Peru Compras and the organizations involved in the supply chain.

ii) The Supervisory Agency for State Procurement (OSCE): This body supervises conformity to standards for selection procedures for the state purchase of goods and services. It also manages the Electronic State Contracting System (SEACE), a platform used by state entities to register the different selection stages and procedures for the contracting of goods and services (www2.seace.gob.pe).

iii) If there are unsatisfactory processes on the platform, the OSCE can intervene to enforce the regulations. However, the interviewees mentioned that the OSCE no longer has the funding it once did, greatly limiting its capacity to intervene. Accordingly, the monitoring process is very slow and cumbersome.

iv) The Center of Public Purchases, "Perú Compras", began its functions in March 2016. It oversees the promotion, coordination and the standardization of product and service characteristics with the different ministries, through "homologation" (explained later) and the "list of common goods and services". It also has the mandate to consolidate the demand for certain products and perform purchases through corporate purchase mechanisms. It is also charged with creating, promoting, and maintaining electronic catalogues for national purchases of goods and supplies.

Electronic catalogue

The purpose of an electronic catalogue is to articulate the demand for and supply of a good or service. It functions through a web page accessible to registered users, in which goods and services and their prices can be seen. Only public sector employees can access this portal. Peru Compras has more than 30 electronic catalogues, mostly related to office supplies. Regarding diagnostics, only the rapid serological test for COVID-19 is in the catalogue.

How is an electronic catalogue generated?

Peru Compras is charged with determining which goods and services are included within the electronic catalogues. It uses the Kraljic matrix, which places goods and services in four quadrants, considering the level of expenditure and the "risk" in the supply chain. Goods that are ordinary and whose risk level in the supply market is medium to low, are candidates to be included in the catalogues. Additionally, if: i) the products are offered by many distributors, ii) the market share of the competing distributors is small or medium, and iii) the market and prices have matured, making the goods competitive, the products are more likely to be included in a catalogue. The analyses are carried out by Peru Compras, which estimates the demand for a product prior to its incorporation in a catalogue.

Who generates the technical sheets for the products? Who revises them? Who approves them?

Once it has identified and evaluated the products that are to be included in the catalogues, Peru Compras determines the characteristics and conditions of the goods and services, with respect to the requirements of the demanding entities and the supply present in the market. If deemed pertinent, Peru Compras can ask for the opinion of distributors, sectors, producers, guilds, and other supply-side agents. Peru Compras also revises and approves the technical sheets.

Who identifies the market actors and the products that comply with the required specificities and how are they contacted?

Once Peru Compras has identified the goods and services and has determined their characteristics and conditions, a public process of selection takes place, in which all the distributors dedicated to the sale of a particular good or service are invited. Through the selection process, information concerning the products, brands, prices, and distributors is obtained. This information is added to the electronic catalogue.

Which companies can be included in an electronic catalogue?

- For a company to be included in an electronic catalogue, it must comply with the following obligatory requirements:
- Must possess a Unique Taxpayer Registry (RUC)
- Must be currently registered in the National Registry of Suppliers (RNP) associated to the RUC
- Must not be included in the RNP list of distributors disqualified from being awarded state contracts
- Cannot be suspended from being awarded state contracts
- Cannot have an impediment to participate in the selection process

In the case of IVD tests (as in the case of the COVID-19 tests), the companies must possess a sanitary registration of the products offered in the catalogues. This is a condition that is included in the technical sheets.

How are the electronic catalogues used?

- The unit in each institution responsible for purchases selects a product that complies with their requirements.
- Once the desired product in the electronic catalogue has been identified, the distributor from which it will be purchase is selected.
- If the purchase is less than 100,000 soles ($28,470 USD), the buyer can choose from a list generated by Peru Compras.
- If the purchase is greater than 100,000 soles ($28,470 USD), the Peru Compras system uses an algorithm to automatically select the best distributor.
- Purchases through electronic catalogues function in similar way to e-commerce.
- A purchase takes 4 to 5 days to complete. The delivery of products happens according to the time stated by the distributors.

Box 4.1: Commentary from an interviewee regarding Peru Compras

> "Peru Compras is a new system in implementation. Unfortunately, it is not well known, and its functioning is unfamiliar. Many distributors do not enter their products to the electronic catalogs or show little interest. It is complicated and requires a lot of paperwork. For this reason, only a small number of distributors appear in the catalogs."

During the COVID-19 pandemic, the INS commissioned Peru Compras to include serological tests and personal protective equipment (PPE) in electronic catalogues. Table 4.1 outlines the health products that have been included in the electronic catalogues to date.

Table 4.1: Peru Compras Electronic Catalogues of Medical Devices (valid and undergoing implementation)[50]

Valid Electronic Catalogue	Undergoing implementation
In vitro diagnostic medical devices (only one item is found: the rapid serological COVID-19 IgG/IgM test)*	Disposable hospital clothing
Materials for healthcare protection	Plastic materials for laboratories
	Haematological tubes for laboratories
	Glass materials for laboratories
	Medical materials (e.g. face masks)

*In the Peru Compras electronic catalogue, the rapid tests available are:

- ABBOTT: ABBOTT RAPID DIAGNOSTICS JENA GmbH ICO-T402
- ECOTEST Assure Tech (Hangzhou) Co., Ltd. DM-DIV3400-E
- LABNOVATION: LABNOVATION TECHNOLOGIES, INC. LX-401201
- LECCURATE Beijing Lepu Medical Technology Co., Ltd. 0010
- LYHER HANGZHOU LAIHE BIOTECH CO., LTD COV-001
- ACON: ACON Biotech (Hangzhou) Co., Ltd L031-11711
- CELLEX: CELLEX BIOTECH (SUZHOU) CO., LTD WI5513C
- DIASOURCE: DIASOURCE INMUNOAASAY S.A. RAPU08COVID19
- SURE SCREEN Sure Screen Diagnostics Ltd. COVID19C

The details and characteristics of these tests can be found by clicking the following link: https://buscadorcatalogos.perucompras.gob.pe/

According to the interviewees, one of the problems with Peru Compras relates to its responsibilities. It is tasked with developing and approving technical sheets for the products and services that form part of the "list of common goods and services". It is additionally tasked with the revision and approval of technical sheets generated by other state entities. In the case of MINSA, Peru Compras has not been very proactive in including products such as medical devices (e.g. prostheses, catheters and diagnostic tests) within its "list of common goods and services" or its electronic catalogues, despite having been requested to do so.

The IVD test supply chain in the public sector

In 2018, the Ministry of Health approved the directive "Management of the Integrated System for the Public Supply of Pharmaceutical Products, Medical Devices and Sanitary Products – SISMED" (In Spanish: "Gestión del Sistema Integrado de Suministro Público de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios – SISMED").[51] This outlines six main steps involved in the supply chain of health supplies: i) selection, ii) programming, iii) acquisition, iv) storage, v) distribution and vi) use.

i) *Selection*

This is the process of defining the main official list (*Petitorio*) and complementary lists of pharmaceutical products and essential medical devices required for a specific period.

ii) *Programming*

The Law of State Contracting[52] and its Regulation[53] establish that the entities must elaborate a table of needs for goods and services (within which IVD tests are included) and identify the budgetary resources needed for their purchase. Once the annual budget has been approved, the entities formulate a management instrument named the "Yearly Contracting Plan",[54] containing the procedures for selection that the entities intend to carry out to achieve their purchasing requirements. This process takes place in the year prior to the execution of the planned annual budget. It is important to point out that the DGA, the governing body of the SNA, recently established that from 2022 onwards, the table of needs will be formulated for a minimum period of 3 years.[55]

The entities are obligated to publish and communicate their Yearly Contracting Plan through the electronic state contracting system (SEACE),[56] allowing potential distributors to be informed of the demand for IVD tests required by each entity during a fiscal year.[iv]

iii) *Acquisition (purchases)*

Acquisitions are covered by the Law of State Contracting and by standards issued by the DGA, OSCE and Peru Compras. It includes aspects such as the public tender process, simplified adjudication, electronic reverse auction, direct contracting, and purchases through electronic catalogues. Table 4.2 shows a comparison of the alternatives for acquisitions. It also shows the requirements, advantages, and disadvantages of each type of acquisition mechanism. Table 4.3 compares the different types of product sheets required for the acquisition of a good or service. More information concerning homologation sheets can be found in the section "additional information", at the end of this chapter.

[iv] The Yearly Contracting Plans can be found at: https://prodapp4.seace.gob.pe/pac3-publico/

Table 4.2: A comparison of the alternative approaches to buy any type of supplies in the public sector (including IVD tests)

Type	Price range	Term*	Requirements	Advantages	Disadvantages
According to National Rules of Procurement					
Public tender (Licitación Pública - LP)	> 109,590 USD	99 working days (corporate purchases can take up to 1 year)	Technical specifications including a description of the characteristics, quantity and conditions of tests.	• Techno vigilance by a local provider. • Importation, distribution, customs clearance, and payment of taxes is carried out by the distributor. • Power to sanction the supplier for non-compliance. • Buying of large volumes encourages competition and, in theory, better prices.	• Extensive delays to achieve contracts (may take more than 1 year). • Risk of high prices with respect to the international market. • Risk of speculation and presentation of measures that delay processes. • Risk of being deserted and having to start the process again.
Simplified adjudication (Adjudicación simplificada)	> 9,645 USD and < 109,590 USD	69 working days	Same technical specifications as for public tender. Also used in tests with homologation sheets, in which case there are no limits on the amounts.	• - Similar to public tender	• Risk of high prices with respect to the international market. • Risk of speculation and presentation of measures that delay processes. • Risk of being deserted and having to start the process again.
Reverse auction (Subasta Inversa)	> 9,645 USD	69 working days	Only for tests that have a technical sheet.	• Low prices due to competition and bids • Requires less time to be realized. • Suppliers cannot question technical data sheets, as they are already standardized. • Being electronic, they are more efficient and demand fewer resources from the state and the distributor and offer increased transparency. • Power to sanction the supplier for non-compliance.	• Risk that a single supplier appears and the auction is declared void. • Risk of suppliers from the same business group forming a cartel and speculating with the price and bids.
Direct contracting (Contratación directa)	> 9,645 USD	49 working days	Only in emergency situations or in shortage situations due to the existence of a unique supplier.	• Enables goods and services to be obtained quickly. • Power to sanction the supplier for non-compliance.	• In the absence of competition, there is a risk of high prices. • Subject to review and reports by the control bodies. • There is a higher risk of corruption or complaints of corruption.

Type	Price range	Term*	Requirements	Advantages	Disadvantages
Electronic catalogue (Catalogo electrónico)	There is no minimum or maximum	15 working days	Only for tests included in electronic catalogues.	• In theory, should be a faster process, however, there is a wide variation in prices and commercial conditions offered by distributors. • Being electronic, they are more efficient and demand fewer resources from the state and the distributor, increased transparency. • Possibility of making several purchases, according to the availability of resources, without breaking rules.	• Some conditions, such as delivery time, are established by the supplier. • Suppliers offer products, but do not specify their available stock. • Suppliers do not accept orders placed by the entity.
Agreement with International Cooperation agencies[v]					
PAHO	There is no minimum or maximum	88 working days	Any diagnostic test, as long as the conditions are more advantageous than those identified in the national market.	• Access to diagnostic tests prequalified by WHO or countries with a high level of surveillance. • Access to low prices obtained by cooperating organizations through aggregation of regional demand. • There are no delays due to questioning of suppliers, as there are medium- and long-term agreements with cooperating organizations.	• Delay in obtaining prices from the cooperating body • Techno vigilance by CENARES. • Hiring must be carried out 6 to 12 months in advance. • Difficulty of coordination with the manufacturer as the acquisition is made through a cooperating agency. • Quality control by CENARES. • Weak capacity to sanction a supplier for non-compliance.
UNICEF	There is no minimum or maximum	88 working days			
UNFPA	There is no minimum or maximum	88 working days			
Non-domiciled suppliers[vi]					
Non-domiciled distributors	> 9,645 USD	44 working days	Any diagnostic test, as long as the conditions are more advantageous than those identified in the national market.	• Access to low prices as products are acquired directly from the manufacturer. • Access to products certified by the US Food and Drug Administration or the European Medicines Agency, which do not have a presence in the local market. • Ease of coordination with the supplier. • Power to sanction the supplier for non-compliance.	• Techno vigilance by CENARES. • Hiring must be carried out 6 to 12 months in advance. • Quality control by CENARES.

*Days that demand hiring, including activities from the requirement to the formalization of the contract. Deadlines are estimated, they may increase according to the number of items, following supplier complaints and by errors in the process that require going back to a previous stage. It can also decrease if the entities manage to complete the preparatory work in less time, there are no errors in the basic or technical specifications, and if the supplier does not present a challenging appeal to question the rules of the process and evaluation of offers.

[v] More details at the end of the chapter: Procurement through agreements with international cooperation agencies
[vi] More details at the end of the chapter: Procurement through non-domiciled suppliers

Table 4.3: Comparison between the different "sheets or specification forms" for acquisitions

Name of the sheet	Who elaborates and who approves it?	Entities or bodies involved	Lists or catalogues in which they are grouped	Type of acquisition mechanism
Technical Sheet (*Ficha Técnica*)	Perú Compras elaborates and approves the sheet.	Perú Compras can request information from sectors, technical entities and distributors.	List of Common Goods and Services	Electronic reverse auction
Homologation Sheet (*Ficha de homologación*)	Ministries elaborate and approve the files, after receiving the green light from Peru Compras.	Requires the participation of experts, distributors, industry, and/or unions and technical entities.	List of Homologated Goods and Services	Simplified adjudication
Product Sheet (*Ficha del producto*)	Perú Compras implements the catalogue, describes the characteristics and conditions of the good or service, allowing distributors to offer their products.	Peru Compras evaluates the characteristics of historical purchases and can request information on sectors, technical entities and distributors.	Framework Agreement and/or Electronic Catalogue	Electronic catalogue
Technical Specifications (*Especificaciones técnicas*)	Elaborated and approved by the entity that requires the product or through their user or technical areas.	User areas and internal technical areas of the entity that requires the good.	---	Public tender*, simplified adjudication** for purchases of < 9,645 USD

* For goods that do not have an approval form, with purchase value > 109,590 USD
** For goods that do not have an approval form, with a purchase value > 9,645 USD and < 109,590 USD.

iv) *Storage*

The public sector possesses warehouses that belong to CENARES, tertiary level health establishments (hospitals and institutes), DIRIS, DIRESAS/GERESAS, EsSalud, FFAA, PNP and the regional governments. Each of these organizations is obligated to hold a BPA certification. The entities can outsource their storage services, which must also have a BPA certificate. However, a report from the MINSA mentions that in 2018, out of 253 active warehouses, only the CENARES warehouses complied with the certification of good storage practices.

The movements of stock and inventory generated from the entry and exit of products from these warehouses are registered in the information system established by the SNA, the Integrated Administrative Management System (*Sistema Integrado de Gestión Administrativa, SIGA-MEF*).[57] However, this information system does not allow for the registration of distributed and consumed products, including accessible stocks, each institution must rely on additional methods or applications to track their supplies. EsSalud does not use SIGA-MEF, it uses another system called SAP.

v) *Distribution*

IVD tests are distributed from the warehouses to hospitals, institutes, or specialized warehouses of the DIRIS, DIRESAS, GERESAS, EsSalud, FFAA or PNP. This distribution depends on the location, with transportation via land, air, or water. The distribution of IVD tests can be outsourced or carried out using personal vehicle units. In both cases, these must comply with Good Distribution and Transportation Practices certification (BPDT).

Distribution is often carried out by a contractor supplier specialized in the transportation of pharmaceutical products and medical devices, who receives the products from the warehouse of origin then transfers them to the destination warehouse, on average within 2 to 3 days. Once the products have been delivered to the carrier, the origin and destination warehouses do not know exactly where

their products are located, as there is no tracing system. Information about the products to be distributed from the warehouse of origin (including product, brand, batch, expiration date, sanitary registration, unit price, quantity) is usually recorded manually in a paper-based registration system at the warehouse of destination. This happens in the same way at each level of the supply chain until reaching the health establishment that finally delivers the product to the service and/or patient for use. This means that the entities in charge of carrying out the follow-up, monitoring and supervision of these products have no information on the existing quantities in warehouses and health establishments, cannot identify in a timely manner those products that are about to expire so they can be redistributed, and cannot identify product losses. This lack of an information system and tools that allow the systematization and automation of the identification and geolocation of products means there is no traceability of products (either pharmaceuticals or medical devices, including IVD tests) and generates inefficiency throughout all stages of the distribution process.

Supply chain for strategic IVD tests (centralized purchases)

In the IVD test supply chain, diagnostic tests can be classified as either "strategic" or "non-strategic" IVD tests. Strategic IVD tests are those that are selected and prioritized by the National Health Strategies (ESN) and whose budget and acquisition process is overseen by CENARES. It was only in 2019, through the Urgent Decree 007-2019,[58] that the definition of strategic health resources (RES) was formalized (although it had been in use for almost a decade), and the entire supply chain was entrusted to CENARES. RES comprises pharmaceutical products, medical devices, and sanitary products that MINSA recognizes as essential in the corresponding national list, elaborated to conform with Law No. 29459 and its complementary lists approved by ministerial resolutions.

CENARES oversees formulating, implementing, and supervising the procedures, guidelines and normative documents concerning the sectoral supply of RES. It also prepares the technical specifications for products to be purchased, the list of diagnostic tests (List of RES) and proposes and negotiates the development and approval of homologation sheets (see the end of the chapter for the homologation sheet). It is important to mention that in 2019, the Peruvian state established that the programming of RES should be conducted and coordinated by CENARES, with help from participating entities such as the health establishments from the MINSA, EsSalud, Ministry of Defense, Ministry of Interior, the National Penitentiary Institute, and the regional governments. CENARES approved the RES programming guidelines through which the provisions and procedures involved in the said processes are established.[59]

ESN are technical groups that propose policies, standards, guidelines, and strategic interventions in public health in their areas of competence. Table 4.4 shows the ESN active in 2021 in MINSA. All the ESN answer to the DGIESP of the MINSA.

Table 4.4: National Health Strategies (ESN) of the MINSA (active during 2021)

Immunization	Prevention and Control of Disabilities
Sexual and Reproductive Health	Health Promotion
Prevention and Control of Cancer	Prevention and Control of Tuberculosis
Prevention and Control of Metaxenic and Zoonotic diseases	Prevention and Control of Non-Transmissible and Rare Diseases
Interventions and Comprehensive Care by Life Course	Prevention and Control of HIV-AIDS, STIs and Hepatitis
Oral Health	

Through its ESN, DGIESP prioritizes the diagnostic tests it requires for its public health interventions and establishes its coverage objectives. On this basis, the health institutions consolidate their requirements through CENARES, which oversees the acquisition, storage, and distribution of IVD tests.

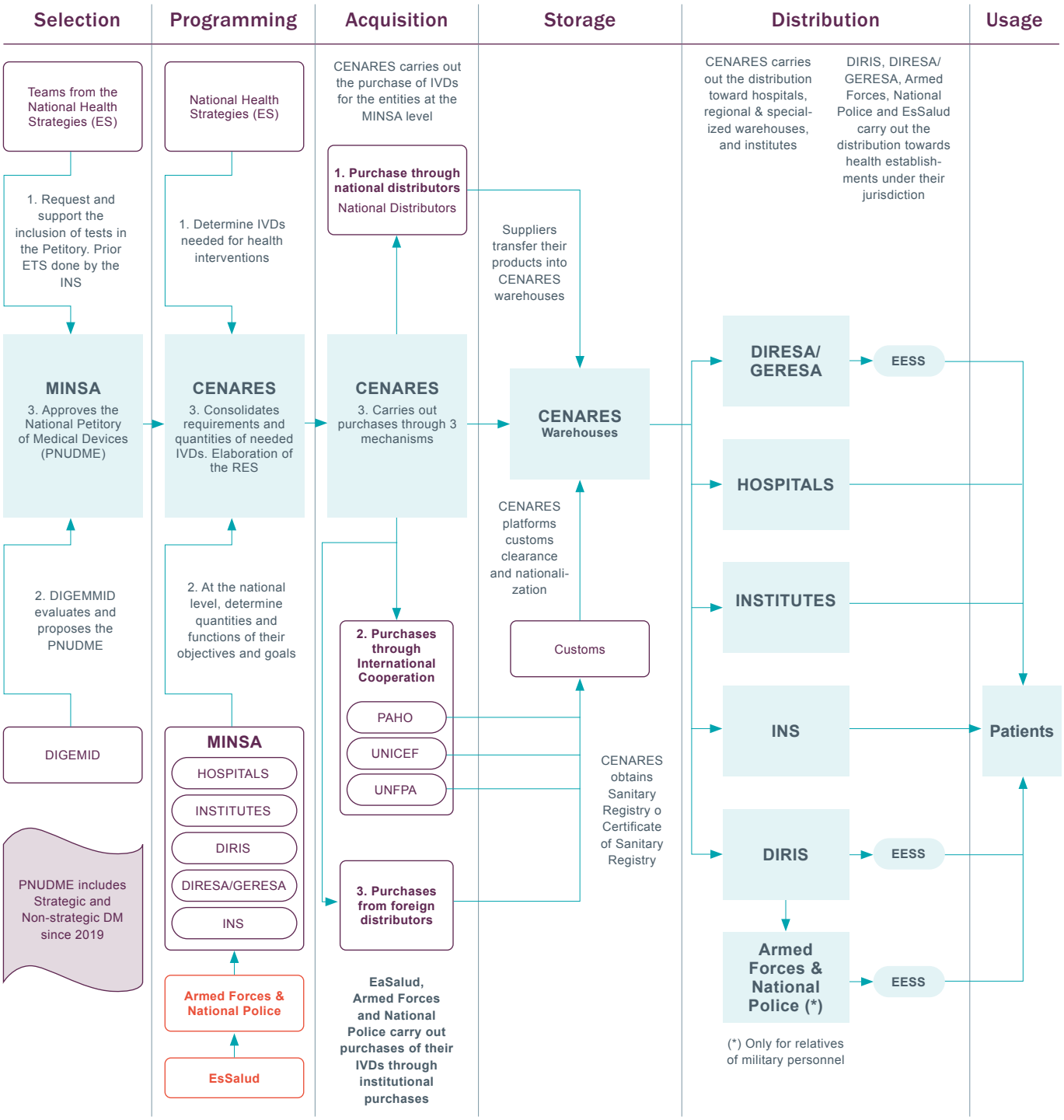
CENARES can acquire tests through (1) national purchases (national providers), (2) international purchases (non-domiciled providers) and (3) international cooperation agencies (such as PAHO, UNICEF, UNFPA, etc). For acquisition routes 2) and 3), CENARES acts as the local distributor, obtaining the sanitary registration, customs clearance and distributing the product. The main acquisition mechanism used by CENARES is reverse auction. However, this mechanism has not been used for IVD tests as there are no technical sheets for them. Currently, technical sheets only exist for medicines and some medical devices.

The supply chain for strategic IVDs is shown in Figure 4.2. The selection process is performed every 2 years and can take up to 1 year. The process of programming begins in the year prior to the purchases and takes around 1 year. The acquisitions/purchases can take between 4 months to 1 year.

Products are stored in warehouses and can be distributed

at various frequencies, for example monthly or every 3 months. CENARES distributes products every 3 months. The quantities required are confirmed by hospitals, institutes, DIRIS, DIRESA/GERESA, FFAA and PNP, who are then charged with distributing products to each health establishment at a frequency that is dependent on the available transportation. Products tend to be stored in warehouses for around 5 to 6 months prior to their distribution, hence the requirement for expiration dates of 12 to 18 months.

Figure 4.1: Supply chain for strategic IVD tests



PNUDME: Peruvian National list of essential medical devices (Petitorio Nacional Único de Dispositivos Médicos Esenciales para el sector salud); ETS: Health Technology Assessment; RES: List of Strategic Health Resources (Listado de Recursos Estratégicos en Salud).

Peruvian national list of essential medical devices (PNUDME) and the supply chain

The PNUDME is a technical document proposed by DIGEMID and approved by the MINSA. It comprises a list of prioritized essential medical devices, including IVD tests, to be used for the prevention, diagnosis, treatment, and control of diseases. This is the equivalent of the EDL in Peru. The first PNUDME was only recently approved, in 2019, by the ministerial resolution 670-2019-MINSA;[60] it contains 119 medical devices, of which only 20 are IVD tests. The list details the common names of the tests, their usage according to the healthcare level, and accompanied with a general description of the medical device. The PNUDME recommendations should be reviewed every 2 years.

The way in which the PNUDME is generated and how it functions is described in the administrative resolution *"Directiva Administrativa 249-MINSA/2018/DIGEMID Gestión del Sistema Integrado de Suministro Público de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios—SISMED"*, approved by the Ministerial Resolution (RM)116-2018-MINSA[51] and the document *"Guía de elaboración del PNUDME para el sector salud"*.[61]

As part of the process, DIGEMID summoned the national public health establishments to propose medical devices that should be included, through the Heads of Pharmacy or technical coordinators of the respective Health Strategies. The Heads of Pharmacy of the health establishments revised, evaluated and, where relevant, forwarded the applications for the incorporation of medical devices to DIGEMID. These requests had to be accompanied by supporting technical documents.

During the process of creating the PNUDME,[61] the following specific considerations were established for the inclusion of medical devices:

1. The need for these medical devices, considering the facility's service portfolio and morbidity and mortality profiles.
2. Proven effectiveness and safety.
3. Comparative evaluation that identifies and determines the benefit of opting for a specific medical device versus the cost of the available alternatives for each need.
4. Non-inclusion of medical devices that incorporate an active pharmaceutical ingredient.
5. Use of the generic version of the product.
6. The availability in the national market and convenience of use, among other considerations.

The PNUDME does not include biomedical equipment or medical instruments; it essentially includes strategic IVD tests (proposed by the ES) and non-strategic IVD tests. In theory, since July 2019, medical devices that are not found in the PNUDME require a sanitary technological evaluation (ETS) prior to their acquisition, dispensation, or use. This must be requested by the pharmaco-therapeutical committee of the corresponding DIRIS, DIRESA, GERESA, hospital or institute. This evaluation must be performed by the Center for Technology Assessment of the National Institute of Health of Peru (CETS). However, according to the interviewees, to date, the INS only carries out evaluations of high-cost medicines, and no evaluations of IVD tests has been performed. If an IVD is required at a health establishment, it could be bought by the establishment and reimbursed by SIS if it is listed in the PNUDME. If an institution purchases a test that is not in the PNUDME, it does not receive any reimbursement.

Prior to the creation of the PNUDME, national health establishments and health strategies independently determined the medical devices and IVD tests they needed to purchase and CENARES would consolidate these requirements. Nowadays, independently of the PNUDME, CENARES, as part of its acquisition process, has created a list called the "*Listado RES*". This includes some products listed in the PNUDME, as well as others that are not found in the PNUDME, and that are required by ESN, hospitals, or other entities. The problem is that if these products are not found within the PNUDME, a process of evaluation and approval must be carried out to include the products within an RES, which results in additional delays. Unfortunately, the PNUDME is incomplete, especially for IVD tests. The interviewees commented that this could be improved in time, but that the PNUDME currently complicates the supply chain processes rather than facilitating them, due to its incompleteness. Table 4.5 shows a comparison between the PNUDME, the RES and the third version of the WHO EDL.

Table 4.5: Comparison of the WHO EDL, PNUDME, and IVD tests prioritized for the 2019 and 2020 CENARES RES

Discipline	EDL v3 - WHO	PNUDME (RM 670-2019) – MINSA (20 items in total as IVD tests)	CENARES 2019 (RES)	CENARES 2020 (RES)	ES
I. Community settings and health facilities without laboratories					
Blood typing (Ia) *	A, B and O blood groups and Rhesus (Rh) factor	Test for determination of blood groups of the ABO system and Rh factor	No	No	SSR
Clinical chemistry (Ia)	Albumin (dipstick urine)	Rapid microalbuminuria test (test strip)	Urine test strip, 11 parameters	Urine test strip, 11 parameters	SSR
	Bilirubin (dipstick urine)	**	Urine test strip, 11 parameters	Urine test strip, 11 parameters	SSR
	Glucose (glucose meter)	Blood glucose (RDT)	No	No	CV
	Ketones (dipstick urine)	**	Urine test strip, 11 parameters	Urine test strip, 11 parameters	SSR
	Urinalysis test strips	Rapid urine test **	Urine test strip, 11 parameters	Urine test strip, 11 parameters	SSR
Haematology (Ia)	Erythrocyte sedimentation rate (ESR)	No	No	No	NA
	Haemoglobin (Hb) capillary/venous blood	Haemoglobin blood test	No	No	CV
		Disposable microcuvette for portable haemoglobinometer with diagnostic reagent	Disposable microcuvette for portable haemoglobinometer with diagnostic reagent	Disposable microcuvette for Hemocontrol / Hemocue HB 201 haemoglobinometers	CV
	Haemoglobin (Hb) urine	**	Urine test strip, 11 parameters	Urine test strip, 11 parameters	SSR
Pregnancy testing (Ia)	Human chorionic gonadotrophin (hCG) rapid diagnostic test (RDT)	Human chorionic gonadotrophin hormone (hCG) RDT	No	No	SSR
Chagas disease (Ib)	Trypanosoma cruzi IgG antibody (RDT)	RDT for Chagas disease diagnosis‡	No	Recombinant Chagas ELISA kit (x 96)	MTX
COVID-19 (Ib)	SARS-CoV2 antigen	No †	No	No	NA
Glucose (Ib)	Glucose (dipstick urine)	Rapid urine test **	Urine test strip, 11 parameters	Urine test strip, 11 parameters	SSR
	Haemoglobin A1c (handheld and small analysers)	No	No	No	NA

Discipline	EDL v3 - WHO	PNUDME (RM 670-2019) – MINSA (20 items in total as IVD tests)	CENARES 2019 (RES)	CENARES 2020 (RES)	ES
Hepatitis B (Ib)	Hepatitis B surface antigen (RDT)	RDT for hepatitis B ‡	RDT for hepatitis B (x 30) RDT cassette for detection of hepatitis B, hepatitis C, HIV 1/2 and syphilis (IgA, IgG, IgM) (x 25)	RDT for hepatitis B (x 30) RDT cassette for detection of hepatitis B, hepatitis C, HIV 1/2 and syphilis (IgA, IgG, IgM) (x 25) Hepatitis B - surface antigen ELISA (x 96)	VIH-ITS-H
	Hepatitis B e antigen (RDT)	‡	No	Hepatitis B e antigen ELISA (x 96)	VIH-ITS-H
Hepatitis C (Ib)	Hepatitis C antibodies (anti-HCV RDT)	RDT for hepatitis C ‡	RDT cassette for detection of hepatitis B, hepatitis C, HIV 1/2 and syphilis (IgA, IgG, IgM) (x 25)	RDT cassette for detection of hepatitis B, hepatitis C, HIV 1/2 and syphilis (IgA, IgG, IgM) (x 25)	VIH-ITS-H
HIV (Ib)	HIV 1/2 antibody for self-testing (RDT)	No	No	No	NA
	HIV 1/2 antibody (RDT)	RDT for HIV 1/2	RDT for HIV 1/2 (x 25)	RDT for HIV 1/2 (x 25)	VIH-ITS-H, SSR
	Combined HIV antibody/p24 antigen (anti-HIV/p24 ag) (RDT)	No	Rapid immunochromatographic HIV 1/2 test for antigen and antibody detection (RDT)	Rapid immunochromatographic HIV 1/2 test for antigen and antibody detection (RDT)	VIH-ITS-H
Influenza (Ib)	Influenza A/B antigen	No	No	No	NA
	influenza A/B NAT (point-of-care)	No	No	No	
Malaria (Ib)	Plasmodium spp. antigens, species-specific and/r pan species-specific (RDT)	RDT for malaria diagnosis	RDT for malaria (x 25)	RDT for malaria (x 25)	MTX
Syphilis (Ib)	Antibodies to *Treponema pallidum* (RDT)	RDT for syphilis diagnosis (RPR) ‡	RDT for HIV, syphilis (x 25)	RPR antigen (x 100)	SSR
	Combined Abs for syphilis + HIV 1/2 (RDT)	RDT for HIV 1/2 and syphilis diagnosis	RDT for HIV, syphilis (x 25)	RDT for HIV, syphilis (x 25)	VIH-ITS-H
Other STIs	No	No	NG susceptibility set NG screening set	NG identification set	VIH-ITS-H
Tuberculosis (Ib)	Tuberculin skin test (TST) PPD	No	Tuberculin - PPD 5 UI/0.1 mL, injectable	Tuberculin - PPD 5 UI/0.1 mL, injectable	TB

Discipline	EDL v3 - WHO	PNUDME (RM 670-2019) – MINSA (20 items in total as IVD tests)	CENARES 2019 (RES)	CENARES 2020 (RES)	ES
Others not epidemiologically important in Peru (Ib), including cholera, Streptococcal. pharyngitis, sickling disorders, visceral leishmaniasis	*Vibrio cholerae* antigen	No	No	No	NA
	Group A *Streptococcus* antigen	No	No	No	NA
	Sickle cell testing	No	No	No	NA
	Recombinant K39 antigen	No	No	No	NA
II. Healthcare facilities with clinical laboratories					
HIV (IIb)	Antibodies to HIV 1/2 (immunoassay)	No	HIV 1-2 ELISA test	No	VIH-ITS-H
	CD4 cell enumeration kits	No	Complete CD4/CD8 lymphocyte count kit (includes buffer and controls) (x 50) CD4, CD3 lymphocyte count kit (portable cytometer) (x 100) CD4, CD8, CD3 lymphocyte count kit (x 50)	Complete CD4/CD8 lymphocyte count kit (includes buffer and controls) (x 50) CD4, CD3 lymphocyte count kit (portable cytometer) (x 100) CD4, CD8, CD3 lymphocyte count kit (x 50)	VIH-ITS-H
	Qualitative HIV nucleic acid test (NAT)	No	Qualitative detection of DNA and RNA of HIV-1 diagnostic kit (x 48)	Qualitative detection of DNA and RNA of HIV-1 diagnostic kit (x 48)	VIH-ITS-H
	Quantitative HIV NAT	No	HIV 1 real-time viral load kit (includes components and consumables) (x 96) HIV-1 quantification real-time PCR kit (x 120)	HIV 1 real-time viral load kit (includes components and consumables) Quantification of HIV viral load real-time PCR kit (x 10)	VIH-ITS-H
Human papilloma virus (IIb)	HPV NAT	No	No	No	NA
Dengue (IIb)	Qualitative dengue virus NAT	No	No	No	NA
	Dengue virus IgM antibody RDT or immunoassay	ELISA test for dengue diagnosis	Anti-dengue IgM antibody ELISA Tariki (x 96)	Anti-dengue IgM antibody ELISA Tariki (x 96)	MTX
	Dengue virus antigen (NS1) RDT or immunoassay	No	No	RDT cassette for dengue detection (IgM, IgG and antigen) (x 25)	MTX

Discipline	EDL v3 - WHO	PNUDME (RM 670-2019) – MINSA (20 items in total as IVD tests)	CENARES 2019 (RES)	CENARES 2020 (RES)	ES
Syphilis (IIb)	Antibodies to *Treponema pallidum* (immunoassay) (also in category IIc)	ELISA test for syphilis diagnosis	No	No	SSR
	Non-treponemal rapid plasma regain (RPR)	RDT for syphilis diagnosis (RPR)	RDT for syphilis diagnosis (RPR) kit (x 200)	RDT for syphilis diagnosis (RPR) kit (x 200)	VIH-ITS-H
	Non-treponemal venereal disease research laboratory (VDRL) test	No	No	No	NA
	T. pallidum hemagglutination test (TPHA) and T. pallidum article agglutination (TPPA)	No	*Treponema Pallidum* Hemagglutination Kit (TPHA) (x 200)	*Treponema Pallidum* Hemagglutination Kit (TPHA) (x 200)	VIH-ITS-H
	No	No	FTA-ABS kit for syphilis diagnosis (x 60)	FTA-ABS kit for syphilis diagnosis (x 60)	VIH-ITS-H
Human papilloma virus (IIb)	HPV NAT	No	No	No	NA
Cancer (IIb)	Prostate cancer: Prostate Specific Antigen (PSA)	No	No	No	NA
	Colorectal cancer: Faecal immunochemical test (FIT)	No	No	No	NA
Tuberculosis (IIb)	TB NAT (to detect and simultaneously or sequentially detect rifampicin resistance)	No	Rapid molecular detection kit for resistance to rifampicin/isoniazid P/*M. tuberculosis* (x 96) (RDT)	Rapid molecular detection kit for resistance to rifampicin/isoniazid P/*M. tuberculosis* (x 96) (RDT)	TB
Chagas disease (IIb)	*Trypanosoma* IgG Ab	No	Recombinant Chagas ELISA kit (x 96)	Recombinant Chagas ELISA kit (x 96)	MTX
Hepatitis B (IIb)	HBs antigen (immunoassay)	No	Hepatitis B – surface antigen ELISA (x 96)	Hepatitis B – surface antigen ELISA (x 96)	VIH-ITS-H
	Quantitative HBVv NAT	No	Quantification of hepatitis B viral load PCR kit (x 72)	Quantification of hepatitis B viral load PCR kit (x 72)	VIH-ITS-H
	Hepatitis B e antigen (immunoassay)	No	Hepatitis B e antigen ELISA (x 96)	Hepatitis B e antigen ELISA (x 96)	VIH-ITS-H

Discipline	EDL v3 - WHO	PNUDME (RM 670-2019) – MINSA (20 items in total as IVD tests)	CENARES 2019 (RES)	CENARES 2020 (RES)	ES
Hepatitis B (IIb) (continued)	No	No	Hepatitis B e antigen - antibody ELISA detection kit (x 96)	Hepatitis B e antigen - antibody ELISA detection kit (x 96)	VIH-ITS-H
	IgM- specific antibodies to hepatitis B core IgM anti-HBc (acute hepatitis B infection)	No	Hepatitis B anti-core IgM ELISA (x 96)	Hepatitis B anti-core IgM ELISA (x 96)	VIH-ITS-H
	No	No	Hepatitis B total anti-core ELISA (x 96)	Hepatitis B total anti-core ELISA (x 96)	VIH-ITS-H
	Antibodies to Hepatitis B surface antigen (anti-HBs) (immune status due to immunization)	No	Hepatitis B anti-surface antigen (anti-S) ELISA (x 96)	Hepatitis B anti-surface antigen (anti-S) ELISA (x 96)	VIH-ITS-H
Helminthiases (IIb)	Kato-Katz faecal smear	No	No	Kato-Katz Kit	MTX
Other diseases not included in the WHO EDL: yellow fever, mucocutaneous leishmaniasis, brucellosis Chikungunya leptospirosis, fasciolosis	No	Yellow fever ELISA test	No	Yellow fever ELISA (x 96)	MTX
	No	Reagent for the identification of the antibody for the diagnosis of leishmaniasis	No	Leishmanin antigen diagnostic reagent (Leismanin solution) vial (x 10)	MTX
	No	No	Brucella antigen supplementary test (x 25) *Brucellas abortus* antigen for Rose Bengal test x 5 mL (x 160)	Brucella antigen supplementary test (x 25) *Brucellas abortus* antigen for Rose Bengal test x 5 mL (x 160)	MTX
	No	No	Chikungunya IgG detection ELISA kit (x 96) Chikungunya IgM detection ELISA kit (x 96)	Chikungunya IgG detection ELISA kit (x 96) Chikungunya IgM detection ELISA kit (x 96)	MTX
	No	No	Leptospirosis IgM ELISA detection kit (x 96)	Leptospirosis IgM ELISA detection kit (x 96)	MTX
	No	No	No	*Fasciola hepatica* antigen - antibody (FAS 2) ELISA detection kit (x 96)	MTX

Discipline	EDL v3 - WHO	PNUDME (RM 670-2019) – MINSA (20 items in total as IVD tests)	CENARES 2019 (RES)	CENARES 2020 (RES)	ES
Other products	No	Vacuum blood collection tube with anticoagulant	No	No	NA
	No	No	Adult disposable retractable lancet (x 100)	Adult disposable retractable lancet (x 100)	NA
	No	No	Retractable lancet with three levels of penetration (x 200)	Retractable lancet with three levels of penetration (x 200)	NA
	No	No	Monofilament (10 g)	Monofilament (10 g)	NA

* Categorized according to the WHO EDL-2019: Ia and IIa: general IVD test; Ib and IIb: disease-specific IVD tests, IIc: disease-specific IVD tests for blood-screening laboratories. In category II, we mainly only included those for which there was a test in the PNUDME. The PNUDME does not categorize tests by type of health establishment.

** The PNUDME only lists a non-specific test for urinalysis (rapid urine test). The parameters of the test are not described.

† The COVID-19 tests are considered in an emergency list of diagnostics from 2020 (NAT, antigen test, RDT serology). The WHO EDL only includes SARS-CoV-2 NAT and antigen.

‡ The PNUDME only lists a non-specific RDT for hepatitis B (RDT for hepatitis B), hepatitis C (RDT for hepatitis C) and syphilis (RDT for syphilis diagnosis). It is not described whether they correspond to an antigen or antibody test.

ES, National Public Health Program or Strategy; SSR, Reproductive and Sexual Health; CV, Curso de vida (course of life); VIH-ITS-H, HIV, STDs and Hepatitis; NT, noncommunicable disease; MTX, transmitted by vectors and zoonoses; TB, tuberculosis program; NA, not classified in any National Public Health Program or Strategy; NAT, nucleic acid amplification test; RDT, rapid diagnostic test.

Non-strategic IVD test supply chain

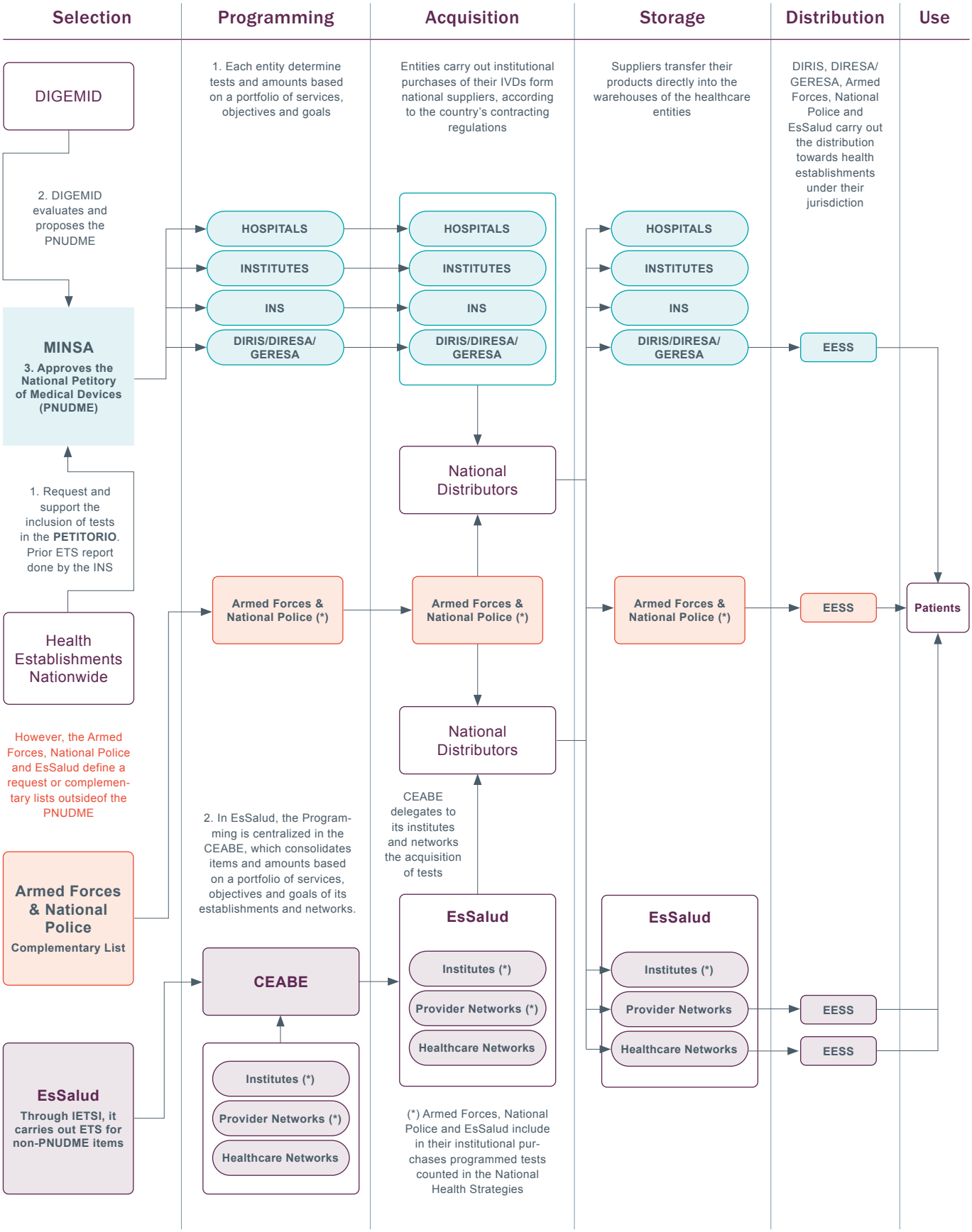
Purchases of non-strategic IVD tests are those that have not been requested in a centralized manner, whose budget and acquisition are managed directly by institutions themselves, such as health establishments dependent on the MINSA, GORES, EsSalud, FFAA, PNP and local governments. These can only be obtained in the local market from national distributors. This is a fragmented and inefficient form of state expenditure, which fundamentally allows institutions to perform acquisitions more rapidly. The budgets for these purchases are assigned to the institutions from the MEF or the SIS, and there is no suggestion that either the MINSA or CENARES will centralize these purchases.

The MINSA institutions (DIRIS, DIRESAS/GERESAS and hospitals) determine the products and quantities required according to their service portfolio. The medicine's director or head of pharmacy revise and evaluate the information, which is then validated. These must purchase tests cited in the PNUDME, otherwise they do not receive reimbursement from the SIS. However, the PNUDME is new and still incomplete, further complicating the process. For institutional purchases, the FFAA, PNP and EsSalud define their own lists and complementary lists outside of PNUDME.

In the case of EsSalud, sanitary evaluations are performed through their Institute for Health Technology and Research (IETSI). Through CEABE (the National Center for the Procurement of Strategic Resources for Health from EsSalud), EsSalud determines the necessary quantities of products that are required for its various health establishments each year and manages the appropriate budget allocation. As indicated in the interviews, the CEABE does not consider centralization of IVD purchases as strategic, hence it delegates the activities of acquisition, storage and distribution to some of the bigger hospitals and to the directions of the networks of health establishments. (26)

In the MINSA, the regional governments purchase non-strategic IVD tests through their own regional health directorates. In the case of EsSalud, FFAA and GORES, they usually manage the distribution of IVD tests from warehouses to health centres. Hospitals at the national level and health establishments that are executive units can also purchase IVD tests independently through institutional purchases.

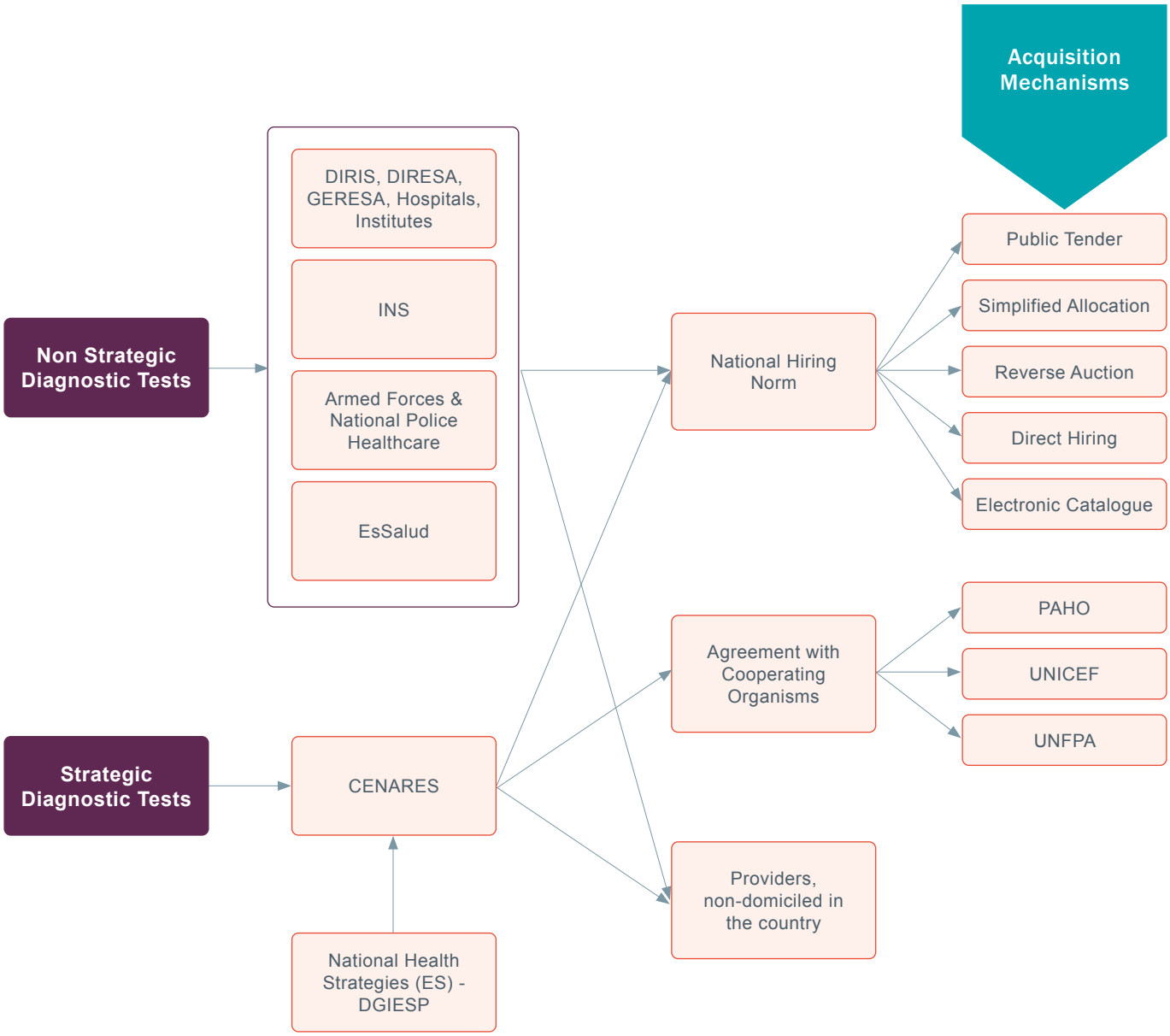
Figure 4.2: Supply chain for non-strategic IVD tests



Alternatives for the purchase of IVD tests

Figure 4.3 summarizes the alternatives for the purchase of IVD tests by the type of test and the type of institution.

Figure 4.3: Alternatives for the purchase of IVD tests



Information systems related to the IVD test supply chain

The information systems in healthcare are as fragmented (or more) as the healthcare systems themselves, with the information systems for the IVD supply chains being no exception. Each of the actors in the supply chain uses different information systems with incompatible data and indicators. These systems are not interoperable or integrated, and chronically lack coordination, which limits the decision-making abilities of actors throughout the different supply chain processes. Table 4.6 summarizes these diverse information systems and some of their characteristics.

Table 4.6: Information systems related to the IVD test supply chain

Information system	Process	Administrator	Information collected	Who registers the information?	Product generated	Who uses the information?
SI-CENARES	Programming	CENARES	Number of diagnostic tests established by Health Strategies (ES)	MINSA: institutes, hospitals, INS, DIRIS, DIRESAS, GERESAS • EsSalud, FFAA y FP	Consolidated list of tests required by the ES	• CENARES • ES
	Storage	CENARES	Entry, exit and stock of pharmaceutical products, medical devices and sanitary products in warehouses	Logistics areas of each entity: institutes, hospitals, INS, DIRIS, DIRESAS, GERESAS	A report of the distribution	Logistics areas of each entity • CENARES • DIGEMID
SIGA-MEF	Programming	MEF	Needs for goods and services	User areas of each entity: • CENARES, institutes, hospitals, INS, DIRIS, DIRESAS, GERESAS • FFAA and FP	Table of necessities for goods and services (including IVD tests)	• Administration and logistics areas of the entities • MEF
	Acquisition	MEF	Generation of purchase orders	Logistics areas of each entity: • CENARES, institutes, hospitals, INS, DIRIS, DIRESAS, GERESAS • FFAA and FP	Purchase orders	Suppliers and entities that generate the purchase orders
	Storage	MEF	Entry and exit of goods from warehouses Inventory	Logistics areas of each entity: • CENARES, institutes, hospitals, INS, DIRIS, DIRESAS, GERESAS • FFAA and FP	Document of entry and exit from warehouses • Kardex	Logistics areas of the entities • MEF
SIAF	Acquisition	MEF	Budget and expense records for purchases	Every state entity that performs purchases	Report of budget assigned and expenditure	• MEF • State entities that perform purchases
SEACE	Acquisition	OSCE	Performance of selection procedures carried out for purchases (national and international)	Every state entity that performs purchases	• Supervision of selection procedures • Access to information for distributors and the public	• OSCE • State entities • Distributors • Comptroller • General public

Information system	Process	Administrator	Information collected	Who registers the information?	Product generated	Who uses the information?
SISMED	Storage	DIGEMID	Stocks in small, regular, and specialized warehouses	Warehouses and pharmacies of health establishments	Report of stock, entry and exit of pharmaceutical products, medical devices and sanitary products in specialized warehouses and sub-warehouses	Logistics and pharmacy of areas of each entity
	Distribution		Distribution of products to health centres and healthcare posts	Warehouses and pharmacies of health establishments	Records and reports of pharmaceutical products, medical devices and sanitary products in health posts and health centres	Specialized warehouses and pharmacy of each entity
	Use		Supply of pharmaceutical products, medical devices and sanitary products	Warehouses and pharmacies of health establishments	• Report of integrated consumption (ICI) • Records of stocks and consumption of pharmaceutical products, medical devices and sanitary products at the pharmacy level	Director of medicines and/or the pharmacy of each entity
SIHCE - eQHALI	Use	MINSA	Evaluation, diagnosis, and treatment of diseases	IPRESS	Electronic medical records (implementation is incomplete and currently paused)	EESS, MINSA
SIA-SIS	Use	SIS	Registers the prescription of pharmaceutical products and medical devices	IPRESS	Report of costs and expenses of the health benefit expenses of insured individuals	• SIS • EESS
SAP	Programming	EsSalud	Needs for goods and services	Only used in EsSalud	List of required goods and services	• EsSalud
	Acquisition	EsSalud	Generation of purchase orders	Only used in EsSalud	Purchase orders	Entities that generate the order and distributors
	Storage	EsSalud	Entry and exit of goods from warehouses Inventory	Logistics areas of each entity: - institutes, hospitals, INS, DIRIS, DIRESAS, GERESAS - FFAA - PNP	Entry and exit to warehouses document	• Logistics areas of each entity • MEF

Control and supervision

The Ministry of Health oversees the regulation and supervision of pharmaceutical products, medical devices, and sanitary products through different institutions; however, there is limited coordination amongst them.

Table 4.7 summarizes the diverse entities, which are linked, in theory, to the various steps in the supply chain.

Table 4.7: Control and supervision in the IVD test supply chain

Supervisory entity	Function	Ability to impose sanctions	Efficiency (scale of 0 - 10)
National Health Superintendency (SUSALUD)	Assure the respect for the rights of patients, regarding the health benefits they receive in the healthcare establishments. This includes availability and access to IVD tests	Yes	5
DIGEMID (ANM)	Control and monitoring of EESS. Authorizations and compliance with BPM, BPA, BPDT	Yes	6
At the national level	Control and monitoring of sanitary registrations and certificates, product quality and pharmacovigilance	Yes	
DIRIS/DIRESA/GERESA (ARM)	Control and monitoring of EESS. Authorizations and compliance with BPM, BPA and BPDT	Yes	4
At the regional level	Control and monitoring of sanitary registrations and certificates, product quality and pharmacovigilance	Yes	
CNCC (INS) and regional laboratories for quality control	Product quality analysis	No	5
OSCE	Monitors and controls the efficiency and effectiveness of public purchases	Yes	5
General Comptroller of the Republic	Controls and evaluates budget management, contracting and its impact on the achievement of institutional objectives	Yes	4
National Superintendency of Customs and Tax Administration (SUNAT)	Customs control and inspection of products entering the country	Yes	9
National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI)	Protection of intellectual property and consumer rights	Yes	7
Local Governments	Issuance of operating licences	Yes	5
Attorney General's Office	Address complaints of illegal trade in pharmaceutical products, medical devices and sanitary products	No	7
National Ombudsman Office	Channel complaints about availability and access to IVD tests	No	5

Comments from interviewees and conclusions

An improvement in resource programming is needed

In the case of strategic resources, the requirements for IVD tests are usually based on the average requirements of the previous 3 years, plus, ideally, the addition of newly detected cases. This can result in under- or over-stocking. Some of the ESN programme their needs and requests for IVD tests according to the population affiliated to the SIS, others according to the general population, which can generate differences and duplications. Some ESs set objectives lower than those required according to their assigned population, which implies buying less IVD than they would need, due to budgetary constraints. Additionally, DIRESAS personnel may not have the necessary expertise to select and calculate the number of tests needed. Each ES presents a list of required strategic resources to CENARES, however there is no standardized method of preparing the list or a fixed frequency to review and update the list. Some ESs review their list each year, while other ESs have a short, static list, which is infrequently modified.

Interviewees also mentioned that the programming, acquisition, and distribution of IVD tests can take too long. For example, some screening tests requested in 2017 were only purchased in 2021. It can also be the case that a programmed goal is not met due to the fact that the acquisition process for some tests may be unsuccessful (no suppliers apply, or the process is not completed) or may suffer delays in the delivery and/or distribution of products. The programming of new IVDs is slower in EsSalud than in the MINSA, which can be explained by the centralized organization of resources, and the need for IETSI approval for any new test, a process that can take up to 3 years.

Lack of knowledge or familiarity with the PNUDME

Among those interviewed, the PNUDME was almost unknown, and the few who knew about it were not very familiar with its content. The need for a database containing the available standards concerning such a list was mentioned. This would enable the ongoing revision of its content and the consolidation of current regulations.

Complicated process for the development and approval of product sheets

To begin the purchasing process, the relevant product sheets require approval, which can differ depending on the case. There is a duplication of functions that could even be considered a conflict of interest, as buyers such as CENARES and Peru Compras oversee the drafting and approval of product sheets. On the other hand, it was ascertained that the lack of technical support sometimes did not allow for many bidders, thus “directing” the terms of reference towards a single supplier.

Acquisition processes are too long

Some interviewees commented that the acquisition processes for the purchase of strategic IVD tests take far too long, leading to termination of the purchases.

Problems in distribution systems

Some interviewees pointed out that the distribution process is inadequate, as many establishments report a lack of medicines or supplies, while DIRESA or other warehouses are filled with these very supplies. There is also frequent over-stocking of some products in some health establishments or warehouses, whereas in others, these same products may be under-supplied. This shows a total lack of coordination between the processes of storage and distribution. There is also no system for controlling and replacing supplies.
Additionally, during the distribution process, ambulances and other vehicles may be used, which do not have appropriate storage systems, due to the limited availability of suitable vehicles or a lack of resources to hire a transport service. This infringes BPT and is evidence of the improvisation that can occur during this process. It also highlights the lack of a distribution network at all levels.

If purchases increase, there could be a scarcity of warehouses

At the MINSA, we were told about the existence of logistics problems at the regional level, due to a lack of storage capacity, which also limits purchases and deliveries. On the other hand, EsSalud does have regional warehouse capacities.

Information system problems

A common problem in the public sector, at both the warehouse and regional level, is the lack of logistic capacity to carry out permanent control of the supplies that enter the warehouses. In relation to the storage system, the interviewees told us that they lack an information system to supervise, control and enable the replacement of supplies. They do not possess an automated alert system to detect product expiration dates and inadequate storage conditions. This leads to large losses of supplies. The interviewees mentioned the need to have an information system that could integrate the entire supply chain and coordinate the public healthcare system at each of the different levels.

Problems in quality control

Quality control is a problem. Currently, the only requirement is to “test” a few units once the IVD tests are already in the country. The interviewees mentioned

that if, during the use of an IVD test, it is thought to be suspicious or of dubious quality, it is confiscated and sent to the Center for Quality Control of the INS (CNCC), where its technical specifications are verified, and quality controls are executed. The final report on its quality is sent to DIGEMID or IETSI, which have the capacity to impose sanctions and can remove the product from the market.

Some interviewees mentioned that the INS quality reports are sometimes inconclusive and do not clarify whether a product is within the acceptable range. Reports can conclude "cautious usage", which generates doubt and delays at the user level. Such reports rarely result in the removal of an IVD test and are never considered during future purchases.

In conclusion, the public sector supply chain is fragmented and complex, despite recent efforts to develop a national supply policy. In 2019, the first national list essential of medical devices was approved, which included IVD tests, and was effectively a Peruvian equivalent of the WHO EDL. However, this list is incomplete and appears to complicate purchases, although this has been temporarily resolved by the creation of the "List of RES" by the CENARES.

In addition, IVD tests selection processes remain unclear, while acquisition is complicated, inefficient and requires different instruments (product sheets). Furthermore, no single information system exists that allows products to be traced throughout the entire supply chain, and even the surveillance and control processes are highly fragmented.

Additional information for chapter IV:

I. Homologation sheet in the public sector (see Figure 4.5)

What is the homologation of goods and services?
It is a process through which the heads of the sectors (the MINSA being one of them), standardize the technical specifications and requirements of those goods and services that they consider strategic in their field of competence. The ministries prepare the homologation sheet for a good or service and it is approved by means of a ministerial resolution. This is a way to standardize files so that they can be used for future purchases.

What is the role of CENARES in homologation?
To carry out the homologation process, the MINSA appoints a homologation committee, which is composed of representatives from CENARES, the General Directorate of Health Operations (DGOS) and the General Office of Administration (OGA) of the MINSA. Within this group, CENARES prepares and proposes the homologation sheet referring to pharmaceutical products, medical devices, and health products. The DGOS and MINSA's OGA are in charge of the homologation of all other goods and services.

What is the process for the preparation of a homologation sheet?
The MINSA establishes a homologation committee, which works on the homologation sheets. This committee then works with Peru Compras until they reach an agreement. Once the product is homologated, the entities have the obligation of purchasing using the homologated characteristics.

The entire process is shown in the flowchart in Figure 4.5.

How long does the homologation process take?
Currently, there is limited experience on this process. For the process of homologation for intraocular nits in 2018, CENARES took 139 working days, due to the need to obtain technical information (quality standards, national and international technical standards, ISO, and other documentation) as well as the purchase history over the previous 5 years in the whole of the public sector. It also had to ensure that the homologation sheet guaranteed competition (plurality of suppliers and brands), that the requirement was well supported (why a homologation sheet is needed for such a product), and to have consensus between health establishments, industry, expert health professionals and others. To date, there is no homologation sheet for an IVD test.

What does a homologation sheet contain?
A homologation sheet includes the technical characteristics, the conditions for use and other requisites, according to the following structure:

I. General description of the good

1.1 Code of the good, according to the Unique Catalogue of Goods, Services and Works of the SEACE (CUBSO)

1.2 Name of the product (Denomination)

1.3 Unit of measurement

II. Specific description

2.1 Technical characteristics

2.1.1 Characteristics and specifications

2.1.2 Marking and labelling

2.1.3 Container and packaging

2.2 Execution conditions
Contract execution conditions, quality verification and/or evaluation procedures.

2.3 Qualification requirements

2.3.1 Legal capacities

Describes the documents that enable the distributor to carry out the economic activity subject to the contracting process.

2.3.2 Bidder's experience in the specialty
Considers the documents that must be submitted to prove the experience of the bidder.

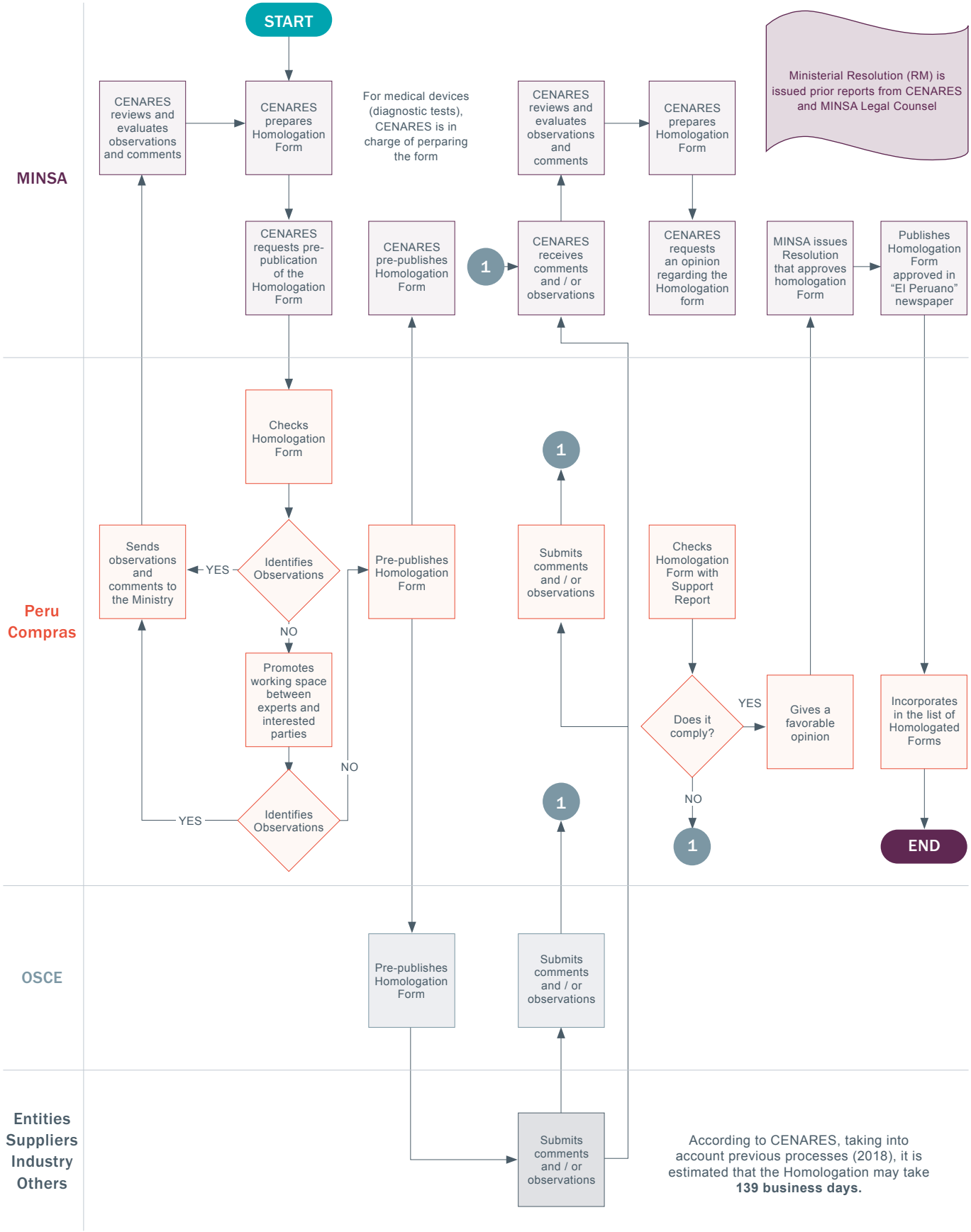
III. Complementary information
Establishes additional conditions or other information for the use of the homologation sheet.

IV. Annexes
Annexes that the Ministry considers necessary for the use of the homologation sheet are included, for example:

- Formats.
- Labelling figures on primary and secondary packaging.
- Other.

What are the standards in connection with homologation sheets?
The standards are described in "Resolución Jefatural No. 069-2020-PERU COMPRAS", which approves Directive Number 006-2020-PERUCOMPRAS or the requirement approval process (*Proceso de homologación de requerimientos*).

Figure 4.5: The process of preparing, reviewing, and approving a homologation form



II. How does an entity make a purchase via electronic catalogues?

1. Within an institution, the unit responsible for purchases searches the Peru Compras platform, identifying the appropriate electronic catalogue. It selects a product and its characteristics, detailing its requirements on the platform.

2. Within 3 working days, the platform automatically generates prices or pro forma invoices to attend to the product requirements of the purchasing entity. The platform contemplates two situations*:

   i. If the price of the purchase does not exceed US$ 27,000, the platform proposes a list of companies that offer the required product, detailing the prices, delivery times, and other relevant information.

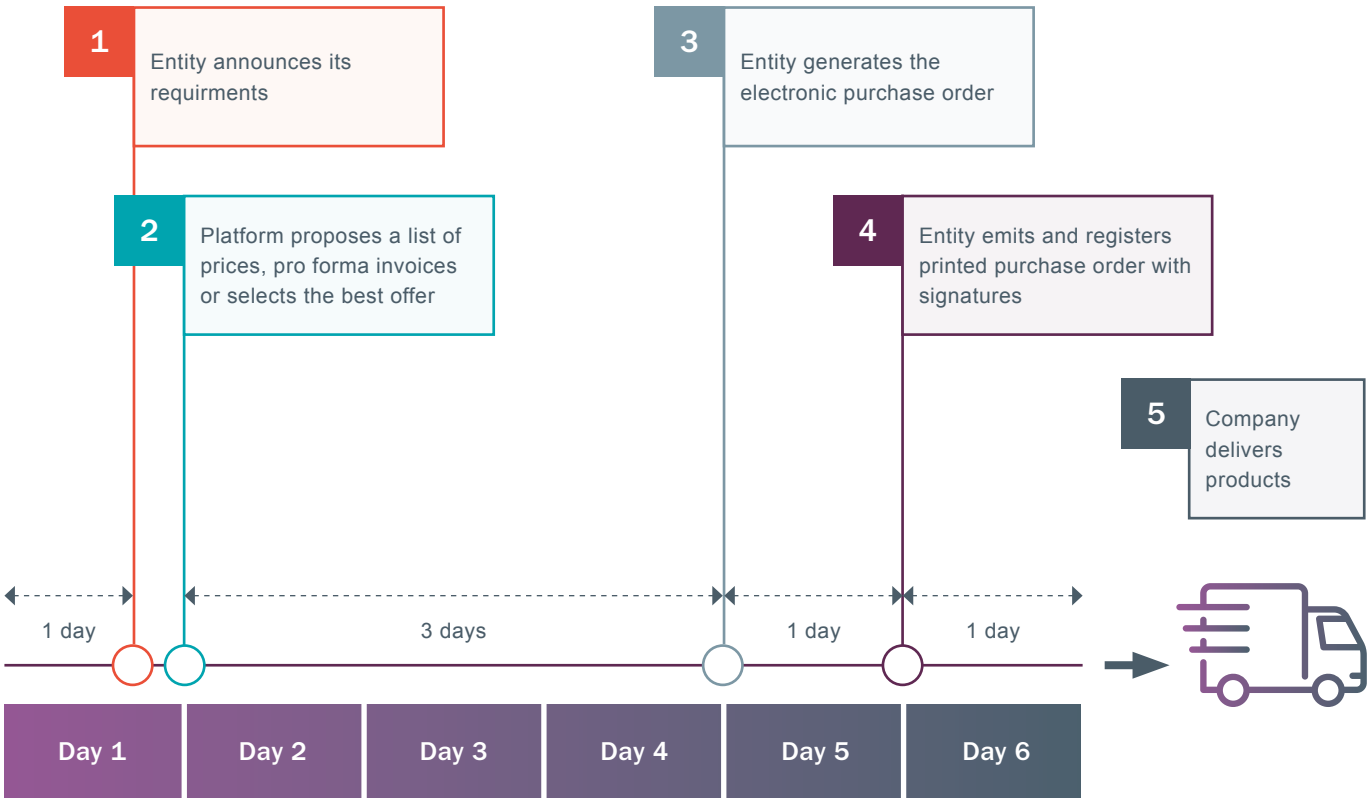
   ii. If the price of the purchase exceeds US$ 27,000, the system uses an algorithm to automatically select the best distributor to attend to the entity's requirements.

3. The entity generates an electronic purchase order through the platform. In the case of purchases less than US$ 27,000, the entity selects the distributor from a list proposed by the platform (it does not have to be the cheapest provider). In the case of purchases greater than US$ 27,000, an electronic purchase order is issued according to the distributor that is automatically selected by the platform.

4. Consequently, the entity generates a purchase order through its own information system. The entity must pre-emptively obtain certification of budgetary credit that assures the existence of budgetary resources for the purchase. This order is printed, signed by the relevant functionaries of the entity, and is then uploaded to the platform, formalizing the contract.

5. The contracted company receives the purchase order from the entity via the platform and realizes the delivery of the product within the established time.

Figure 4.6: The process of purchasing through an electronic catalogue (showing the ideal timing)



* In 2016, a local news investigation reported that a series of purchases performed through electronic catalogues could have been involved in a corruption scandal. This motivated Peru Compras to create new rules, to avoid and mitigate similar events, which also meant the addition of three more working days and more steps and paperwork in the purchase process.
(https://elcomercio.pe/economia/peru/saavedra-paso-compra-computadoras-minedu-229998-noticia/)

III. How do Solidarity Hospitals purchase IVD tests?

According to SEACE, during the COVID-19 pandemic in 2020 and 2021, the Solidarity Hospitals (SISOL) purchased COVID-19 tests following the standards stated in the Law of State Purchases. However, SISOL regularly purchases laboratory services through "associated contracting" or "contracts of participation through association" rather than purchasing IVD tests, based on a directive issued by the Metropolitan Municipality of Lima (Directiva No. DIR-GCO-001-SISOL/MML). These acquisition procedures function through the outsourcing of services to a third-party contractor using terms of reference (ToR) established by the hospitals. These ToRs contain a description of the characteristics and conditions of the services that are required. In the case of laboratory services, this includes the services and analyses required and mentions the schedules and tariffs of the contract. It also details the time and place where the service is to be performed and the software and services that will be facilitated by SISOL. Finally, the percentages of profits are divided between the SISOL and the contracted entity. Services such as ophthalmology, dermatology, urology, pneumology, mammography and even pharmaceutical needs are performed using the same outsourcing method.

IV. Procurement through agreements with international cooperation agencies

The acquisition of IVD tests from international cooperation agencies require a technical cooperation agreement with the Ministry of Health.[vii] For example, to acquire tests from FIND, CENARES would require a technical cooperation agreement similar to the ones signed with PAHO, UNICEF or UNFPA. Similarly, the issuance of a legal standard at the same level as Emergency Decree 007-2019 would be necessary, adding FIND as a cooperating organization from which CENARES can acquire tests and other products.[viii]

To procure a product from an international cooperation agency, CENARES informs them of its IVD test requirements. The agency then sends the prices of the tests included in their catalogues and details of their medium- and long-term agreements with laboratories and suppliers. However, it should be noted that the procurement of tests by CENARES from the cooperating organizations requires several documents from these organizations that may become barriers and/or cause delays in the procurement process. The acquisition of these tests is financed using the CENARES resources received from MEF.

V. Procurement through non-domiciled suppliers

CENARES explores the international market through the commercial agencies of the various embassies in Peru or through suppliers who have expressed an interest in selling their products directly in the country, without intermediaries. However, the international market is large and the investigation by CENARES includes only a small part of the market. The FIND marketplace would be a valuable tool for CENARES as it would allow it to identify more alternatives for a test in a centralized and efficient manner.

Once CENARES obtains the prices from a supplier not domiciled in the country, it evaluates whether this is more advantageous compared with the alternatives obtained in the national market or from cooperation agencies. If so, CENARES issues a purchase order which, once received by the supplier, formalizes the contract.

CENARES generally pays once the products have been delivered, and after verifying compliance with the characteristics and conditions established in the technical specifications. In some cases, when the supplier has established advance payment as a condition, CENARES manages the requirement through the issuance of "letters of credit", which generates greater security for both parties.

VI. Bottlenecks in the public sector supply chain of IVD tests and proposed solutions

See Table 4.8

[vii] These cooperation agreements are included in the appendix.

[viii] This decree number 7.4 clearly states the three agencies: "7.4 The Ministry of Health, through the corresponding body, is authorized to make purchases through the Pan American Health Organization (PAHO/WHO), the United Nations Children's Fund (UNICEF) and the Population Fund of the United Nations (UNFPA), of strategic resources in health".

Table 4.8: Bottlenecks in the public sector supply chain of IVD tests and proposed solutions

Process	Bottleneck	Proposed solution	Legal standards and projects that have made progress
Requisition	The autonomy of the regional governments, EsSalud, the armed forces and the national police, limits the ability of the MINSA to perform actions related to the processes of programming, acquisition, and distribution of tests.	Issue and implement provisions at the sectorial level, which allow improvements to the processes of selection, programming, acquisition and distribution of tests in the public sector.	• Law 30895 – a law that strengthens the governing function of the MINSA • Supreme Decree No. 030-2020-SA, a Supreme Decree that approves the Regulation of Law 30895. • Emergency Decree 007-2019 • Supreme Decree No. 026-2019-SA
Selection	The PNUDME only includes 20 diagnostic tests and does not consider others used by FFAA, PNP or EsSalud. This generates additional, complementary lists parallel to the PNUDME.	Update the PNUDME, taking as a reference the third EDL issued by WHO and including the tests that are already used in health facilities nationwide.	
	Outdated clinical practice guidelines or a lack of such guidelines means the IPRESS has discretion to choose the tests used to diagnose patients' health problems.	Update and/or draft practical clinical guidelines that establish the tests to be used for diagnosis, taking as reference the third EDL issued b WHO. However, this could take a long time.	
	Issuance of sanitary registration is not carried out within the established deadlines, constituting a barrier to the entry of new tests to the country.	Optimize the process of issuing sanitary registration, facilitating those that have authorization from the US FDA, the EMA or agencies in countries with a high level of surveillance.	
Programming	The programming process is fragmented and unarticulated. The governing body is unaware of the total pharmaceutical products, medical devices and sanitary products requirements.	The MINSA, through CENARES, should lead the programming of all pharmaceutical products, medical devices and sanitary products at the national level. There should be a transition from manual and fragmented programming to automated programming, reducing typing and use of spreadsheets, focusing on patient satisfaction.	• Emergency Decree 007-2019 • Supreme Decree No. 026-2019-SA • Investment Program for the Creation of Integrated Health Networks (PCRIS) (Unique Investment Code: 2416127) World Bank Component 5: Improvement of the management of pharmaceutical products and medical devices in prioritized areas in Metropolitan Lima and prioritized regions.

Process	Bottleneck	Proposed solution	Legal standards and projects that have made progress
Programming (continued)	The tests and quantities programmed for purchase do not correspond with the actual demand for these products, generating over-stock or shortages.	Review and improve the guidelines for programming strategic health resources issued by CENARES. Extensive and mandatory use of these guidelines in pharmaceutical product, medical device and sanitary product programming by all public sector entities, whose management and consolidation must fall under the remit of CENARES.	• Emergency Decree 007-2019 • Supreme Decree No. 026-2019-SA • Directorial Resolution No. 389-2020-CENARES - Guidelines for programming strategic resources in health • Investment Program for the Creation of Integrated Health Networks (PCRIS) (Unique Investment Code: 2416127) Component 5: Improvement of the management of pharmaceutical products and medical devices in prioritized areas in Metropolitan Lima and prioritized regions.
Acquisition	Technical specifications vary depending on the entity and sector that performs the purchase; there are no uniform or standard technical specifications for the country.	Preparation of catalogues and sheets with standard technical specifications for diagnostic tests, based on the third EDL issued by WHO. Obtain external technical support and work with a committee comprising representatives of EESS, ESN, INS, DIGEMID and CENARES.	
	Homologation process for the standardization of technical specifications and requirements have only managed to homologate 22 products in more than 4 years.	Make demands to the Ministry of Economy and Finance and Peru Compras that the process of homologation of diagnostic tests should be carried out according to the procedures established by the MINSA, prioritizing technical reasons of public health over market conditions. Develop the homologation sheets and have them approved.	
	The acquisition of a group of tests is carried out through institutional purchases, with different characteristics and conditions.	Establish a list of IVD tests, the acquisition of which will be carried out centrally, through the logistics operator of the sector (CENARES). This could also be specified in the PNUDME.	• Emergency Decree 007-2019 • Supreme Decree No. 026-2019-SA
	Even through Peru Compras, the purchasing process is burdensome and requires many steps.	With external technical assistance, review procedures and simplify them. Initially, the system was designed to be simple but, due to complaints of corruption, other procedures were added, complicating the system.	

Process	Bottleneck	Proposed solution	Legal standards and projects that have made progress
Acquisition (continued)	The existence of different systems/catalogues for medical devices (SISMED, SIGA, SEACE, EsSALUD, FFAA and PNP) limits the ability to identify the tests that are programmed, acquired and distributed.	Preparation of a unique national catalogue of medical devices, with identification mechanisms based on coding established through international standards and integrated and coordinated information systems.	Investment Program for the Creation of Integrated Health Networks (PCRIS) (Unique Investment Code: 2416127) Component 5: Improvement of the management of pharmaceutical products and medical devices in prioritized areas in Metropolitan Lima and prioritized regions.
Storage	Limited capacity, inadequate infrastructure, and warehouses that do not comply with BPA certification all increase the risk of affecting the characteristics and properties of the tests.	Improve infrastructure and conditions and ensure warehouses are BPA certified.	Same as above
	Absence of software or tools that allow the use of warehouse resources to be optimized, including the reception, storage, extraction and dispatch of tests.	Implement a warehouse management system (WMS) to optimize the use of resources and storage capacity.	Same as above
	The lack of traceability weakens the surveillance and control of falsified and illegally traded tests.	Establish automatic and systematized standard identification mechanisms (identification codes) and implement an integrated and coordinated information system for the entire IVD test supply chain.	Same as above
Distribution	Distribution is carried out based on historical consumption patterns and not in accordance with the monthly requirement of health establishments, generating shortages or expiration of tests in warehouses due to a lack of rotation.	Optimize the distribution of IVD tests through automated systems and based on the daily consumption of pharmacies or laboratory services.	Same as above
	Limited availability of means of transport or resources to outsource transportation services.	• Provide vehicle units or resources to contract specialized transport services. • Include in the conditions for the purchase of IVD tests the transportation, and direct delivery to health establishments.	
Use	The lack of IVD tests in pharmacies and the lack of laboratory services prevents adequate diagnosis and treatment to alleviate health problems in patients.	• Improve distribution capacity through the design of a distribution network, the systematization of stocks and online consumption. • Implement a computerized tool that allows information on prescribed tests to be recorded, not those delivered for patient care.	

Process	Bottleneck	Proposed solution	Legal standards and projects that have made progress
Financing	The fragmentation in budget allocation by categories* and by sources of financing** limits the acquisition of tests	Develop proposals to improve the allocation and management of budget resources, to allow flexibility and agility in the purchase of IVD tests.	
	Insufficient financing for the acquisition, storage and or specialized transport of tests.	• Demand that the Ministry of Economy and Finance allocate sufficient budgetary resources for the acquisition of IVD tests. • Adopt strategies that allow the optimization of the limited budgetary resources assigned (aggregation of demand to obtain benefits from economies of scale).	
Information systems	There are various systems that collect information on programming, acquisition, distribution, and consumption, which are disjointed and not integrated, limiting decision-making by the different actors in the supply chain.	Implement an information system that is interoperable between and coordinates the different sources of information.	Investment Program for the Creation of Integrated Health Networks (PCRIS) (Unique Investment Code: 2416127) World bank funding. Component 3: Improvement and Expansion of the Unified Health Information System at the national level.
	A lack of equipment and connectivity limits the ability to collect information on daily consumption in pharmacies and by laboratory services.	Provide computer equipment and internet access to health establishments to allow information about daily consumption levels to be obtained.	Same as above

*There are three budget categories: 1. APNOP: Budget allocations that do not result in outputs 2. PP: Budget Program 3. AC: Central actions.

**There are five sources of financing: 1. RO: Ordinary Resources; 2. RDR: Directly Raised Resources; 3. RD: Determined resources; DyT: Donations and Transfers; 4. ROOC: Resources from Official Credit Operations

FIND

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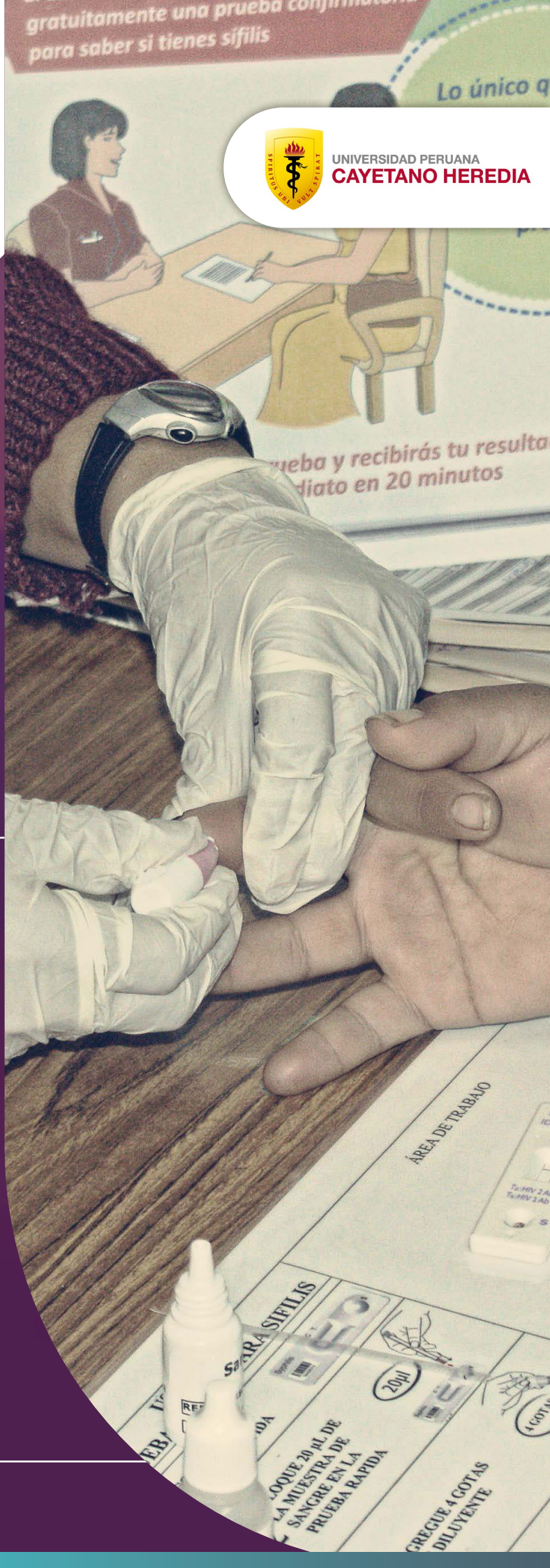
CAYETANO HEREDIA



V

DIAGNOSTICS AND THE PRIVATE SECTOR

V
DIAGNOSTICS AND THE PRIVATE SECTOR

Despite accounting for a relatively limited proportion of healthcare provision in Peru (covering only about 8% of the total population), the private sector comprises an intricate network of entities that are fragmented both in their capacities and in the services they provide. These entities can cover varied types of services; some possess very specific and limited responsibilities, such as X-ray services or COVID-19 testing centres, while others cover a wide range of services, such as tertiary hospitals for treatment of complex conditions or specialized laboratories. The size of these entities also varies depending on the number of patients they cover. The private sector can be further separated into profit or non-profit entities.

The non-profit sub-sector is very small and mainly comprises local and international nongovernmental organizations, local associations, religious organizations, or other civil society institutions. Some important non-profit entities include The Red Cross Peru, AIDESEP, Voluntary Firemen, religious organizations and churches, and international organizations such as Doctors without Borders, CARE, and Partners in Health, among others. These associations usually provide primary care health services and tend to be financed by external entities or private and/or governmental donations. They have a limited area of influence and usually have time-limited objectives, representing a very small proportion of the services provided in the private sector. Their actions usually take place in poor regions, where healthcare services are often lacking. However, MINSA facilities play an important role where they are located, which limits the scope of intervention of some of these non-profit institutions.

The for-profit sub-sector includes a complex web of many, fragmented entities that offer a wide range of services. Some of these entities, such as pharmaceutical companies and equipment manufacturers, specialize in the manufacture of healthcare supplies. Most are centred around the distribution and storage of these supplies or their importation into the country. Healthcare is provided by a wide range of establishments, ranging from simple and small image-based diagnostic centres, practitioners' offices, and screening or testing centres to more complex centres, such as diagnostics laboratories, private clinics, and polyclinics. Private businesses may have their own healthcare services and insurance cover, in sectors such as mining or oil and gas. Also included in this sub-sector are other informal services, what is known as non-traditional health providers, such as traditional healers (shamans or "*curanderos*"), pharmacy workers recommending medications (which is not legal but happens) and different types of alternative therapies.

Pharmacies are other crucial establishments that must be considered for the provision of healthcare. Not only do they sell medicine and health products but they also play an important role in offering health counselling and even informal treatment recommendations to customers, although this is not legal in Peru.[62] At the national level, pharmacies are the main healthcare establishments where individuals seek advice for a health problem. In 2018, of all individuals with a health problem only 44% sought healthcare services. Of these, 16.7% of individuals sought care at a pharmacy, whereas 14.1% had a consultation in a MINSA or regional health establishment, and 5.5% sought help via EsSalud. Private healthcare establishments represented 6.8% of total consultations.[63] However, pharmacies are not allowed to offer diagnostic services.

Despite the extensive coverage by the SIS (the Comprehensive Insurance System from the MINSA) and EsSalud, private insurers play an important role in financing healthcare in Peru, especially in the larger cities. Depending on the type of tariff, these insurers cover a broad range of services, centres and operations. They are integrated to form a large network of entities offering various services, including clinics, specific treatments and ambulance services. Individuals and employers alike can purchase private insurance. Larger clinics and hospitals can also offer their own insurance services to their clients.

Although in theory the SIS covers the population that lacks insurance, and despite the supposed universality of healthcare, many individuals seek care in the private sector, some of which is covered by private insurance. Individuals covered by the SIS or EsSalud may also resort to private services and paying OOP, particularly in the case of specialized or more complex treatments, diagnostics or operations; due to a lack of supplies; or due to poor quality services. The cost and quality of these services is highly variable and dependent on the type of establishment. Uniformity of service in the private sector is non-existent. Despite higher costs (the vast majority of which are financed through OOP expenditure) and acute fragmentation, private health services remain in high demand. This is mainly due to the general opinion that their services are qualitatively superior to publicly provided healthcare.

The perceived low quality of public health services complemented by episodes of high-profile scandals has tarnished their reputation and increased the perception that the private system is more functional. It is also important to note that health providers, especially physicians, work in both the public and private sectors.[64,65] Frequently, their

public sector jobs enable them to find more customers for their private practice. These dual practices are often detrimental to public health services, as evidenced by journalistic investigations showing that doctors preferred leaving their jobs at public institutions early to attend their private clients.[66] Similarly, during the COVID-19 epidemic, dual-practitioners who requested leaves of absence from the public sector because they were presumably part of the vulnerable population were discovered to be practicing in the private sector.[67] Publicly available reports estimate that 60% of users of the MINSA healthcare establishments and 90% of EsSalud users ultimately spend some money on healthcare services in the private sector.[68]

Loosely regulated and opaquely complex in their functioning, the private healthcare sector has shown a tendency towards concentration and vertical integration during the past two decades, generating major health conglomerates that offer a wide variety of services. This has resulted in the concentration of services and the creation of oligopolies in private healthcare provision, to the detriment of the quality of care for patients.

The private sector supply chain

Within this intricate context, the market for IVD tests in Peru is limited and, until the COVID-19 pandemic began, did not represent an important sector. Prior to 2020, IVD tests were a marginal and niche market, barely known and often unfruitful, economically speaking. It remains to be seen whether the pandemic will help to consolidate the market for IVD tests in Peru. The main actors in the market for IVD tests do not always understand their role and importance and often base their decisions on economic rather than healthcare considerations.

The private sector supply chain of IVD tests, from the manufacturer to the user, comprises a wide variety of actors who take part in diverse processes, which can be categorized in the following way:

1. Manufacture: international manufacturing laboratories
2. Distribution: local subsidiaries of international manufacturers, local representatives or other distributors
3. Sample processing: hospital- or clinic-dependent laboratories and “walk-in” laboratories
4. Sample collection (testing): public or private clinics, testing centres
5. Financing: private insurance

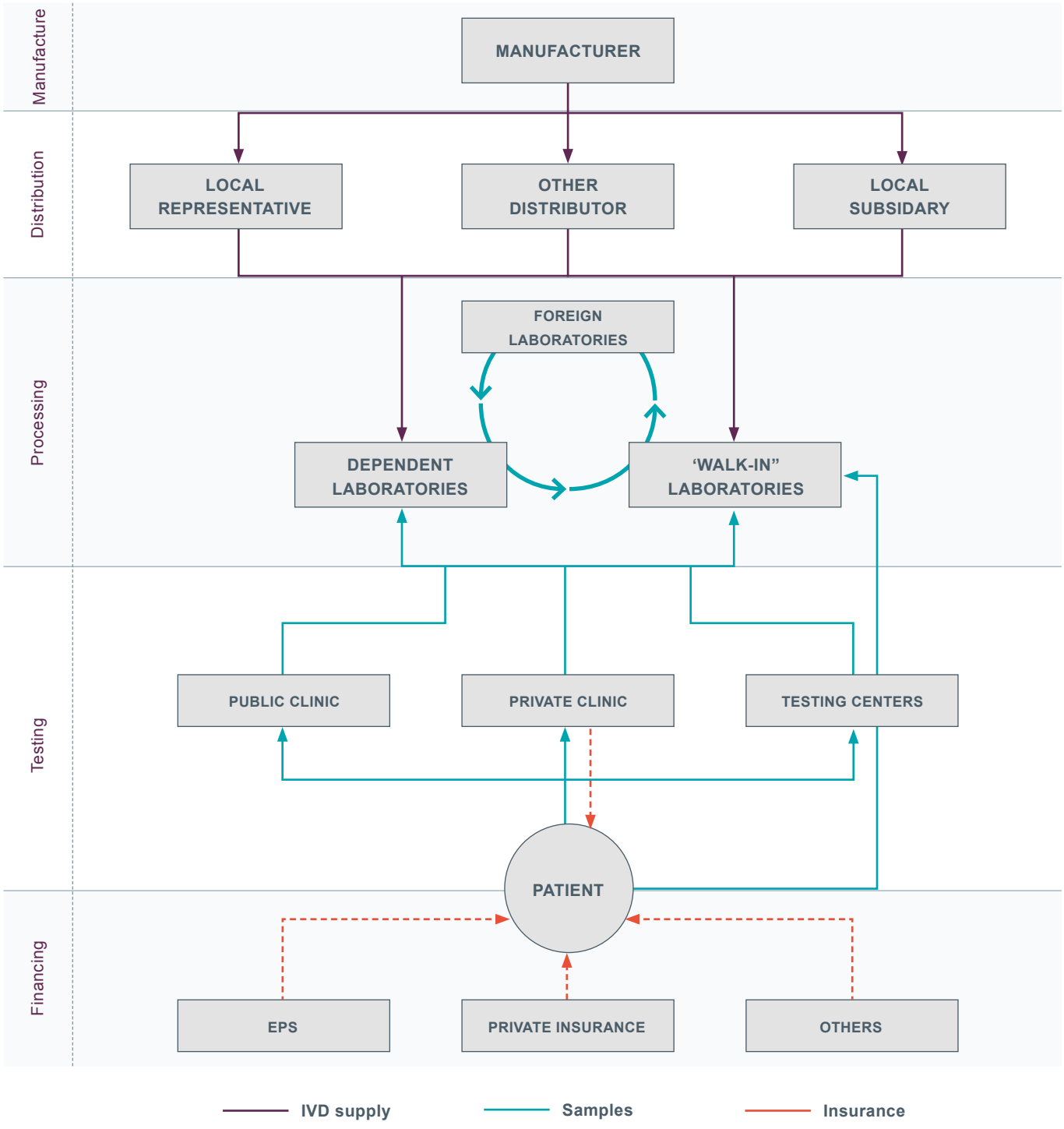
The private sector supply chain of IVD tests is illustrated in Figure 5.1, and each of the components will be described on the next page.

All IVD tests used in Peru are manufactured outside of the country. They can be distributed within Peru by a local subsidiary of the manufacturing company, a local (officially or non-officially) authorized representative (distributor), or by any other distributor who goes through the process of obtaining a sanitary registration or who purchases a certificate of sanitary registration for a product that has already been issued with one.

Distributors then sell IVD tests to laboratories. These laboratories may be dependent on a specific clinic or hospital for their inflow of patients, or in the case of larger and more important laboratories, they can be independent of a clinic or hospital. In the case of these “walk-in” laboratories, demand can be derived either from the patients of the clinic in which they are located, from independent individuals, from patients of other clinics or from patients from testing centres located outside of the main laboratory. In cases where a laboratory does not possess a specific test, it can send samples to another more specialized laboratory or to a laboratory in another country.

Patients may go for sample collection (testing) to a private clinic, a public clinic (which may on occasion send samples to a private laboratory for processing) or to a testing centre, which may or may not be owned by a laboratory or a clinic. Most users are covered by private insurance of different types, such as Health Providing Companies (EPS) or private insurance companies. The larger and most important private clinics usually have their own pre-paid health insurance programmes, known as “*Prepagas*”. Often, insurers do not cover the cost of IVD tests, and these costs must be entirely covered by the patients, outside of their insurance.

Figure 5.1: The private sector supply chain for IVD tests



Manufacturers

As seen in the list of sanitary registrations of DIGEMID, virtually all IVD tests are manufactured outside of Peru. The only IVD test with a sanitary registration in Peru is manufactured in the country, is a test used for the detection of dengue; it is manufactured by the INS. According to the interviewees, there is no company in Peru that manufactures IVD tests, and there is no manufacturing of IVD tests in Peru performed by foreign companies.

The list of sanitary registrations of DIGEMID provides information about the manufacturer of the product and the main distributor in the country. While it does not provide any information concerning total sales, it does give a sense of the importance of each actor and of the relations between manufacturers and distributors.

In Peru, as of July 2021, 2,584 IVD tests have a sanitary registration and can thus be marketed. These IVD tests are manufactured by companies from 40 countries. Nearly a quarter of the tests are manufactured in the USA, while Germany and China account for 18% and 15%, respectively. Other important manufacturers are Spain (6%), Italy (5%), South Korea (4%), France (4%) and Argentina (3%) (Table 5.1).

There are around 412 manufacturers, of which Abbott Laboratories, Beckman Coulter Inc, Becton Dickinson Inc, Diasorin Inc, Roche Diagnostic GmbH, Siemens Healthcare Diagnostics Inc, Wiener Laboratories S.A.I.C. and Shenzhen Mindray Bio produce the greatest amount of IVD test products. Roche and Abbott each manufacture around 9% of the different types of IVD tests used in Peru. Importantly, this does not necessarily indicate that these companies dominate the market through their sales, but it does indicate that they possess a greater diversity of products sold in the country.

The eight companies previously mentioned only account for one third of the total sanitary registrations filed in Peru, the remaining 66% is distributed among 404 other companies with less than 0.2% of the total sanitary registrations each. This is consistent with comments from the interviewees, who mentioned both Abbott and Roche as the main producers of IVD tests used in Peru. It was also mentioned that Roche was planning to withdraw from Peru, outsourcing its sales in the country to a locally authorized representative called “Rochem Biocare del Perú”. We have not been able to verify this information.

The Peruvian market for IVD tests is considerably smaller than that in some other Latin American countries, such as Argentina, Brazil, Mexico, and Chile. In general, it is not a particularly profitable market for foreign companies, who would prefer to enter a market with greater demand. For example, the interviewees signalled that the Latin American market represents only about 8% of the total trade in IVD tests, of which Mexico accounts for half of the consumption. The Peruvian market is about half the size of the Chilean market and only about one third the size of the Colombian market. Therefore, Peru does not represent an important market for foreign companies.

Essentially, a foreign laboratory will only decide to sell its products in a country if it finds sufficient demand in the national market. This will depend largely on the laboratories and clinics in the public and private sectors and their requirements.

Table 5.1: Country of origin of IVD tests used in Peru

Country of origin	Frequency	Percent
Argentina	77	2.98
Australia	2	0.08
Austria	27	1.04
Belgium	23	0.89
Brazil	21	0.81
Canada	32	1.24
Chile	14	0.54
China	390	15.09
Colombia	4	0.15
Cuba	2	0.08
Czech Republic	19	0.74
Denmark	23	0.89
Egypt	5	0.19
Finland	20	0.77
France	110	4.26
Germany	472	18.27
Hungary	3	0.12
India	22	0.85
Ireland	73	2.83
Israel	1	0.04
Italy	119	4.61
Japan	50	1.93
Jordan	2	0.08
Luxemburg	9	0.35
Malaysia	3	0.12
Netherlands	4	0.15
Norway	6	0.23
Peru	1	0.04
Poland	3	0.12
Russia	2	0.08
Singapore	3	0.12
South Africa	1	0.04
South Korea	110	4.26
Spain	154	5.96
Sweden	22	0.85
Switzerland	14	0.54
Taiwan	11	0.43
Turkey	17	0.66
United Kingdom	88	3.41
United States of America	625	24.19
Total	**2,584**	**100**

Additional bureaucratic impediments can often deter the potential importation of products. For example, the interviewees reiterated that the Peruvian market is over-regulated and that the regulatory agencies demand "*unnecessary amounts*" of "*confidential documentation*" from manufacturing companies and distributors, often resulting in long delays in registering products. According to one interviewee, Peru experiences 2 to 3 years of delays in the commercialization of a new IVD test, longer in comparison with that of neighbouring Chile, which possesses a more flexible registration system but a more robust and efficient quality control entity. With respect to the adequate rollout of IVD tests, the interviewee suggested that the technological delay could be even greater, at up to 10 years.

Out of the 412 manufacturers of IVD tests whose products are sold on the Peruvian market, only 4 have a direct presence in the country as distributors. Of these, three (Roche, Abbott and Siemens) are among the top three companies which have obtained the largest numbers of sanitary registrations. This suggests that only companies with a large number of sanitary registrations are able to directly establish a subsidiary company to sell their products in their country.

Excluding these four companies, we found no signs of any integration between foreign manufacturing companies and local distribution companies. We also found no integration between manufacturers and the rest of the supply chain. Some companies, such as Roche, have agreements with local distributors, for example "*Química Suiza*", but they are not part of the same conglomerate. Foreign manufacturers who do not possess a local subsidiary sometimes distribute their products through a locally authorized representative.

An important issue to note is that local production of IVD tests is non-existent and that Peru possesses no capacity to produce them. Local companies have little incentive to invest in a manufacturing facility when the market for their products is minute, demand is comparatively low and competition from foreign products is high. Additionally, investment in research and development (R&D), both from the private and public sector, has been largely absent throughout recent decades, and human resources as well as infrastructure for the manufacturing of IVD tests are lacking.

COMSALUD (the healthcare branch of the Lima Chamber of Commerce, which includes distributors of IVD tests and other companies involved in pharmaceutical healthcare products) recently launched an initiative for the creation of a technological complex for the manufacturing of IVD tests and health supplies used in the treatment of COVID-19 and other diseases. They sought an alliance between the public sector, academia, and the private sector. The project was subsequently presented to the government. However, the change of government in July 2021 has slowed down the discussions and the future of this project is as yet unknown.

In contrast to IVD tests, there is considerable production of medicines for the local market. This indicates that with sufficient demand and incentives, local companies could be willing to invest in the production of nationally manufactured IVD tests, at least for simple and common diseases.

The importation of IVD tests is, in many cases, carried out by local distributors who perform their transactions in foreign currencies (mainly US dollars). This generates a situation in which the local supplies and prices of IVD tests are highly dependent on exchange rates and can be impacted and fluctuate rapidly due to external forces. This can have major consequences on the provision of IVD tests on the local market. For example, one interviewee mentioned that because of the political disruption caused by the 2021 presidential elections in Peru and its effect on exchange rates, in the short-term imported IVD tests would see a sharp increase in their prices, which would affect the prices charged for testing. This ultimately translates into increased prices for consumers, which negatively affects the demand for IVD tests.

The supply of IVD tests essential for the provision of healthcare services is thus dependent on external factors (exchange rate fluctuations, foreign prices of production, international market price fluctuations) that cannot be controlled. Moreover, because of the 1993 constitution, no mechanism for price controls can be enforced to avoid price fluctuations in these products.[69]

Distributors

Distributors of IVD tests are the channel between foreign manufacturers and the user at the national level. They are the entities in charge of importing and commercializing IVD tests in Peru. They must be registered by DIGEMID (see Chapter III) and are the entities responsible for obtaining the sanitary registration of IVD tests. Using both the OSCE database and the DIGEMID registry of sanitary registrations, we identified 227 distributors of IVD tests in the Peruvian market, of which 72 have had contracts with the Peruvian government during the past 3 years.

At the national level, distributors are regulated by DIGEMID and must complete the requirements for the registration as a distributor to be able to sell IVD tests in the local market. Delays in obtaining sanitary registrations from DIGEMID (from 3 months up to more than a year) and in retrieving the products from customs can affect the provision of IVD tests, increasing costs, generating additional transactional costs, and resulting in disincentives, which ultimately hampers the efficient and swift access to innovative or new IVD tests. As

mentioned by one interviewee, "*the revision is slow, which in the long run makes the processes more expensive, or deters suppliers from investing in the Peruvian market, unintentionally resulting in a monopoly and generating limitations on supply*". Importers can also, on occasion, be asked for the sanitary registration of every part of a kit or test instead of a single sanitary registration for the complete product. One interviewee commented that this is due to over-regulation by the controlling agency (DIGEMID), which demands unnecessarily complex details and procedures without possessing the adequate technological infrastructure or trained human resources to perform their inspections and which "*pretends to be stricter than the FDA without being even close to the FDA*".

An example of such excessive regulation pointed out by the interviewees is the requirement for obtaining a new sanitary registration if a product's appearance is changed, despite having the same content. If a test that was originally packaged in a white box is now packaged in a red box, the company must obtain a new registration.

In addition, various interviewees reported that this situation differs in other countries in the region, such as Ecuador, Chile, Colombia and or Bolivia, where control processes for the entry of a new IVD test have been optimized, generating a wider variety of IVD tests on offer on their markets and making them more attractive to foreign companies. As mentioned in Chapter III, DIGEMID also has a regulatory framework more akin to a pharmaceutical controlling agency, with standards that are not applicable to IVDs, making the registration process even more challenging.

COMSALUD told us that they had proposed changes for better regulations of IVD tests based on regulations used in Colombia and Mexico. This was presented prior to the COVID-19 pandemic; however, no advances have been made. We were told by the interviewees from the private sector that the private sector is always interested in innovating, as this can create new commercial possibilities, but that the greatest bottlenecks are the regulatory processes of DIGEMID.

As previously mentioned, the distributor of an IVD test in the local market can either be a local subsidiary of the manufacturing company, a local authorized representative, or other type of distributor. There are only five local subsidiaries of foreign manufacturers, and represent the main international companies, namely Roche, Abbott, Siemens, Becton Dickinson and a local representative of Shenzhen Mindray Bio, called Mindray Peru.

Considering the limitations and costs associated with the entry, registration, and collection of products from customs, as well as the limited size of the Peruvian market, it is fair to assume that only companies with a sufficient volume of sales, who can manage economies of scale and whose portfolio of IVD tests is large enough, can see a potentially profitable outcomes from setting up a local subsidiary of their company.

Local representatives are distributors who are authorized to market products obtained from a foreign manufacturing company and are thus in charge of obtaining the sanitary registration for the product; however, they are not integrated with or part of the same commercial group as the manufacturer. For example, Rochem Biocare del Perú does not form part of Beckman Coulter Inc, but is their official distributor in the country, and it is the main entity that has proceeded to register their products with DIGEMID. Some of these representatives may be the sole authorized representatives of a foreign manufacturer (such as Labin SAC, the local representative of Wiener Laboratories), whereas others may be authorized by a manufacturer alongside other distributors (such as Sistemas Analíticos SAC, which is an authorized distributor of Abbott products alongside the local subsidiary of Abbott Laboratories). Frequently, however, these local representatives require manufacturers to sign exclusivity contracts, so that they are the only company distributing a specific type of IVD test, thus creating a monopoly.

Many of these distributors are local subsidiaries of larger regional importing companies and do not necessarily centre their activities solely around the distribution of IVD tests. These local distributors may be part of larger importation companies that offer products of various brands from a range of sectors, such as veterinary, pharmaceutical and chemical products.

Other companies that commercialize IVD tests are neither subsidiaries nor local representatives of the manufacturing companies. Any distributor can potentially obtain a sanitary registration for a product, regardless of whether it is the subsidiary of the manufacturing company or its representative. Moreover, a distributor other than the owner of the original sanitary registration can apply for a certificate of sanitary registration, which allows them to import and market products without prior authorization from the original holder.

In theory, this system is intended to generate greater access to IVD tests in the country by facilitating the importation of products by other distributors and preventing the formation of importation monopolies. In practice, however, sanitary registrations function as non-rival goods, in which the original distributor who decides to initiate the process of registration bears the bulk of the costs, whereas other distributors freely benefit from the other distributor's prior investments. This could generate disincentives for the registration of new IVD tests on the national market.

Table 5.2: Main distributors of IVD tests in Peru by the number of sanitary registrations obtained

Distributor	Number of sanitary registrations obtained	Percentage of the total
Inmunochem S.A.C.	67	3%
Comercial Importadora Sudamericana S.A.C	69	3%
Mont Group S.A.C.	73	3%
Vikmar S.A.C.	86	3%
Labin Peru S.A.	87	3%
Simed Peru S.A.C.	100	4%
Rochem Biocare Del Peru S.A.C.	121	5%
Sistemas Analíticos S.R.L.	147	6%
Siemens Healthcare S.A.C	157	6%
Productos Roche Q.F.S.A.	283	11%
Abbott Laboratorios S.A.	291	11%
Others	1103	43%
Total	**2584**	**100%**

The main distributors in terms of the number of sanitary registrations filed are Abbott Laboratorios SA (local subsidiary of Abbott Laboratories), Productos Roche Q.F.S.A (local subsidiary of Roche Laboratories), Siemens Healthcare SAC (local subsidiary of Siemens Laboratories), Sistemas Analíticos S.A.C (local representative of Abbott), Rochem Biocare del Perú S.A.C, Simed Perú (local representative of DiaSorin), Labin Peru S.A (local representative of Wiener Laboratories), Mont Group S.A.C, Vikmar S.A.C. and Comercial Importadora Sudamericana S.A.C. These 11 distributors account for 57% of the total sanitary registrations filed, while the remaining 43% of registrations filed are distributed among 189 other distributors. Additionally, 28 other distributors did not register any IVD tests with DIGEMID.

COMSALUD is an association of between 300 and 320 companies that commercialize health products, of which only about 30 are distributors of IVD tests. According to an interviewee, of these 30 companies, about 10 to 12 of them were already solidly established actors pre-COVID-19, and include Roche, Bio-Medical Systems, Diagnostica Peruana SAC, Milenium, Johnson and Johnson, Multimedical Quimtia and Immunochem. One of the benefits of COMSALUD is its expertise, both nationally and internationally, which enables it to have direct contact with the head of certifications in DIGEMID, facilitating the acceptance of registrations of companies who are members of COMSALUD.

According to the interviewees, local representatives, and local subsidiaries, as well as other distributors pertaining to COMSALUD, tend to be well connected and aware of the latest innovations in the field of IVD tests. They have direct links to the manufacturers and are thus conscious of technological advances taking place in the international market. When a new product is manufactured, subsidiaries and local representatives are informed by the parent company, and the product is immediately presented to private laboratories. One interviewee stated that *"the industry finds out about innovations before anyone else, even before the medical world."* Accordingly, there is rapid transmission of information regarding innovations, but it is then complicated to get those innovations into the country.

Distributors import IVD tests for the local market based on the profitability of the demand generated by local entities, both private and public, who only rarely purchase products from international distributors. The demand for IVD tests is determined by the needs of local laboratories in the private sector, as well as the needs of public hospitals, health establishments, national laboratories and the MINSA.

Peru is lagging behind other countries in the region in terms of access to IVD tests. One interviewee mentioned that a country such as Ecuador, which has a population one third that of Peru, uses more IVD tests than Peru. One of the reasons outlined is the lack of knowledge of the utility and worth of an IVD test-based healthcare system. However, the COVID-19 pandemic has generated important changes and opened possibilities for the implementation of IVD tests. According to one interviewee, there is a potential projected growth of 8% over the next four years.

Due to the limited size of the national market in Peru, however, distributors tend to enforce multi-year deals with private laboratories, pooling the sales of reagents and equipment in a contract and offering discounts for these commodities. Thus, distributors also act as demand-setting entities, using medium-term contracts to secure demand. This allows distributors to consolidate sufficient demand and generate returns on the importation of products due to economies of scale.

According to the interviewees (from a distributor perspective), it is common for distributors to offer 5-year contracts, including both the diagnostic equipment and

a continuous supply of reagents. This enables a greater reduction in costs and secures the supply of IVD tests for a foreseeable term, although it also generates a major disincentive for laboratories to invest in new equipment and technology, as they are restrained for a non-trivial period from investing in innovative IVD tests due to higher costs. Imported IVD tests are stored in a distributor's warehouses, and the distribution is managed according to the contracts.

The majority of IVD tests available on the local market are sold to the public sector. As stated by one interviewee, close to 80% of imported IVD tests are sold to government institutions, with the remaining 20% sold directly to private laboratories. Accordingly, all of the IVD tests sold to the private sector are purchased by laboratories, as clinics do not offer diagnostics. They usually have a laboratory within their facilities that purchases IVD tests directly from a distributor. According to an interviewee, the relationship between distributors and private laboratories functions better than that with public entities due to their superior scheduling and payment system.

Despite being crucial players in the supply of healthcare and medical products in general, pharmacies do not sell IVD tests (except for pregnancy tests) and are thus minor players in the supply of IVD tests.

The interviewees mentioned that some local distributors lacked medical knowledge and were guided chiefly by economic interests, hindering the provision of higher quality IVD tests. These distributors provide cheaper, low-quality tests, which ultimately has repercussions for the healthcare provision for Peruvian patients.

Clinics

In the Peruvian private health system, diagnostic testing depends on an intricate interplay among private clinics, healthcare networks and laboratories. Clinics are mainly tasked with the evaluation and treatment of patients; for testing they work with laboratories, which may or may not have any relationship with the clinics.

Regardless of their public or private nature, each health sub-sector operates separately through their own health providing institutions and centres (IPRESS). Healthcare centres are classified into three categories: I, II and III. Type I health establishments are health centres and health posts that offer primary care services. Type II health establishments consist of small hospitals, while type III health establishments are the larger hospitals that offer more specialized services.[70]

Private clinics also follow this categorization and can be either type II or III. Nearly all clinics belong to type II, with some exceptions such as Clinica San Felipe, Clinica San Borja and Clinica Ricardo Palma, which are type III and offer more complex operations and services. These clinics tend to form part of a greater network of healthcare services and clinics belonging to the same entrepreneurial conglomerate.

To achieve greater economic sustainability and viability, clinics require sufficient volumes of patients to justify initial and continuous investment costs, which often results in the demand for the "massification" of a clinical network (the transformation from an individual clinic into a network of clinics). As stated by one interviewee *"if we* [private clinics] *are to survive, we need to exist as a network or a chain…we cannot sustain ourselves as single, isolated clinics"*.

Some smaller clinics, such as Stella Maris, Anglo-American, Maison de Santé and Policlínico Peruano-Japones, function in a more independent manner as isolated clinics, through their own network of insurance and services. However, most private clinics are integrated within chains and networks of health centres, within which they can share medical equipment, resources and supplies as well as transfer patients and samples between establishments.

Clinics purchase their supplies through their Purchase and Acquisitions department, which determines the needs and requirements by means of a technical committee composed of medical experts. This does not encompass IVD tests, as these are purchased and used directly by laboratories, whose services are outsourced by private clinics. The "outsourcing" of laboratory services in Peru is unusual, as even laboratory services that belong to the same network of healthcare establishments and to the same conglomerate as the private clinic are required to be a different commercial entity. The relationships between clinics and laboratories are explained in the next chapter.

Although clinics and health centres do not directly manage the provision of IVD tests and their usage, these are indirectly standardized through the ministerial resolution RM N° 076-2014,[70] which indicates the minimal infrastructure and equipment required for the categorization of health establishments according to their level of complexity. This categorization is however unclear and provides virtually no detail on the IVD tests required by each level of complexity.

Private clinics have lists of pharmaceutical products, medical equipment and devices as well as IVD tests provided, which form part of the services they offer. This list of IVD tests is determined by a technical committee within the clinic. New IVD tests can be demanded by specialists and doctors at a clinic, and these can be incorporated in the clinic's list if they are backed by a technical report that includes clinical evidence, proof of cost effectiveness and proof of demand. If a new IVD test is too expensive or lacks demand locally, the probability of opening a commercial channel for it is minimal.

Apart from private clinics, patients can also access IVD tests at collection/testing centres that may perform simple diagnostic tests but can also send samples to private laboratories for processing. These centres may form part of a healthcare network, or they can be independent centres. This last category has seen a surge during the past year, particularly due to the COVID-19 testing boom, which resulted in a growth of collection centres that are dependent on private laboratories for subsequent sample processing.

Laboratories

In the Peruvian private health system, IVD tests are performed within private laboratories. These can either be dependent or independent, walk-in laboratories. They are entirely supplied by the local distributors previously described. The differentiation between dependent and walk-in laboratories is based on their relationship with private clinics.

As mentioned previously, private laboratories tend to be located within private clinics and often form part of the same entrepreneurial group. In the case of dependent laboratories, they obtain most of their patients through the services offered in their hosting clinic and are thus dependent on them for their economic viability. For example, Anglo-Lab depends on the inflow of patients from its hosting clinic, Clinica Anglo Americana, and is located within it.

Other types of dependent laboratories function through their network of clinics. These laboratories are still dependent on their affiliation with a clinic but have expanded in accordance with the expansion of their affiliated network of clinics. An example is the Precisa Laboratories; these are located within clinics of the Sanna health establishment chain. Each Sanna clinic possesses a Precisa Laboratory counterpart within its premises. The initial Precisa laboratory was dependent upon the Clinica San Borja and, as the Sanna healthcare chain expanded, so did its Precisa Laboratories counterpart. Similarly, Auna Laboratories are dependent on the Auna Clinics, and Qualab Laboratories are dependent on the San Pablo Group Clinics.

On the other hand, walk-in laboratories are those that do not necessarily require the referral of patients from a hosting clinic. These laboratories receive an inflow of individuals who directly walk into the laboratory for testing without first going through a private clinic or being referred by their private physician. They also tend to have contracts with testing/sampling centres or function as a reference laboratory for clinics for whom they process samples or for smaller laboratories that offer few IVD tests.

Most walk-in laboratories are located within a major clinic, although the bulk of their clients are not necessarily from the clinic in which they are located. For example, UniLabs Laboratories are located within a building of the Clinica Internacional network, but also offer laboratory services to the Kailin and Barton hospitals, which are public–private hospitals dependent on the EsSalud network.

Similarly, Roe laboratories are located at the San Felipe Clinic and receive referral patients from this clinic, while simultaneously providing services to other laboratories/clinics and to independent individuals who do not come from any clinic. These independent individuals represent close to 70% of the population served by Roe. Roe also offers its services to Precisa Laboratories, which sends samples requiring more complex tests, such as molecular tests, genetic tests, or special antibody tests for specific diseases. Additionally, Roe provides services to the public sector (around 5% of the samples it receives are referrals from the public sector). According to one interviewee, patients from the public sector who have been unable to find an adequate service will pay OOP for private laboratory services. This represents, in the case of Roe, close to 20% of their total samples. Other examples of this type of walk-in laboratory include UniLabs Laboratories and SynLab Laboratories.

Other types of walk-in laboratories function completely independently from a network of clinics. For example, MultiLab Laboratories possess their own network of testing and sampling centres connected to their headquarters, a larger and more complex establishment in which the samples are processed. MultiLab began in the suburbs of Lima and has subsequently grown, opening centres in various districts of the city.

Walk-in laboratories can also work by solely offering services to other clinics and laboratories. For example, Suiza Lab offers its laboratory services to public sector institutions, such as the Naval Hospital and the Military Hospital, and processes samples from other independent testing and sampling centres, as well as smaller laboratories. These are solely contract providers of diagnostic testing, meaning that they do not exclusively belong to any network or clinic.

Walk-in laboratories do not offer packages of tests or specific coverage to their independent patients; instead, they sell individual tests, which are ultimately financed through OOP expenditure. As reported by one of the interviewees *"we answer to demand, we don't promote supply"*. Independent individuals who seek services at walk-in laboratories tend to be patients requiring routine tests, such as a check-up for cholesterol or glucose levels, and may or may not have been sent by their private physician.

Table 5.3: Classification of private laboratories in Peru

Type of laboratory	Sub-type of laboratory	Depends on patients or samples derived from an associated clinic?	Part of a network?	Located within a clinic?	Example
Dependent laboratory	Dependent laboratory	Yes	No	Yes	AngloLab
	Network-dependent laboratory	Yes	Yes	Yes	Precisa, AUNA
Walk-in laboratory	Walk-in laboratory	No	Yes	Yes	Roe, SynLab
	Autonomous walk-in laboratory	No	Yes	No	MultiLab
	Individual walk-in laboratory	No	No	No	Suiza Lab

The portfolio of IVD tests provided by a laboratory is decided by the medical director in coordination with the manager of the laboratory. These IVD tests are provided entirely according to the demand for the test, as no laboratory will provide tests for which demand is weak. In the words of one private sector interviewee *"you don't offer a test if you are going to lose money"*. Laboratories are directed by a manager who decides on the course of action to be taken, with the decisions of the medical director of secondary importance. For some interviewees, this explains the bias towards economic returns rather than the optimum and timely provision of healthcare, which would result in an equilibrium between medical and economic decisions. Some are *"good laboratories and good businesses, whereas others are bad laboratories but good businesses"*. If a laboratory does not have a particular IVD test in its portfolio, it will collect a sample and send it to a local laboratory that does offer this IVD test. In cases where an IVD test is not available within the country, samples are sent to international laboratories, usually in Spain or the USA, that have broader portfolios. The results are subsequently communicated via email or through a web portal.

Around 90% of laboratories are sustained by the privately insured population, mainly through an EPS or a clinic's own private insurance (known as *Prepagas*). IVD tests covered, prices and co-payments are negotiated directly between clinics and insurance companies, while laboratories maintain a fixed price. The prices charged for each test are regulated depending on supply and demand and considering a unique tariff system, named SEGUS, which details the prices of medical operations and the tests covered by insurance. SEGUS was developed by private sector insurance companies.

Laboratory licences and applications are processed by the DIRIS/DIRESAs, and their functioning is supervised by SUSALUD, an organization that is dependent on the MINSA. With regards to technical procedures, laboratories depend directly on the National Health Institute, which is responsible for supervising compliance with national standards for biosecurity, waste management, use of PPE and more.

Laboratories with greater commercial demand usually have automated equipment, for which the cost effectiveness depends on the volume of samples processed per hour. This type of equipment is very expensive, in some cases costing close to 300,000 USD, and is therefore inaccessible to smaller laboratories. This explains the need for smaller laboratories to rapidly expand and process greater numbers of samples, to dampen the high initial costs of equipment and machinery.

With reference to the purchase of supplies and laboratory equipment, interviewees (from a laboratory perspective) mentioned that in contracts between laboratories and distributors, the latter normally provided the equipment, such as analysers. That is, the equipment is made available to the laboratory at a lower price, with a contract including the purchase of reagents for a fixed term, usually a period of 5 years. Some distributors even provide the equipment through a rental–reagent agreement, making the equipment available free of charge but demanding that a higher volume of reagents be purchased. For this, laboratories must possess sufficiently high processing volumes to render it a profitable investment.

The problem with this system, however, is that it inhibits the adoption of newer technologies. If a laboratory signs a contract with a distributor for costly equipment and a supply of reagents for a fixed 5-year term and a newer/better product appears on the market, adoption of the new product will incur tremendous financial costs. A purchase that does not generate returns due to a change in equipment is too costly for a company to risk. One

interviewee stated that most laboratories use Roche equipment, due to its large quantities of stock and offers maintenance contracts for highly specialized laboratories, as well as its direct presence locally, which makes it more accountable in the case of litigation.

Private laboratories do not usually buy large volumes of IVD tests, unlike the public sector, as they tend to make purchases based on monthly forecasts and by estimating potential demand to achieve greater cost-efficiencies. This is partly due to their storage limitations. According to one interviewee, these laboratories ideally work with a maximum critical stock of 15 days, illustrating the continuous nature of the programming and purchasing in the private sector supply chain. For the same reason, these laboratories have fewer concerns about the expiry of IVD tests, reagents, and other supplies.

Each laboratory also uses its own internal system of vigilance to avoid over-stock of products and to register sales. The capacity for data analysis and management of their information systems allows private sector laboratories to develop predictive models for the demand for certain IVD tests. For example, influenza tends to be more prevalent during the months of July, August, and September (winter in the southern hemisphere), thus a greater number of IVD tests for influenza will be needed during this time. Data management not only enables the generation of predictions associated with historical trends but also with epidemiological factors. These tools mean the private sector can make more accurate predictions and reduce the likelihood of over- or under-stock of IVD tests.

According to the interviewees, the private sector has a greater capacity to identify potential opportunities within the market and can import products much more quickly than the public sector, which has *"a purchasing process way more complicated than within the* [private] *sector*". These processes in the public sector are more challenging and take longer due to the higher degree of beaurocratic control and regulation, which delays purchases.

Other interviewees, however, identified potential flaws in the private sector supply chain, mentioning that finding a distributor in the market that distributes certain products can sometimes be complicated or impossible. One interviewee declared that this had happened with their laboratories for seven different pathogens for which they required rapid IVD tests. In particular *"something as easy as obtaining test strips to realize strep tests, to rule out bacterial upper respiratory infection from a viral one, was impossible. At the end, we were unable to find a distributor which would provide this type of tests which are necessary at the community level"*.

The interviewees mentioned similar problems related to the lack of supply of certain types of IVD tests, which they traced back to the lack of overall demand caused by the small size of the national market. Others stated that part of the problem lies in the fact that most distributors are just small traders, with little to no knowledge of medicine, resulting in a lack of supply in crucial medical fields due to them not being seen as economically attractive for distributors. On the other hand, larger distributors seem to inspire greater confidence and security due to their direct connection with medical experts and the links their staff have with the medical world outside of Peru.

We were also given the example of a private laboratory whose distributor was leaving the country and thus ending the provision of the reagents needed for the biomedical equipment used in the laboratory. This laboratory searched for another local distributor but could not find one, so it searched for alternatives in Bolivia, where it found a distributor that ended up being less expensive than its previous one in Peru.

Other evidence from the interviewees describes the existence of corrupt practices between laboratories and clinics, in which medical experts send patients to a particular laboratory in return for a percentage of the price charged by the laboratory for an IVD test. This appears to be a normal practice in the country.

Insurance

According to SuSalud, close to 33.4 million Peruvians are covered by some type of insurance, meaning that around 97.5% of the population is "insured". An insurer, also known as an Administrative Institution of Health Insurance Funds (IAFA), is a *"public, private or mixed entity or company, created or to be created, that receives, attracts and/or manages funds to cover healthcare or that offers health risk coverage, under any modality."* An insurer must be registered with SuSalud prior to offering coverage.

In Chapter II, we discussed the public sector insurers, which include the SIS, FISSAL, EsSalud, and the insurance cover provided by the armed forces (FOSPEME, FOSFAP and FOSMAR) and the national police (FOSPOL). Altogether, these are responsible for the healthcare coverage of close to 92% of the Peruvian population. The main insurer is the SIS, followed by EsSalud.

The private sector comprises a myriad of heterogeneous insurers, with considerable variations with respect to their size, targeted population and function. Most private insurers are limited to financing and covering the health services required by their insured population, but the largest insurance entities are also providers of health services through their own network of clinics and laboratories.

An insurance company in the private sector can either be an EPS, a *Prepagas*, a private insurance company or another type of insurer. There are 98 IAFAs registered in SuSalud, of which we have been able to identify 94. Of these, 7 are public and 87 are private.

An EPS (Health Providing Company in English) is a company that offers insurance schemes for formal workers and businesses. Any formal company or independent formal worker is typically obligated to obtain an EsSalud insurance. An EPS is a private complement to EsSalud that businesses and workers can contract. In practice, EPSs function as a private counterpart to EsSalud, and are financed through the contributions of their insured population. The EPSs have extensive networks of clinics and laboratories in most regions and cover the main population centres of the country. There are five EPSs: Rimac EPS, Pacifico S.A. EPS, Mapfre Peru S.A. EPS, Sanitas Peru S.A. EPS and La Positiva EPS, covering close to 883,000 clients. Of these, 89% are covered by Rimac and Pacifico.

Table 5.4: Number of health insurance providers per type of IAFA registered by SuSalud in 2020

Type of IAFA	Frequency
SIS	1
EsSalud	1
FISSAL	1
FFAA	3
FOSPOL	1
EPS	5
Private health insurance companies	11
Prepagas	20
Autonomous mixed healthcare funds	14
Traffic accident funds (AFOCAT)	41
Total	**98**

A private health insurance company covers their clients' needs through a network of healthcare facilities. Private insurance companies function similarly to EPSs, but do not depend on the formality of a worker. They can cover any individual who can pay for it.

There are eleven private insurance companies, of which only seven are active. Of these seven entities, the four most important in terms of population covered are Pacifico Seguros, Rimac Seguros, La Positiva Seguros and Mapfre Peru Seguros, which also have an EPS counterpart. The remaining three are Chubb Peru Seguros, Crecer Seguros and Protecta Seguros. These seven companies cover close to 1 million individuals, mainly located in Lima and the regional capitals such as Arequipa and Trujillo.

A *Prepagas* is an insurance policy offered directly by a private clinic, without operating through an insurance company network. Seventeen of the 20 *Prepagas* insure approximately 956,000 clients and are mainly found in Lima. Oncosalud, a specialized oncologic insurance policy (the only private one in the country offering coverage for cancer-related costs), is responsible for 86% of all *Prepagas* clients.

Finally, there is a further 55 other types of health insurances, mainly traffic accident funds and autonomous mixed healthcare funds, that only cover 3% of the population. Traffic accident funds (AFOCAT) refer to regional funds aimed at insuring individuals against car accidents, mainly with respect to material damages, but also including healthcare coverage. Autonomous mixed healthcare funds are public or private–public healthcare funds that insure public sector workers (e.g. from the Peruvian Central Bank, public universities and others).

Insurers directly contract with clinics, health centres and laboratories, creating a network to provide services to the insured clients they cover. The services covered depend on the specific plan a client takes out. More expensive plans grant access to more coverage in terms of services and health establishments available. Any insurance plan offered is composed of diverse benefits and services, which include ambulatory services, in-patient services, medical treatments, surgery and medicines. Within these services, laboratory services cover IVD diagnostic tests and represent a small proportion of the coverage provided by these companies.

The role of insurance companies in the IVD test supply chain is limited, as they mainly act as financers who contract a network of clinics/laboratories, which are the establishments that offer IVD tests. Insurers are obligated to cover a minimum pre-determined number of services and IVD tests outlined in the basic PEAS (Essential Health Insurance Plan) of the Ministry of Health. Additional IVD tests may be covered, depending on the insurance scheme taken out by a client, otherwise they are covered OOP.

Each insurance company independently negotiates the costs of services covered directly with each clinic in a network. According to the interviewees, the main insurance companies, such as Rimac, Pacifico and Mapfre, cover similar networks of health establishments and offer very similar insurance schemes in terms of their respective services and benefits. More expensive schemes imply greater coverage in terms of health establishment options, as well as a larger number of services covered, which includes IVD tests. The main insurance companies offer around eight different insurance schemes.

Insurance schemes base their prices on a tariff system named SEGUS, which details the prices charged for medical operations and tests. According to the interviewees, *"the SEGUS tariff is a disgrace, it is antiquated and includes tests which don't even exist anymore, whereas it hardly*

covers any newer tests." and *"The insurers do not pay much attention to diagnostic tests. Nor does the client. The client asks: What clinic do you cover? He never asks: What diagnostic test do you cover?"*. These prices are subsequently negotiated with each individual clinic whose services are covered by the insurance.

It is unusual for insurance companies to update their schemes and tariff lists, thus the incorporation of new IVD tests is infrequent. According to the interviewees, there is a set package of coverage, which may on some occasions be tweaked, although *"It is not the case that people continuously knock at our [the insurer's] door to tell us to cover a new test"*. However, it seems to be the case that insurers can potentially incorporate a new IVD test in their tariff list quite rapidly. For example, during the COVID-19 pandemic, COVID-19 tests and care were swiftly incorporated following an executive meeting between the members of APESEG (Peruvian Association of Insurance Companies).

One of the interviewees mentioned that, in 2005, there was an attempt by the Association of Clinics to incorporate a new national policy of standardized tariffs, which was boycotted by the insurance companies. Additionally, through the Association of Clinics, a review of tariffs was proposed, which suggested that *"30% of tests covered should see their prices reduced, 30% should see them increased, and 30% should maintain the prices"*. This evaluation was not accepted by the insurance companies.

According to one interviewee, one of the main problems in the private sector is that healthcare has become a business, in which many actions are taken without adequate medical underpinning. The only objective is to obtain greater economic returns, noting that *"in the preventive part, the tests covered by insurance companies are not necessarily based on guides or clinical protocols based on scientific evidence"*.

Guilds and supervision of the private healthcare sector

Most of the private sector entities tend to cluster into closed entrepreneurial guilds. The larger guilds and companies form part of the CONFIEP, the largest entrepreneurial guild in the country, which yields considerable influence over political decisions. The main guilds are as follows:

COMSALUD (Healthcare committee/branch of the Lima Chamber of Commerce)

The health guild COMSALUD of the Lima Chamber of Commerce (CCL) includes between 300 and 320 manufacturing and distribution companies, as well as pharmaceutical companies and medicine distributors. This includes companies that manufacture and distribute medical equipment and materials, laboratory equipment and supplies, and pharmaceutical products. Among these, a sub-sector is dedicated to the distribution of IVD tests in the country, making ComSalud the only entrepreneurial guild in the country to possess representation from distributors of IVD tests. It comprises all of the main distributors that operated in the sector prior to COVID-19, and thus companies who have been active for a long time.

Association of Private Clinics (ACP)

The Association of Private Clinics (Asociación de Clínicas Privadas, ACP in Spanish) is a guild comprising the private companies that offer medical services through their health establishments. It includes more than 65 associates, among which are the main private clinics in Peru, such as Clínica Anglo Americana, San Judas Tadeo, Clínica Arequipa, Clínica Internacional, Resomasa, Suizalab, Medlab, Clínica San Juan de Dios, Clínica San Pablo, Clínico San Felipe,Tezza, Montefiori and Clínica Peruano Japonesa.

Participation in the ACP is voluntary. The ACP may suggest specific common policies and actions, but it has no official capacity, and its decisions are non-binding.

The ACP played a dominant role during the COVID-19 pandemic due to their efforts to open up PCR testing for COVID-19 to the private sector.

National Association of Pharmaceutical Laboratories (ALAFARPE)

The National Association of Pharmaceutical Laboratories (Asociación Nacional de Laboratorios Farmacéuticos, ALAFARPE) is a guild created in 1953, which unites the main national and international pharmaceutical laboratories who operate in the country. Its members include GSK, Abbie, AstraZeneca, Grunenthal, Jansen, Bayer, Merck and Deutsche Pharma. It includes 23 innovation laboratories, and for 65 years it has been solely dedicated to pharmaceutical products. However, companies present in ALAFARPE have counterparts that are part of the IVD test supply chain, for example Jansen's relationship with Johnson & Johnson and Roche Pharma with Roche diagnostics.

Other guilds

- **ALAFAL (Association of Latin American Pharmaceutical Laboratories)** Established in 2003, it unites Latin American pharmaceutical laboratories.
- **ADIFAN (National Pharmaceutical Industries Association)** Created in 1982, it unites national pharmaceutical laboratories.
- **ANCAB (National Association of Chains of Boticas)** *Boticas* are like pharmacies, but they do not require a pharmacist to work in them. In Peru, they are more common than pharmacies, and they

tend to be organized in chains. ANCAB unites approximately 2000 *boticas*, mostly in chains such as InkaFarma or MiFarma.

- **APESEG (Association of Insurance Providers)** is the guild that unites insurance companies.
- **APEPS (Association of Health Providing Entities)** is the guild that unites the EPS companies.

In general, all entrepreneurial guilds mainly focus on achieving less regulation and greater agility of administrative and technical processes, to lower barriers to the entrance of new products and innovations.[71]

Supervision of the private sector

Despite in theory having a supervisory capacity, in practice, neither the INS nor DIGEMID seem to control the quality of IVD tests that are purchased and imported into Peru. Laboratories, insurers, and clinics are supervised by SuSalud, which is the National Health Superintendency, who are officially in charge of overseeing the services provided by these establishments. SuSalud's main objective is to protect the health rights of each Peruvian citizen, for which it directs its actions to empower and place the citizen at the centre of the national health system.

The laboratories are meant to be overseen by the INS, which supervises compliance with biosecurity, waste management and PPE use standards. The inspection of laboratories is coordinated by DIRIS or DIRESAs and should be carried out every six months. However, the lack of staff means that these inspections may occur less frequently.

One of the main problems with IVD tests in the private sector is the absence of quality control in the country. Neither the INS, DIGEMID nor SuSalud possess sufficient technical capabilities and trained staff to monitor the quality of IVD tests registered and used in the laboratories. Moreover, not only reagents but also the equipment lacks adequate monitoring and quality control. In practice, a laboratory can produce incorrect measurements because of faulty equipment and dysfunctional reagents, and no supervisory mechanism exists to detect such errors. Patients are essentially entirely dependent upon the good-will of private laboratories and IVD test distributors.

During the COVID-19 pandemic, for example, large quantities of various types of tests (rapid tests, molecular tests, etc.) were purchased by different laboratories and clinics, without any standardization, quality control or comparison by regulatory agencies. Not only was there deficient regulation and control when registering these products in DIGEMID but also the quality control in laboratories and standardization of products was non-existent. As mentioned by one interviewee, *"This happened with a high vigilance level disease, with everyone looking and attentive to it. Imagine how this happens with other diseases…"*

As mentioned previously, one of the main reasons for the situation described by the interviewees is the lack of trained DIGEMID personnel, as there are few medical experts in IVD tests in charge of the registration process. The registration of new IVD tests is merely an administrative checklist, in which files are revised mechanically without paying too much attention to whether the tests actually work. DIGEMID should play a more proactive role, by supervising and assisting companies with the registration of products and helping to determine the quality of the products being registered.

Market concentration

The effect of Peru's liberal turn in the 1990s, ratified through the constitution of 1993, cemented an economic model of an extreme free market in which state entities were relegated to a secondary role in terms of their action and regulation of market activity.[69] Their auditing competency, as well as their regulatory and supervisory capacities, were weakened and assigned minor roles, while direct state intervention was virtually excluded. Within this economic context, coupled with the weakening and dispersion of civil society, corporate actors consolidated high levels of economic, media and political influence, transforming and merging to become multi-company entrepreneurial conglomerates.[72]

The increasing concentration of economic power, which generated an asymmetry of power that was favourable to corporate actors to the detriment of state entities, was accompanied by a decrease in the already low levels of investment in public healthcare and a worsening of the deficient supervision of the private healthcare sector. Oriented towards the acquisition of high rents and economic returns, the management of the private healthcare sector, and the presence of a permissive and unvigilant state influenced by private interests, allowed the formation of oligopolies in health, which provide services through networks of health providing companies.[73]

Attracted by the large economic returns, economic groups have diversified their investments towards the healthcare sector and integrated clinics, laboratories, insurance companies, pharmaceutical laboratories, ambulance services and other medical establishments and services into larger healthcare conglomerates. The provision of a large array of vertically integrated services decreases transaction costs and generates greater returns. Three of the five main entrepreneurial conglomerates in the Peruvian economy (Romero Group, Brescia Group and Intercorp) have activities in the healthcare sector, which were expanded through mergers and acquisitions.

In general, health conglomerates have a dominant position, not only due to their high levels of investments

and monopoly on the provision of healthcare but also due to their high degree of influence on the state, policymakers, and the media.[73]

Regulation of monopolies being absent from the constitution and insufficient regulation of the system, as well as the inability of the state to exert any control on prices or market processes, inevitably translate into practices that harm patients and the adequate provision of healthcare in the country, allowing healthcare inequalities to perpetuate.[13,69] Dishonest and arbitrary prices are common, as observed with the sales of overpriced medicines by pharmacies,[75] and the direct effects of managing the healthcare sector from a purely economic perspective results in essential equipment and medical supplies being overpriced, as evidenced during the COVID-19 pandemic with the surge in prices of medicinal oxygen.[75]

In practice, due to a lack of competition, health conglomerates can charge exorbitant prices throughout their companies in a completely unregulated fashion. Often, INDECOPI (National Institute for the Defense of Competition and the Protection of Intellectual Property, the state entity in charge of consumer rights) is unable to resolve the harm realized upon patients, due to its insufficient capacity.

According to Durand & Salcedo (2020), there are eight private conglomerates that cover close to 2 million patients, which own virtually all of the important private health centres, laboratories, insurance companies, pharmacies, funeral homes and other health services, concentrating the companies that cover all processes, from the financing entities to manufacturing to the user-facing services.[73] These are the Romero Group, the Brescia Group, Intercorp (Rodriguez Pastor Group), the Enfoca Group, Mapfre Group, Ferreycorp (Ferreyros Group), Cruz Blanca Group, San Pablo Group, Ricardo Palma Group and Luis Quito Group. Of these, the first three stand out as the major players in the supply chain of IVD tests in Peru. The entire supply chains of many pharmaceutical products or medicines are controlled by a few conglomerates via their companies, which are present at every step of the process.

The Romero Group is one of the main financial groups in Peru through its company Credicorp and its banking entity the Banco de Crédito del Perú (BCP). It possesses monopolies and important companies in other critical sectors that are determinants of healthcare, such as food production (with Alicorp, the agro-alimentary monopoly in Peru), cooking products, storage facilities, docks, ports, and private pension funds (AFP Prima, one of the largestprivate pension funds in the country). In terms of the IVD test supply chain, the Romero Group controls a network of 74 medical centres, 5 clinics, 3 chains of laboratories (Precisa, ROE & Arias Stella), private laboratories (Análisis Clinicos ML, Sequence Lab), a private EPS (Pacífico EPS, which represents close to 35% of the market), a private insurance company (Pacífico Seguros), and the Sanna chain of clinics. It has Prepagas insurance linked to its network of private clinics (Prepagas Clinica San Felipe, Prepagas Clinica El Golf, Prepagas Stella Maris), and it also manufactures pharmaceutical products through Laboratorios AC Farma SA.

The Brescia Group, which holds the Banco Continental BBVA in the finance sector, owns the main fishery companies and has an important network of hotels, complexes, industrial companies and mining services, among others. In terms of the health sector and the IVD test supply chain, it controls the Clinica Internacional network of clinics, as well the Medicentro clinics. It also possesses Rimac Seguros EPS (around 30% of market) and the Rimac Seguros insurance company, one of the main insurance companies in the country.

The Rodriguez Pastor Group, also known as InterCorp, the owner of Interbank, has important networks of educational centres, commercial malls, cinemas, restaurant franchises, among others. In the health sector, it has a monopoly on pharmaceutical distribution in the country (around 80% of the market),[76] due to rapid mergers and acquisitions of competitors, with its companies Eckerd Perú (which owns Inkafarma) and Quicorp S.A. (which owns Química Suiza, MiFarma, BTL, among others). It also holds recent investments in its own network of clinics, called Aviva; this currently comprises just one clinic, but it is seeking to expand to 12 clinics throughout the country.

The Enfoca Group, a private equity fund, controls companies in various sectors, including education, telecommunications, airports and universities. It has investments in healthcare and is important in the IVD test supply chain due to its control of the Auna Group, which includes Auna Laboratories, Auna Clinics, polyclinics, medical centres and testing centres. It also controls additional laboratories and testing centres, as well as Oncosalud, a network of clinics that dominates the market for cancer treatments. Additionally, it has purchased important clinics such as Clinica Delgado, incorporating them into the Auna network. It also incorporates Prepagas insurance in its network of clinics, such as the Oncosalud Prepagas.

The Mapfre group controls Mapfre EPS, Mapfre insurance company, and a network of medical centres in Lima. It also owns funeral homes and maternal care centres.

The Ferreycorp group controls two EPSs, La Positiva EPS and Sanitas EPS, as well as a network of clinics and polyclinics in Lima.

Regarding the supply chain of IVD tests in the private sector, we can see the high concentration of clinics, laboratories, and insurance companies in the hands of a few health conglomerates. However, probably because

of the small size of the market and the absence of local incentives for manufacturing, we have found no evidence of concentration of the market for the distribution of IVD tests. One could, however, argue that the market for the manufacture and distribution of IVD tests could potentially grow in the coming years as a result of COVID-19. In this scenario, it is quite plausible to assume that the same pattern of market concentration will occur as occurred with medicines and pharmaceutical products.

In any case, the oligopolization of private healthcare in Peru is detrimental to the appropriate and desirable delivery of healthcare; this directly affects patients due to a business-driven approach, unfavourable prices of consumer products, and cartelization of supply, which drives up the costs of treatment and care. In the case of IVD tests, this situation coupled with the lack of regulation and supervision of the sector could potentially lead to the deficient provision of and access to IVD tests on the local market.

Figure 5.2: Market concentration in the IVD test supply chain

IVD MARKET				
ENTREPRENURIAL GROUP	**DISTRIBUTION**	**LABORATORIES**	**CLINICS & HEALTH ESTABLISHMENTS**	**INSURANCES**
ROMERO GROUP	*Unclear, further research is needed*	• Laboratorios Arias Stella (4 establishments) • Laboratorios Precisa (9 establishments) • Laboratorios ROE (16 establishments) • Instituto Aria Stella • Analisis Clinicos ML • Sequence Reference Lab	• Aliada Centro Oncológico • Clínica Sánchez Ferrer • Clínica Belén • Clínica del Sur • Clínica San Borja • Clínica el Golf • Clínicas Sanna (8 establishments) • Centro Médico Clínica Sánchez Ferrer • Centro Odontológico Americano (37 establishments)	• Pacifico EPS • Pacifico Peruano Suiza Compañía de Seguros • Prepagas - Clínica el golf • Prepagas - Clínica San Borja • Prepagas - Centro Odontológico Americano • Prepagas - Clínica Stella Maris
BRESCIA GROUP			• Ambulância votorantim • Clínica Internacional (6 establishments) • Oncológica Miraflores • Medicentro (8 establishments) • Tópico Mina Pierina • Servicios De Auditoria De Salud S.A.C	• Rimac EPS • Rimac Internacional Compañia de Seguros
INTERCORP			• AVIVIA - Sede Los Olivos	
ENFOCA GROUP		• Laboratorio Cantella • Cantella Lab Center • AUNA (Various establishments) • ONCOSALUD (Various establishments)	• Clínica Delgado • Clínica Bellavista • Clínicas AUNA (7 establishments) • Servimédicos Chiclayo • Toma De Muestras Sagrado Corazón De Jesús • Clínica Cantella • Oncosalud (5 establishments) • Radiocologia	• Prepagas - Oncosalud S.A.C

Sources: Durand & Salcedo 2020, Interviews.

Summary

Here, we summarize the findings described in this chapter. Several items relate to important bottlenecks that should be analysed and improved to strengthen the landscape of IVD tests in Peru.

Manufacture:

- Non-existent production of IVD tests at the local level. There is zero capacity to produce IVD tests due to limited incentives (e.g. small market-size, heavy regulation, challenging administrative processes) and a lack of infrastructure, technology and adequate human resources and expertise.
- The Peruvian market for IVD tests is small and relatively less attractive for investment by foreign companies.
- Dependence on foreign production and importation. Local supplies and prices are subject to exchange-rate fluctuations and the willingness of distributors and manufacturers to invest in the country.
- The excessive and sometimes unnecessary bureaucracy at the regulatory level renders the Peruvian market less attractive than others in the region.
- The over-regulation on behalf of DIGEMID inhibits the adoption of new IVD tests, disincentivizing manufacturers and distributors to register new products.

Distribution:

- The large quantity of evidence and documentation demanded by DIGEMID for the generation of a sanitary registration creates disincentives to innovation and provision of IVD tests.
- Long delays in delivering sanitary registrations and retrieving products from customs (the complete process can take up to 4.5 years) increases costs and inhibits the adoption of new technologies.
- Insufficient demand and technological delays in terms of both commercialization and use by local laboratories create disincentives for distributors to import products.
- The DIGEMID regulatory framework is directed towards pharmaceutical products; there is a lack of detail and precision concerning the regulation of IVD tests.
- The current constitution of Peru does not allow price controls, rendering the provision and cost of IVD tests dependent upon market fluctuations and external factors.
- Peru lags behind in terms of its adoption of new technologies. There is a lack of knowledge of the usefulness and benefits of prevention-based medicine, which could be assisted by increased use of IVD tests.
- There is a lack of adequate integration of IVD tests within the national list or Petitorio and standards; this inhibits demand aggregation.
- Distributors may lack medical knowledge and be driven mainly by an economic imperative. This leads to the provision of low-quality IVD tests or the absence of supply of critical IVD tests due to their perceived lower financial viability.

Testing:

- Lack of clear standards concerning the basic requirements for IVD tests that clinics and health centres should offer.
- Non-inclusion of pharmacies in the provision of IVD tests when these are the main type of establishment where Peruvians seek health counselling.

Processing:

- Bias towards economic calculations rather than a medical perspective in some laboratories due to the composition of the chain of command. The opinion of the medical director is not always considered in decision-making.
- High cost of equipment and supplies for the adoption of more complex tests.
- Fixed-term contracts between laboratories and distributors may inhibit the adoption of innovative IVD tests. High costs of initial investment and binding contracts deter laboratories from adopting newer technologies.
- Absence of distributors on the local market for some IVD tests. Distributors may leave the market, ending the supply of IVD tests, reagents, or technical support.
- Existence of corrupt practices between laboratories and clinics, which harm the adequate provision of healthcare and basic rights of patients.
- Existence of poor-quality laboratories, the quality of which may remain poor due to a lack of effective supervisory agencies.

Financing

- Use of the SEGUS tariff to establish prices is outdated. Absence of critical IVD tests and presence of outdated IVD tests.
- Low level of coverage of IVD tests by insurance companies. High levels of OOP expenditure by patients to cover the costs of IVD tests.
- Business-driven rather than healthcare-centred type of coverage. Insurers often base their coverage on financial returns, without adequate clinical and scientific evidence.
- Lack of precision concerning the coverage of IVD tests within insurance company tariff schemes. Low diversity of IVD tests offered.
- Tariff schemes are not frequently updated to include technological innovations. This is even more true of IVD tests.

Supervision:

- Absence of adequate quality control both when registering products in DIGEMID and in the supervision of laboratories.
- Absence of quality control of laboratory equipment, reagents and IVD tests. Patients depend on the good-will and professionalism of laboratories to receive appropriate services.
- Lack of training, infrastructure, and technology in DIGEMID, INS, SuSalud and other supervisory agencies for the quality control of IVD tests.
- Accreditation and certification are optional, and many establishments do not possess them, hindering access to higher quality IVD tests and testing.

Market concentration:

- Lack of regulation of monopolies. Cartelization of supply has a direct impact on prices, which affects consumers' access to healthcare.
- The state plays no active role in regulating or supervising economic groups and their merger and acquisition processes, when these could be detrimental to the adequate provision of healthcare.
- Lack of regulation and supervision of prices charged by private healthcare companies. Overpricing of products and services when there is an absence of competition or during emergencies.
- INDECOPI possesses insufficient auditing capacities. Actions are seldom taken against companies that make infringements.
- Arbitrary decision-taking on key matters concerning healthcare can be taken by a small number of individuals. Ultra-concentration of the market in the hands of a few conglomerates.

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VI

PUBLIC PERCEPTIONS ABOUT IN VITRO DIAGNOSTIC TESTS IN PERU

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Introduction

Scientific progress in recent decades, particularly in areas such as immunology and molecular biology, has led to the development of a large variety of IVD tests. Few studies have explored providers' perceptions about future IVD tests. The main barriers identified in focus groups involving clinical staff have been concerns about accuracy, cost, impact on personnel and processes, as well as potential regulatory and logistical problems. (77) A systematic review of the perceptions of clinicians in relation to point-of-care blood testing also found concerns about accuracy and cost, but also about the effect of IVD tests on clinical skills and the limited usefulness of such tests. A review by Ibitoye and colleagues found that, in general, home tests provide accurate results, but the self-collection of blood samples can be challenging (78). Home tests can also be a useful aid for public health. We found no studies that explored the perceptions of potential users around future home-based IVD tests.

Exploring the perceptions of users concerning the role IVD tests may play in healthcare, as well as their perceptions about home IVD tests, would help guide future developments to ensure successful implementation. We were particularly interested in exploring the perceptions of Peruvian women living in underprivileged areas of large cities and women living in small towns. In 2012, we conducted a population-based household survey in Peru, exploring people's perceptions and expectations regarding new IVD tests. Adult mothers (at least 18 years old) of children aged ≤2 years were randomly selected and invited to participate in the survey. We also included all fathers that were available during the visit to interview the mother. Participants were enrolled at three sites: Pachacutec, a shanty town on the outskirts of Lima; Quispicanchis, a mostly rural province in the Andean mountains; and Yurimaguas, a small city located in the Peruvian Amazon basin.

Demographic characteristics

Of the 1,294 children identified, all the mothers and 469 of fathers participated in the survey, including 7 fathers whose female partners were not interviewed. The mothers were generally younger and less educated than the fathers, but the most common level of education was secondary (Table 6.1). Most couples were cohabiting; for 18 couples, the marital status reported by the mother differed from that reported by the father. Most mothers considered themselves to be housewives, and most fathers considered themselves to be workers. The most common health insurance reported was the Comprehensive Health Insurance (SIS), a system for persons not formally employed, followed by EsSalud, accessible to those formally employed and their families. Almost a quarter of the participants reported they had no access to health insurance.

Household characteristics

About half of the participants lived in households connected to the public sewage system, with almost 60% having dirt floors. The most common material used for walls was wood, followed by brick/concrete and quincha/adobe.

Table 6.1: Demographic and household characteristics

	Mothers (N=1,294)	Fathers (N=467)
Demographic characteristics		
Study site	**N (%)**	**N (%)**
Pachacutec	425 (32.8)	138 (29.6)
Quispicanchis	331 (25.6)	144 (30.8)
Yurimaguas	538 (41.6)	185 (39.6)
Age (years)		
18 – 25	515 (39.8)	99 (21.72)
26 – 35	562 (43.4)	209 (44.8)
36 – 49	217 (16.7)	159 (34.1)
Education		
None	29 (2.2)	2 (0.4)
Primary	299 (23.1)	78 (16.7)
Secondary	720 (55.6)	272 (58.2)
Higher	246 (19.0)	115 (24.6)
Marital status		
Cohabiting	886 (68.5)	370 (70.2)
Married	217 (16.8)	92 (19.7)
Widow(er)	4 (0.3)	
Separated	54 (4.2)	
Single	132 (10.2)	5 (1.1)
No response	1 (0.1)	
Occupation		
Works	391 (30.2)	452 (96.8)
Studies	56 (4.3)	13 (2.8)
House chores	847 (65.5)	2 (0.4)
Health insurance		
None	295 (22.8)	
EsSalud	184 (14.2)	
SIS	810 (62.6)	
Other	5 (0.4)	
Household characteristics		
Water disposal system		
Public network	624 (48.2)	
Septic tank	68 (5.3)	
Latrine	482 (37.3)	
None	120 (9.3)	
Dirt floors	756 (58.4)	
Wall material		
Brick or concrete	360 (27.8)	
Woven cane	6 (0.5)	
Wood	596 (46.1)	
Quincha/Adobe	316 (24.4)	
Other	16 (1.2)	

Testing for children

Blood tests performed on children were equally valued by mothers and fathers: 94% of mothers and 93% of fathers considered them important or very important (Table 6.2). Parents were asked to think of a situation when their child had a respiratory infection and needed a test. They were then asked what they considered to be the most important aspect of testing. Almost half of the participants (48% of both mothers and fathers) considered that the test should be performed by health personnel, with 53% of mothers and 45% of fathers stating that the most important aspect when receiving the results of that test is that the results are properly explained to them.

Table 6.2: Perceptions about diagnostic tests for children

	Mothers (N=1,294) n (%)	Fathers (N=467) n (%)
How important are blood tests for children		
Not important	9 (0.7)	7 (1.5)
Not very important	18 (1.4)	7 (1.5)
Somewhat important	50 (3.9)	20 (4.3)
Important	811 (62.7)	274 (58.7)
Very important	406 (31.4)	159 (34.1)
Most important aspect of a test for a respiratory infection in a child		
Painless	156 (12.1)	62 (13.3)
Fast	295 (22.8)	99 (21.2)
Hygienic	222 (17.2)	79 (16.9)
Performed by health personnel	620 (47.9)	225 (48.2)
Other	1 (0.1)	2 (0.4)
Most important aspect when receiving results of such a test		
Privacy	66 (5.1)	43 (9.2)
Speed in processing	223 (17.2)	68 (14.6)
Results properly explained	679 (52.5)	208 (44.5)
Actions to be taken explained	82 (6.3)	36 (7.7)
Reliability	165 (12.8)	68 (14.6)
Certified results	78 (6.0)	44 (9.4)
Other	1 (0.1)	

Of 846 mothers that were requested to have their infants undergo a blood test, 799 (94%) had their child tested, reflecting good acceptability of existing clinical tests. For those that paid for that test, the reported cost of the test ranged from 0.10 to 700 USD. Nevertheless, most (75%) did not pay for the test. Although 83% of those insured through SIS and 72% of those in EsSalud had the test covered by the insurance, among those that reported having no insurance, 54% said they did not pay for the test.

Testing for mothers

Forty percent (40%) of the mothers interviewed had purchased a test to confirm that they were pregnant with their youngest child. Of these, 91% purchased the test at a pharmacy. Of those who purchased a pregnancy test, 60% received instructions on how to use it. The test was performed at the place of purchase in 25% of cases; 56% of the mothers used the test unaided. The remainder were helped by relatives or friends. Among women that did not perform the test at the place of purchase, 95% had no problems performing the test. For the remainder, the most frequently reported problems were: "the procedure was difficult", "the test did not perform well" and "reading the test was difficult".

Almost all women reported at least one visit for antenatal care during their previous pregnancy (98%). The facilities that were used most frequently across the three sites were the MINSA facilities in Quispicanchis (87.5%) and Yurimaguas (87.3%), with EsSalud facilities more frequently used in Pachacutec (16.2%). The least used facilities were private (3%). During their most recent pregnancy, almost all women reported having had at least one antenatal blood test, with the lowest rate in Quispicanchis (92.75%). The main reason for not having a blood test in the overall population was that it was not recommended by a health provider. The most frequent blood test reported was for HIV, although with different proportions among the sites. Urinalysis and ultrasound during the most recent pregnancy were reported by 77% of women. The main reason for urine testing was infection (81.5%) and the main reason for ultrasound was to check foetal wellness (63.0%) Most participants across the three study sites considered screening tests during pregnancy to be important or very important. Data concerning antenatal care access and screening tests are shown in Table 6.3.

Table 6.3: Antenatal healthcare and test access across the three sites in Peru (N=1,294)

	Yurimaguas N=538 (41.58%) n (%)	Quispicanchis N=331 (25.58%) n (%)	Pachacutec N=425 (32.84%) n (%)
At least one antenatal care visit during most recent pregnancy	520 (96.7%)	327 (98.8%)	419 (98.6%)
Antenatal care facility			
Ministry of Health (MINSA) primary care	338 (64.9%)	281 (85.7%)	282 (67.3%)
MINSA hospital	117 (22.5%)	6 (1.8%)	47 (11.2%)
EsSalud primary care	0	10 (3.0%)	45 (10.7%)
EsSalud hospital	59 (11.3%)	26 (7.9%)	23 (5.5%)
Private or Other	7 (1.3%)	5 (1.5%)	22 (5.3%)
At least one antenatal blood test during most recent pregnancy	517 (96.1%)	307 (92.8%)	417 (98.1%)
Specific blood test			
HIV	429 (79.7%)	116 (35.1%)	269 (63.3%)
Syphilis	242 (44.9%)	28 (8.5%)	53 (15.5%)
Glucose	190 (35.3%)	46 (13.9%)	117 (27.5%)
Haemoglobin	292 (54.3%)	107 (32.3%)	278 (65.4%)
Blood type	171 (31.8%)	50 (15.1%)	145 (34.1%)
Other antenatal tests during most recent pregnancy			
Urine	485 (90.2%)	300 (90.6%)	385 (90.6%)
Ultrasound	461 (85.7%)	317 (95.8%)	417 (98.1%)

Women were asked about the tests they had received during the pregnancy for their youngest child and, if they had to pay for it, how much it cost. Table 6.4 shows the proportion of women tested and payments made for blood and urine tests, as well as for sonograms. The proportion tested and the costs were similar for blood tests and sonograms, however a significantly higher proportion of women had to pay for their sonograms.

Table 6.4: Tests performed during the pregnancy of their youngest child

Test	% tested	% who paid for the test	Amount paid for the test (USD), median (range)
Blood	96	18	4.17 (0.55 – 125)
Urine	90	--*	--*
Obstetric ultrasound	92	57	5.56 (0.56 – 83)

*Data not available

Perceptions on a future test for children

The survey also explored the potential receptivity for a not-yet invented home IVD test to determine whether a child is sick enough to be taken to a health facility. The majority (86% of mothers and 88% of fathers) said they would use such a test (Table 6.5), while 46% of mothers and 59% of fathers said such a test should primarily be available at health establishments (health centres, hospitals, or clinics). Pharmacies would be the favoured providers for 47% and 37% of mothers and fathers, respectively. When asked about the most important characteristic of that test, the most common response was "it should have instructions on how to use it", by 28% of mothers and fathers, followed by "sealed and hygienic" by mothers (17%) and "Inclusion of all required materials" by fathers (22%).
Parents were also asked what they considered more important when reading the results of such a test. Their most common answers, for both mothers (29%) and fathers (34%), was the reliability of the test, followed by the availability of instructions on how to read it for 29% and 31% of the mother and fathers, respectively.

Most mothers and fathers (88%) said they would pay for a home test like the one proposed, that is fast, reliable and hygienic. The median amount both mothers and fathers were willing to pay was 2.78 USD, although some fathers would be willing to pay more than the mothers (up to 139 vs. 83 USD). Similarly, most mothers (89%) and fathers (88%) would be willing to pay for a test like the one proposed if it could screen for several diseases simultaneously. The median amount they would be willing to pay for such a test was double what they would pay for a test for a single condition; 88% and 92% of the mothers and fathers, respectively, would consider such a test useful or very useful.

Perceptions on a future test for pregnant women

Parents were also asked to imagine a test that could be performed at home to determine if a pregnant woman needed to urgently go to a health establishment. Most participants (83% of mothers and 88% of fathers) said they would pay for this (Table 6.6). There were 63% of mothers and 70% of fathers who considered that such a test should be sold at health establishments, while 34% and 26% of mothers and fathers, respectively, thought they should be available at pharmacies. The most important feature a test like that should have according to both mothers and fathers (33% for each) is the instructions on how to use it. For mothers (32%) and fathers (36%), the most important characteristic when interpreting the results of such a test is reliability.

A total of 84% of mothers and 86% of fathers said they would pay for such a test. For those willing to pay, the median cost of a test would be about 2.78 USD (both for mothers and fathers). The same proportion of mothers and fathers would pay for a test like this that could simultaneously screen for several conditions. In such a case, they would be willing to pay double the amount (5.56 USD for both mothers and fathers) they would pay for a test to screen for a single condition. The majority (87% of mothers and 91% of fathers) would consider such a test to be useful or very useful.

Table 6.5: Perceptions on a future home IVD test that could determine if a child is so sick that they must be taken to a health facility

	Mothers (N=1,294) n (%)	Fathers (N=467) n (%)
Would buy the test		
Yes	1,112 (85.9)	413 (88.4)
Where should it be sold		
Health establishment	647 (50.0)	276 (59.1)
Pharmacy	601 (46.5)	172 (36.8)
Other	46 (3.6)	19 (4.1)
Most important characteristic of such test		
Ease of use	151 (11.7)	79 (16.9)
With instructions on how to use	364 (28.1)	139 (27.8)
Instructions with figures	157 (12.1)	60 (12.9)
Inclusion of all required materials	222 (17.2)	103 (22.1)
Fast	69 (5.2)	26 (5.6)
Sealed and hygienic	224 (17.3)	46 (9.9)
Painless	102 (7.9)	21 (4.5)
Other	5 (0.4)	2 (0.4)
Most important characteristic when reading test results		
Easy to read results	285 (22.0)	76 (16.3)
Instructions on how to interpret results	379 (29.3)	145 (31.1)
Short waiting time	240 (18.6)	85 (18.2)
Reliable	380 (29.4)	159 (34.1)
Other	10 (0.8)	2 (0.4)
Would pay for such a home test that is fast, reliable and hygienic		
Yes	1,126 (87.9)	412 (88.2)
Amount (USD*), median (range)	2.78 (0.03 – 83.33)	2.78 (0.28 – 138.89)
Would pay for such a test that would also screen for several diseases		
Yes	1,121 (88.6)	411 (88.0)
Amount (USD*), median (range)	5.56 (0.06 – 166.67)	5.56 (0.28 – 138.89)
Usefulness of a test like this		
Useful	755 (58.4)	263 (56.3)
Very useful	389 (30.1)	166 (35.6)

* Using an exchange rate of 3.6 Peruvian soles per USD

Table 6.6: Perceptions about a future home IVD test that could determine if a pregnant woman needs to go to a health facility

	Mothers (N=1,294) n (%)	Fathers (N=467) n (%)
Would buy the test		
Yes	1,073 (82.9)	410 (87.8)
Where should it be sold		
Health establishment	809 (62.5)	328 (70.2)
Pharmacy	440 (34.0)	123 (26.3)
Other	45 (3.5)	16 (3.4)
Most important characteristic of such test		
Ease of use	289 (22.3)	116 (24.8)
With instructions on how to use	420 (32.5)	154 (33.0)
Instructions with figures	162 (12.5)	59 (12.63)
Inclusion of all required materials	169 (13.1)	79 (16.9)
Fast	59 (4.6)	19 (4.1)
Sealed and hygienic	130 (10.1)	31 (6.6)
Painless	52 (4.0)	5 (1.1)
Other	13 (1.0)	4 (0.9)
Most important characteristic when reading test results		
Easy to read results	298 (23.0)	83 (17.8)
Instructions on how to interpret results	316 (24.4)	138 (29.6)
Short waiting time	261 (20.2)	76 (16.3)
Reliable	407 (31.5)	169 (36.2)
Other	12 (0.9)	1 (0.2)
Would pay for such a home test that is fast, reliable and hygienic		
Yes	1,088 (84.1)	402 (86.1)
Amount (USD*), median (range)	2.78 (0.03 – 83.33)	2.78 (0.03 – 138.89)
Would pay for such a test that would also screen for several diseases		
No	53 (4.1)	10 (2.1)
Not sure	156 (12.1)	56 (12.0)
Yes	1,085 (83.9)	491 (85.9)
Amount (USD*), median (range)	5.56 (0.08 – 138.89)	5.56 (0.83 – 138.89)
Usefulness of a test like this		
Useless	16 (1.2)	2 (0.4)
Almost useless	36 (2.8)	14 (3.0)
Somehow useful	110 (8.5)	25 (5.4)
Useful	811 (62.7)	281 (60.2)
Very useful	321 (24.8)	145 (31.1)

* Using an exchange rate of 3.6 Peruvian soles per USD

Conclusion

Women very frequently access health services. For antenatal care and for childcare, both they and their spouses recognize the importance of IVD tests. Although half of the parents considered that IVD tests should be performed by health personnel, most of them would use home IVD tests to determine the health status of their child or as a diagnostic aid for health issues during pregnancy. In both cases, they would rely on good instructions for use from the manufacturer. Moreover, women and men were both willing to pay out-of-pocket for IVD tests, and in a population in which most of the women were insured, around 20% of them had paid for a blood test and 57% for an ultrasound.

Access to IVD tests is important for public health and, as one way to ensure access, we must understand the perceptions of the final users, the people themselves. For successful implementation we must consider strategies that involve the individuals and the communities that could help in pushing the introduction of IVD tests from the bottom up. If community members genuinely believed that IVD tests were important for their health, they could make valuable suggestions about the design of such tests that could empower individuals to carry out self-care and to demand the availability of IVD tests from the health services.

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VII

THE DIAGNOSTICS MARKET

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THE DIAGNOSTICS MARKET

Introduction

The Peruvian market for IVD tests is highly fragmented, with a multitude of buyers, sellers and products interacting in a relatively limited marketplace. Furthermore, the lack of norms to specifically regulate IVD tests, together with the requirements which need "national distributors", and the lack of clear national priorities for investments in IVD tests (exemplified by an inadequate national list), have complicated the consolidation of a dynamic Peruvian market.

As we have seen previously, the acquisition of IVD tests can be carried out either by the public or the private sector. The public sector has two main mechanisms of procurement, one for strategic IVD tests (centralized) and the other for all the other IVD tests (institutional). Diseases that require strategic targeting as part of public health programmes are identified by the ESN, who develop yearly objectives and programme the IVD test requisites for each of these strategic IVD tests. IVD tests that are not programmed by the ES are bought directly by institutions that require them. Despite possessing centralized purchasing institutions (such as CENARES and CEABE), which should secure the supply of IVD tests, high levels of direct purchases by regional state institutions persist, highlighting the prevalence of a fragmented public acquisition system. It was only in 2019 that Peru released the first National Essential List of medical devices, including IVD tests (PNUDME); however, this list is incomplete.

The private system, on the other hand, comprises two types of institutions, the distributors that buy/represent IVD tests and sell them locally to other establishments, and a constellation of different health-providing entities, each of which purchases their own IVD tests. According to one interviewee, the public sector accounts for roughly 60% of purchases of IVD tests (approximately 30% for the MINSA and 30% for EsSalud), while the other 40% is covered by the private sector. Interestingly, the private health system insures only about 8% of the Peruvian population, while the public health system covers the remaining 92% of the population.

Accordingly, a considerable proportion of the population acquires their healthcare services from the private system through OOP purchases, regardless of their main insurer, due to the perception that private health services represent higher quality services. This could also indicate that the private sector makes more intensive usage of IVD tests and other health technologies than the public sector, further cementing pre-existent asymmetries in the provision of healthcare. A small percentage of the population has access to more expensive private health services and, as a result, to more diagnostic-based treatment.

IVD tests are imported into the country for different reasons, mainly for commercialization and use in health facilities throughout the country. Nonetheless, other IVD tests can be imported as samples or as part of a research study. However, these cases tend to be minimal and represent a low percentage of imported IVD tests. Being isolated cases and representing negligible and episodic purchases, these are not included as part of our market assessment, as their uses are outside of regular commercial exchange.

All products with a sanitary registration in Peru can be accessed through DIGEMID's database[79] (the complete list is shown in the Final Appendix), which recognizes the applications for sanitary registration of 2784 different products in the "In vitro diagnostic test" category. Of these, 2584 products are IVD tests for which their sanitary registrations are currently valid and can be marketed by the holder of the sanitary registration or by a third party possessing a certificate of sanitary registration expedited by DIGEMID. No product has been suspended by DIGEMID, while 189 sanitary registrations have been cancelled. Finally, one sanitary registration has been extended.

Data for the market analysis

Information systems and databases of the Peruvian health system are highly deficient and suffer from poor vertical integration and coordination among different entities. As mentioned in earlier chapters, each health institution possesses a distinct information system with its own corresponding database, which functions independently from other systems and institutions. As a result, information is fragmented and navigating through the different systems is complicated.

The private sector institutions and healthcare facilities do not have publicly available information concerning their acquisitions and commercial activities. Even if this were not the case, it would be necessary to assemble each individual database for every single purchaser of IVD tests in the private sector. Apart from general details concerning the supply chain of IVD tests, our interviewees from the private sector did not supply us with any statistics or additional information regarding their sales and acquisitions. Admittedly, this would jeopardize their commercial activity.

On the other hand, any purchase in the public sector is required to be "transparent" and the information is meant to be "available" to the general population. In theory, any citizen should be able to find data related to the purchases of public institutions, or in any case, demand specific information through transparency mechanisms. Usually, state institutions have a section within their webpages detailing information about the institution, including purchases. If not, any citizen can request the information that requires from the governmental institution by sending an email and completing a specific form to the corresponding transparency office.

In practice, however, information surrounding public purchases is often opaque and difficult to access, and you can send a request, but may not get what you asked for. In fact, despite being told repeatedly that such information was available on government or institutional web pages, it was mostly impossible to find for us. Delays for the delivery of documents and databases through transparency mechanisms extended beyond the standard 14 days. Of our four transparency requests, only two received answers. Furthermore, the information with which we were supplied was poorly scanned, often illegible and bore little to no relation to the data requested.

Additionally, individual databases consulted for different institutions used different nomenclatures and indicators, which further complicated their use and unification. As mentioned previously, the MINSA does not possess a centralized database covering the purchasing, programming, and distribution of its medical supplies. There is an evident absence of clarity and transparency within the MINSA's information systems, which hinders the determination of the size and specificities of the public sector market.

To identify the total market for IVD tests, we thus had to identify the public and private sectors. For public purchases, we resorted to an organ of the MEF, the OSCE, which is charged with overseeing, regulating and, if necessary, intervening in state purchases. It contains the CONOSCE platform,[ix] which includes details of every public purchase of products or services from 2018 to 2020.

In terms of the private sector, there are no available databases detailing the purchases of IVD tests as such. One possible alternative would be to use the national customs databases, which include every product, private and public, that enters the country. This is highly problematic, however, as a product can have different tariff headings depending on its final use. For example, an IVD test used as a sample will have a different heading to a test used for an investigation or that is destined for commercial use. IVD tests are also mixed up in various categories of items within the customs nomenclature, obstructing their identification. Additionally, the quality and completeness of the data recorded is not known.

A further challenge is that there is no openly available national customs database, and our attempts to retrieve one directly from SUNAT were unsuccessful. However, the Association of Exporters (ADEX) data trade platform compiles and updates its own database using information from SUNAT. This database is not always up-to-date and may be unreliable for the real-time analysis of imports, but it is very useful for monitoring imports that have happened in recent months and years. It indicates the type of product, quantity and price, and the importer. However, the final purchaser of the product remains unknown. An IVD test can be imported by "company A" and sold either to "private company B" or "state institution C".

Data management and analysis of available datasets to calculate the public health market

In the case of the public sector, all state purchases can be found in the CONOSCE platform. CONOSCE categorizes state purchases of products and services into 37 categories according to the CUBSO catalogue,[x] for the years 2018, 2019 and 2020. It contains datasets that can be downloaded, which consist of many variables including the total cost of products, quantity of products purchased, unitary costs, institutions responsible for the purchases, variability of prices and provider RUC (Single Taxpayer Registry).

IVD tests fall within the category of *"Equipos de Laboratorio, Medición, Observación y Comprobación"* (Laboratory Equipment, Measurement, Observation and Verification). Importantly, when downloading the datasets, not all the information is directly available. One of the variables in the datasets includes a link that redirects the searcher towards a new dataset with additional data for the chosen product or service purchase. This functions similarly to a Russian doll, in which one dataset is found within another dataset. Unfortunately, these have to be joined manually. Despite asking the OSCE for these variables in a unified dataset via transparency mechanisms, we received no answer.

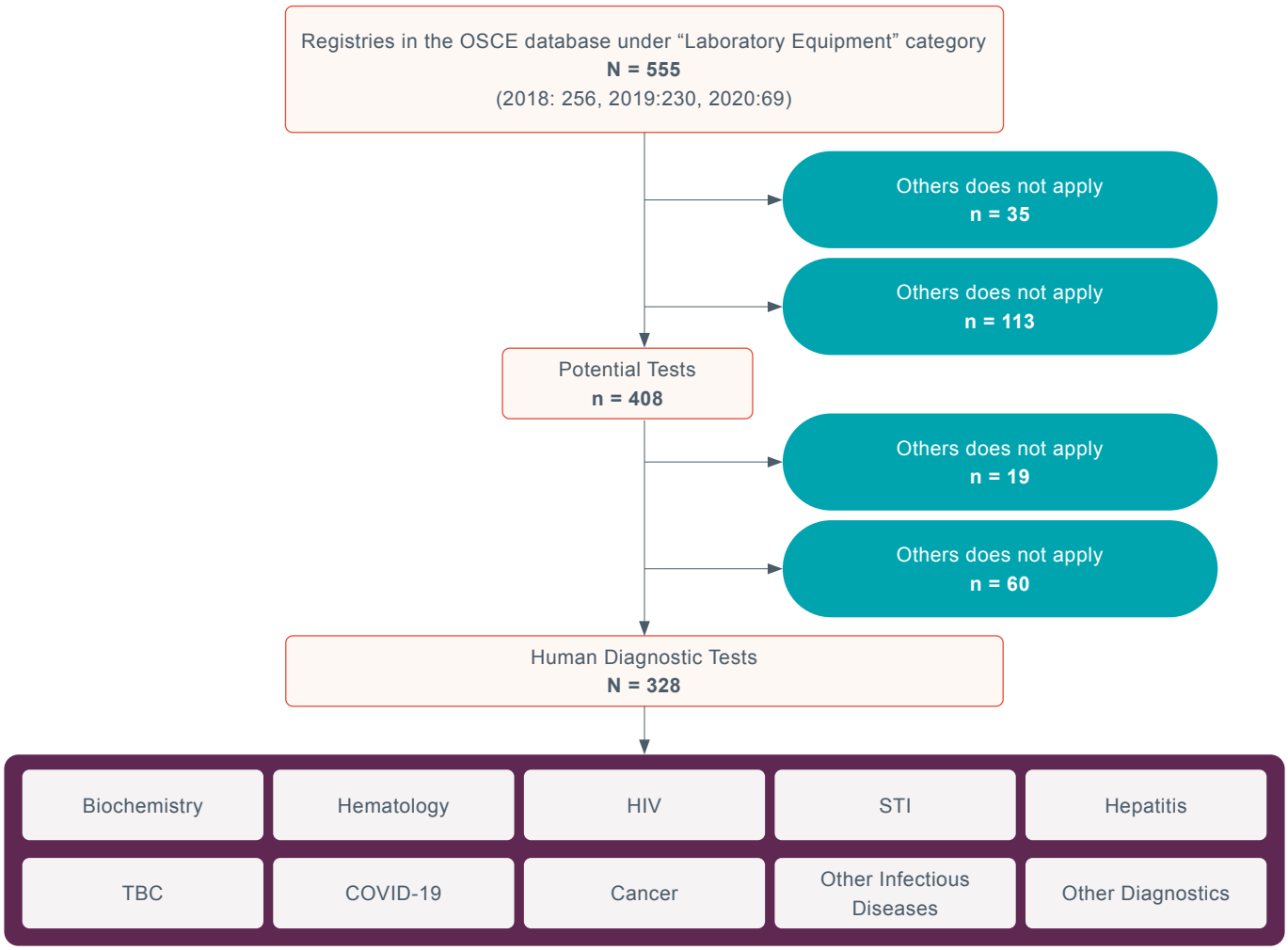
An additional problem emerges when identifying providers for each of the public purchases. The variables for providers only indicate the provider's RUC, which must

[ix] https://portal.osce.gob.pe/osce/conosce/
[x] https://www.gob.pe/8233-acceder-al-catalogo-unico-de-bienes-servicios-y-obras-cubso-del-seace

be individually filtered through the SUNAT's RUC search function to find the name of the provider firm. The RUC then must be replaced with the name of the provider firm for every purchase in the dataset. To facilitate this replacement, we unified the datasets for the three available years.

Figure 7.1 illustrates how we managed the OSCE databases. First, we unified the databases of the three available years to facilitate the replacement of the RUC variable with the provider names. This resulted in a total of 555 registries. When cleaning the data, we found a number of purchases that bore no relation to IVD tests or even the medical field in general (e.g. steel sheeting and diesel). There were 35 registries that we classified as an "Others, does not apply" category. Similarly, many records referred to purchases of medical supplies that were not IVD tests (such as vaccines or equipment); there were 113 such records and these were classified in the "Supplies" category. With 408 potential IVD tests, we next had to filter out 19 IVD tests used for veterinary purposes (e.g. hepatitis tests for molluscs and rabies tests for animals) and 60 strain/control tests. This left 328 IVD tests. We reclassified these 328 IVD tests into 11 categories, based on those categories outlined by the third WHO EDL list, as shown in Table 7.1.

Figure 7.1: A flowchart showing the process of organizing the registries in the OSCE database for 2018 to 2020



An additional limitation of the OSCE database is that it does not include geographic information related to where the IVD test will be deployed. The database only includes the location of the institution purchasing the test. For institutional procurement (non-strategic IVD tests) we have some idea of where the tests will be used, at least by region, but this is not the case for strategic IVD tests.

Table 7.1: Classification of tests identified in the OSCE database analysis (Based on WHO EDL categories)

Category	Tests included
Biochemistry	Diabetes, tests for autoimmune diseases, liver tests, toxicology tests, thyroid tests, others (e.g. urine tests)
Haematology	Blood group tests and others
HIV	HIV tests (ELISA, PCR, CD4 cell counts etc.)
STIs	Syphilis, chlamydia, gonorrhoea (serological tests, molecular tests, culture tests, rapid tests for syphilis)
Hepatitis	Tests for hepatitis B and C
TB	TB PCR, microscopy, culture
COVID-19	COVID-19 tests (PCR, rapid serological tests, other serological tests, antigen tests)
Cancer	Colon cancer, haematologic cancers, cervical cancer, prostate cancer and others
Other infectious diseases	Brucellosis, candidiasis, Chagas, Chikungunya, adenovirus, amoebiasis, aspergillosis, CMV, cryptococcosis, dengue, HTLV, gastrointestinal diseases, respiratory diseases, Epstein–Barr virus, ehrlichiosis, typhoid, giardiasis, herpes, histoplasmosis, leptospirosis, listeria, malaria, paracoccidioidomycosis, pneumonia, rabies, toxoplasmosis, other
Other diagnostics	Genetic diseases, other

Many purchases were episodic, and many public institutions purchased only a single product type throughout the 3-year period. Most of these institutions were DIRIS/DIRESAS/GERESAS hospitals or institutes (specialized hospitals) which are all part of the MINSA and were thus categorized as “MINSA” in the analysis. Other institutions, such as the SUNAT, national universities or the SISOL-SALUD hospitals were grouped into the “Other” category, as they represented a negligible percentage of the market.

Finally, and perhaps most crucially, the database failed to indicate the quantity of products purchased. First, units of measurement were not unified: some purchases were measured in litres, others in kilos and still others in “kits”. This rendered any analysis of the quantities purchased more complicated. Moreover, it was common to find purchases where the data indicated that a single unit was purchased for an extremely large amount of money. The unitary price is thus extremely and unrealistically high. For example, the database shows that in 2019 a single urine dipstick test was purchased for 47,146 USD, that is, the unitary price was 47,146 USD. This is probably because the unitary price and the quantity purchased were unknown, and thus only the total price was available.

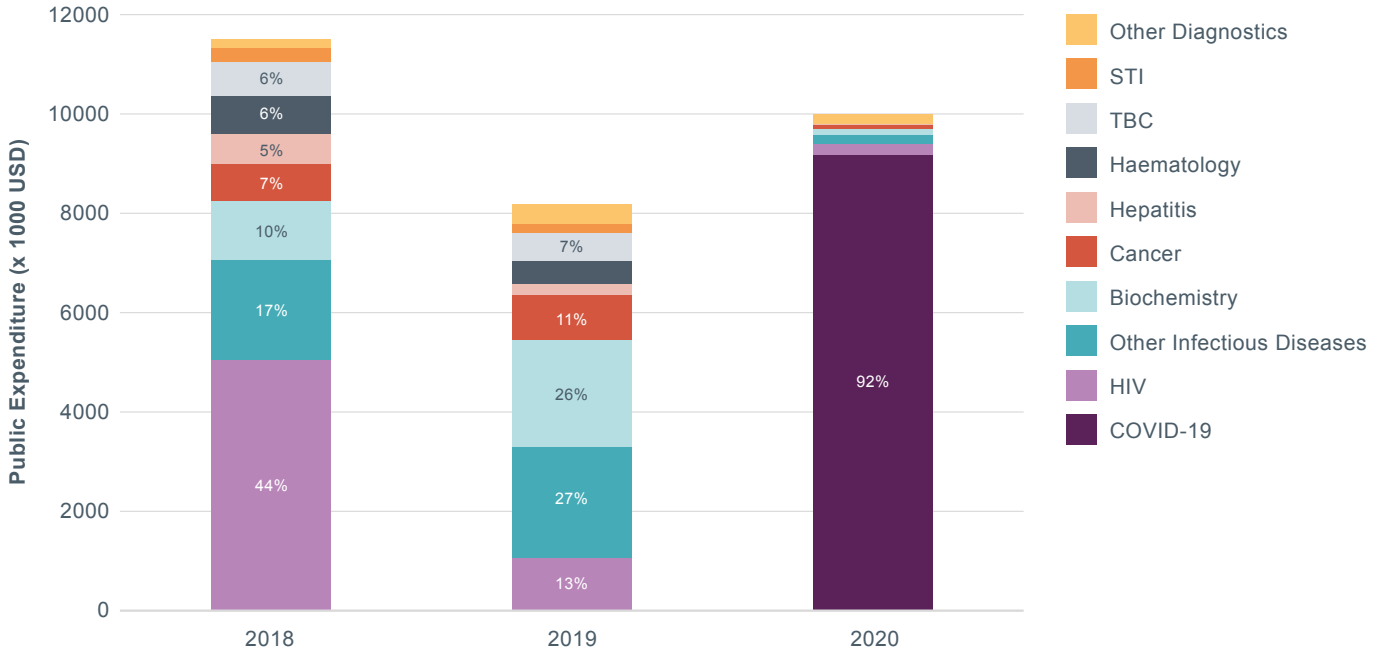
Due to these issues being recurrent throughout the data, we were unable to analyse the market in terms of the quantities purchased and had to rely on the total price paid for each purchase. The market analysis is henceforth presented in terms of public spending.

Public sector market characteristics of IVD tests, 2018–2020

Public sector expenditure on IVD tests

Investment in the acquisition of IVD tests in the Peruvian public sector fluctuated between 2018 and 2020, representing a total of approximately 11.48 million USD (40.3 million soles)[xi] in 2018, 8.17 million USD in 2019 and 9.98 million USD in 2020. In 2020, Peruvian public institutions only recorded about 40 purchases of IVD tests; however, this represented greater spending than that spent on 136 purchases in the previous year. Figure 7.2 shows the expenditure by year and category of test.

Figure 7.2: Public expenditure on IVD tests in 2018 to 2020 by category of tests (USD)



The COVID-19 pandemic and the subsequent efforts made to concentrate medical supplies and resources towards mitigating its spread, plus the closure of most non-COVID medical services and all primary care in Peru, has inevitably impacted the provision of other medical supplies, including IVD tests. Indeed, out of the 40 IVD test purchases made by the state in 2020, 22 related to tests for COVID-19 detection. The purchase of cancer, HIV, hepatitis, and other infectious disease tests decreased by approximately 88.7% between 2019 and 2020. Around 91% of public spending on IVD tests was concentrated on COVID-19 tests, with the provision of IVD tests for other health interventions effectively replaced by the urgent provision of COVID-19 tests worth around 9.16 million USD.

This contrasts with the previous year, during which public spending was more homogeneously distributed among different test categories. Indeed, test for other infectious diseases accounted for 27% of total spending in 2019, closely followed by biochemical tests (26%). HIV (13%), cancer (11%) and TB (6.9%).

Purchase patterns in 2018 differed substantially from 2019 and 2020, with a greater amount of funding put towards the acquisition of HIV tests, which represented close to 44% of total spending. This was followed by a relatively homogenous distribution of public funds for other types of tests, including tests for other infectious diseases (17.4%), biochemistry (10%), cancer (6.6%), haematology (6.3%), TB (6.1%) and hepatitis (5%). Table 7.2 summarizes public expenditure on IVD tests by type of test and year.

[xi] Using the reference exchange rate of 0.2847 dollars per Nuevo Sol Peruano; average rate for the year 2020.

Table 7.2: Public expenditure on IVD tests in 2018 to 2020 by category of tests (USD)

	2018	2019	2020
Tests included	**USD (x 1000)**	**USD (x 1000)**	**USD (x 1000)**
Biochemistry (total)	**1.154**	**2.153**	**104**
Diabetes tests	466	340	15
Autoimmune disease tests	54	1.026	NP
Liver tests	NP	17	NP
Toxicology tests	NP	40	39
Thyroid tests	16	128	NP
Urine tests	213	259	12
Others	406	344	37
Haematology (total)	**724**	**453**	**NP**
Blood group tests	260	358	NP
Others	465	95	NP
HIV (total)	**5.069**	**1.077**	**228**
ELISA	1.339	410	NP
Rapid HIV tests	486	203	NP
PCR	3.032	98	228
CD4	211	357	NP
Others	NP	10	NP
STI total	**449**	**165**	**NP**
Rapid syphilis tests	NP	NP	NP
Dual syphilis and HIV tests	184	NP	NP
Chlamydia tests	139	NP	NP
Gonorrhoea tests	NP	NP	NP
Others	126	NP	NP
Hepatitis total	**611**	**231**	**30**
Hepatitis B tests	465	205	30
Hepatitis C tests	146	26	NP
TB total	**707**	**569**	**NP**
PCR	NP	NP	NP
Microscopy, cultures	NP	NP	NP
COVID-19 (total)			**9.158**
PCR	NA	NA	6.544
Rapid serological tests	NA	NA	2.614
Other serological tests	NA	NA	NP
Antigen tests	NA	NA	NP
Cancer	**761**	**910**	**81**
Colon cancer	41	17	NP
Haematologic cancers	NP	NP	NP
Cervical cancer	21	238	NP
Prostate cancer	NP	142	NP
Others	698	513	81
Other infectious diseases (total)	**2.006**	**2.212**	**189**
Brucellosis	8	NP	NP
Candida	NP	0.2	NP

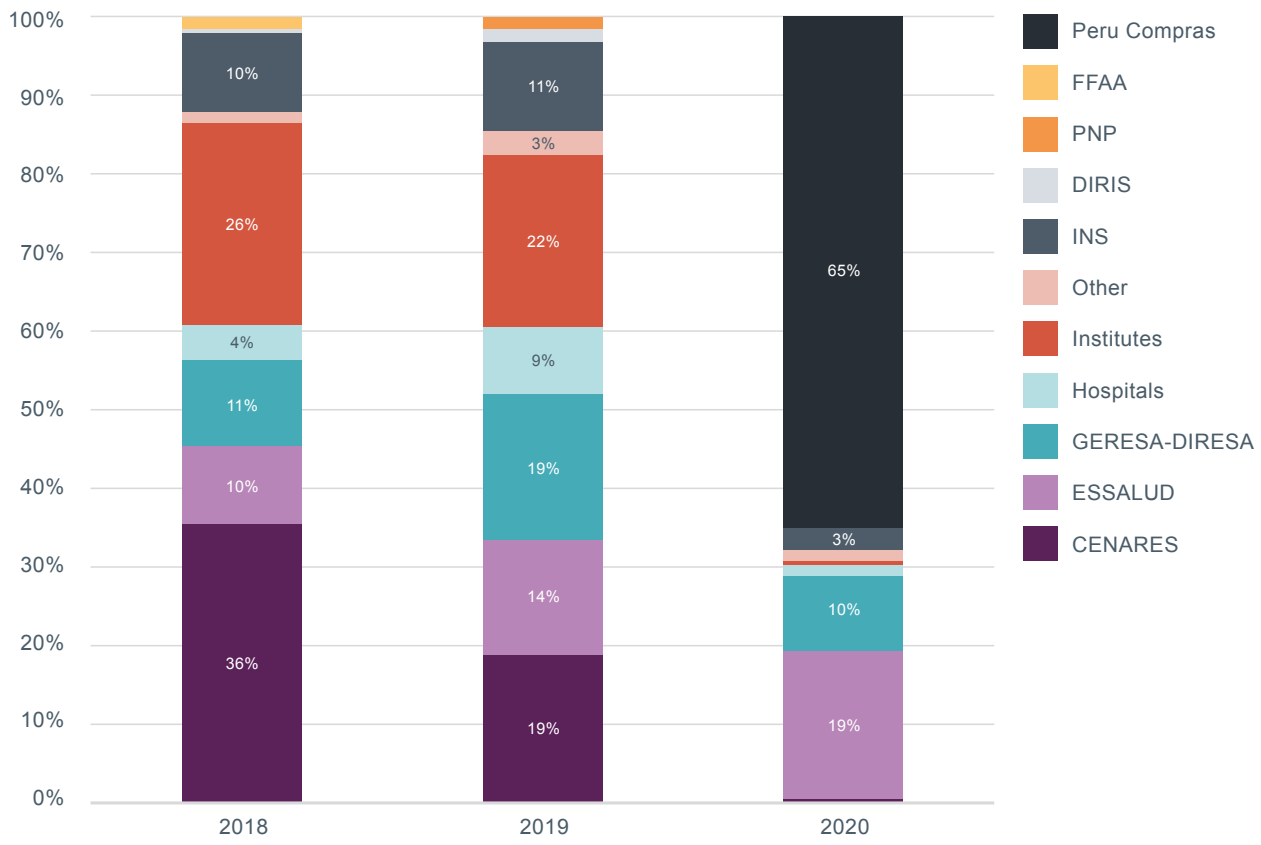
Tests included	2018 USD (x 1000)	2019 USD (x 1000)	2020 USD (x 1000)
Chagas	28	26	NP
Chikungunya	75	220	NP
Adenovirus	NP	37	NP
Amoebiasis	0.4	NP	NP
Aspergillosis	239	199	NP
CMV	NP	3	NP
Cryptococcosis	14	NP	NP
Dengue	NP	NP	16
HTLV	393	314	11
Gastrointestinal diseases	128	116	
Respiratory diseases	11	112	55
Epstein Barr	NP	13	36
Typhoid	40	NP	NP
Herpes	19	495	NP
Ehrlichiosis	NP	1	NP
Giardiasis	0.4	1	NP
Histoplasmosis	0.1	NP	NP
Leptospirosis	341	341	NP
Listeria	NP	NP	NP
Malaria	265	NP	NP
Paracoccidioidomycosis	0.1	NP	NP
Pneumonia	5	NP	NP
Rabies	0.3	NP	1
Toxoplasmosis	204	NP	NP
Others	235	334	71
Other IVD tests (total)	**NP**	**402**	**189**
Total expenditure on IVD tests	**11.482**	**8.172**	**9.978**

NP = No purchase; NA = Not available

Public institutions' purchasing of IVD tests: strategic IVD tests (centralized purchases) versus non-strategic IVD tests (institutional purchases)

In terms of the institutions that purchase IVD tests in Peru, these vary considerably by year. The buyers include CENARES; Peru Compras (since 2020); DIRESAS/GERESAS for the health establishments and hospitals in the regions of Peru; DIRIS for the health establishments in Lima; hospitals (from Lima); specialized hospitals known as institutes (eight in total: (1) National Institute of Ophthalmology (2) National Children's Institute-Breña, (3) National Children's Institute- San Borja, (4) Maternal and Perinatal National Institute (Maternity of Lima) (5) National Institute of Mental Health (6) National Institute of Neurological Sciences (7) National Institute of Rehabilitation (8) National Institute of Cancer (INEN), ESSALUD, the National Institute of Health (a public health institute) and others (universities or other institutions). Figure 7.3 shows the public sector market share of Peruvian institutions that purchased IVD tests.

Figure 7.3: Public sector market share of Peruvian institutions that purchased IVD tests in 2018- 2020



An important change in 2020 was the negligible impact of CENARES and the INS in the IVD test market, compared with their predominant role in the previous two years. Perú Compras, which was not a player in the IVD test market in 2018 or 2019, was given the responsibility of purchasing COVID-19 tests. They created electronic catalogues and concentrated 70.7% of total COVID-19 test purchases, totalling 6.48 million USD.

As mentioned in previous chapters, the CENARES coordinates its operations in acquiring IVD tests based on the programmed necessities of the various health interventions in the country, and the INS similarly responds to internal factors within the Peruvian health landscape. Due to the COVID-19 pandemic, funding for health was diverted from these health interventions and their corresponding diseases towards a COVID-19-centred response. As a result, various important disease groups targeted by the health interventions were virtually abandoned, and the role played by CENARES and INS in the IVD test market faltered.

In 2019, the market was dominated by direct acquisitions from MINSA regional and local health facilities, which represented 29% of all acquisitions. This was followed by CENARES (19%), the National Cancer Institute (17%), EsSalud (14%) and the INS (11%). This exemplifies the fragmentation of the Peruvian market and the difficulty of coordinating centralized purchases by state institutions.

In 2018, the CENARES was the main buyer of IVD tests in the Peruvian market (37%), followed by the National Children's Institute (22%), the MINSA (16%), INS (10%) and EsSalud (10%). An analysis of IVD test acquisition depending on the purchasing institution does not provide a consistent picture of the market structure. The variability in the institutions' purchases between 2018 and 2020 is notable. Table 7.3 shows the expenditure on various categories of IVD tests by the type of procurement, i.e. centralized vs. institutional. Large economies of scale could be achieved through a centralized corporative purchase process that united the demand from the various institutions shown. However, the high levels of direct purchases (institutional) from regional and local hospitals (29% and 16% in 2019 and 2018, respectively) illustrate chronic failures of the MINSA public health sub-sector in terms of the centralized purchasing of IVD tests.

Table 7.3: Public expenditure on IVD tests by type of test, year and type of procurement

	2018		2019		2020	
	USD (x 1000)		USD (x 1000)		USD (x 1000)	
Type of test	Central	Institutional	Central	Institutional	Central	Institutional
Biochemistry (total)	-	1.154	-	2.153	-	104
Haematology (total)	-	723	-	453	-	-
HIV (total)	3.282	1.787	465	612	-	228
STI (total)	-	449	116	49	-	-
Hepatitis (total)	-	611	57	174	30	-
TB (total)	704	3	468	101	-	-
COVID-19 (total)	-	-	-	-	-	9.158
Cancer	-	761	-	910	-	81
Other infectious diseases (total)	306	1.7	441	1771	-	189
Other IVD tests (total)	-	-	-	402	-	189
Total expenditure	**4.292**	**7.188**	**1.547**	**6.625**	**30**	**9.949**

Distributors of IVD tests for the public sector

In terms of distributors, the public sector market is quite competitive, with many firms that each concentrate relatively limited portions of the market. Except for Roche, which has consistently positioned itself in the top three providers of IVD tests in Peru, the rankings of providers varied between 2018 and 2020, and their sales have fluctuated. Table 7.4 summarizes the distributors of IVD tests for the public sector and purchases by year.

Table 7.4: Distributors of IVD tests for the public sector and purchases by year (USD x 1000)

	2018	2019	2020
Distributor	USD (x 1000)	USD (x 1000)	USD (x 1000)
Productos Roche QF S.A	3.299	805	1.823
Rochem BioCare del Perú S.A.C	1.385	259	1.936
Simed Perú S.A.C	843	312	-
Belomed S.R.L	740	235	-
Diagnostico UAL S.A.C	675	-	11
Diagnostica Peruana S.A.C	622	-	809
Sistemas Análiticos S.R.L	600	785	-
Becton Dickinson del Uruguay SA SUC Peru	574	434	-
Diagnostics Test S.A.C	501	-	-
Consorcio Vikmar S.A.C y Grupo Vikmar S.A.C	483	173	15
CIA Importadora Americana S.A	321		343
W.P Biomed E.I.R.L	243	185	
Lab Depot S.A.	216	106	37
Inmunochem SAC	174	414	276
DIVCOM S.A.C	112	96	-
Representaciones Hospitalarias Nachaccov E.I.R.L. y Medical ISVIL S.A.C	95	-	-
Labsystems S.A.C	92	-	52
Corporacion MDC Peru S.A.C	62	-	-

Distributor	2018 USD (x 1000)	2019 USD (x 1000)	2020 USD (x 1000)
Abastecimiento Medico Total S.A.C	60	11	-
Corporacion Medical Berth's S.A.C	58	14	-
Diagnostics Test S.A.C		2.013	-
Bayer S.A		342	-
Importadora Labmol S.A.C	35	335	-
Universal SD S.A.C		318	-
Comercial Importadora Sudamericana S.A.C	42	294	141
Gen Lab del Peru S.A.C	-	263	21
Belomed S.R.L	-	235	36
Gadorpharma S.A.C	-	153	-
Deltalab Peru E.I.R.L	-	127	-
JRM Medical S.A.C – Corporacion Medica JL S.A.C	-	57	-
Consorcio Tecnomed	-	-	2.783
Importadora Fabhet SRL	-	-	1.109
Dispositivos Medicos E.I.R.L	-	-	295
USD Corporation S.A.C	-	-	128
Anden Bio Naturals USA LLC	-	-	39
BTS Consultores S.A.C	-	-	39
Genia Tech S.A.C	-	-	22
LC Biocorp S.A.C	-	-	18
Medical Insight S.A.C	-	-	16
Others	248	440	27
Total	**11.482**	**8.172**	**9.978**

In 2018, there was a total of 38 firms with relatively low market shares. Except for Roche and Rochem, which controlled 29% and 12% of the market, respectively, most firms represented less than 7% of the market. Sismed Peru (7%), Belomed SRL (6%) and Diagnostico UAL (6%) were other important providers in the market.

Competition during 2019 was even greater, with 45 firms competing in a smaller market. Diagnostics Test SAC represented 25% of the market, with Roche (10%), Sistemas Analíticos SRL (10%) and Becton Dickinson (5%) being the other main providers. The other 50% of the market was covered by firms representing less than 5% of the market each, i.e. less than 0.4 million USD.

In 2020, about 24 firms sold IVD tests on the Peruvian market, of which five stand out: Consorcio Tecnomed (28%), Rochem (19%), Roche (18%), Fabhet (11%) and Diagnóstica Peruana SAC (8%). The remainder of the market comprises a group of firms representing less than 4% of the market each. As already mentioned, COVID-19 tests dominated the market in 2020, with providers mainly concentrating on these.

Strategic IVD test purchases

Strategic health supplies, which include strategic IVD tests, are those programmed by the national health strategies (ES) in coordination with CENARES. Currently, there are 13 ES, which were described in chapter 4. Of these, only seven include IVD tests in their requirements.

The CENARES database includes data for the programming of yearly requirements by the ES and the actual purchases from CENARES. In 2018, around 40 different IVD tests were programmed, while just 14 were purchased. Similarly, in 2019, less than half of the 39 different programmed IVD tests were purchased and registered through the OSCE. In 2020, practically no programmed IVD tests were purchased by the CENARES, probably due to the COVID-19 pandemic, which redirected priorities towards COVID-19 tests and PPE.

Table 7.5 shows details of IVD test purchases made by CENARES between 2018 and 2020.

Table 7.5: Purchases of strategic IVD tests by CENARES, 2018–2020

Year	Disease	Test type	Unitary price (USD)	Quantity	Total cost (USD)
2018	**TB**	Kit for Tuberculosis Rapid Test (x100)	158	88	13,939
		Antibody - Anti-*Mycobacterium tuberculosis* IgA, IgG and IgM ELISA (x40)	1,253	400	501,072
		Kit for the Detection of 1st-line Drug Resistance for Mycobacterium tuberculosis (x40)	226	55	12,454
		Reagent for the identification of *Mycobacterium tuberculosis* (x25)	261	678	176,895
	HIV	HIV-1 Real-Time Viral Load (x48)	27	29,52	798,413
		HIV-1 Real-Time Viral Load (x96)	3,115	717	2,233,802
		CD4/CD8 Lymphocyte Count - including buffer and controls (x50)	1,356	156	211,465
		HIV 1-2 Rapid Test (x25)	1	36	38,435
	Leptospirosis	Leptospira IgM ELISA (x96)	612	500	306,053
2019	**Hepatitis B**	Hepatitis B Total Anti-Core ELISA (x96)	201	100	20,106
		Hepatitis B Anticore IgM ELISA (x96)	256	78	19,986
		Hepatitis B Antigen ELISA (x96)	171	100	17,082
	Chikungunya	Chikungunya ELISA Kit for IgG detection (x96)	184	185	34,038
		Chikungunya ELISA Kit for IgM detection (x96)	237	390	92,415
	Leptospirosis	*Leptospira* IgM ELISA (x96)	594	530	314,683
	Syphilis	FTA-ABS Rapid Test for the diagnosis of syphilis RPR (x100)	71	75	5,328
		Treponema pallidum Hemaglutination Kit (x200)	228	230	52,385
		RPR Antigen (x100)	17	3.5	57,794
	TB	Rapid Molecular detection Kit for Rifampicin/Isoniazid P/M. tuberculosis resistance (x96)	1,253	320	400,858
		Kit for the identification of *Mycobacterium tuberculosis* (x25)	261	212	55,312
		Kit for the detection of Pyrazinamide P/*Mycobacterium tuberculosis* resistance (x50)	227	53	12,054
	HIV	Kit for CD4/CD8 lymphocyte recount - including buffer and controls (x50)	1,356	263	356,508
		Qualitative HIV PCR (x48)	40	2,448	98,444
		Kit for CD4/CD3 lymphocyte recount by portable cytometry (x100)	971	10	9,709
2020	**Hepatitis B**	Hepatitis B Anti Australian Antigen ELISA Kit (x96)	370	80	29,609

Additionally, CENARES can purchase IVD tests through international organizations and acquire tests at prices lower than those offered on the local market. This allows for important economies of scale and a greater number of tests to be purchased. Notably, these purchases are not registered in the OSCE database, and this information was obtained directly from the interviewees (Table 7.6),

Table 7.6: International purchases of strategic IVD tests by CENARES, 2018–2020

Year	Disease	Test Type	Unitary Price (USD)	Quantity	Total Cost (USD)	Total Cost (S/)	International Agency
2018	**HIV-Syphilis**	Syphilis + HIV 1-2 Combined Rapid Test	2	1,525,000	2,548,310	8,950,861	UNICEF
		Syphilis + HIV 1-2 Combined Rapid Test (x25)	39	61,918	2,436,314	8,557,479	PAHO
	Malaria	Malaria Rapid Test Kit (x25)	19	3,900	75,957	266,796	PAHO
	Chagas	Chagas disease screening test kit	36	600	21,537	75,649	PAHO
2019	**Dengue**	Dengue ELISA Anti-NS1 (x96)	233	900	209,972	737,519	UNICEF
2020	**Chagas**	Chagas disease screening test kit (x96)	44	200	8,818	30,972	PAHO
	COVID-19	Molecular COVID-19 test	10	130,000	1,329,750	4,670,707	PAHO
		SARS-CoV-2 Antigen Rapid Test	6	1,582,250	9,104,493	31,979,251	PAHO
	Malaria	Malaria Rapid Test Kit (x25)	20	5,200	104,858	368,311	PAHO

We discussed the methods of programming the needs for IVD tests in chapter 4. The Peruvian market for IVD tests, as presented in the chapters above, is far from covering the needs of the population. We decided to review Peruvian guidelines and the literature (published and other documents available) to estimate what the need is in Peru for six different categories of IVD tests. In Table 7.7, we show these estimates and compare them with the actual number of tests that CENARES purchased in 2018, 2019 and 2020. We have also calculated the gap between the estimated need and the actual purchases.

Table 7.7: A comparison of the estimated need for IVD tests by disease and the actual purchases made by CENARES, 2018–2020

Category of test	Tests according to WHO EDL	Number of tests estimated to cover the needs of ES	Number of strategic IVD tests purchased by CENARES					
			2018	% covered	2019	% covered	2020	% covered
Cancer	PCR HPV	1,283,263	.	.	.	.	.	.
	PSA (prostate cancer)	1,437,726	.	.	.	.	.	.
	FIT (DNA-Test colon cancer)	2,582,919	.	.	.	.	.	.
HIV	HIV Rapid Test (Anti-HIV Ab)	1,829,724	900,000	49	.	.	.	.
	Syphilis + HIV 1-2 Combined Rapid Test	1,320,000	3,072,950	233	.	.	.	.
	ELISA HIV 1-2	413,318	.	.	.	.	.	.
	Combined ELISA HIV 1-2 + p24	NA	.	.	.	.	.	.
	Quantitative HIV PCR	75,040	1,485,792	1,980	.	.	.	.
	Qualitative HIV PCR	270	.	.	117,504	43,520	.	.
	CD3, CD4 cell count	150,080	7,800	5	14,150	9	.	.
STI	Syphilis Rapid Test	1,829,724	.	.	7,500	0.4	.	.
	RPR/VDRL	265,007	.	.	350,000	132	.	.
	TPPA/TPHA	132,504	.	.	46,000	35	.	.
	ELISA Syphilis (for donors)	337,978	.	.	.	.	.	.
Hepatitis	Hepatitis B virus (HBV) rapid test (HBsAg)	434,931	.	.	.	.	7,680	2
	HBV rapid test (HBeAg)	132,504	.	.	.	.	.	.
	ELISA IgM Anti-core HBV	NA	.	.	7,488	.	.	.
	ELISA Anti-HBs HBV (for donors)	337,978	.	.	9,600	3	.	.
	Quantitative HBV PCR	1,325	.	.	.	.	.	.
	Hepatitis C virus (HCV) Rapid test (ab anti-HCV)	427,431	.	.	.	.	.	.
	Combined antibodies to HCV (anti-HCV) and HCV core antigen (HCVcag)	21,372	.	.	.	.	.	.
	ELISA HCV	337,978	.	.	.	.	.	.
	Anti-HCV core antigen	21,372	.	.	.	.	.	.
	Quantitative HCV PCR	21,372	.	.	.	.	.	.
	ELISA Anti-Core Total (IgM+IgG) HBV	NA	.	.	9,600	.	.	.
Biochemistry	Glucose rapid test	542,705,473	.	.		.	.	.
	HbA1c	5,905,516	.	.	.	.	.	.
	Haemoglobin	8,100,000	.	.	.	.	.	.
	Blood groups A, B, O and Rh Factor	937,978	.	.	.	.	.	.

Conclusion

Various conclusions about the market for IVD tests in Peru can be drawn from the analysis we have conducted. First, there is no clear pattern concerning the acquisition of IVD tests according to their test category. While HIV was clearly the focus of public spending on IVD tests in 2018, this changed in 2019, with greater spending in infectious disease and biochemistry tests, and again in 2020, with greater spending on COVID-19 tests. For example, HIV tests represented an expenditure of 5, 1.1 and 0.2 million USD in 2018, 2019 and 2020, respectively. This denotes a lack of consistency in public purchases of IVD tests throughout the past 3 years.

Second, despite having institutions responsible for purchasing essential health supplies in a centralized manner, including IVD tests, purchases in the Peruvian public sector are carried out by many institutions, with direct purchases by regional and local hospitals and health facilities being widespread. There is no clear pattern or predominance of any one institution, although the CENARES, the MINSA, EsSalud and INS tend to be important buyers. Peru Compras should be considered as an important new player in the purchase of IVD tests, although it is unclear whether it will consolidate its role in the future.

The private health sector in Peru is small and highly fragmented, with total dependence on foreign production and importation of IVD tests and most other health supplies. There is an ultra-concentration of the health market in the hands of a few conglomerates; this includes services, clinics, and medications, although IVD tests were not seen as an important market until the COVID-19 pandemic. Distributors are the main link between the private and public sectors. However, it is hard to find consistency within the sales of the distributors that provide IVD tests to the public sector on the Peruvian market.

One could conclude that the market is fragmented, with a multitude of sellers concentrating limited proportions of the market. Except for Roche, the sales rankings of most providers varied between 2018 and 2020. Even in the case of Roche, sales of IVD tests are highly variable, representing 3.3, 0.8 and 1.8 million USD in 2018, 2019 and 2020, respectively. Furthermore, the IVD test market far from covers the public health needs in Peru. A combination of poor programming and a complicated process of acquisition results in a relatively small number of IVD tests (in terms of both variety and actual numbers) being purchased.

It is likely that the COVID-19 pandemic will have an unprecedented impact on the provision and acquisition of IVD tests in Peru. Primarily, the pandemic has highlighted the importance of IVD tests in healthcare and has shone a light on the chronic lack of these tests in the Peruvian public healthcare system.

The concentration of spending and attention towards the fight against COVID-19 has led deviation from and even abandonment of other critical disease categories and health interventions. The large reduction in spending on non-COVID tests in 2020 (and possibly the first half of 2021) will have important repercussions in the years to come, and the gaps that have opened during these years will have to be filled according to decisions made in relation to public health policies.

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VIII

RECOMMENDATIONS MOVING FORWARD

VIII
RECOMMENDATIONS MOVING FORWARD

Recommendations moving forward

1. The public sector for health in Peru serves approximately 92% of the total population and is the most important buyer of medical supplies, including IVD tests. It depends on the private sector for the supply of IVD tests, mainly through local distributors of products manufactured elsewhere (no IVD tests are manufactured in Peru), although there are channels for direct international purchases. It will be important to create direct links between FIND and the relevant Peruvian institutions that are key players in the IVD test supply chain of the country.

   We propose to:

   - Invite key stakeholders from CENARES, DIGEMID, Peru Compras, INS, as well as national ES directors and others, to learn about FIND and the "virtual market" and to seek their direct input and suggestions.

2. Due to the poor regulatory framework in Peru, there are difficulties and unclear pathways for the introduction of innovative medical devices, including IVD tests. Additionally, the quality of the IVD tests available is not currently being assured. There are no clear signs of harmonization of the regulatory processes in Peru. There is a lack of human resources, infrastructure, and investment, which hinders efficient regulatory processes.

   We propose to:

   a. Analyse in detail the gaps in the regulations for IVD tests, and the changes needed, and work on a proposal for new regulations for IVD tests.

   b. Share the proposed new regulations with local authorities, seek their feedback and offer to provide technical support.

   c. Find/create opportunities to improve the technical capacity of local regulators.

   d. Create a bridge between local regulators and the Latin American Group on Harmonization of IVD tests.

3. Although Peru has had an essential diagnostics list (PNUDME) since 2019, it is incomplete, so CENARES had to create another list (RES) to procure strategic IVD tests.

   We propose to:

   - Prepare recommendations to improve the Peruvian EDL (PNUDME) and unify this with the RES, working with the appropriate stakeholders (coordinators of the ES, DIGEMID and CENARES).

4. The procurement process is fragmented, takes a long time, with one of the critical steps being to prepare the various "product sheets" (fichas).

   We propose to:

   - Improve the procurement of strategic IVD tests using the EDL. One practical step would be to help in the preparation and approval of homologated files for IVD tests based on the WHO EDL, starting with those corresponding to primary care.

5. Peru Compras has recently started preparing catalogues for products and, during the pandemic, buying COVID-19 tests. It will probably become an important player in the process of purchasing IVD tests in the country.

   We propose to:

   - Establish connections with Peru Compras to address the barriers and facilitators to ensure IVD tests are included in the catalogues.

6. The information system used for the procurement process is fragmented and inefficient.

   We propose to:

   - Explore digital solutions that could support a

better information system for the procurement of IVD tests, which could be offered to the Peruvian government to address this issue.

7. The absence of automated alert systems to detect expiration dates of supplies and IVD tests and to maintain adequate storage standards has resulted in the loss of large quantities of medical supplies.

   We propose to:

   a. Explore the feasibility of quantifying this loss in monetary terms.

   b. Explore digital solutions that could be offered to the Peruvian government to address this issue (e.g. inventory management systems).

8. The demand for IVD tests has not been clearly established. Programming for IVD tests is performed based on "historic" numbers of tests used rather than actual needs. Although we have estimated the demand, there is a need to validate this among relevant stakeholders. It will also be important to map laboratory capacity at a regional level.

   We propose to:

   a. Validate the estimated need for IVD tests (establish the demand) with ES.

   b. Map the capabilities of the regional public health laboratories in Peru.

9. We have been able to identify some data sources to help with our analysis of the IVD test market in Peru. Currently, this is a fragmented market that does not fulfil the needs of the Peruvian public health system.

   We propose to:

   a. Continue our analysis of the data to improve our estimates of the market for IVD tests (by region, prior years, etc).
   b. Perform an in-depth analysis of the interactions and landscape of IVD test distributors in Peru.

10. There are limited IVD tests available on the Peruvian market. It is difficult to access innovative IVD tests, which are not imported because they are not requested through the ES or by the MINSA. It is also possible that innovative IVD tests are not requested because they are not available in the country. CENARES procures IVD tests centrally but has problems each year in fulfilling all requests from the ES and buys fewer types of IVD tests than the ones programmed. Seeking more tests and at better prices, the government has approved a channel for international purchases through cooperation agencies, but the tests currently on offer remain relatively limited. The price of IVD tests is an issue that we have not fully explored here, but from the interviews it is clear that quality is sometimes sacrificed for price.

    We propose to:

    a. Use the data available to explore issues related to the pricing of IVD tests.

    b. Present and validate the concept of the FIND marketplace to stakeholders, as a tool to openly and transparently obtain innovative IVD tests, at better prices.

11. There is no existing local production of IVD tests in Peru. Moreover, the country has no capacity to produce such tests, due to a lack of infrastructure, human resources, expertise, technology, and incentives, and depends entirely on the importation of foreign products. This creates a paradigmatic situation in which, although it is considerably smaller than the public sector, the private sector plays a critical role in the provision of IVD tests via its distributors, who supply both private and public healthcare systems. Despite being key players in the supply chain, little is known about the distributors of IVD tests or their practices and functions within the health system.

    We propose to:

    a. Expand upon this initial evaluation of the role played by distributors, pursuing a greater understanding of this key player, including practices, roles in the supply chain, management structure, market concentration and corporate functioning.

    b. Generate links with ComSalud and the CCL, which are the main distributors of IVD tests in Peru and represent potential strategic partners

for the appropriate and timely delivery of healthcare.

12. The private sector is poorly regulated and rarely supervised by the competent authorities and supervisory agencies. These organizations lack sufficient human resources, clear mandates and standards, competencies, training, infrastructure, and technology to fulfil their role. This generates continuing detrimental scenarios, including opaque practices (in the relationships between laboratories and clinics; secret insurance tariff systems), low-quality services (unsupervised laboratories; distribution of poor-quality IVD tests), consumer rights vulnerability (irregular cost of healthcare provision due to price concertation, cartelization and oligopolization of private healthcare) and mercantilization of healthcare (business-driven entrepreneurial practices detrimental to the provision of quality healthcare to patients).

We propose to:

a. Identify and further analyse the issues and illegal/hidden practices that hinder the desirable and timely delivery of healthcare, in both the public and private sectors.

b. In collaboration with the Ministry of Health, relevant competent authorities (DIGEMID, INS, SuSalud) and private actors (COMSALUD, CCL, CONFIEP, ACP, ALAFARPE, APESEG and APEPS, among others), generate guidelines and recommendations to address the issues, as well as to reinforce preventive and supervisory mechanisms and institutions with the aim of achieving greater transparency, efficiency and equality in the provision of IVD tests in Peru.

c. Further examine the extent of market concentration in the private sector, estimating the impact on consumer prices and public healthcare provision.

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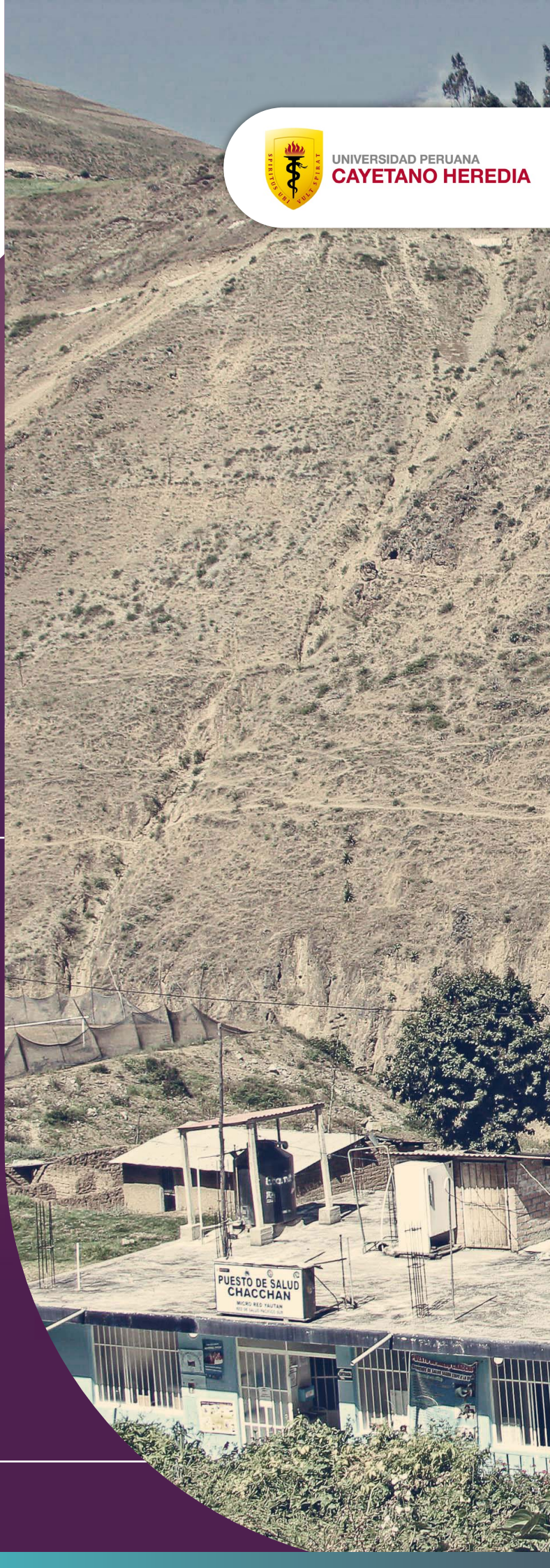
IX

APPENDIX



IX
APPENDIX

1	Approved protocol (Spanish)	Description
	1. FIND_Protocol_21.01.21.docx	Approved Spanish Protocol IRB Number 201930
	2. FIND_Consent_Forms_21.01.21.docx	Approved Spanish Verbal Consent Forms IRB Number 201930
2	**Qualitative data (Public sector)**	**Description**
2.1	**Key Actors and Guides for Interviewees**	
	1. Qualitative_key_actors_information.xls	Database containing characteristics from key actors'
	2. GI_Programming/Users.docx	Guide interview for programming or users
	3. GI_ Control/Surveillance.docx	Guide interview for control and surveillance
	4. GI_ Acquisition/Selection/Storage.docx	Guide interview for acquisition, selection, or storage
	5. GI_ Acquisition/Selection.docx	Guide interview for acquisition or selection
	6. GI_ Information systems.docx	Guide interview for information systems
	7. GI_InformationSystems/Programming/Users.docx	Guide interview for information systems, programming, or users
	8. GI_ Financing.docx	Guide interview for financing
	9. GI_Users/Providers/Selection.docx	Guide interview for users, providers, or selection
	10. GI_Distributors/ Users/Providers.docx	Guide interview for distributors, users, or providers
	11. GI_Providers and Distributors.docx	Guide interview for providers and distributors
	12. GI_Health Providers.docx	Guide interview for health providers
2.2	**Spanish in-depth interviews**	
	01_PUS.docx	Summary of in-depth interview from key actor 1 from the public sector
	02_PUS.docx	Summary of in-depth interview from key actor 2 from the public sector
	03_PUS.docx	Summary of in-depth interview from key actor 3 from the public sector
	04_PUS.docx	Summary of in-depth interview from key actor 4 from the public sector
	05_PUS.docx	Summary of in-depth interview from key actor 5 from the public sector
	06_PUS.docx	Summary of in-depth interview from key actor 6 from the public sector
	07_PU.docx	Summary of in-depth interview key actor 7 from public the sector
	08_PUS.docx	Summary of in-depth interview key actor 8 from the public sector
	09_PUS.docx	Summary of in-depth interview key actor 9 from the public sector
	10_PUS.docx	Summary of in-depth interview key actor 10 from the public sector
	11_PUS.docx	Summary of in-depth interview from key actor 11 from the public sector
	12_PUS.docx	Summary of in-depth interview from key actor 12 from the public sector

	13_PUS.docx	Summary of in-depth interview from key actor 13 from the public sector
	14_PUS.docx	Summary of in-depth interview from key actor 14 from the public sector
	15_PUS.docx	Summary of in-depth interview from key actor 15 from the public sector
	16_PUS.docx	Summary of in-depth interview from key actor 16 from the public sector
	17_PUS.docx	Summary of in-depth interview from key actor 17 from the public sector
	18_PVS_01.docx	Summary of in-depth interview from key actor 1 from the private sector
	19_PVS_02.docx	Summary of in-depth interview from key actor 2 from the private sector
	20_PVS_03.docx	Summary of in-depth interview from key actor 3 from the private sector
	21_PVS_04.docx	Summary of in-depth interview from key actor 4 from the private sector
3	**Public IVD purchases database**	**Description**
	OSCE.2018-2020.xls	Database from the Peruvian Supervisory Agency for State Procurement (OSCE) containing public purchases of IVDs from 2018 to 2020
4	**List of Peruvian IVD distributors**	**Description**
	Peruvian IVD Distributors.xls	Database containing information from Peruvian distributors of IVDs
5	**Main Peruvian regulatory documents related to IVDs and Medical Devices (PDF)**	**Description**
	1.Law 26842.pdf	General Law on Healthcare.
	2. DS-010-97-SA.pdf	Approval of the Regulation for the Registration, Control and Sanitary Surveillance of Pharmaceutical and Related Products.
	3. Law 29459 – Victor Dongo.pdf	Victor Dongo article on the analysis of Law 29459.
	4.Law 29459.pdf	Law of Pharmaceutical Products, Medical Devices, and Sanitary Products.
	5. DS-016-2011-SA.pdf	Approval of the Regulation for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Health Products.
	6. DS-001-2012-SA.pdf	Modification of the Regulation of Registration, Control and Surveillance.
	7. DS-003-2020-SA.pdf	Regulation that establishes the Classification and Essential Principles of Safety and Performance of Medical Devices.
	8. DS-014-2011-SA.pdf	MINSA Pharmaceutical Establishments.
	9. RM-737-2010-MINSA.pdf	Administrative Directive for the certification of Good Manufacturing Practices in National and Foreign Laboratories.
	10. RM-132-2015-MINSA.pdf	Manual of Good Storage Practices for Pharmaceutical Products, Medical Devices and Health Products in Laboratories, Drugstores, Special Storages.

	11. RM-833-2015-MINSA.pdf	Manual of Good Distribution and Transportation Practices for Pharmaceutical Products, Medical Devices and Health Products.
	12. DS-016-2013-SA.pdf	Modification of the Articles of the Regulation for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products.
	13. DL-1439-MEF.pdf	Establishment of Principles, definitions, composition, norms and procedures of the National Supply System.
	14. RM-116-2018-MINSA.pdf	Management of the Integrated Public Supply System for Pharmaceutical Products, Medical Devices and Health Products — SISMED.
	15. DS-082-2019-EF.pdf	Publication of the Single Ordered Text of Law N ° 30225, Law of State Procurement.
	16. DS-344-2018-EF.pdf	Approval of the Regulation of Law N° 30225, Law of State Procurement.
	17. RP-014-2019-OSCE-PRE.pdf	Formalization of the Approval of Directive N° 002-2019-OSCE-CD, Annual Contracting Plan.
	18. RD-0003-2021-EF-54.01.pdf	Approval of the Directive for the Multiannual Programming of Goods, Services and Works.
	19. DU-007-2019-MINSA.pdf	Declaration that establishes Medicines, Biological Products and Medical Devices as an Essential Part of the Right to Health and Provide Measures to Guarantee Their Availability.
	20. RD-389-2020-CENARES-MINSA.pdf	Approval of the Document Called Guidelines for the Programming of Strategic Resources in Health.
	21. RM-670-2019-MINSA.pdf	Approval of the Single National Petition Technical Document for Essential Medical Devices for the Health Sector. (PNUDME)
6	**Database of registered & authorized IVD**	**Description**
	Excel_Sanitary_Registration_active_IVD.xls	Database in excel containing a list of IVDs with Active Sanitary Registration
7	**Qualitative data for the private sector**	**Description**
7.1	**Key Actors and Guides for Interviewees**	
	1. Qualitative_key_actors_information.xls	Database containing characteristics from key actors'
	2. GI_ Manufactures and Distributors.docx	Guide Interview for Manufacturers and distributors representatives
	3. GI_Distributors.docx	Guide Interview for Distributors representative
	4. GI_ Dependent laboratory inside a Private Health Clinic.docx	Guide Interview for a dependent laboratory representative working inside a Private Clinic
	5. GI_ health guild COMSALUD.docx	Guide Interview for representative from the health guild COMSALUD of the Lima Chamber of Commerce (CCL)
	6. GI_ Guild Association of Private Clinics.docx	Guide Interview for representative from the Association of Private Clinics
	7. GI_ Pharma laboratories guild ALAFARPE.docx	Guide Interview for representatives from the National Association of Pharmaceutical Laboratories (ALAFARPE)
	8. GI_ Health insurance.docx	Guide Interview for Health insurance representatives

	9. GI_ Dependent laboratory working through a network of Private Health Clinics.docx	Guide Interview for a dependent laboratory representative working through a network of clinics
	10. GI_ Walk in laboratory.docx	Guide Interview for representatives from a walk-in laboratory
	11. GI_Private Health Clinic.docx	Guide Interview for a Private Health clinic representative
7.2	**Spanish in-depth interviews**	
	1_ Manufactures and Distributors.docx	Summary of In-depth Interview from key actor 1 representative from the manufacturers and distributors sector
	2_ Manufactures and Distributors.docx	Summary of In-depth Interview from key actor 2 representative from the manufacturers and distributors sector
	3_ Distributors.docx	Summary of In-depth Interview from key actor 3 representative from the distributors sector
	4_ Dependent laboratory inside a Private Health Clinic.docx	Summary of In-depth Interview from key actor 4 representative from dependent laboratory
	5_ Health guild COMSALUD.docx	Summary of In-depth Interview from key actor 5 representative from COMSALUD
	6_ Guild Association of Private Clinics.docx	Summary of In-depth Interview from key actor 6 representative from guild of Private clinics
	7_ Pharma laboratories guild ALAFARPE.docx	Summary of In-depth Interview from key actor 7 representative from ALAFARPE
	8_ Health insurance.docx	Summary of In-depth Interview from key actor 8 representative from a health insurance
	9_ Dependent laboratory working through a network of Private Health Clinics.docx	Summary of In-depth Interview from key actor 9 representative from a dependent laboratory link to a clinic network
	10__ Walk in laboratory.docx	Summary of In-depth Interview from key actor 10 representative from a walk-in laboratory
	11__Private Health Clinic.docx	Summary of In-depth Interview from key actor 11 representative from a Private health Clinic
8	**List of International Manufacturers of IVDs sold in Peru**	**Description**
	Peru_Manufacturers_IVD.xls	Database detailing the companies which manufacture the IVDs sold in Peru
9	**List of Peruvian IVD Distributors**	**Description**
	Peru_Distributors_IVD.xls	Database including two sheets 1. Distributors in Peru (some with information about sanitary registrations) 2. Distributors which have had contracts with the public sector in 2018, 2019 and 2020 and the amounts.
10	**List of Peruvian Insurances**	**Description**
	Peru_Insurances_IVD.xls	Database detailing the insurance companies which operate in Peru
11	**PPT Report**	**Description**
	FIND-UPCH_Access to DX REPORT presentation.pptx	Power Point Presentation with Final work Results

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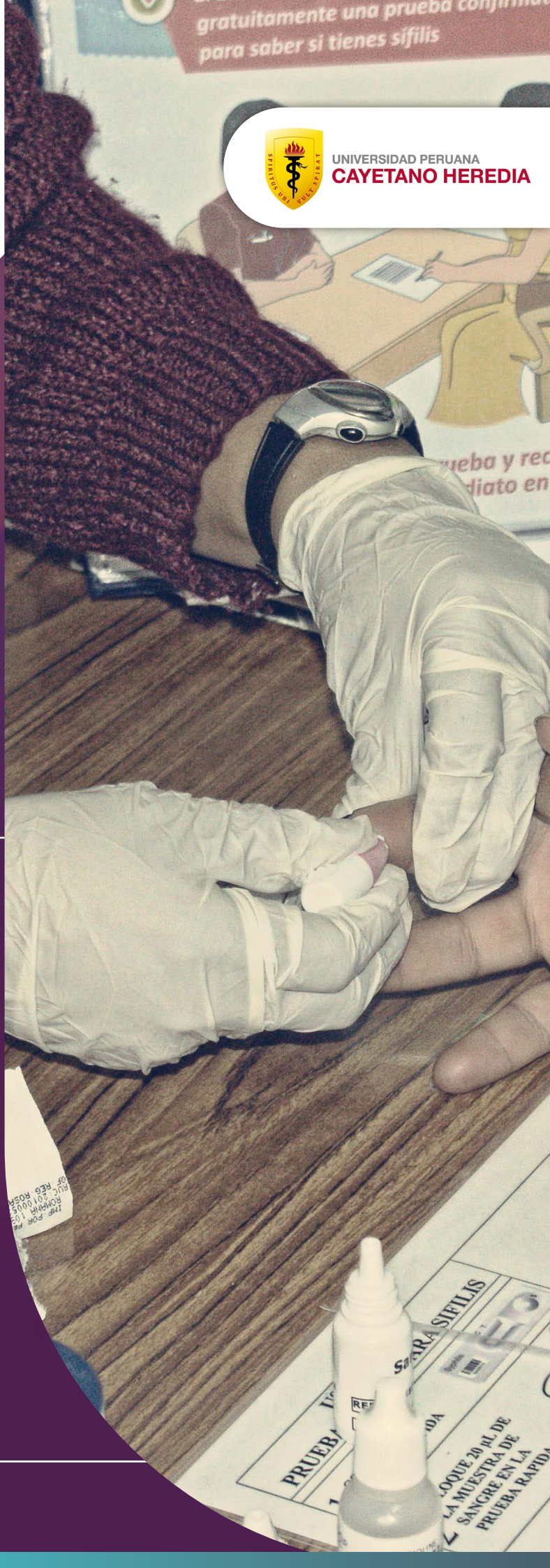

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