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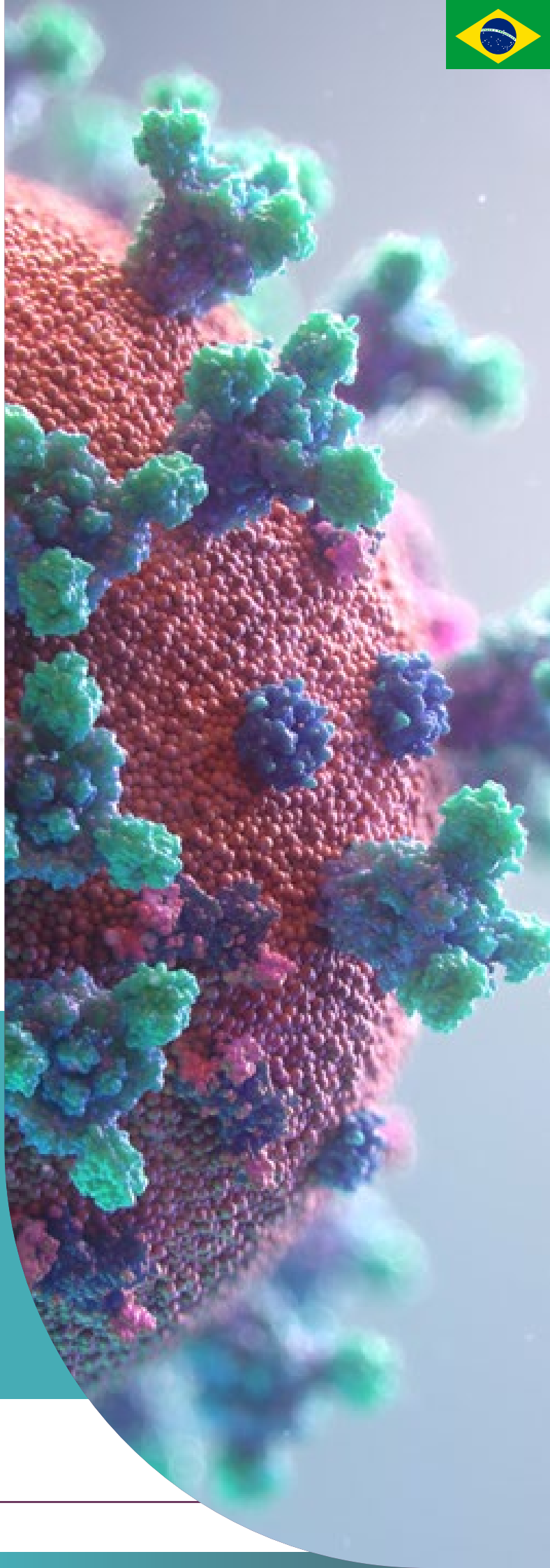

MEDICAL DIAGNOSTICS IN BRAZIL

MARKET LANDSCAPE ASSESSMENT

November, 2021

ACKNOWLEDGEMENTS

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CONTENT

EXECUTIVE SUMMARY

Brazil has over 213 million citizens, with almost 10% of the population aged over 65 years. Health expenditure, as a share of national GDP, accounted for 9.51% in 2018 and USD 1.44 million in 2020. Administrative power is divided between federal, state and municipal units, each with their own duties and responsibilities regarding the health sector. The COVID-19 pandemic has shed light on the need for greater cohesion around testing strategies in the country.

Brazil's Unified Health System (SUS) is financed through public funds and the National Social Security Institute (*Instituto Nacional do Seguro Social, INSS*). It comprises both public and private providers and is the only healthcare available to 77% of the population. Supplementary healthcare is offered by health plan providers and insurance companies and is regulated by an auxiliary national agency linked to the Ministry of Health (ANS).

The process for registering pharmaceutical products (e.g. services, technologies, drugs, procedures and diagnostic tests) includes obtaining authorization from the Brazilian Health Regulatory Agency (Anvisa) and compliance with economic regulations by the Chamber for Drug Market Regulation (CMED). Additionally, Brazil's National System of Public Health Laboratories (SISLAB) conducts health activities, such as epidemiological/environmental surveillance, and medical care management to ensure quality standards are met. Commercialization is also regulated, and companies that import, export, manufacture, distribute and store in vitro diagnostic (IVD) tests must obtain an official licence and permit that vary depending on the company's location, purpose and size. Foreign companies are required to have legally constituted partners in Brazil, who are allowed to request authorizations directly from national agencies.

Once ready to be sold, health products are subject to a health technology assessment (ATS) and must be incorporated in the SUS list. Anyone (individual or institution) can request an ATS to include, alter or exclude technologies from the public health network. Supplementary healthcare is also open for individuals and legal entities to submit proposals to be evaluated and included in a mandatory list. Being listed in the ATS means that an IVD test can be provided through the public sector system. In the private market, products must go through sanitary and price compliance processes before they can be made directly available to consumers. In Brazil, patients can access diagnostics products via public, supplementary or private markets. Data from the Brazilian Chamber of Laboratory Diagnostics (CBDL) indicate that Brazil represents a 3.5% share of the global IVD test market, equal to approximately USD 68,410 million in 2020, as evaluated by Mordor Intelligence.

One of the most critical issues is the dependence on imported IVD tests and challenges faced in expanding internal production. The pandemic is accelerating a willingness to improve interoperability, connectivity and supply chain efficiency. Discussions within the sector are converging to more extensive use of technology and consolidated purchases, which may create an opportunity for the FIND diagnostics marketplace.

The COVID-19 pandemic has been severe in Brazil, with 21 million cases and 598,000 deaths. Difficult coordination and disagreement between federal and state governments regarding testing strategies, as well as a shortage of tests, have demonstrated the need to further engage a coherent testing strategy/policy in the country.

As a way forward, it is recommended that strategic stakeholders become engaged while positioning FIND as a partner to improve access to diagnostics. Society-organized groups (sectoral and patient associations, disease networks and professional alliances) are currently conducting discussions regarding the importance of implementing preventive health measures and the need to expand the outreach and adoption of diagnostics at the primary healthcare levels.

ABBREVIATIONS

ABIA	Associação Brasileira Interdisciplinar de AIDS (Brazilian Interdisciplinary AIDS Association)
ABIIS	Aliança Brasileira da Industria Inovadora em Saúde – (Brazilian Alliance of Innovative Health Industry)
ABNT	Assdociação Brasileira de Normas Técnicas (Brazilian Association of Technical Standards)
ABRAFARMA	Associação Brasileira de Redes de Farmácias e Drogarias (Brazilian Association of Pharmacy and Drugstore Chains)
ABRAID	Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde (Brazilian Association of Importers and Distributors of Products for Health)
ABRAMED	Associação Brasileira de Medicina Diagnóstica (Brazilian Association for Diagnostic Medicine)
ABRASCO	Associação Brasileira de Saúde Coletiva (Brazilian Association of Collective Health)
AE	Autorização Especial (Special Authorization)
AFE	Autorização de Funcionamento da Empresa (Company Operation Authorization)
AFRMM	Adicional ao Frete para Renovação da Marinha Mercante (Additional Freight for Renewal of the Merchant Marine)
ALADDiV	Aliança Latino Americana para o Desenvolvimento do Diagnóstico in Vitro (Latin American Alliance for the Development of In Vitro Diagnostics)
AMG	Programa de Automonitoramento Glicêmico (Self-Monitoring of Blood Glucose Programme)
ANAHP	Associação Nacional de Hospitais Privados (National Association of Private Hospitals)
ANS	Agência Nacional de Saúde Suplementar (National Supplementary Health Agency)
Anvisa	Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency)
APAC	Autorização de Procedimentos Ambulatoriais de Alta Complexidade e Custo (Authorization of High Complexity Outpatient Procedures)
APIB	Articulação dos Povos Indígenas do Brasil (Articulation of Indigenous Peoples of Brazil)
ATS	Avaliação de Tecnologia em Saúde (Health Technology Assessment)
CBDL	Câmara Brasileira de Diagnóstico Laboratorial (Brazilian Chamber of Laboratory Diagnostics)
CBPDA	Certificado de Boas Práticas de Distribuição e/ou Armazenagem (Certificate of Good Distribution and Storage Practices)
CC	Centros de Colaboração (Collaborating Centers)
CFM	Conselho Federal de Medicina (Federal Council of Medicine)
CGLAB	Coordenação-Geral de Laboratórios de Saúde Pública (General Coordination of Public Health Laboratories)
CIB	Comissão Intergestores Bipartite (Bipartite Interagency Commission)
CIT	Comissão Intergestores Tripartite (Tripartite Interagency Commission)
CMED	Câmara de Regulação do Mercado de Medicamentos (Chamber of Drug Market Regulation)
CNES/MS	Cadastro Nacional de Estabelecimentos de Saúde/ Ministério da Saúde (National Registry of Health Facilities/ Ministry of Health)
CNS	Conselho Nacional de Saúde (National Health Council)
COEP	Rede Nacional de Mobilização Social (National Social Mobilization Network)
COFINS	Contribuição para o Financiamento da Seguridade Social (Social Security Financing Tax)
CONASEMS	Conselho Nacional dos Secretários Municipais de Saúde (National Council of Municipal Health Secretaries)
CONASS	Conselho Nacional dos Secretários de Saúde (National Council of State Health Secretaries)
CONITEC	Comissão Nacional de Incorporação de Tecnologias no SUS (National Commission for the Incorporation of Technologies at SUS)
COSAÚDE	Comitê Permanente de Regulação da Atenção à Saúde (Permanent Committee for Health Care Regulation)
COSEMS	Conselhos de Secretarias Municipais de Saúde (State Councils of Municipal Health Secretaries)
CPF	Cadastro de Pessoa Física (Social Security)
AVA-GATT	Acordo de Valoração Aduaneira (Customs Valuation Agreement)

DI	Declaração de Importação (Import Declaration)
DICOL	Diretoria Colegiada da ANS (ANS Collegiate Board)
DIFOT	Delivered In-Full On-Time
DUIMP	Declaração Única de Importação (Single Import Declaration)
e-GITS	Sistema para Gestão Eletrônica de Processos de Incorporação de Tecnologias no SUS (Electronic Management of Technology Incorporation Process at SUS)
EMBRAPA	Empresa Brasileira de Pesquisa Agropecuária (Brazilian Agricultural Research Corporation)
ENF	Escola Nacional dos Farmacêuticos (National Pharmacists School)
EPI	Equipamento de Proteção Individual (PPE, personal protective equipment)
FBH	Federação Brasileira de Hospitais (Brazilian Federation of Hospitals)
FENAD	Federação Nacional das Associações e Entidades de Diabetes (National Federation of Diabetes Associations and Entities)
GDP	Gross domestic product
GMP	Good Manufacturing Practices for Health Products
GRU	Guia de Recolhimento da União (Federal Tax Collection form)
IAL	Instituto Adolfo Lutz (Adolfo Lutz Institute)
IBGE	Instituto Brasileiro de Gesografia e Estatística (Brazilian Institute of Geography and Statistics)
ICMS	Imposto sobre Operações Relativas à Circulação de Mercadorias e sobre Prestação de Serviços de Transporte Interestadual e Intermunicipal e de Comunicação (State Tax on Goods and Services)
IDF	International Diabetes Federation
IDIS	Instituto para o Desenvolvimento do Investimento Social (Institute for the Development of Social Investment)
IEC	International Electrotechnical Commission
IEC	Instituto Evandro Chagas (Evandro Chagas Institute)
IFA	Ingredientes Farmacêuticos Ativos (Active pharmaceutical ingredients)
CI	Comprovante de Importação (Import receipt)
INMETRO	Instituto Nacional de Metrologia, Qualidade e Tecnologia (National Institute of Metrology, Quality and Technology)
INSS	Instituto Nacional do Seguro Social (National Social Security)
IPI	Imposto Produtos Industrializados (Federal Tax on Industrial Products)
IVD	In vitro diagnostic
LACEN	Laboratório Central de Saúde Pública (Central Public Health Laboratory)
LF	Laboratórios de Fronteira (Frontier Laboratories)
LGPD	Lei Geral de Proteção de Dados (Brazilian General Data Protection Law)
LIS Brasil	Associação Brasileira das Empresas Desenvolvedoras de Sistemas de Informação Laboratorial (Brazilian Association of Laboratory Information Systems' Developers)
LL	Laboratórios Locais (Local Laboratories)
LRE	Laboratórios de Referência Estadual (State Reference Laboratories)
LRM	Laboratórios de Referência Municipal (Municipal Reference Laboratories)
LRN	Laboratórios de Referência Nacional (National Reference Laboratories)
LRR	Laboratórios de Referência Regional (Regional Reference Laboratories)
MAPA	Ministério da Agricultura, Pecuária e Abastecimento (Ministry of Agriculture, Livestock and Food Supply)
MDSAP	Programa de Auditoria Única em Produtos para a Saúde (Medical Device Single Audit Program)
MS	Ministério da Saúde (Ministry of Health)
NCM	Nomenclatura Comum do Mercosul (Mercosul harmonized/common nomenclature)
OEA	Operador Econômico Autorizado (Authorized Economic Operator)
PAHO	Pan American Health Organization
PCDTs	Protocolos Clínicos e Diretrizes Terapêuticas (Clinical Protocols and Therapeutic Guidelines)
PERC	Programa de Excelência no Relacionamento com a Cadeia de Suprimentos (Supply Chain Relationship Excellence Program)
PIS	Programa de Integração Social (Social Integration Program)

POCT	Point-of-care test
RADAR	Ambiente de Registro e Rastreamento de Atuação do Intervenientes Aduaneiros (Platform for Registering and Tracking Customs Agents' Activities)
RDC	Resolução da Diretoria Colegiada (Collegiate Board Resolution)
RDT	Rapid diagnostic test
RF or RFB	Receita Federal (Brazilian Federal Revenue)
RFP	Request for proposal
RNLSP	Redes Nacionais de Laboratórios de Saúde Pública (National Network of Public Health Laboratories)
SADT	Serviço de Apoio Diagnóstico Terapêutico (Therapeutic Diagnostic Support Services)
SAES	Secretaria de Atenção Especializada à Saúde do Ministério da Saúde (Department of Specialized Health Care, Ministry of Health)
SAPS	Secretaria de Atenção Primária à Saúde do Ministério da Saúde (Secretariat of Primary Health Care, Ministry of Health)
SAS	Secretaria de Atenção à Saúde (Healthcare Secretariat)
SBD	Sociedade Brasileira de Diabetes (Brazilian Society of Diabetes)
SBEM	Sociedade Brasileira de Endocrinologia e Metabologia (Brazilian Society of Endocrinology and Metabolism)
SBIBAE	Sociedade Beneficente Israelita Brasileira Albert Einstein (The Albert Einstein Israeli Beneficent Society)
SBPT	Sociedade Brasileira de Pneumologia e Tisiologia (Brazilian Society of Pneumology and Phthisiology)
SCTIE	Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos (Secretariat of Science, Technology, Innovation and Strategic Inputs)
SES	Secretarias Estaduais de Saúde (State Health Secretariats)
SISCOMEX	Sistema Integrado de Comércio Exterior (Integrated System of External Commerce)
SISLAB	Sistema Nacional de Laboratórios de Saúde Pública (National System of Public Health Laboratories)
SMS	Secretarias Municipais de Saúde (Municipal Health Secretariats)
SRAG	Síndrome Respiratória Aguda Grave (severe acute respiratory syndrome)
SUS	Sistema Único de Saúde (Unified Health System)
SVS	Secretaria Vigilância Sanitária (Health Surveillance Department)
TFVS	Taxa de Fiscalização de Vigilância Sanitária (Health Surveillance Inspection Fee)
WHO	World Health Organization

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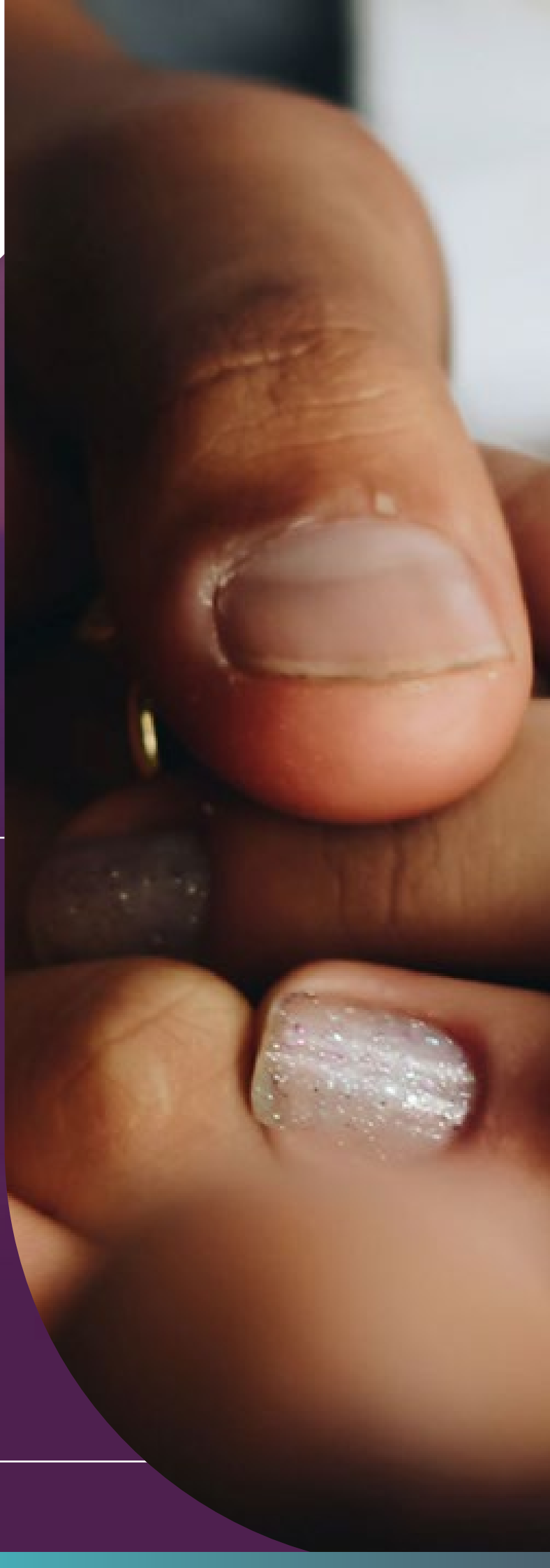
I

INTRODUCTION



INTRODUCTION

Diagnostic tests are a fundamental component for the provision of health service. They are the essential first step towards guiding patient care. This report presents an overview of the diagnostic testing landscape in Brazil. It covers topics related to the structure of the health system, regulatory system, diagnostics market and supply chain. It also provides a comprehensive map of the stakeholders, and sheds light on relevant data related to COVID-19 and diabetes testing practices in the country.

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OBJECTIVES

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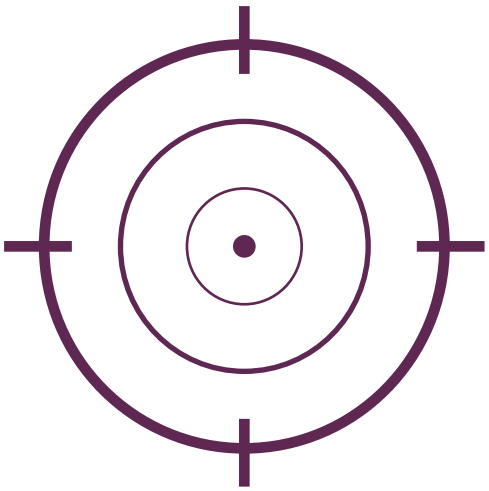
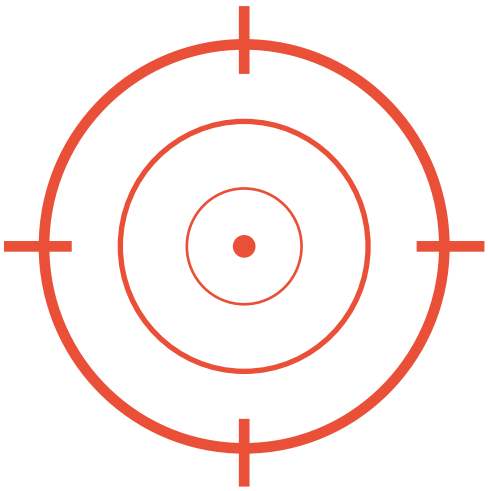


Provide an assessment of the diagnostic testing landscape in Brazil, with a focus on diabetes and COVID-19.



Support FIND, the global alliance for diagnostics, in assessing current opportunities to expand access to quality and affordable diagnostics in Brazil, focusing on rapid diagnostic tests (RDTs) for COVID-19 and diabetes.

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III

METHODOLOGY

III
METHODOLOGY

The methodology involved an exhaustive desk study of official Brazilian agencies and websites of national organizations relevant to the diagnostics market. The findings were supplemented by one-on-one interviews with key stakeholders to better understand the national landscape, especially in relation to the challenges and opportunities for the Brazilian diagnostics market.

The researchers collected data relating to official healthcare protocols, public- and private-sector buying processes, regulatory frameworks and market information, to describe the procedure for importing COVID-19 and diabetes diagnostics to the Brazilian market. Sources included governmental websites and databases, publications from trade and market associations, and materials shared or referred by the individuals interviewed. A specialized customs and tax consulting firm described the flow of products and reagents used to manufacture COVID-19 and diabetes diagnostics. The Market Landscape Report produced for FIND by IQVIA in February 2021 was used as a source of information regarding the market share.

Key actors in conversations regarding COVID-19 and diabetes in Brazil were interviewed through online video meetings. These included C-Level executives of top tier private and public hospitals; researchers from federal universities (Pernambuco, Espírito Santo, Rio Grande do Sul); presidents of non-governmental organizations (NGOs) that deal with specific diseases; government relations professionals from specific disease society associations; C-Level executives of diagnostic medicine associations; C-Level executives of top tier private diagnostics laboratories; executive secretaries and health secretaries of a regional public consortium; and one technical assistant director of a top tier public hospital. The names of the professionals interviewed will not be disclosed as they participated on the basis of anonymity. The recordings of the interviews used to support the evidence provided here have been saved under the Brazilian General Data Protection Law (LGPD). All interviewees were informed that this market study was being conducted at the request of FIND.

Media data were only used when published by tier-1 traditional outlets and confirmed by the professionals interviewed. Appendix B details the channels used for the study. All BRL (Brazilian Real) values were converted to USD at a rate of 5 to 1.

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IV

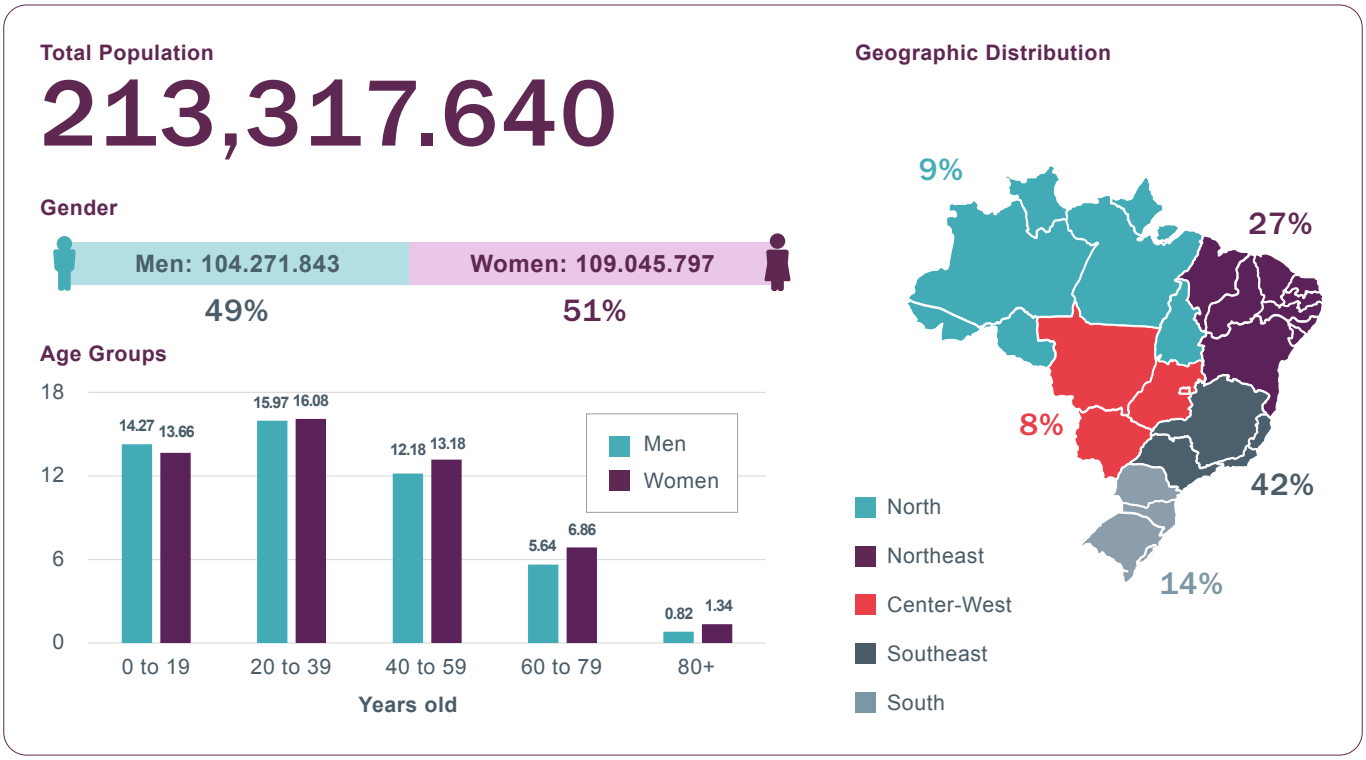
COUNTRY CONTEXT

IV
COUNTRY CONTEXT

Demographics

Brazil occupies the sixth position in world population, ranking behind China, India, United States, Indonesia and Pakistan. In 2020, the ratio of males to females was 96.59 males per 100 females. The country has been going through a rapid demographic transition, with almost 10% of the population aged over 65 years. Divided into 20-year age groups, the highest percentage of the population is concentrated in those aged 20 to 39 years, followed by 0 to 19 years (Fig. 1). Regarding geographic distribution, most of the population lives in the southeast (42%), followed by the northeast (27%).

Figure 1: Demographic data for Brazil



Source: IBGE - Brazilian Institute of Geography and Statistics[1]

The Demographic Census in Brazil has been carried out every 10 years since 1940. The most recent was conducted in 2010. Due to the COVID-19 pandemic, the census initially scheduled for 2020 was postponed until 2022.

Economics[2]

- GDP (USD current): **1.44 trillion** (2020)
- GDP per capita (USD current): **6796.8** (2020)
- GDP growth (annual %): **-4.06%** (2020)
- GNI per capita, Atlas method (current USD): **7,850** (2020)
- GNI per capita PPP (current international USD): **14,680** (2020)

Health Expenditure[3]

- Current health expenditure (% of GDP): **9.51 (**2018)
- Current health expenditure per capita (current USD): **848.39** (2018)
- Current health expenditure per capita, PPP (current international USD): **1530.82** (2018)
- Government health expenditure (% of current expenditure): **41.67** (2018)
- Private health expenditure (% of current expenditure): **58.24** (2018)
- Out-of-pocket expenditure (% of current expenditure): **27.54** (2018)

Political and administrative systems

The political system in Brazil is a federal presidential representative democratic republic, with a President who is both head of state and head of government. Elections take place every four years, and candidates can be re-elected just once. The current president of Brazil is Jair Messias Bolsonaro (no party), who took office in 2018.

From an administrative point of view, the country is divided into states and municipalities, with three levels of governance – federal, state and municipal, each with its own representatives and responsibilities (Fig. 2).

Figure 2: Political–administrative organization in Brazil

26 states + Federal District

5,570 municipalities

Branches and administrative level

Branches/ level	Federal	State	Municipal
Legislative	National Congress (Chamber of Deputies – Federal Deputies and Federal Senate – Senators)	Legislative Assembly (State Deputies)	City Council (municipal councillors)
Executive	President of the Republic, Vice-president and Ministers	Governor, Vice-Governor and Secretaries	Mayor, Vice-Mayor and Secretaries
Judicial	The Supreme Federal Court, The Higher Court of Justice, Federal courts and judges.	Courts and judges	--
Public Ministry	Union Public Ministry	Branches and administrative level	

Source: IBGE - Brazilian Institute of Geography and Statistics[4]

Key takeaways:

- Due to the size of its population, Brazil is one of the biggest consumer markets in the world.
- Most people in Brazil are adults and the population is rapidly ageing. Interventions aimed at chronic diseases, such as diabetes and, in the context of COVID-19, at services that can mitigate risks for the most vulnerable in the population, i.e. the elderly, are highly relevant.
- Brazil's economy has entered a recession, and a negative growth rate in GDP was recorded in 2020. This factor must be considered, as it affects both public and private sector expenditures.
- Health spending in Brazil as a share of the national GDP resembles that of other countries with universal health coverage strategies. The private health sector market is relevant, as it spends proportionally more than the public sector.
- Administrative power is divided between national, state and municipal units, each with their own duties and responsibilities regarding the health sector.

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V

HEALTH SYSTEM OVERVIEW

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HEALTH SYSTEM OVERVIEW

Organization of the healthcare system

Brazil has a national health system (similar to the English model), the Unified Health System (SUS), created as part of the 1988 Federal Constitution. SUS decrees that "health is a right for all" and a "duty of the state". The health system is financed through public funds and employer/employee contributions to the National Social Security system (INSS).

SUS offers access to health services through a mix of public and private providers. About 77% of the population uses SUS exclusively, while 23% also have access to healthcare through supplementary health schemes offered by health plan providers and insurance companies. The regulation of these health plans is the responsibility of the National Supplementary Health Agency (ANS), an agency linked to the Ministry of Health.

Governance

The following principles govern the organization of the system and the operation of SUS:

Ethical–doctrinal principles	Organizational principles
• Universality	• Decentralization
• Equity	• Hierarchy of actions
• Integrality of services and actions in health	• Social participation

These principles define the way policies are oriented and organized in the national territory.

The responsibility for managing SUS is shared between the three federated entities, as shown in Fig. 3.

Figure 3: Administrative representation in the healthcare sector

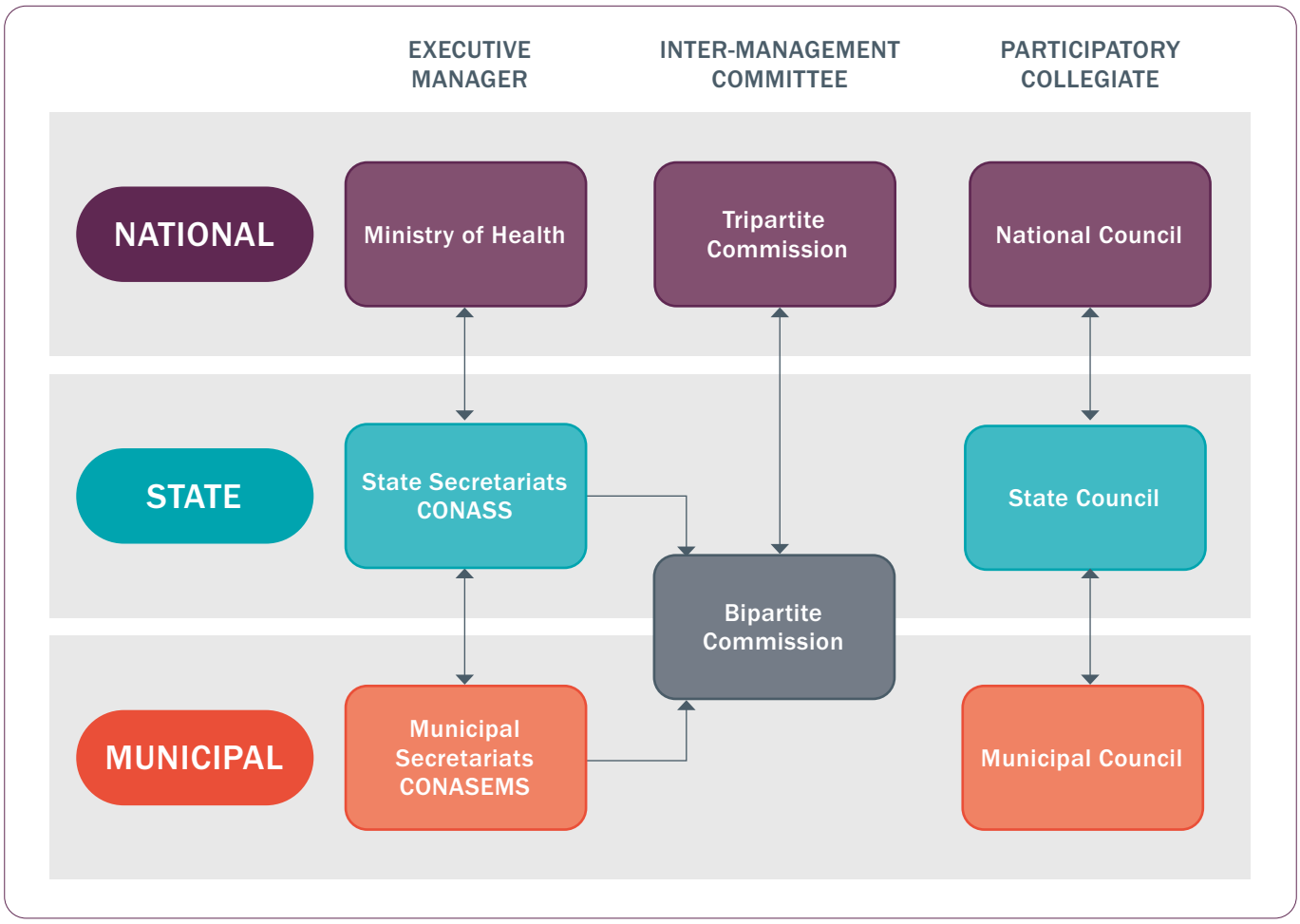
SUS
Sistema Único de Saúde

Level	Representative	Assigments
Federal	Ministry	• Coordinate high-complexity health systems and public laboratories • Plan and supervise SUS activities throughout the country.
State	State Secretariats	• Create their own health policies • Assist in the execution of national policies • Coordinate the network of laboratories and blood centers, and define reference hospitals • Manage complex services' units in the region.
Municipal	Municipal Secretariats	• Ensure basic health care services and provide services in their location, in partnership with the state and federal governments. • Create health policies and collaborate with the application of national and state policies.

Source: Federal Law 8,080/1988[5]

The responsibility for health decisions, on the other hand, is shared among the three levels, as shown in Fig. 4.

Figure 4: Institutional structure and decision-making of SUS



Source: Decree 7,508 Ministry of Health/2011[6,7]
UBS - Unidade Básica de Saúde (Primary Health Care Unit); UPA - Unidade de Pronto Atendimento (Emergency Care Unit)

Any agreement made between the different government levels must go through the inter-management commissions. These commissions are led by public managers, responsible for the operation, financing and management of the federated entities. They define the geographic areas covered by healthcare networks, determine organization guidelines and describe how service will be provided to guarantee the integrality of care.

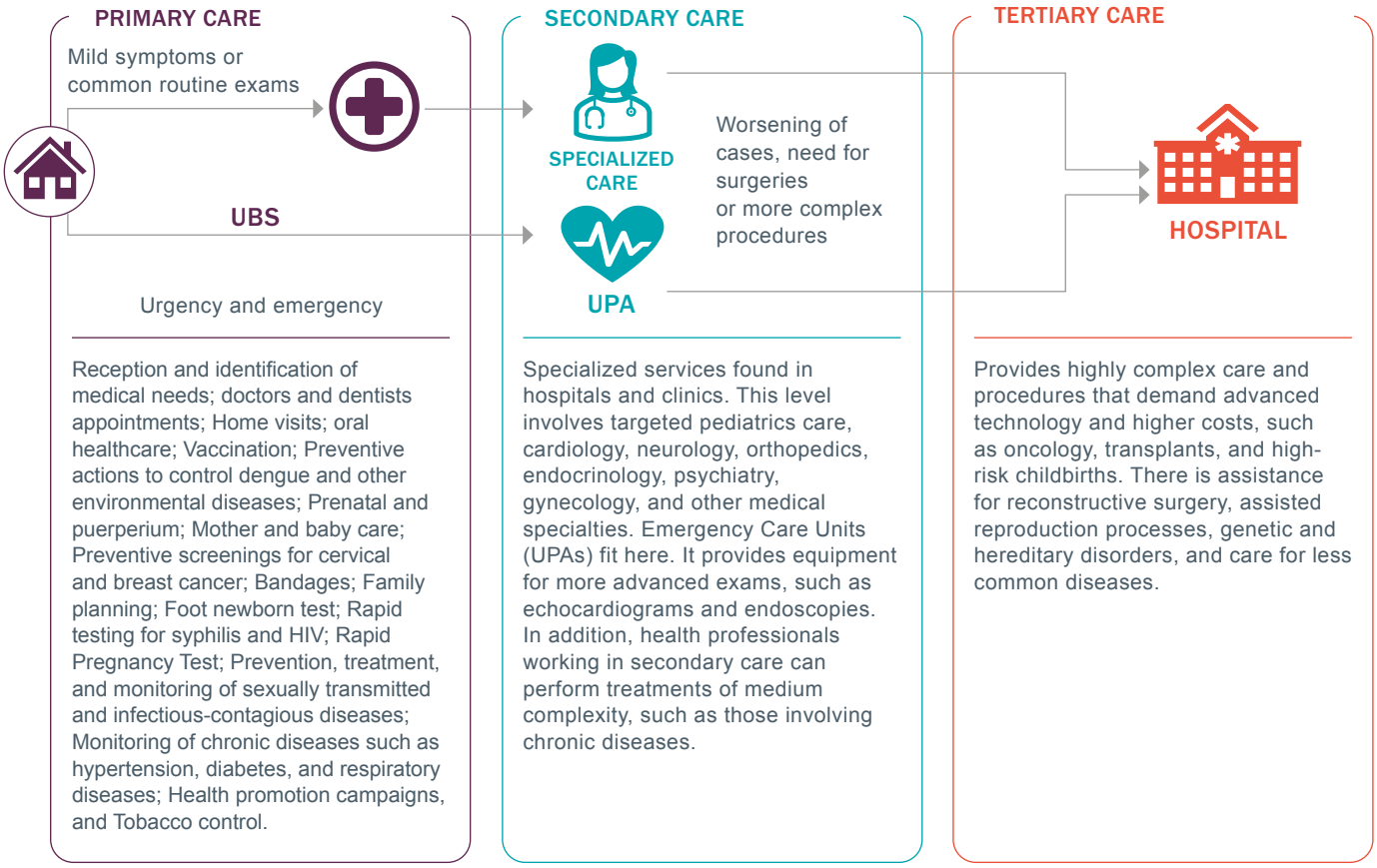
Additionally, SUS has committees for social participation, as required by its constitution, such as health councils. These councils are formed by government representatives, service providers, health professionals, and users from each administrative sphere (federal, state and municipal). The councils are responsible for formulating strategies and overseeing health policies, including their economic and financial roles. For example, they are responsible for informing public authorities about the needs of patients with diabetes, helping to formulate relevant healthcare policies and deliberating on actions planned in their respective geographical areas. The councils also establish policy priorities at the municipal, state and national levels and have representation on tripartite and bipartite commissions.

Healthcare levels

Healthcare in Brazil is structured according to healthcare networks, which connect primary, secondary and tertiary care services. They have increasing levels of complexity to ensure the comprehensiveness of healthcare, as established by the doctrinal principles of SUS.

Fig. 5 shows a patient's journey through the health system according to the levels of healthcare and describes the services at each point of care.

Figure 5: Healthcare services provided at each level of SUS

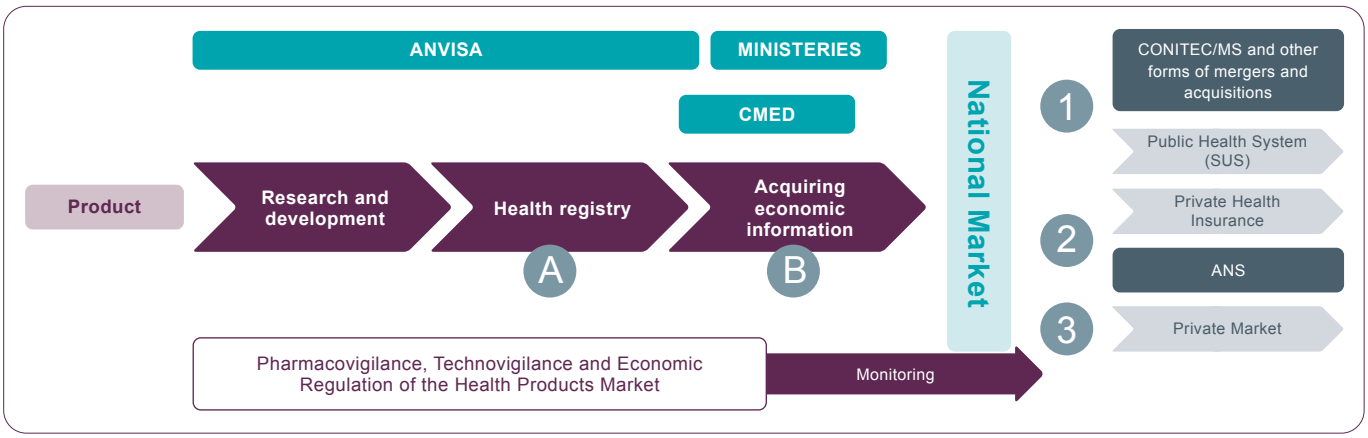


Source: Ordinance Ministry of Health 4,279/2010

Regulation and access of diagnostic tests

In the healthcare system structure, the registration of any healthcare product, such as an in vitro diagnostic (IVD) test, must follow a process like the one shown in Fig. 6.

Figure 6: Registration of and access to health products in Brazil



Source: Ministry of Health[8]

Registration of health products such as IVD tests follow the steps outlined below:

Health registry

A

Marketing authorization granted by the Brazilian Health Regulatory Agency (Anvisa)

- Authorization of manufacturing, or importing by entities authorized by the federal government or licensed by local authorities (municipal or state government)

Acquiring economic information

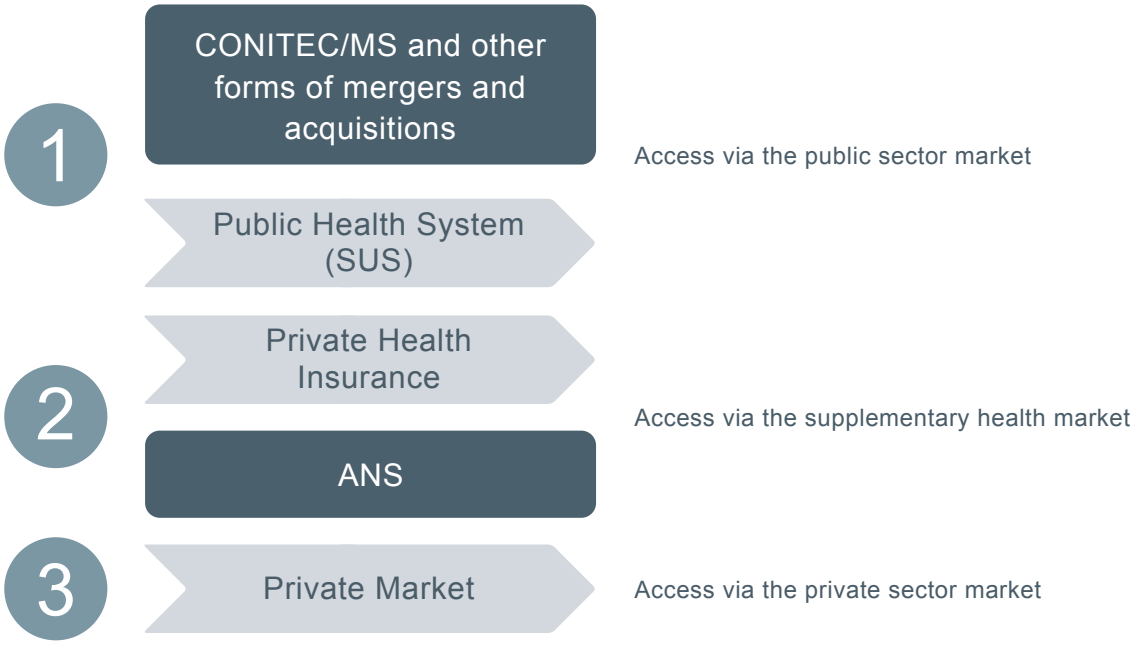
B

Market regulation by the Chamber for Drug Market Regulation (CMED). This includes IVD tests, as defined by Federal Law 10.742/2003 and Resolution 185/2006, updated by the Collegiate Board Resolution RDC 478/2021 (RDC), in relation to economic monitoring of medical devices.

Source: Ministry of Health[9]

These two steps guarantee authorization to sell or distribute the product/diagnostic in the domestic market.

Once available, users can access the products via one of three channels:



Source: Ministry of Health[10]

A) Registration of IVDs

All pharmaceutical products, including IVD tests, must be registered with Anvisa before being commercialized in Brazil. Regulation RDC n. 36/2015 covers the registration of IVD products, establishing risk classification, registration of control procedures and labelling requirements and instructions for IVD tests, including any associated instruments. Products are classified according to risks they pose to health. The risk classification of an IVD test depends on the purpose of the device (see Table 1).

Table 1: Anvisa classification of health risks and administrative procedures for IVD products

Health risk classification of the medical device	Purpose of the device	Administrative procedure at Anvisa
Risk Class I	• Reagents or other auxiliary items for IVD procedures • Products intended for calibration, cleaning or maintenance of instruments in technical assistance or maintenance and cleaning procedures by trained users, as indicated by the manufacturer and specified in the product manual • Culture media and devices for identifying microorganisms • Products for DNA and RNA extraction, auxiliary to IVD procedures • Sample collectors or receptacles for the collection, storage and transport of biological samples to be used in laboratory testing • Instruments for preparing and processing samples for IVD tests	**Register**
Risk Class II	• Products intended for self-testing in which the result is not a determinant of a severe condition; that is, the result is preliminary and requires follow-up with the appropriate laboratory test.	
Risk Class III	• Blood or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues or organs intended for transfusion or transplantation • Notifiable disease diagnosis • Detect the presence or exposure to a sexually transmitted agent • Detect the presence of an infectious agent in cerebrospinal fluid or blood, with risk of limited propagation • Detect the presence of an infectious agent and where an incorrect result could cause death or severe disability of the individual or a fetus • Prenatal screening of women to determine their immune status against communicable agents • Determine infectious disease or immune status where there is a risk that an incorrect result will lead to a patient management decision resulting in an imminent life-threatening situation • Monitor viral load of patients suffering from a generally incurable infectious disease • Screening, staging or diagnosing cancer • Human genetic testing • Screening for congenital disorders in the fetus • Control the levels of drugs, substances or biological components where an incorrect result could lead to a patient management decision that results in a life-threatening situation • POCT products intended for self-testing that do not fall under classification II	**Record**
Risk Class IV	• Detect presence of, or exposure to, a blood-transmissible agent, its components or derivatives; or cells, tissues or organs, to assess suitability for transfusion or transplantation • Monitor or detect presence of, or exposure to, a communicable agent that poses a risk of death or disease, that is generally incurable, with a high risk of propagation	

Source: Resolution - RDC Nº 36, 26 August 2015[11]

Note 1:

Health risk:

- **Class I:** products with low risk to the individual and low risk to public health
- **Class II:** products with medium risk to the individual and/or low risk to public health
- **Class III:** products with high risk to the individual and/or medium risk to public health
- **Class IV:** products with high risk to the individual and increased risk to public health

Risk classification of IVD devices is based on the following criteria:

- Indication of use specified by the manufacturer
- User's technical, scientific or medical knowledge
- Importance of the information provided by the diagnosis
- Relevance and impact of the result for both individual and public health
- Epidemiological relevance

If a rule from more than one of the different risk classes applies to the same product, the product must be classified in the higher risk class.

Note 2:

According to Anvisa's RDC No. 416/2020 and the recent changes promoted by Anvisa's RDC No. 423/2020, the timing for obtaining an authorization can vary from immediate (Classes I and II) to 320 days (implants, IVD products, etc.). Given the COVID-19 emergency, the analysis of essential and strategic products (such as IVD tests) to fight COVID-19 have been prioritized (RDCs nos. 348/2020 and 349/2020). At the beginning of the pandemic, the maximum time for approval of IVD tests for COVID-19 was 29 days (average 11 days), according to the "Activity Report of the Medical Devices Unit of Anvisa in the Context of COVID-19", April 2020. In the most recent report, published in July 2021, this time had increased to a maximum time of 262 days (average 40 days).[12]

Official fees vary according to the tax regime to which the company is subject and the company's size. For medicines, the official fees range from USD 11,714 to USD 31,483 (for a new drug), while for medical devices, the fees range from USD 140.57 to USD 9,928.24. The product category and authorization regime can also influence the fees.

The registration of products can be performed electronically on Anvisa's website, with the data directly sent via the agency's information system, without any requirement for hard copies. Subsequently, the system generates a monitoring protocol. To file a request for the registration of products for IVD tests, an applicant must submit:[13]

I. Proof of payment, or exemption, of the TFVS (Health Surveillance Inspection Fee), using a specific GRU (official federal payment document).

II. Duly completed electronic petition form provided by Anvisa.

III. For products classified in risk classes II, III and IV, a technical dossier containing the information required for the corresponding risk class.

IV. For domestic products with outsourced manufacturing at some stages, a statement with the corporate name and postal address of the company(s) involved and the corresponding phase(s) in the manufacturing process.

V. For all imported products, a consular authentication statement issued by the manufacturer authorizing the importer to represent and market its product(s) in Brazil. This must include the following information:

a) Company name and full address of the legal manufacturer,

b) Company name and full address of the importer,

c) Express authorization for the importer to represent and market the product(s) in Brazil,

d) Knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board - RDC No. 16, of 28 March 2013.

VI. For products classified in risk classes III and IV, proof of Certification in Good Manufacturing Practices (GMP) issued by Anvisa or proof of protocol requesting a GMP Certificate.

VII. When required, a prior analysis report, considered satisfactory, carried out by a unit of the National Network of Public Health Laboratories as provided for in item IV, art. 16 of Law No. 6,360, of 23 September 1976.

Commercialization of IVD tests: authorization and licences for manufacturing or importing

Companies undertaking import, export, manufacturing, distribution, storage or transport activities must obtain a licence from the local sanitary authority (the state or municipal authority, depending on the establishment's location) and apply for Anvisa's permit to commercialize IVDs. The normative guidelines are described in Anvisa Resolution RCD 81/2008 and updated in Resolution RDC 208/2018.

Foreign companies are not allowed to make administrative arrangements to obtain market authorizations directly with Anvisa. They must have partner companies legally constituted in Brazil that will be officially responsible for the products imported and distributed within Brazilian territory.[14]

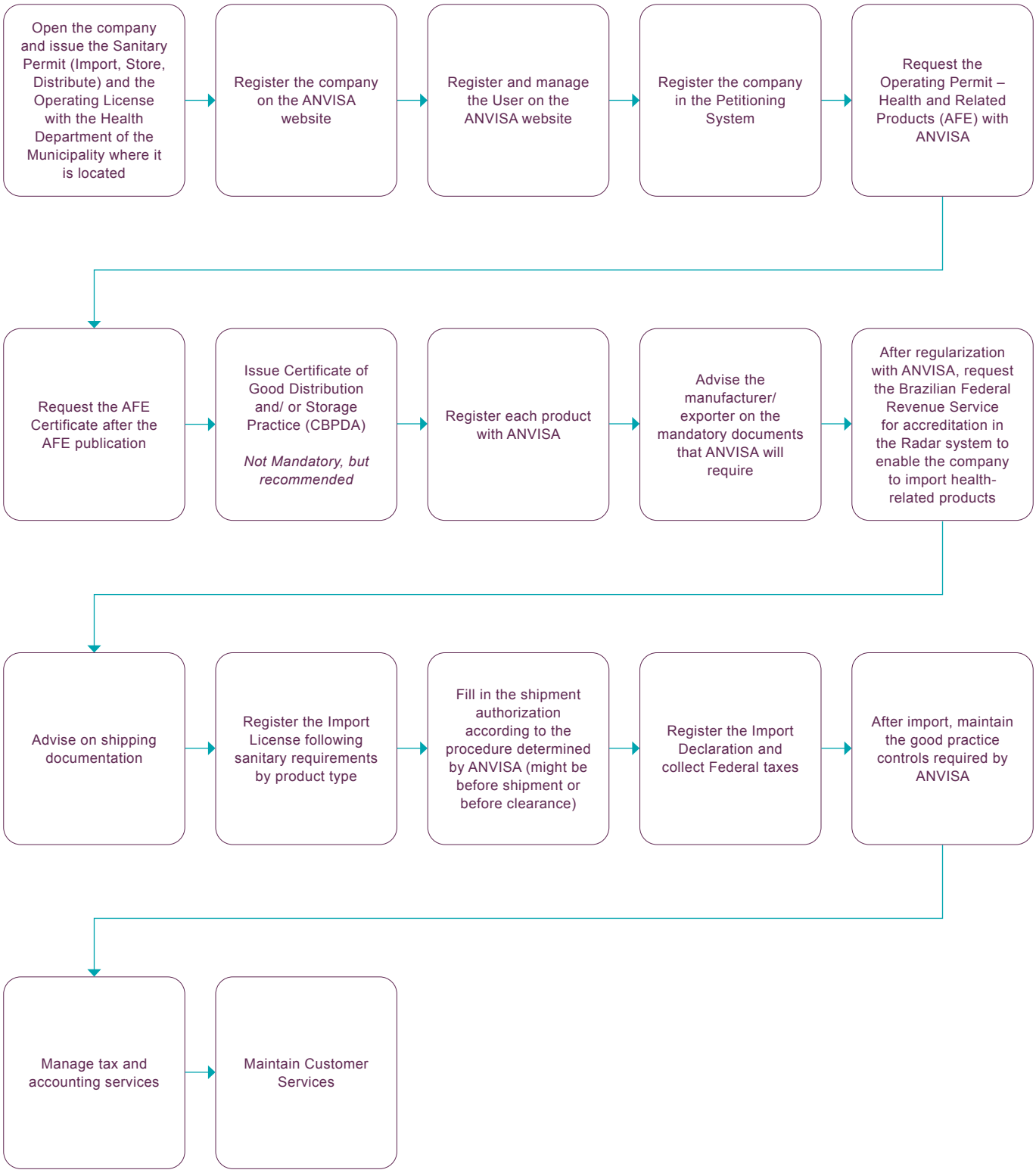
Good Manufacturing Practice (GMP) certificates are also mandatory for all companies that intend to get marketing authorization for medicinal products or medical devices (Classes III and IV only). These certificates expire every two years and may be obtained following local or international inspections conducted by Anvisa officials.[15] In the medical devices sector, Anvisa participates in the medical device single audit programme (MDSAP); therefore, assessments made by third-party auditing organizations are accepted to support the issuance of Brazilian GMP certificates to facilities with MDSAP certification.

Certification by the National Institute of Metrology, Quality and Technology (INMETRO) may also be required for some medical device products. INMETRO certification is often necessary for electromedical devices subject to IEC 60,601, although it may be needed for other product types as well. Needles, syringes, mattresses, gloves, breast implants, mechanical wheelchairs, handpieces and infusion sets are examples of non-electrical medical devices or products that require this certification.

Licence fees vary according to the company's location (state or municipality). The Anvisa permit fees depend on a company's tax regime, size and the number of activities it performs. While licences must be renewed every year, the permits issued by Anvisa have no expiration date. Nonetheless, they depend on the maintenance of the valid licence that initially supported the issuance of the permit.

The following chart indicates the steps regarding customs regulations for importing diagnostics.

Table 2: Import of diagnostic products and reagents



It is not possible to indicate, in advance, values that will affect an import operation; they can only be calculated once the entire operation has been defined (e.g. importer location, size of the company, and so on).

The inspection fee varies according to a product's class, codes and purpose (indicating whether it will be taxable), as well as according to the size and annual gross revenue of the company involved:

Importer Company Size	Annual Revenue
Group I - large size	Over USD 10 million
Group II - large size	Equal to or less than USD 10 million and above USD 4 million
Group III - medium size	Equal to or less than USD 4 million and above USD 1.2 million
Group IV - medium size	Equal to or less than USD 1.2 million
Small Business (EPP)	Equal to or less than USD 520,000 and greater than USD 72,000
Microenterprise	Equal to or less than USD 72,000

For example, to know the range of fees that could be applied for the issuance of a Company Operating Permit (AFE), it is necessary to know what specific activities the importer will perform (e.g. import, store, distribute). If the same company carries out importation, storage and distribution, the fees will be cumulative.

As an exercise in estimating and illustrating the process, fees charged by Anvisa (excluding other registration requests) could be as follows:

- Sanitary permit – depends on the municipality/state where the company is located
- Operating authorization to store and distribute related items – maximum USD 2,127.48 (large enterprise); minimum USD 106.37 (microenterprise),
- Operating permission for importers of health products – maximum USD 2,836.64 (large enterprise); minimum USD 141.83 (microenterprise),
- IVD product registration – maximum USD 4,254.96 per product (large enterprise); minimum USD 212.75 (microenterprise),
- GMP fee varies between USD 265.94 and USD 5,318.7

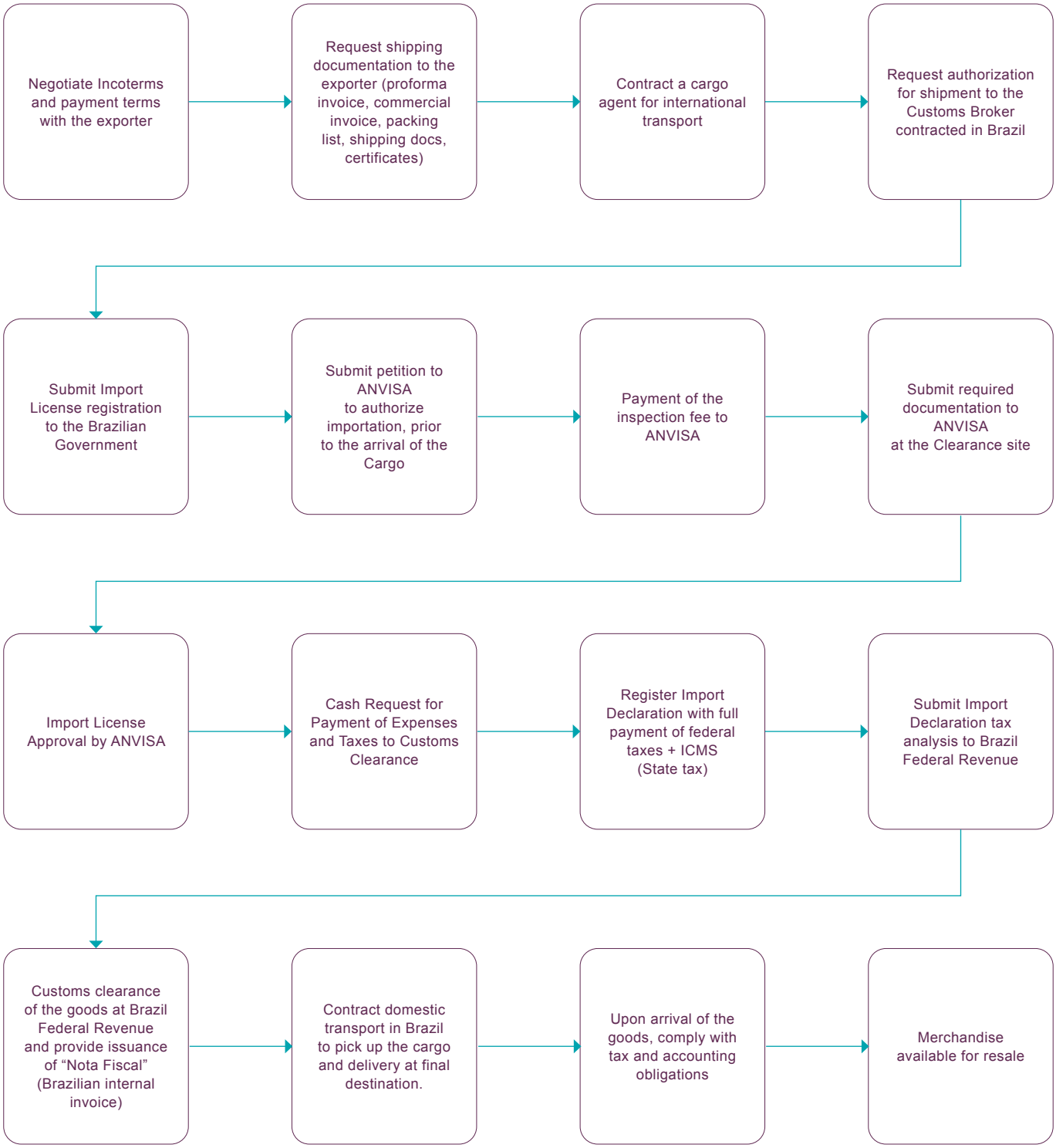
Annex C indicates specific requirements for importing the following IVD products:

- Test strips – self-test for capillary blood glucose
- Glucose meter kit – glucometer (blood glucose monitoring system)
- Auto-lancets
- In vitro reagents for diabetes diagnosis used in fasting, postprandial glucose and glycated haemoglobin (HbA1c) laboratory tests
- IVD reagents for detection of neutralizing antibodies against SARS-CoV-2:
  - RT-PCR
  - Serology
  - Rapid tests: (i) antigen; (ii) antibody
  - Rapid molecular test

Importing procedures

The procedures listed in Table 3 consider that: (1) the importing company and the products to be imported are previously registered/regulated by Anvisa; (2) the RADAR (Registration and Tracking of Customs Agents Activities Platform) of the importing company has been approved and has an import limit previously defined by the Brazilian Federal Revenue; and (3) the registration and qualification in any Anvisa system are enabled. Each of these steps is described in the previous section, “Commercialization of IVD tests: authorization and licences for manufacturing or importing”.

Table 3: From commercial agreement to stock entry



B) Marketing price

The price of drugs and medical devices is regulated by the Chamber for Drug Market Regulation (CMED),[16] a government agency created by Law No. 10,742/2003 to adopt, implement and coordinate activities for the economic regulation of the drug and medical devices market. It aims to ensure the population has access to health products through market mechanisms that foster the supply and competitiveness of the sector. According to CMED's classification system, IVD tests are categorized as medical devices. CMED's primary duties are to:

- Propose and establish criteria for fixing and adjusting the prices of drugs and medical devices,
- Propose and establish standards for setting price caps for new products and new drug formulations,
  - As per Anvisa resolution RDC 478/2021, CMED will not state price caps for medical devices, including IVD tests; instead, they will be monitored.
- Monitor the drug market.

Resolution RDC 478/2021, published by Anvisa in March 2021, has redefined how CMED should conduct the economic monitoring of medical device prices. The new regulatory framework aims to diminish market asymmetries, reduce the costs of medical devices in Brazil and determine reference prices for public and private purchases.

To select and list all the medical devices to be monitored, Anvisa considers the following criteria: a) financial impact on the public health system (SUS); b) financial impact on the supplementary health system; c) relevance for public health.[17]

Only medical devices registered with Anvisa will be subject to economic monitoring. Monitoring results will be published on the Anvisa website, along with statistics about the history of prices of devices with similar technical characteristics. The resolution states that measures will be taken to avoid identifying individual costs, to safeguard sensitive commercial information. Currently (as of September 2021), according to Normative Instruction IN 84 March 2021, there are no IVD tests yet listed as medical devices to be monitored. Therefore, although IVD tests are considered to be medical devices by Anvisa, at this point in time, the resolution remains an indicator of how the price of medical devices will be regulated in the future.

To commercialize a product, a company must file the following economic data (Article 16, VII, Law No. 6,360/76, as amended by Law No. 10,742/03), all of which must be taken into consideration by CMED when setting or adjusting prices:

- Risk classification,
- The price charged by the company in other countries,
- The cost per patient of the treatment with the product,
- The potential number of patients to be treated with the product,
- The number of tests that can be performed with one kit (for IVD tests)
- The price that the company intends to charge on the market, including tax,
- The commercialization plan, including advertising and sales costs,
- A list of all competitor products with their respective prices,
- Information relating to intellectual property, including patents covering the product.

After steps A and B (shown in Fig 6) have been completed and product registration and economic information has been sent to CMED, the product can be commercialized in Brazil. Users can gain access to the product via three approaches:

1 - Access via the public sector market

Once available for sale, companies, users (e.g. patients) and the government can request the incorporation of health products (including IVD tests) in the public sector market so that SUS can access them at no cost to users. This means that such products will be included in the list of products on the public market eligible for mandatory reimbursement once they have gone through a health technology assessment (ATS).

An ATS is mandatory to achieve access via the public sector market and is carried out by the National Commission for the Incorporation of Technologies (CONITEC), created in 2011 under the remit of the Ministry of Health (Fig. 7).[18]

Any individual or institution can request CONITEC's analysis regarding the incorporation, alteration and exclusion of technologies in the public healthcare network. However, the demands must meet the specific documented requirements established by Decree 7.646/2011. According to this decree, health technologies include any medicines, products and procedures through which healthcare is provided to the population, e.g. vaccines; products for IVD testing; equipment; technical procedures; organizational, informational and educational systems and programmes; and protocols.

Figure 7: The structure of CONITEC

Source: CONITEC

The process for submitting an application to incorporate a health technology in the public sector is outlined in the Fig. 8 below:

Figure 8: Documents required to request incorporation of a health technology in the SUS

1 – Letter

The official letter must be the first page of the application, and it must include:
- The identity of the bidder
- The identity of the recipient: CONITEC, SCTIE, , or MS
- Subject (name of the technology and suggested therapeutic indication)
- Date and place
- A signature in blue ink

Note: A copied version of the official letter will not be accepted

2 – Bidder documentation

- **Legal entity**
  - Company's Articles of Incorporation (copy with notarized signature)
  - Power of attorney from the applicant (if the person responsible for signing the request is not included in the Articles of Incorporation)
- **Individual level**
  - Identity card (RG) (certified copy)
  - Social security number (CPF) (certified copy)

3 – Submission of the form

- The form must be submitted to CONITEC using the System for the Electronic Management of Technology Incorporation at SUS available at: e-GITS V-1.7.0 (saude.gov.br)
- An assessment of a request entered on the system will only start once all paper documents have been received (items 1 and 2), including the printed and signed form
- The form to be filled out for private companies corresponds to the "form for external demand" (formulário de demanda externa).

Note: If the submission form is not correctly filled out, the demand may be classified as "nonconforming". This means the process will not proceed to CONITEC's technical analysis.

4 – Main document

The document must contain:
- A description of the disease/health condition related to the use of the technology
- A description of the technology
- A description of the scientific evidence that the technology is an improvement compared with what is already available at SUS (systematic review or technical–scientific opinion)
- An economic assessment for SUS
- A budget impact analysis
- References
- Attachment (copy of the label or instructions for use approved by Anvisa)

Note: The company's dossier will be made available, together with the technical and society reports, on the CONITEC website, at the time of the public consultation.

5 – Scientific studies

- Complete texts of peer-reviewed scientific studies (in digital form only – USB memory stick).

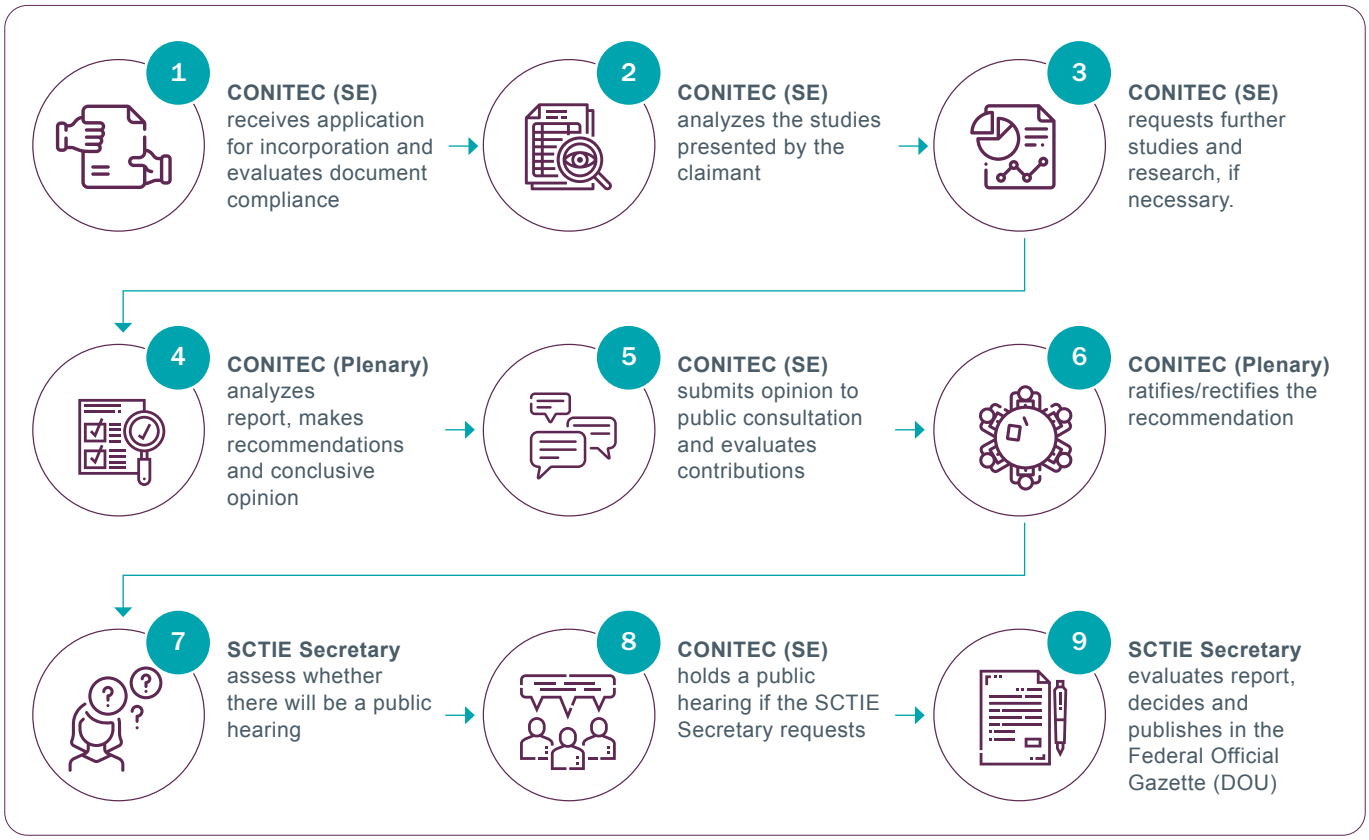
6 – Foreign language articles

- If applicable, documents written in a foreign language other than English, or Spanish, must be certified translated into Portuguese by a certified translator.

Source: CONITEC

Once a request has been made, a technology assessment process is done. This is depicted in Fig 9.

Figure 9: Flow chart showing the process of a health technology evaluation for the public healthcare system



Source: CONITEC[19]

A presidential decree established that a period of 180 days can be taken to complete a request filed for evaluation by CONITEC and, if necessary, this deadline can be extended for a further 90 days. If the technology is approved for incorporation, and after receiving the ATS, the product can be made available for the population within 180 days (extendable for a further 180 days).

Incorporation does not mean that a product is available without a bidding process. Once the government decides that it will reimburse a product, there still needs to be a final price negotiation with the manufacturer. However, this process is conducted on a one-on-one basis and details are not made publicly available.

Public procurement bidding modalities

Law 8.666/1993 has regulated the bidding process in Brazil for the past three decades. In 2021, a new Law on Bids and Administrative Contracts, Law 14.133/2021 (referred to as the "Bidding Law") was approved. Despite the recent approval of this new law, Law 8.666/1993 will only be revoked in 2023. Until then, public administrators can choose, at their own discretion to move forward with a contracting process based on either one of these laws.

Article 75 of the Bidding Law suggests there may be exemptions from bidding. According to this article, bidding is not necessary when, among other examples, the contracting occurs:

> "(...) III - in cases of emergency or public calamity, when an urgent need for a situation that may cause harm or compromise the continuity of public services or the safety of persons, work, services, equipment, and other goods, public or private, and only for the acquisition of the goods necessary to attend the emergency or calamitous situation and for the portions of work and services that can be completed within a maximum period of one (1) year, counted from the date of occurrence of the emergency or calamity, the extension of the respective contracts and the contracting of a company already contracted based on the provisions of this section are closed; (...)

> XII - contracting in which there is strategic products technology transfer to SUS, as listed in its national management act, including at the time of the acquisition of these products during the stages of technological absorption, and values compatible with those defined in the instrument signed for the transfer; (...)
>
> XVI - for the acquisition, by a legal entity of domestic public law, of strategic health inputs produced by a foundation that, regimental or statutory, aims to support the Public Administration, its municipality or foundation in projects of teaching, research, extension, institutional, scientific & technological development, technology transfer, and incentive to innovation, including the project's administrative and financial management, per item XII of the caput of this article, and that has been created for this purpose before this Law if the contracted price is compatible with that practiced in the market. (...)"

However, there must be a formal statement that an emergency or calamity exists. Currently, Law 13.979/2020 is in force in Brazil, at the Federal level, providing measures to cope with the public health emergency resulting from the coronavirus pandemic. This Law applies to states and municipalities. Article 4 of the Law states that:

> "Art. 4º - The bidding for the acquisition of goods, services, and health supplies intended to cope with the public health emergency of international importance resulting from the coronavirus (...)
>
> § 1 - The exemption from bidding referred to in the caput of this article is temporary and applies only if the public health emergency of international importance arising from coronavirus persists.
>
> § 2 - All contracts or acquisitions made with the fulcrum in this Law will be immediately made available on a specific official website (...)"

Thus, tests for the detection of COVID-19 may be purchased through a bidding waiver. However, it is important to note that this bid waiver has not been adopted for the purchase of diabetes-related IVD tests, only those for COVID-19.

Table 4: Public purchasing models

Modality	Price range	Terms	Requirements
Reverse auction	There are no value limits.	The reverse auction is the bidding modality used to acquire common goods and services, whatever the estimated value. The judgement criteria may include the lowest price or the greatest discount.	The auction is made in a public session through written proposals and verbal bids. An electronic reverse auction has two phases: first the commercial proposal is opened and then the documentation is examined.
Competition	This is the appropriate option for large contracts (those whose estimated value exceeds USD 40 million) that do not require prior registration or registration of interested parties, assuming that they meet the prescribed conditions in the notice, which must be published with at least a 30-day interval between publication and receipt of proposals.	Competition is the bidding modality used for contracting special goods and services, and engineering works and services. The judgement criteria may be a) lower price; b) better technical or design content; c) better technical content and price; d) greater economic return; or e) greater discount.	Competition is the bidding modality used for any interested parties who, in the initial phase of preliminary qualification, must prove to have the minimum qualifications required by the notice.
Waiver of bidding process	Due to the public calamity declared in response to COVID-19, bidding can be waived to acquire goods and services to combat the disease. There is no value limit.	The contracts regulated by Law 13.979/2020 last for six months, extendable for an equal period for the duration of the public emergency.	There is no need to do a preliminary study. Risk management is not performed during the planning phase.

2 – Access via the supplementary healthcare market

As already mentioned, supplementary healthcare in Brazil is regulated by the National Health Agency (ANS), a special federal agency created in 2000 and linked to the Ministry of Health. ANS is the body responsible for the standardization, control, regulation and inspection of activities related to supplementary healthcare.

Unlike the public sector health network, in which technology is continuously incorporated, the supplementary health sector updates the minimum list of products (including IVD tests) and procedures available to users every two years.

The updating process begins with deliberation by the ANS Collegiate Board (DICOL). All interested parties (individuals and legal entities) can submit proposals to be included in the updated list, which are then evaluated by the Permanent Committee for Health Care Regulation (COSAÚDE), a forum that establishes a lasting dialogue between supplementary health agents and the larger society.[20]

The last update of the ANS list was conducted through Normative Resolution RN 465 on 24 February 2021. The approved IVD tests for diabetes and COVID-19 are described in section 6 of this report.

3 – Access via the private sector market

Access via the private sector market, directly to consumers or via service providers, is possible if a product has received sanitary regulatory approval (Anvisa) and has gone through the pricing (CMED) procedures described in the previous sections. Negotiations are conducted directly with buyers such as hospitals, laboratories and distributors, among others. Some of the leading agents are listed in the “stakeholders related to diagnostics” section. Appendix I includes information from the supplier’s manual of two buyers of IVD tests.7.5

Health system infrastructure, supply chain, and delivery systems for IVD tests

Brazil’s infrastructure for IVD tests comprises laboratories and Therapeutic Diagnosis Support Services (SADT), in both the public and private healthcare systems.

Public health laboratories are organized in the National System of Public Health Laboratories (SISLAB), a set of national laboratory networks for activities covering health, epidemiological and environmental surveillance, and medical care. Each network is under the responsibility of a government agency, as shown in Fig. 10.

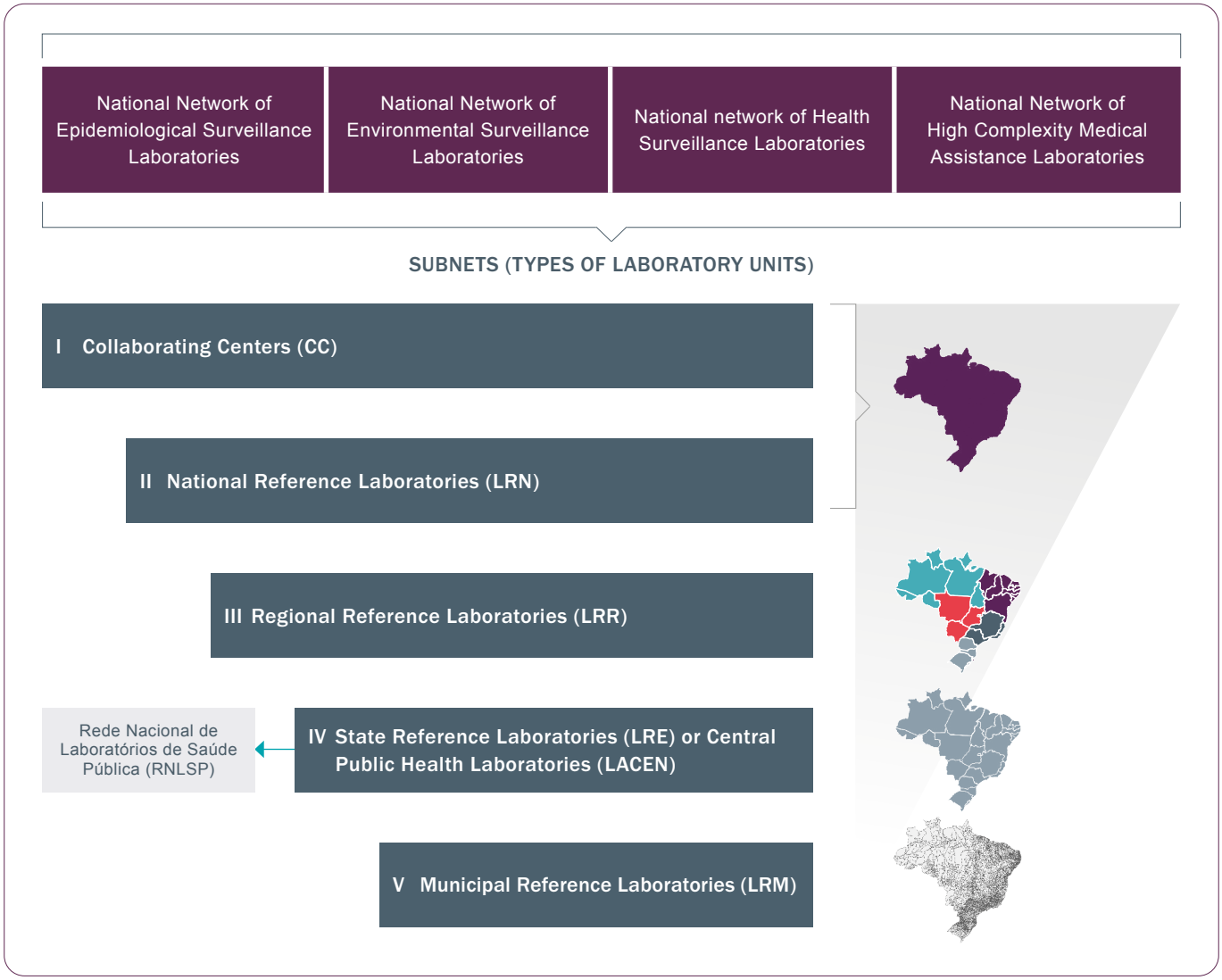
Figure 10: National System of Public Health Laboratories (SISLAB)

Network	Main activities	Responsible agency
I - National Network of Epidemiological Surveillance Laboratories	**I.** diagnosis of compulsory notification diseases; **II.** surveillance of communicable and noncommunicable diseases; **III.** antimicrobial resistance monitoring; **IV.** standardized definitions of diagnostic kits to be used in the Network	Health Surveillance Secretariat of the Ministry of Health (Secretaria de Vigilância em Saúde do Ministério da Saúde - SVS/MS)
II - National Network of Environmental Health Surveillance Laboratories	**I.** surveillance of the quality of water for human consumption **II.** air quality surveillance **III.** soil quality surveillance; **IV.** surveillance of physical and chemical environmental factors; **V.** surveillance of biological environmental factors (vectors, hosts, reservoirs and venomous animals); **VI.** monitoring of human populations exposed to biological, chemical and physical environmental factors	
III - National Network of Health Surveillance Laboratories	Laboratory analyzes related functions of the National Health Surveillance System in: **I.** products, such as: food, medicine, cosmetics and sanitizing products; **II.** immunobiologicals and blood products; **III.** human toxicology; **IV.** biological and non-biological contaminants in health-related products; **V.** products, materials and equipment for use in health; **VI.** surveillance at ports, airports and borders.	Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária - ANVISA)
IV - National Network of High Complexity Medical Assistance Laboratories	Carry out complementary support activities for the diagnosis of diseases and other health problems.	Health Care Secretariat (Secretaria de Atenção à Saúde do Ministério da Saúde – SAS-MS)

Source: Health Ministry Ordinance GM/MS no 2,031/2004[21]

Fig. 11 shows how this network of laboratories is organized into subnetworks in a geographically hierarchical manner by the degree of complexity and according to specific health issues or programmes.

Figure 11: Organization of SISLAB



Source: Fiocruz[22]

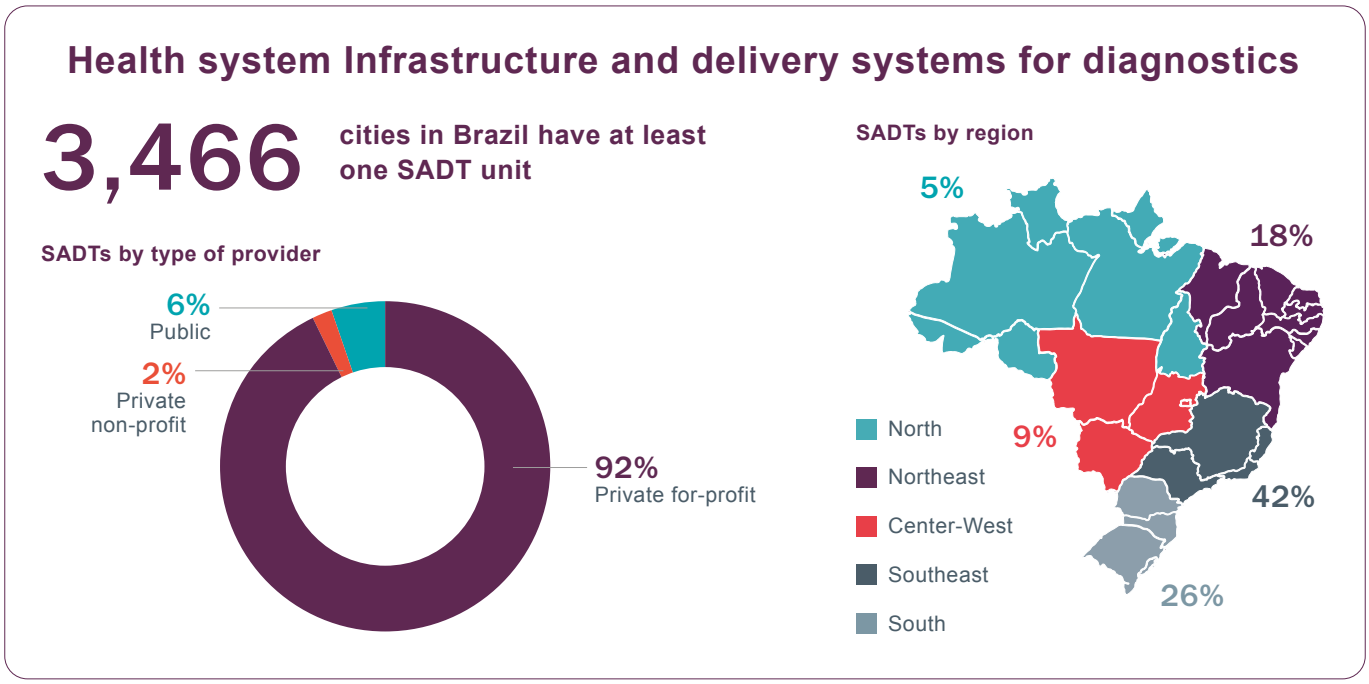
Appendix F outlines the definitions and competencies of each of these laboratory units.

The National Network of Public Health Laboratories (RNLSP) is at the frontline of the laboratory response of SUS to any public health emergency within the national territory. It is supported by the central state laboratories (LACEN). Its role is to carry out the diagnosis of diseases and illnesses that are important to public health, thus contributing to the strengthening of SUS. Apart from diabetes, all the other diseases covered by FIND (COVID-19, tuberculosis (TB), malaria, hepatitis B, hepatitis C, dengue, Chikungunya, and Chagas disease) require compulsory notification.[23]

In addition to the laboratory network, there are the Units of Therapeutic Diagnostic Support Service (SADT). These healthcare units provide complementary tests both for primary and specialized care and support conclusive diagnostics. The tests available vary according to regional health needs. Examples include electroencephalograms, Holter tests, ergometric tests, echocardiograms and ultrasonography.

The National Registry of Health Facilities in the Ministry of Health (CNES/MS) indicated that, by the end of June 2020, there were 24,760 SADTs in Brazil. There is at least one SADT unit for 3,466 cities, corresponding to 62% of municipalities in the country (their distribution is shown in Fig. 12). This number includes units that operate within hospitals, clinics and other health facilities. Most are provided by private organizations and a small proportion by the public sector.

Figure 12: Geographic distribution of SADT units in Brazil and type of provider

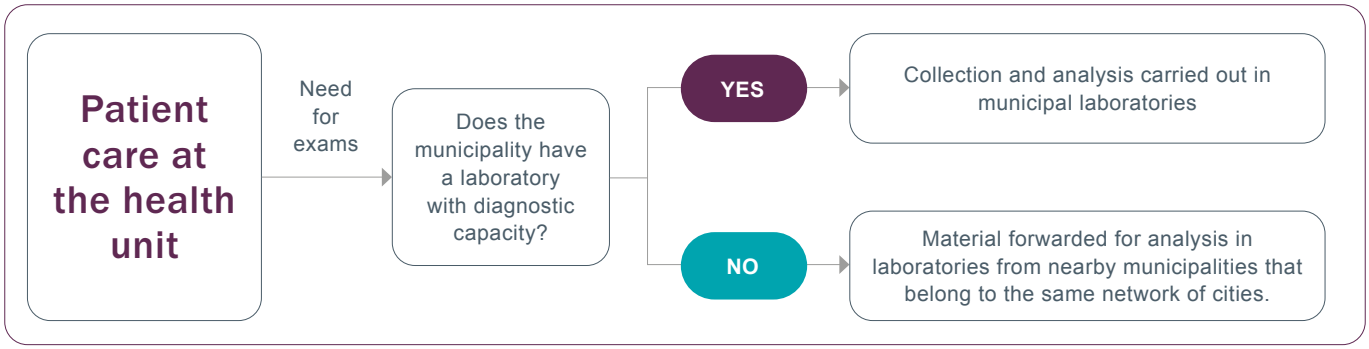


Source: Ministry of Health – National Registry of Health Facilities (CNES).[24]

Diabetes

At the primary care level, local and municipal reference laboratories are responsible for most of the routine examinations for the diagnosis and monitoring of patients with diabetes.[25] If a laboratory lacks the necessary infrastructure to carry out the tests, samples must be sent to a reference laboratory unit in its healthcare network, as shown in Fig 13. SADT may help to collect and transport samples in such cases.

Figure 13: Testing flow procedure for patients suspected of having diabetes



Source: Support Manual for SUS Managers: organization of the clinical laboratory network (2002)[26]

Note: According to the Manual of Diabetes Mellitus (DM) in Primary Healthcare (Booklet 36), during an appointment at a primary healthcare unit, individuals with risk factors for DM should be referred for a screening appointment and blood glucose testing. It is recommended that a nurse performs the screening consultation for the target population defined by the primary healthcare unit and then refers the patient to the doctor for a second examination to confirm the diagnosis of DM in suspected cases.

COVID-19

The National Public Health Laboratory Network has played a central role during the COVID-19 pandemic. It is responsible for testing the population and releasing laboratory reports to assist in assessing the dynamics of the epidemic and control the chain of transmission in Brazil; understanding the natural history of the disease, including possible genomic alterations; and managing the response to the pandemic.

In May 2020, the Ministry of Health launched the programme "Diagnose to Care" (*Diagnosticar para Cuidar*), with the aim of carrying out 46 million tests for COVID-19 in 2020 (22% of the Brazilian population). The programme planned to expand testing and assess the behaviour of the virus by region (e.g. the speed of transmission, and the evolution of the virus, such as the existence of variants).

Since the beginning of the programme until February 2021, 18 million RT-qPCR (reverse transcription quantitative real-time polymerase chain reaction) molecular tests and 9.6 million rapid serological tests were distributed to states throughout Brazil, with approximately 14 million molecular tests carried out within the SUS network. There was an investment in the purchase and distribution of tests, supplies and equipment, expansion of processing capacity, and training of LACEN staff. Table 5 shows the timeline of the main actions taken by the federal government concerning the testing capacity for COVID-19 in the country.

Table 5: Timeline of the testing strategy for COVID-19 in Brazil

January 2020	Compulsory notification of cases and deaths possibly related to COVID-19 was adopted since the first suspected case was registered in the country. Supplies for carrying out the RT-qPCR test for the detection of SARS-CoV-2 were donated PAHO/WHO. Initially, molecular testing was only performed by Brazil's National Influenza Centers (or reference laboratories): • Oswaldo Cruz National Foundation (Fiocruz/Rio de Janeiro) – National Reference Laboratory • Adolfo Lutz Institute (IAL/São Paulo) – Regional Reference Laboratory • Evandro Chagas Institute (IEC/Pará) – Regional Reference Laboratory The training of staff at these laboratories to diagnose the novel coronavirus was carried out by Fiocruz, PAHO and the Ministry of Health (MoH).
February 2020	MoH and Fiocruz trained the 27 LACENs in Brazil in the diagnosis of COVID-19 so that they could also carry out diagnostic tests, in addition to the national reference laboratories.
March 2020	Due to the scarcity of resources to perform RT-qPCR, caused by the worsening of the epidemic, and based on the WHO recommendation for countries to carry out mass testing, the MoH began to carry out RT-qPCR testing for all severe cases hospitalized with SARS-CoV-2 infection and for the maintenance of sentinel flu-like syndromic surveillance, i.e. collection of samples from five patients per week in each sentinel unit.
April 2020	The MoH received a donation of 10 million rapid diagnostic tests (RDTs) for the detection of antibodies against SARS-CoV-2 IgM/IgG, from the manufacturer Guangzhou Wondfo Biotech Co. Ltd. (whose legal representative in Brazil is the company Celer Biotecnologia S/A, which provides the same test nationally under the name of "ONE STEP COVID-19 TEST"). The tests were delivered to states and municipalities through a tripartite agreement. The MoH opened a public call notice to procure more than 12 million RDTs.
May 2020	The national strategy for testing began, and was divided into five stages: deployment, public–private partnership, expansion, deceleration, and legacies, in addition to two fronts: the first, called CONFIRMA COVID-19, involved the use of RT-qPCR tests (molecular tests) while the second, TESTA BRASIL, involved increasing use of RDTs (serological tests). Expansion to public network laboratories to perform RT-qPCR through the operation of high-testing platforms* in Brazil to support states and municipalities with molecular tests. The following high-testing platforms were used: • Fiocruz (Rio de Janeiro, Paraná and Ceará): public laboratories, • Dasa Laboratory (São Paulo): a private laboratory that has a public–private partnership with the MoH, with a pro bono contract. The state of São Paulo had a high-testing platform with Instituto Butantan, which only serves municipalities within the state of São Paulo. *High-testing platforms are laboratories with the capacity to diagnose samples that the public laboratories cannot, due to a lack of infrastructure for testing.
June 2020	The MoH started to include COVID-19 cases confirmed by clinical and imaging diagnosis, in addition to those cases confirmed by laboratory diagnosis.
August 2020	Transfer of R$285 million (~ USD 52 million) to expand the testing capacity of the LACEN and the entire laboratory surveillance network.
February 2021	Actions to optimize RT-qPCR tests to diagnose COVID-19 taken by the MoH through the General Coordination of Laboratories (CGLAB) in partnership with PAHO and Seegene Brazil.

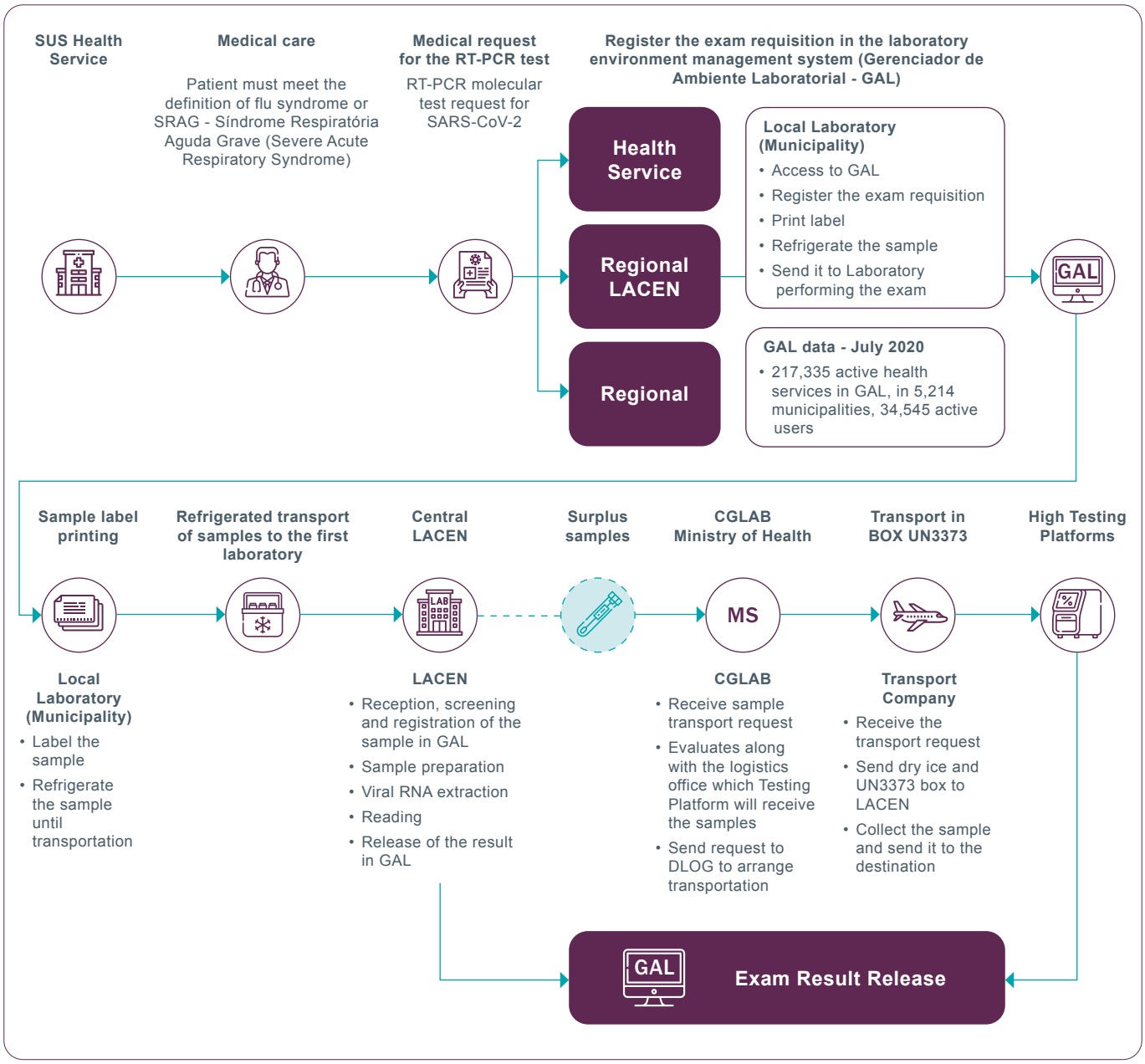
Source: Program Diagnosticar para Cuidar[27]

To increase their testing capacity, some states established a collaborative network formed by laboratories linked to the Ministry of Agriculture and Livestock (Mapa), the Brazilian Agricultural Research Corporation (EMBRAPA), the Ministry of Justice and the Ministry of Education, through the public universities.

Private laboratories may also offer COVID-19 diagnostic tests independently or in partnership with the government. In the case of independent offers, users pay out-of-pocket or through their health insurance provider. If it is a partnership with the government, as occurred with Dasa Laboratory in the state of São Paulo, the government opens a “public notice” to select companies interested in offering tests. The company must comply with a series of requirements, such as not having legal or judicial matters pending, having a business licence and registration, and having all appropriate approvals from health surveillance agencies. This public notice can be made by the federal, state or municipal governments and is published via official outlets.

Fig. 14 shows a flow diagram of COVID-19 logistics and diagnosis through the public laboratories.

Figure 14: Flow diagram for samples submitted for COVID-19 diagnosis in the laboratory management system



Source: Program Diagnosticar para Cuidar[28]

Key takeaways:

- SUS is one of the largest public health systems in the world. Although government health spending in Brazil is less than 50% (total health expenditure), 77% of the population uses SUS exclusively, signifying its importance in the national scenario.
- An essential aspect of SUS is its decentralized organization and the hierarchy between the federated levels. This is important because all federated entities must agree upon any decisions related to public health through commissions established for this end. In addition, there is integration between services, which are structured according to their level of care. It is essential to know how each level is responsible for providing health services to the population. This is demonstrated by the organization of the laboratory network and the flow of tests for diabetes and COVID-19.
- Channels for social participation (e.g. health councils) are crucial to engage stakeholders in public policy advocacy.
- IVD tests have a transparent registration process concerning regulation and access. They must go through a registration and economic monitoring process before being commercialized in the country. There are three possible ways of accessing the diagnostics market in Brazil – public, supplementary and private healthcare. For access via public and supplementary healthcare, some processes must be followed. Knowing these processes allows us to explore possibilities to improve patients' access to IVD tests in Brazil.
- Information about healthcare infrastructure can help us understand what type of on-the-ground access patients must have to qualified professionals (and equipment), so that they can receive proper diagnosis and treatment. The laboratory network is organized in a decentralized and hierarchical way. Although a patient's first contact is in their municipality, depending on the type of test required, the samples collected may be sent to state reference laboratories, as is the case with COVID-19. Understanding the flow of samples helps in defining strategies for the marketplace of companies.
- The COVID-19 pandemic has reinforced the importance of cooperation between the public and private sectors, with partnerships between laboratories having expanded diagnostics capacity in Brazil.

FIND

VI

DISEASE OVERVIEW, PATIENT JOURNEY, POLICIES AND GUIDELINES

VI
DISEASE OVERVIEW, PATIENT JOURNEY, POLICIES AND GUIDELINES

Diabetes

According to a 2021 report published by the Brazilian Society of Diabetes (*Sociedade Brasileira de Diabetes* - SBD), the prevalence of diabetes in Brazil is 7.6% of the population[29] (approximately 16 million people). Brazil ranks fifth highest in the number of diabetes cases, behind China, India, the United States and Pakistan. Diabetes is the third leading cause of mortality in Brazil, with cardiovascular diseases and cancer being number one and two, respectively.

According to the SBD, it is estimated that among all diabetic patients:

- 7% are insulin-dependent,
- 41% use medication,
- 29% only take care of their health through their diet,
- 23% do not receive any type of treatment.

Brazil has policies and regulations aimed at caring for all patients with diabetes in the public health network. Table 6 describes the national regulations for diabetes and related diagnostics.

Table 6: Government rules related to diabetes

Normative	General aspects	Diagnostic tests or other supplies	Date and link
Federal Law 11,347	Determines that patients with diabetes receive from SUS, free of charge, the necessary medicines for treatment, the materials required for its application, and the monitoring of capillary glycaemia.	Materials for monitoring capillary blood glucose (does not mention the type of materials).	2006: LINK
Ministry of Health Ordinance 2,583	Defines the list of medicines and supplies made available by SUS to users with diabetes mellitus.	Available supplies: a) syringes with a needle attached for insulin delivery, b) capillary blood glucose test strips, and c) fingerstick lancets.	2007: LINK
National Policy for the Prevention of Diabetes and Comprehensive Assistance to the Diabetic Person	General guidelines for the prevention of diabetes.	Health units provide capillary blood glucose tests or others that are easy to perform and immediately assessed.	2019: LINK Approved law that needs additional regulation by the MoH.

Regarding the delivery of healthcare services, the primary healthcare network is responsible for identifying, managing and preventing diabetes mellitus (DM) and carrying out all tests and examinations required by a patient. The primary care professionals themselves must refer cases that require follow-up to other specialized professionals. For patients with health insurance plans, a suspected diagnosis of diabetes can be confirmed by tests ordered by their physician, who may be a general practitioner or a specialist.

In the public health network, the types of tests and examinations necessary for the management of diabetes are defined by the Clinical Protocols and Therapeutic Guidelines (PCDTs) and carried out for SUS by CONITEC. There are PCDTs for three types of diabetes, as shown in Table 7.

Table 7: Guidelines for diagnostic and therapeutic support for diabetes available from SUS

Available PCDTs	Diagnostic tests and monitoring exams performed	Date and link to the guidelines
Diabetes insipidus (DI)	Water restriction test, Magnetic resonance imaging (MRI) of the hypothalamic–pituitary region for patients with central DI.	2017: LINK
Type 1 diabetes mellitus	For clinical conditions with specific symptoms of insulinopaenic diabetes (polyuria, polydipsia, polyphagia, nocturia and unexplained weight loss) or the occurrence of previous ketoacidosis, the laboratory tests indicated are: • Random blood glucose, • Blood glucose 2 hours after oral overload (post-prandial), • Fasting blood glucose, • Glycated haemoglobin (HbA1c).	2019: LINK
Type 2 diabetes melitus	• Fasting blood glucose, • Random blood glucose, • Oral glucose tolerance test with overload of 75 g in 2 hours (OTG), • Glycated haemoglobin (HbA1c).	2020: LINK

Each of these tests is available in the public healthcare system, through the local and municipal reference laboratories[30] or via the network of private healthcare insurers through laboratories accredited by each health insurance operator. Table 8 lists the tests required and the frequency for monitoring individuals who have diabetes, as recommended by the MoH.

Table 8: Frequency of tests and assessments for monitoring individuals with diabetes

Assessments and tests	Frequency	
Fasting blood glucose	At diagnosis and as clinically indicated	
Glycated haemoglobin (HbA1c)	If HbA1c is on target, every six months; if it is off target, every three months	
Total cholesterol **Triglycerides** **HDL cholesterol** **LDL cholesterol* (formula)** **Creatinine and GFR calculation**** **Albuminuria or albumin: creatinine ratio (ACR) in a urine sample***** **Type 1 urine test (Sediment Evaluation)**	At diagnosis and yearly or as clinically indicated	
Electrocardiogram (ECG or EKG)	At diagnosis and as clinically indicated	
Fundoscopy or digital retinography	Type 1 DM – yearly after five years of disease or annually from diagnosis, if onset from puberty	Type 2 DM – yearly from diagnosis
Monofilament foot examination	Yearly; if the results change, see the specific chapter	

(*) The following formula can be used to calculate LDL cholesterol if the triglyceride values are <400 mg/dL:
LDL cholesterol = total cholesterol – HDL cholesterol – (triglycerides/5).
(**) Glomerular filtration rate (GFR) should preferably be estimated using the CKD-Epi equation, which best represents the entire spectrum of renal function (http//:www.kidney.org/professionals/kdoqi/gfr_calculator.cfm). If it is not possible to access the calculator, it can be estimated by the formula:
TFH = [9140 – age (years)] x weight (kg))/72 x creatinine) (x 0.85 if female).
(***) Normal values: albuminuria in an isolated sample <17 mg/L, albuminuria in 24-hour urine <30 mg, albumin: creatinine ratio (ACR) <30 mg/g.

Source: Cadernos de Atenção Básica - Primary Care Manual 36 - Ministry of Health[31]

According to the government relations and access director of a diabetes civil society association who was interviewed, to determine whether a patient is capable of self-monitoring and treatment, a medical team must first evaluate whether the patient has access to self-tests and then whether they have the necessary skills to perform such tests. For example, in remote and more impoverished regions, patients may need an initial educational phase for this approach to be successful. According to this professional, "*access is not uniform for the whole country, even for uncomplicated tests, and, specifically for diabetes diagnosis, the medical infrastructure does not satisfactorily serve regions far from economic centres, such as the Amazon.*"

The interviewed professional also suggested that there is room for improvement in tracking complications of diabetes: "a series of self-tests could be made available via public health to help combat extreme worsening situations. The Diapason Monofilament self-test is an example of a basic test that detects complications early, but SUS doesn't use it extensively. With an eventual need for amputation, people at risk of developing ulcers could be trained to do the self-test, reducing the chance of developing into a highly complex case." Other innovative and inexpensive technologies, such as the fundus self-examination, carried out by using a cell phone application, were also identified as being positive but having limited outreach in Brazil.

Comprehensive care is a patient's pathway through the health system, a practice the federal government encourages as part of its prevention policies. Each federal entity (states and municipalities) can adopt specific comprehensive care programmes according to their local needs. For example, the city of São Paulo has the Self-Monitoring of Blood Glucose Program (AMG), which was introduced in 2010. In addition to providing the inputs necessary to guarantee self-monitoring of blood glucose, the programme offers guidance on nutrition for the prevention of diabetes and control of existing cases, changes in habits, treatment of the disease, and its potential complications. The programme uses clinical protocols that enable follow-up by primary care or, if necessary, complex care providers.[32]

COVID-19

Brazil confirmed its first case of COVID-19 on 25 February 2020, in the municipality of São Paulo, the capital of São Paulo state. Since then, nearly 20 million cases and 553 000 deaths have been confirmed, according to data obtained from the Panel of the Council of State Health Secretaries (CONASS) on 29 July 2021. Table 9 presents the primary data for Brazil, updated on 5 October 2021.

Table 9: Indicators related to COVID-19 in Brazil

Indicator	Number
Confirmed cases*	21,483,224
Deaths*	598,400
Vaccinated, first dose**	147,921,790 (69.34% of the population)
Vaccinated, second dose or a single dose**	94,792,385 (44.44% of the population)
Tests**	62,071,065 (until 19 August 2021)
Lethality rate*	2.8%
Mortality rate*	263.2/100,000 population
Incidence rate*	9,420.6/100,000 population

Sources: *CONASS PANEL[33]

** COVID-19 no Brasil Twitter: @coronovirusBra1 (Platform used by Fiocruz in Brazil, Johns Hopkins University and other institutions)[34]

Regarding testing, the MoH published guidelines in April 2020, although a new testing plan is currently under discussion by MoH, CONASS and CONASEMS, as shown below.

Table 10: Guidelines and instructions for diagnosis of COVID-19 in Brazil

Month/Year	Guidelines	Responsible body	Link to publication
April 2020	Guidelines for the diagnosis and treatment of COVID-19	Secretariat of Science, Technology, Innovation and Strategic Inputs - MoH (SCITIE).	LINK
May 2020	Clinical Management Protocol for the New Coronavirus (2019-nCov)	Department of Specialized Health Care - MoH (SAES)	LINK
	Clinical Management Protocol for the New Coronavirus (COVID-19) in Primary Health Care	Secretariat of Primary Health Care, MoH (SAPS)	LINK
	Instructions guide for coping with the pandemic in the Health Care Network	CONASS and CONASEMS, based on the diagnostic tests recommended by the MoH	LINK
May 2021	New Testing Plan for COVID-19, under discussion by the MoH, CONASS and CONASEMS. It includes: 1. extensive testing for symptomatic cases at healthcare points 2. active search for asymptomatic, pre-symptomatic or suspected cases due to exposure 3. population sample testing to monitor virus transmission over time	MoH together with CONASS and CONASEMS	As of 16 July 2021, the new plan had not yet been announced; LINK to the news updates

The tests available in the public health network were defined in the COVID-19 Guidelines for Diagnosis and Treatment published in April 2020. The new ANS list published in February 2021 expanded the availability of diagnostic tests to clients in the supplementary healthcare network. Chart 9 shows the tests available through the public and supplementary health networks and their eligibility criteria.

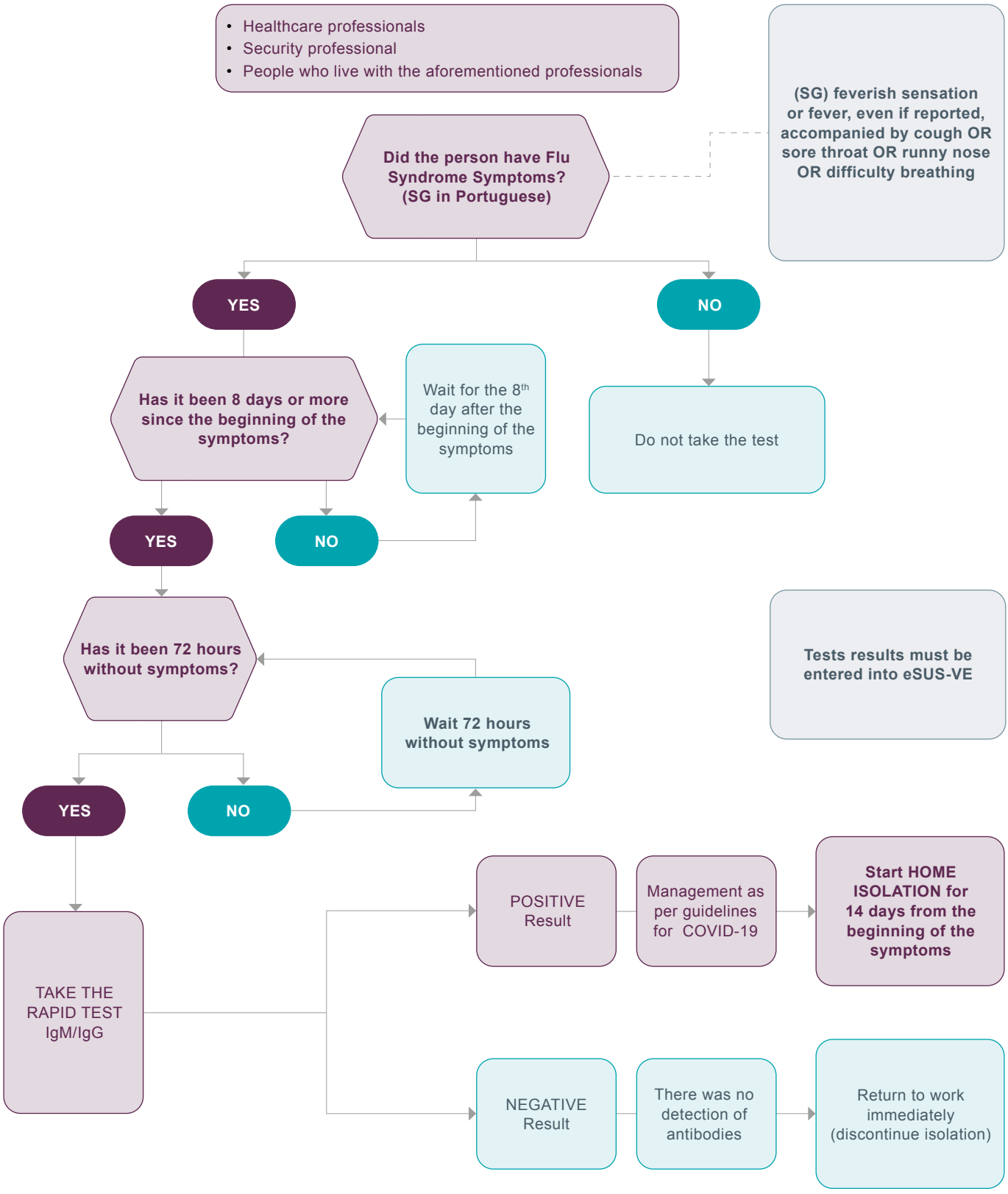
Table 11: Tests available through the public and supplementary health networks

Health network	Criteria	Tests available
Public*	Patients with suspected COVID-19 or a case confirmed by a biochemical test	• Laboratory exam: RT-qPCR • Serological test for the identification of virus antibodies: IgM and IgG in a sample collected after the seventh day of symptoms.
Supplementary**	Patients suspected of having COVID-19 or unless medically indicated	Laboratory test: RT-qPCR
	Patients who present with or have manifested one of the two major symptoms related to COVID-19	Serological test for the identification of virus antibodies: IgA, IgG, IgM

Source: * Diretrizes para Diagnóstico e Tratamento da COVID-19 – MS (Guidelines for Diagnosis and Treatment of COVID-19 - MoH)[35]
** Agência Brasil[36]

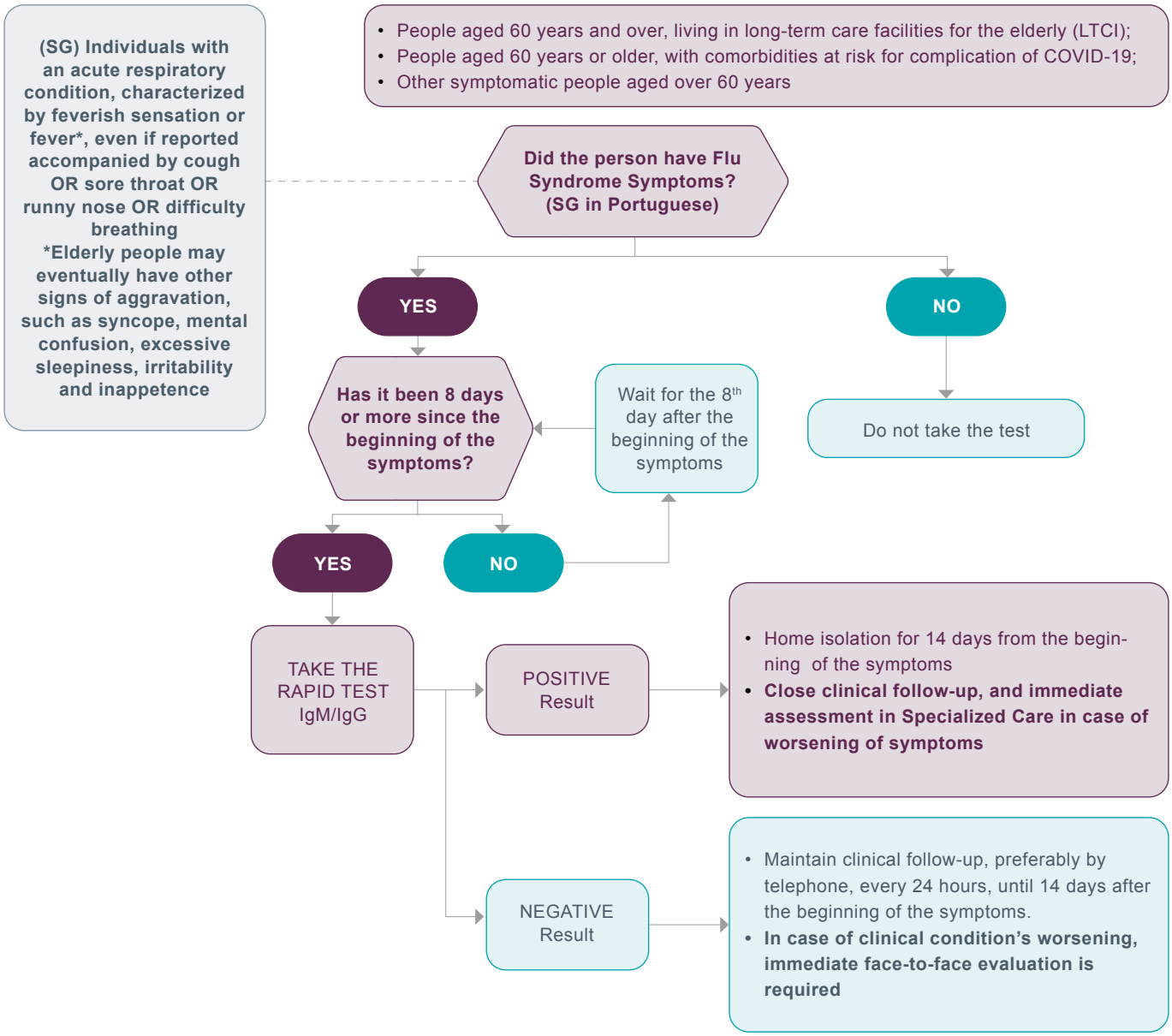
The manual published by CONASS and CONASEMS to guide the procedures provided by public healthcare services recommends the following pathways for the use of COVID-19 rapid tests:

Group 1: Healthcare professionals, security professionals and people who live with them



Source: Diretrizes para Diagnóstico e Tratamento da COVID-19 – MS[37]

Group 2: (when there is greater availability of tests) people aged 60+ years, individuals living in long-term care facilities for the elderly; individuals with co-morbidities and at risk of developing COVID-19 complications; other symptomatic people aged 60+ years.



Source: Diretrizes para Diagnóstico e Tratamento da COVID-19 – MS (Guidelines for Diagnosis and Treatment of COVID-19 - MoH)[38]

RT-PCR tests for investigation and confirmation of COVID-19 are performed in the public health laboratories that form part of the national network coordinated by the MoH. The MoH is responsible for establishing testing policy guidelines, which means defining the technical criteria used for COVID-19 laboratory investigation and planning the distribution and use of tests according to the needs and capacity of the laboratory network in each state. The municipalities are responsible for collecting samples and sending them to state laboratories according to federal guidelines, for RT-PCR to be performed to test for COVID-19.

The municipal Primary Health Care Units manage all suspected cases of COVID-19, collecting samples and sending them to a reference laboratory, who will return the result to the Primary Health Care Units to initiate any further actions necessary for the patient. These actions include monitoring patients who are self-isolating at home and referring more severe cases to hospitals or Emergency Care Units (UPA). The primary healthcare teams also carry out contact tracing, provide instructions to family members of cases, and notify confirmed cases via the specialized SUS information system within the health surveillance system.

Problems with the testing protocol

In April 2020, the MoH acquired 10 million RT-PCR COVID-19 tests, produced by the Seegene laboratory in the Republic of Korea, with the support of the PAHO Strategic Fund. According to the Federal Government, the acquisition of the tests was part of a programme launched by the MoH to conduct 24.6 million PCR tests by December 2020. The objective was to identify infected people, trace contacts, establish isolation and consequently break the chain of transmission of the infection.

However, the prearranged testing plan did not happen effectively. Since September 2020, the average number of daily tests in Brazil had been falling, revealing a systemic deficiency in the coordination of testing programmes for COVID-19 in the country. At the end of May 2020, Dr Diego Xavier, an epidemiologist at Fiocruz, told BBC News Brazil:

> *"To this day, Brazil continues to test only cases that are almost certain to be COVID-19. Asymptomatic people, whom we know transmit the virus, we are testing practically no one. If the person arrives at a health unit without symptoms or saying that they only had contact with someone who had covid, it is difficult for me to do this test because the offer is small."*[39]

While WHO advocated for extensive testing of patients with moderate and mild symptoms, as well as those individuals with whom the patients had contact, Brazil mainly tested patients in hospitals. As a result, it was difficult to track and establish isolation measures for asymptomatic patients, resulting in a higher level of disease transmission, which facilitated the emergence of new variants. In February 2021, Fabio Arcuri, Board President of the Brazilian Chamber of Laboratory Diagnostics (CBDL), declared that:

> *"Unlike other nations, Brazil's biggest challenge was the testing policy. There was a lack of a better structure for testing [especially regarding national coordination]. The country did not know how to organize itself. We even had to work with Anvisa to extend the validity period of the reagents, as the Government could not distribute and use all the available tests. In addition, the country uses few tests other than RT-PCR, which not all laboratories have the infrastructure to offer."*[40]

This statement was posted on the website of the Brazilian Association for Diagnostic Medicine (*Associação Brasileira de Medicina Diagnóstica* - ABRAMED) and confirmed by an interviewed C-Level executive from this organization.

The explanation for Brazil's poor performance in terms of an effective testing plan involves a number of factors, including the lack of tests, pharmaceutical ingredients (IFA), processing capacity and political will. In addition, due to the lack of a coordinated federal plan, public agents had to choose between acquiring tests or oxygen and intubation kits. Professor Pedro Hallal, from the Federal University of Pelota in the state of Rio Grande do Sul, described the situation, also for BBC News Brazil:

> *"Testing is not a priority because the Ministry of Health has never understood what tests are for. It seems that the Ministry of Health has always thought that testing is to count the number of cases when, in fact, testing is a health policy to identify infections early and prevent the transmission of the disease."*

Other experts shared Professor Hallal's view. A C-Level sectoral association professional who was interviewed for this study remarked that:

> *"There is a big challenge within the IVD market, which is to demonstrate 'the value' of each test for each clinical situation; that is what will guide policymakers. It is not a well-resolved issue in Brazil, and we need more studies than we have now."*

Although referring to a situation beyond the pandemic, this statement expresses the need to reinforce Brazil's testing capacity as a critical component for effective emergency preparedness plans and public health management.

Key takeaways:

- The status of clinical practice guidelines allows an understanding of the clinical environment for disease management, whether they are part of a consolidated system or preliminary recommendations.
- There are national guidelines, policies and specific laws for diabetes, covering a patient's entire healthcare journey, including the IVD tests available in the public and supplementary health networks. Understanding the landscape of available IVD tests and whether they are covered allows one to identify the barriers to access, competing products and their status within the system.
- With regards to COVID-19, there are national guidelines and clear pathways for testing. However, the testing protocol is outdated and faces critical challenges with regards to implementation. There is currently an ongoing discussion in the Ministry of Health about developing a new protocol for Brazil.

FIND

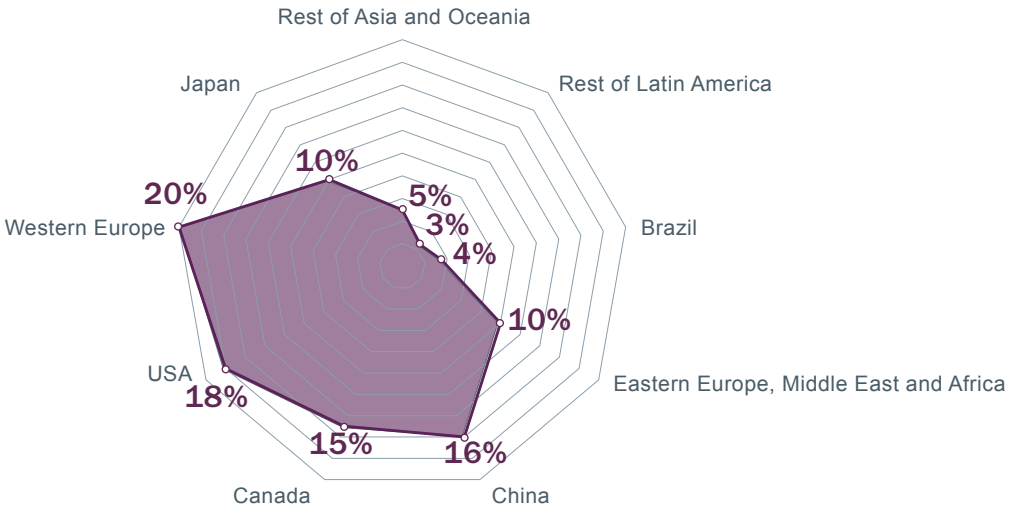
VII

IN VITRO DIAGNOSTICS MARKET

VII
IN VITRO DIAGNOSTICS MARKET

The global market for IVD tests was valued at approximately USD 68,410 million in 2020.[41] The Brazilian Chamber of Laboratory Diagnostics (CBDL) found that Brazil accounted for a 3.5% share of the global IVD test market in 2017 (Fig. 15).

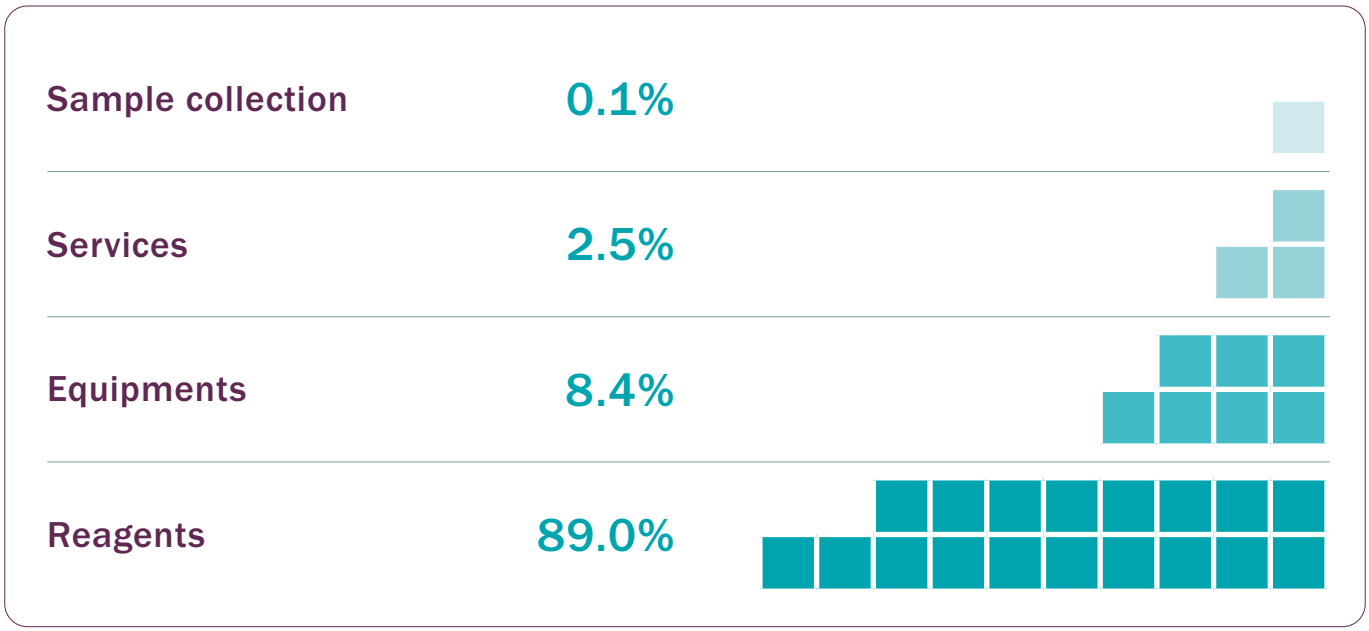
Figure 15: Brazil's share of the global IVD test market in 2017



Source: Laboratory Diagnosis White Paper. Brazilian Chamber of Laboratorial Diagnostic (Câmara Brasileira de Diagnóstico Laboratorial - CBDL)[42]

The Brazilian market for IVD tests includes reagents, equipment and services (Fig. 16).

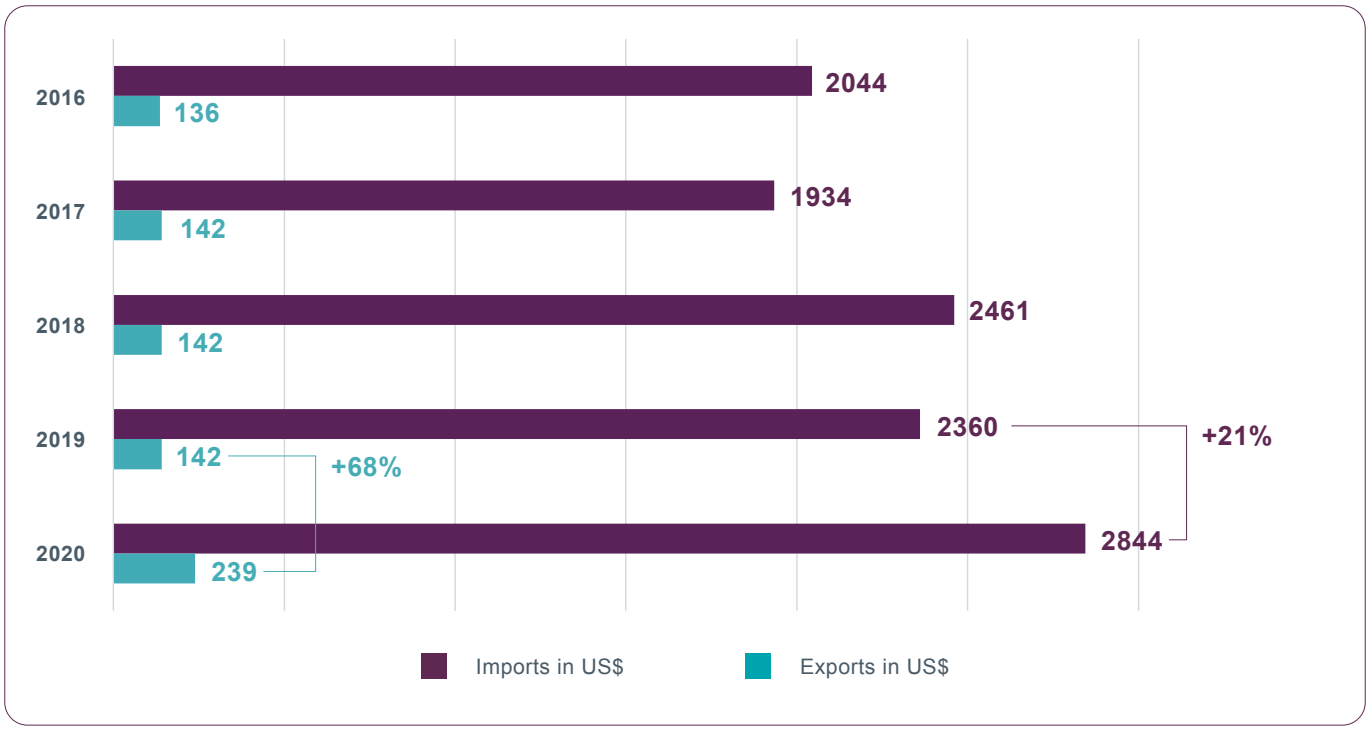
Figure 16: Distribution of the Brazilian IVD test market by major product lines in 2020 (%)



Source: Laboratory Diagnosis White Paper. Brazilian Chamber of Laboratorial Diagnostic (Câmara Brasileira de Diagnóstico Laboratorial - CBDL)[43]

The balance of trade of the reagents market, which represents the largest proportion of the IVD test market, is shown in Fig. 17.

Figure 17: Trade balance of reagents and analyzers for IVD tests (2016 to 2020) (USD millions)



Source: Laboratory Diagnosis White Paper. Brazilian Chamber of Laboratorial Diagnostic (Câmara Brasileira de Diagnóstico Laboratorial - CBDL)[44]

Brands and companies do not publicly disclose details regarding the volumes of their market share for IVD tests in Brazil. According to a report produced by IQVIA for FIND in February 2021:

COVID-19

Secondary sources and primary research mention a variety of vendors for COVID-19 tests in the country. In May 2020, Seegene Inc. announced the export of 10 million PCR test kits to Brazil. During interviews, experts mentioned that approximately 70% of all tests (including PCR test kits, rapid antigen tests, and rapid antibody tests) are from local manufacturers based in Fiocruz. Wama Diagnostics, Abbott, and DFL are other prominent distributors in the country for COVID-19 diagnostics.

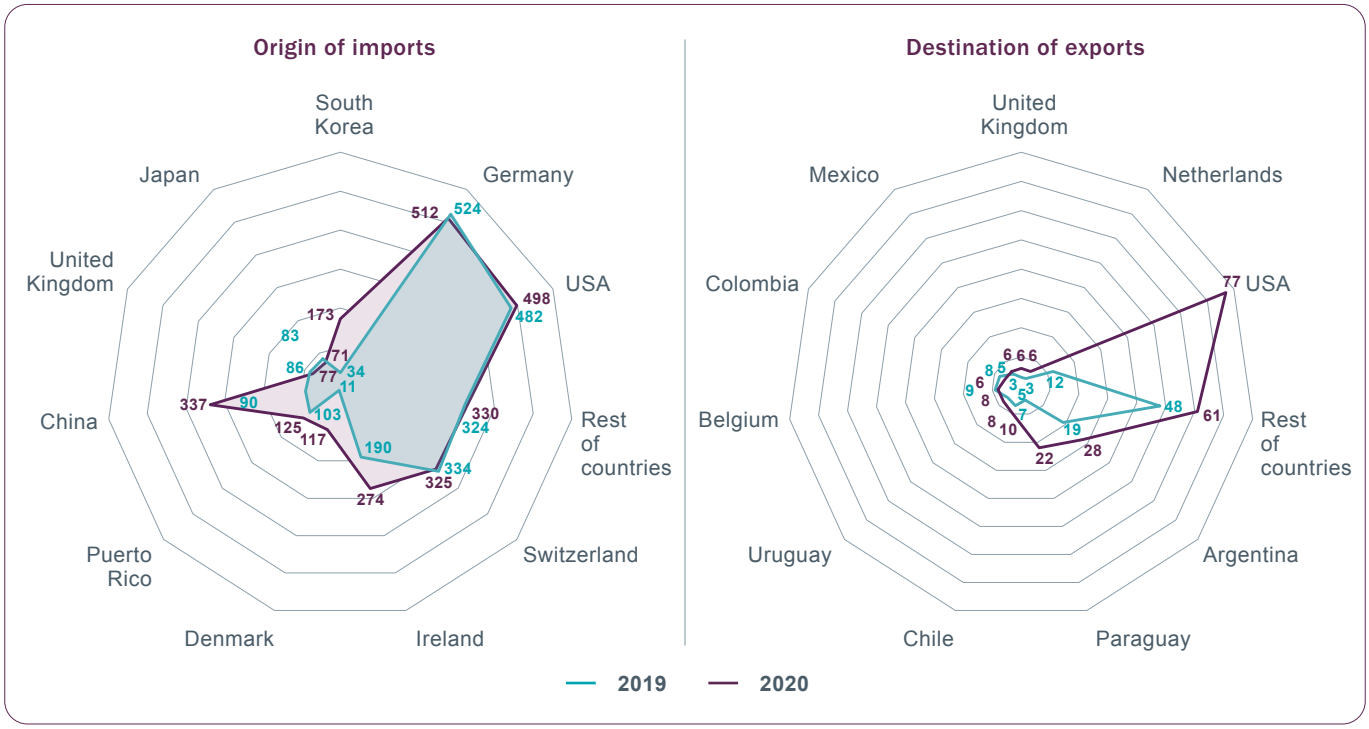
The volume of tests procured for COVID-19 diagnostics is unclear from secondary sources and PMR. However, it is important to note that The Global Fund in September 2020 dedicated an initial USD 50 million from its COVID-19 Response Mechanism to enable LMICs to purchase at least 10 million affordable, quality COVID-19 Ag-detection rapid tests.

Diabetes

According to secondary sources, it is estimated that national penetration by “big four” companies (Johnson & Johnson LifeScan, Roche, Ascensia, Abbott) in the Brazilian blood glucose monitoring market was 90.6% in 2016.

Imports and exports increased between 2019 and 2020, resulting from the increased demand for COVID-19 IVD tests in Brazil itself and in the markets to which Brazil exports IVD tests. Fig. 18 shows the primary sources of imports and destination of exports. Most imports to Brazil come from Germany and the United States, representing around 18% of imports in 2020. Together with China, these countries accounted for 47% of Brazilian imports in this market.

Figure 18: Source of imports and destination of exports of reagents and analyzers for IVD tests (2019–2020) (USD million)

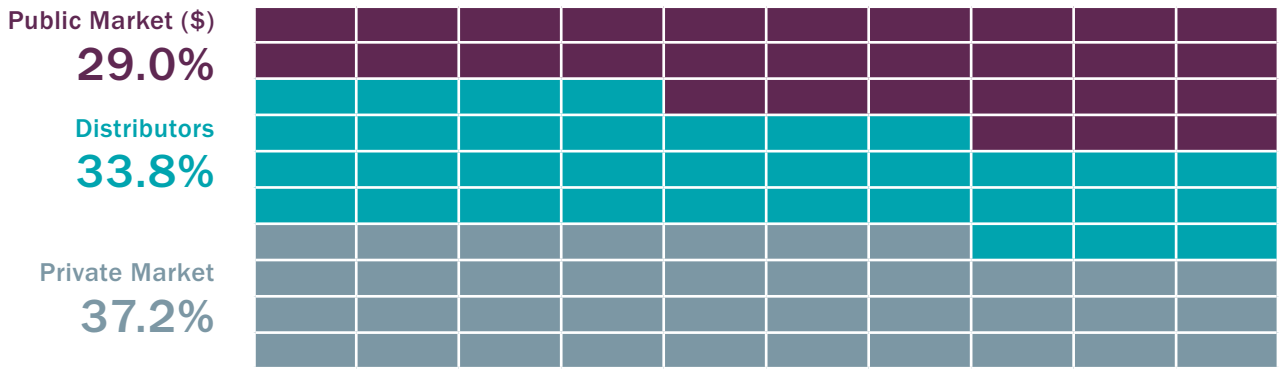


Source: Laboratory Diagnosis White Paper. Brazilian Chamber of Laboratorial Diagnostic (CBDL)[45]

Most Brazilian exports went to the United States, comprising 32% of the total exports in 2020. Together with Argentina and Paraguay, these three countries accounted for 53% of exports in this market (FIG. 17).

Data from CBDL demonstrated that, in 2020, the domestic market for purchasing IVD products was composed as shown in Fig. 19.

Figure 19: Composition of the domestic market in Brazil for purchasing IVD products in 2020

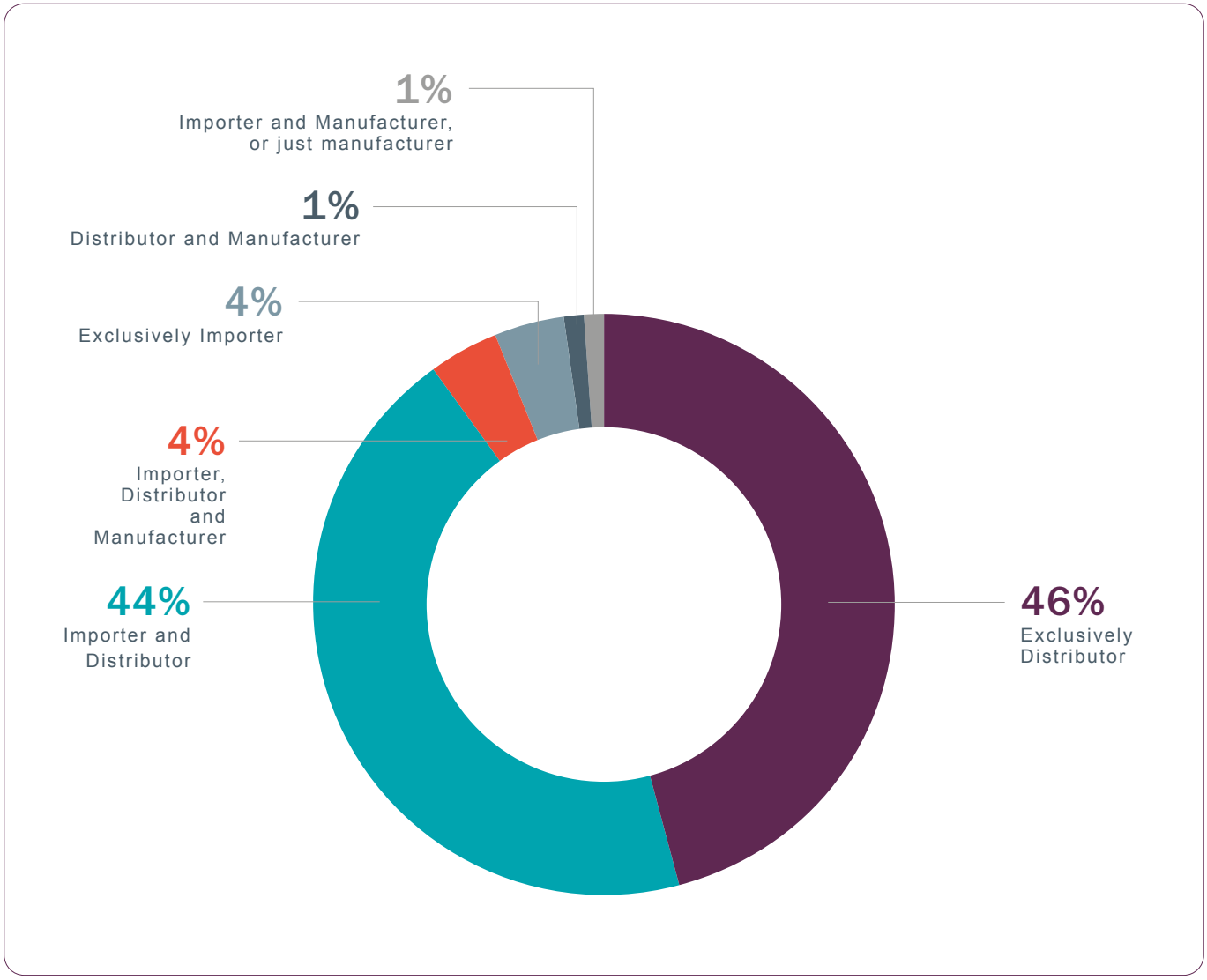


Source: Laboratory Diagnosis White Paper. Brazilian Chamber of Laboratorial Diagnostic (CBDL)

Distributors are the intermediaries between manufacturers and buyers, and their role includes storage, handling and distribution of medications and medical devices. According to Anvisa, a distributor cannot register products, as registration is limited to the manufacturer or the importer. If a distributor wishes to be the registry owner, it can expand its activity into importing, following all technical and legal procedures.

Less than half of the associates of the Brazilian Association of Importers and Distributors of Health Products (ABRAIDI) are exclusively distributors (46%) or importers (4%). There is an overlap of activities they perform, between distribution, importation and manufacturing (Fig. 20).

Figure 20: Activities performed by the associates of ABRAIDI



To transport medicines and medical devices, a distributor must obtain a Company Operating Permit (AFE) from Anvisa. Other authorizations may apply, depending on the classification of the transported item.

When a buyer and a seller sign an outsourcing contract to transport medicines and medical devices, it is not necessary to notify Anvisa. However, the outsourced company must have the standard AFE authorization and, in the case of transporting substances subject to exceptional control, the carrier must also have other Special Authorizations (AE).

A report from the Anvisa Medical Devices Board, with data up to July 2021, showed that 643 types of IVD tests for COVID-19 had been approved for use in Brazil.[46] Chart 10 shows a list of Brazilian companies that, by June 2021, had already had their tests approved by Anvisa.

A real-time list of types of IVD tests for COVID-19 that have been submitted to Anvisa for consideration, including the names of the manufacturer and registered owners, as well as details of processes and status of the application, can be accessed via Anvisa's Microsoft Power Business Intelligence platform.[47]

Table 12: IVD tests for COVID-19 approved by Anvisa, by company

Company	Test type	Manufacturer
Advagen Biotech Ltda (Brasil)	COVID-19 IgG/IgM LF COVID-19 IgA/IgG/IgM MAX ELISA SARS-CoV-2 Ab LF COVID-19 IgG MAX ELISA SARS-CoV-2 Ag LF ADVA COVID-19 RT-LAMP ADVA SARS-CoV-2- IgG RBD Neutralizing	
Alamar Tecno Científica Ltda (Brasil)	Coronavírus COVID-19 IgG/IgM Rapid Test Antigen SARS-CoV-2 Rapid Test	Accubio Tech Co Ltd (China)
Bio Brasil Biotecnologia Ltda (Brasil)	Bio Detechta ELISA IgG SARS-CoV-2 COVID-19 IgM/IgG Rapid Test Detechta Rápido IgG and IgM SARS-CoV-2	
Chembio Diagnostics Brazil Ltda. (Brasil)	DPP COVID-19 IgM/IgG System DPP SARS-CoV-2 Antigen System DPP SARS-CoV-2 Antigen DRR SARS-CoV-2 IgM/IgG OL COVID-19 IgM/IgG OL COVID-19 Ag	Chembio Diagnostic System, Inc (EUA)
Diagnóstica Indústria e Comércio Ltda – ME (Brasil)	COVID-19 Ag Test	Guangzhou Wondfo Biotech Co Ltd (China)
Ebram Produtos Laboratoriais Ltda (Brasil)	Coronavírus IgG/IgM (COVID-19)	Qingdao Hightop Biotech Co. Lt (China)
Eco Diagnóstica Ltda (Brasil)	ECO F COVID-19 IgG/IgM Covid Ag Oral ECO Detect ECO F Covid nAb Standard Q COVID-19 Ag Test SARS-CoV-2 ECO Detect	SD Biosensor, Inc (Coreia do Sul) Certest Biotec SL (Espanha)
Fundação Oswaldo Cruz (Brasil)	TR DPP COVID-19 IgM/IgG – Bio Manguinhos Kit Molecular SARS-CoV-2 (E/P1) – Bio Manguinhos Kit Molecular SARS-CoV-2 (E/RP) – Bio Manguinhos TR COVID-19 IgM/IgG – Bio Manguinhos Kit Molecular SARS-CoV-2 (EDx) – Bio Manguinhos TR COVID-19 Ag – Bio Manguinhos	Chembio Diagnostic Systems, Inc (EUA)
Galileo Biotecnologia S.A (Brasil)	Kit de ELISA to antibody detection IgM and IgG anti-SARS-CoV-2	
Gold Analisa Diagnóstica Ltda. (Brasil)	COVID-19 IgG / IgM Safetest COVID-19 TM IgG/IgM – Rapid Test Covid AG	Guangzhou Wondfo Biotech Co Ltd (China)
Instituto de Biologia Molecular do Paraná (Brasil)	Kit Biomol Onestep/COVID-19 Rapid Test Kit Covid Ag	
In Vitro Diagnóstica Ltda. (Brasil)	SARS-CoV-2 IgM/IgG COVID-19 IgG/IgM N-COVID-19 IgM/IgG Colloidal Gold SARS-CoV-2 Ag InviTest SARS-CoV-2 Antigen InviTest	

Company	Test type	Manufacturer
Labtest Diagnóstica S/A (Brasil)	Anti-SARS-CoV-2 IgM/IgG Rapid Test SD Anti-COVID-19 IgG/IgM Rapid Test COVID-19 AG Rapid Test Anti-SARS-CoV-2 IgG OmniLAMP SARS-CoV-2 (PCR-LAMP) Anti-SARS-CoV-2 IgM/IgG Rapid Test Detect SARS-CoV-2 RT-PCR	ASAN Pharmaceutical Co. Ltda (Coreia do Sul) Hangzhou Alltest Biotech Co. Ltd (China) MedicalSystem Biotechnology Co. Ltda. (China) Osang Healthcare Co. Ltd (Coreia do Sul)
Renylab Química e Farmacêutica Ltda (Brasil)	Imunotest COVID-19	Innovita (Tangshan) Biological Technology Co. Ltd.
Kovalent do Brasil Ltda (Brasil)	Kovid Ab (COVID-19 IgG/IgM)	
LMG Lasers – Comércio, Importação e Exportação Ltda (Brasil)	Basall Teste 2019-nCov Antigen Rapid Test Antigen Family Basall COVID-19 Test Kit COVID-19	Xiamen Amonmed Biotechnology Co. Ltd (China)
Mbiolog Diagnósticos Ltda (Brasil)	Allserum EIA Covid19 IgM/IgG Allserum EIA COVID-19 Dried Blood spot	
Mobius Life Science Indústria e Comércio de Produtos para Laboratórios Ltda (Brasil)	Family Kit Xgen Master COVID-19 - kit master to Coronavirus detection SARS-CoV-2	
NL Comércio Exterior Ltda (Brasil)	NL COVID-19 IgG/IgM Antibody Test NL q SARS-CoV-2 IgG/IgM Cassette Rapid Test	Alfa Scientific Designs Inc (EUA)
Quibasa Química Básica LTDA. (Brasil)	Família BIO GENE COVID-19 PCR Biolisa COVID-19 IgG/IgM Biolisa SARS-CoV-2 IgG/IgM Bioclin Fast COVID-19 IgG/IgM Bioclin Fast COVID-19 Ag Biolisa COVID-19 Neutralizing Antibody Família Biolisa COVID-19 IgA Biolisa COVID-19 Ac Total Bioclin FAST COVID-19 anti-RBD	Health Port Biotech Co. Ltd (China)
REM Industria e Comércio Ltda (Brasil)	Gold ELISA COVID-19 IgG + IgM	
Tocare Industria e Comércio de Produtos Médicos S/A – Brasil	Teste COVID-19 IgG/IgM Tocare	
Vida Biotecnologia Ltda – ME (Brasil)	VIDAFIAteste COVID-19 IgG/IgM VIDAFIAteste COVID-19 Ag COVID-19 Ag SE Rapid COVID-19 IgG/IgM Rapid SAFETEST COVID-19 TM IgG/IgM – Kit Elisa COVID-19 Ag Rapid	Qingdao Hightop Biotech Co. Ltd (China) Hangzhou Alltest Biotech Co. Ltd (China)

Company	Test type	Manufacturer
Vyttra Diagnósticos Importação e Exportação S.A (Brasil)	Smart Test COVID-19 Vytra Smart Test COVID-19 Plus Smart Test Cov Ag Smart Test Cov Ag OS Smart Test Cov nAb BM COVID-19 Smart Test Cov Ag CQ	Genbody Inc (Coreia do Sul) Vivachek Biotech (Hangzhou) Co. Ltd. (China)
Wama Produtos para Laboratórios Ltda (Brasil)	Imuno-Rápido COVID-19 IgG/IgM Imuno-Rápido COVID-19 Ag Biomol RT-PCR in real time SARS-CoV-2	

Source: Anvisa – List of IVD products with approved registrations.[48]

The public laboratory of Fiocruz (Biomanguinhos) in Rio de Janeiro is one of the companies that manufactures IVD tests in Brazil. Other public laboratories also produce IVD test kits for other purposes, especially neglected tropical diseases (Appendix G). IVD tests for COVID-19 are available in both the public and private healthcare systems, and individuals can also purchase IVD tests through out-of-pocket payments. They can even be bought in pharmacies, as is the case with any other tests approved by Anvisa. According to an IVD risk classification, pharmacies may provide specific tests, as authorized by the Anvisa Collegiate Board. Pharmacies have also been authorized to provide RDTs for antigens and antibodies since their approval in RDC 377/2020.

Pharmacies

According to the Brazilian Association of Pharmacy and Drugstore Chains (Abrafarma), from May 2020 to July 2021, 4,262 pharmacies performed nearly 10 million RDTs for COVID-19 for individuals with suspected COVID-19 or who had related symptoms.[49] Antigen tests accounted for 85% of the total tests performed, with antibody tests making up the remaining 15%. Abrafarma and Clinicarx (health technology and market intelligence services for pharmacies) developed a care protocol for pharmacies (following the MoH protocol) that explains to pharmacists how to offer RDTs and a complete clinical service, including medical history taking and clinical screening, reporting, guidance and referral.

Brazilian pharmacies can perform various point-of-care tests (POCTs), such as capillary blood-glucose measurements, and sell multiple self-test devices for many illnesses. Appendix J includes a table that shows pharmacy POCT suppliers and the types of POCTs.

Although there are approximately 89,879 commercial pharmacies and drugstores in Brazil,[50] distributed throughout the national territory and with good outreach to remote regions, the pharmacy market is highly concentrated. Abrafarma lists the ten leading franchises as: Rede Drogasil (São Paulo); Drogaria Pacheco São Paulo (São Paulo); Farmácias Pague Menos (Ceará); Farmácias São João (Rio Grande do Sul); Panvel (Rio Grande do Sul); Extrafarma (Pará); Drogarias Araújo (Minas Gerais); Drogarias Nissei (Paraná); Drogarias Venâncio (Rio de Janeiro); Grupo Tapajós (Amazonas). At outlets belonging to these pharmacy franchises, it is possible to find COVID-19 tests for individual purchase. Table 13 presents the average pricing information (USD) for each type of COVID-19 test in each pharmacy chain.

Table 13: Cost of IVD tests for COVID-19 in each pharmacy chain (in USD)

Pharmacie franchise	Region	PCR	PCR-Lamp	IgG	IgG/IgM	Serology (IgG and IgM)	Nasal antigen
Droga Raia	São Paulo	n/a		n/d	n/a	22	24
Extrafarma	São Paulo	n/a	n/a	n/a	n/a	16	20
PanVel	Porto Alegre	54	n/a	34	52	12	24
Drogal	Campinas	n/a	26	n/a	n/a	18	24
Araújo	Belo Horizonte	70	n/a	n/a	36	n/a	32
Nissei	Curitiba	n/a	n/a	n/a	n/a	16	26
São João	Porto Alegre	n/a	n/a	n/a	n/a	n/a	24
Pacheco	Rio de Janeiro	30	n/a	n/a	n/a	24	18
Pague Menos	Fortaleza	n/a	36	n/a	n/a	16	20
Drogasil	São Paulo	n/a	30	n/a	n/a	22	24

Note: Prices collected by researchers, in June 2021, in Brazilian pharmacy chains

With regards to diabetes, Table 14 shows the types of IVD tests and associated prices.

Table 14: Cost of IVD tests for diabetes (in USD)

Brand	Blood glucose meter	Strips
Accu-Check	11	10.62
Multilaser	7.4	10.98
On Call Plus	8	7.92
Optimum Neo	14	18.98
One Touch	8.6	12.6
Testline	8.4	-
Descarpack	14	7.98
GA-3	20	-
Wellion Luna	16	14.42
Injex	18	11.88
G-Tech	-	7.98
Code Free	14	-

Note: Prices collected by researchers, in June 2021, in Brazilian pharmacy chains

Suppliers

Two of the interviewees mentioned that Brazil's dependence on imported products is a sectoral issue and, if the country is dependent on imports, it will remain susceptible to price gouging. With the pandemic, it became increasingly evident that there is an essential need for Brazil to evolve technologically. However, expanding internal production is considered a challenge, mainly due to the lack of a favourable economic situation for national and multinational companies to manufacture locally.

One of the professionals also highlighted the need to establish good relationships with suppliers to avoid inventory losses. Moreover, relevant players need to improve interoperability, connectivity and supply chain efficiency to: "*achieve maturity, get rid of individual agendas, and think, together, on how to build a more integrated, more efficient and less costly market*."

A sectoral trade association C-Level executive expressed the belief that discussions within the sector are converging to more extensive use of technology. In fact, consolidated purchases might become a trend, creating an opportunity for FIND's marketplace. The interviewees suggested that if buyers can organize themselves and plan collective orders, they can achieve more competitive prices and cheaper freight.

The COVID-19 pandemic has had a major impact on the diagnostics sector, and the need to adopt a collective approach has become more evident. Moving forward, investments in technology should be a high priority for the diagnostics industry.

Key takeaways:

- The Brazilian diagnostics market mainly comprises reagents (chemical components, solutions or preparations, biological or immunological), which account for 89% of all IVD test products. Brazil imports more than it exports, but exports saw a higher percentage growth than imports during 2020, due to the COVID-19 situation.
- Historically, the leading countries of origin for imported IVD tests were the United States and Germany. However, with the COVID-19 pandemic, China has become an important partner. There is no preferential destination regarding exports, but with the COVID-19 outbreak, the United States has become a key international partner.
- Brazil's dependence on imported products is a major issue that has been exacerbated by the pandemic.
- The private sector leads the diagnostics market. The SADT branches that operate in Brazil account for more than 90% of the country's IVD test availability. Between 2020 and 2021, many companies received approval from Anvisa to manufacture IVD tests for COVID-19, some in partnership with national subsidiary companies.
- In the pharmacy sector, IVD tests for COVID-19 are primarily available from outlets belonging to large chains. There are significant differences in price among them, depending on the type of test.
- Players from the diagnostics sector are vocal about organizing and acting collectively to achieve competitive conditions for suppliers.

FIND

VIII

NATIONAL/ LOCAL DISCUSSIONS AND INITIATIVES ON DIAGNOSTICS

VIII
NATIONAL/LOCAL DISCUSSIONS AND INITIATIVES ON DIAGNOSTICS

Diabetes

Discussion/initiative	Description	Leadership
Campaigns	June 26 is Brazil's National Diabetes Day. Each year, organizations promote campaigns on this topic. The latest campaigns focused on promoting the importance of screening tests to prevent type 2 diabetes and control glucose in those diagnosed with the condition. https://diabetes.org.br/ https://www.endocrino.org.br/	Brazilian Society of Diabetes (SBD) and *Sociedade Brasileira de Endocrinologia e Metabologia* (SBEM)
"Pé Diabético" Project	Pé Diabético is a project aimed at preventing aggravated cases of diabetes. CONASS is willing to implement the project, to make innovative and simple self-tests more available and increase access to simple tools, such as monofilament and tuning fork/ diapason. In addition to access, teams on the ground need support to detect cases and educate patients, especially in remote regions. https://www.conass.org.br/forum-debateu-panorama-nacional-do-diabetes/	CONASS

COVID-19

Discussion/initiative	Description	Leadership
Projeto Integra	Projeto Integra was launched in June 2021 to articulate and promote strategies for integrating policies and practices for health surveillance, pharmaceutical assistance, and science, technology and innovation in health, with the participation of social organizations. The project is selecting 300 participants from all Brazilian states to build a network of leaders to confront national health problems, especially those generated by the COVID-19 pandemic. Alongside the National Health Council, Fiocruz and the National Pharmacists School (ENF) have joined the initiative, which is supported by PAHO. Projeto Integra — Português (Brasil) (www.gov.br)	National Health Council (*Conselho Nacional de Saúde* - CNS)
Todos pela Saúde (All for Health)	This alliance aims to tackle the COVID-19 pandemic in the country, targeting the most vulnerable members of the population, and supporting initiatives in public health. Itaú Unibanco bank donated USD 200 million, out of which USD 43 million was intended to purchase IVD tests. In partnership with Fiocruz, the campaign enabled the installation of two PCR and serology processing centre units, located in Rio de Janeiro (RJ) and Eusébio (CE), with an investment of USD 36 million. The initiative is part of the strategy of supporting the Central Public Health Laboratories (LACEN) and expanding the national capacity for processing samples, with the potential to process up to 15,000 molecular tests daily at the Rio de Janeiro unit and up to 10,000 molecular tests daily in Ceará. Both units will remain as a legacy for the country in the post-pandemic period, increasing Brazil's diagnostic capacity for other diseases besides COVID-19. Todos pela saúde (todospelasaude.org)	Philanthropic funding initiative

Discussion/initiative	Description	Leadership
Movimento UniãoBR	UniãoBR is a voluntary movement within Brazilian society to fight the COVID-19 pandemic in Brazil. They work through independent state leagues to support vulnerable communities. They serve as an interface for building partnerships with other organizations, aiming to increase national coverage. Although there is no specific initiative related to testing, it could be a relevant stakeholder as they have partnered with several private stakeholders. Doação | Movimento UniãoBR | Ajude quem mais precisa (movimentouniaobr.com.br)	
Movimento UniãoRio	União Rio is a voluntary movement involving citizens from Rio de Janeiro that brings together people, companies and NGOs. It was created during the COVID-19 epidemic in Brazil to support vulnerable communities and the health sector. They were responsible for donating 36 000 antigen tests to the Municipal Health Secretary of Rio de Janeiro between January and July 2021. Movimento União Rio | Rio de Janeiro (movimentouniaorio.org)	
Fundo Emergencial para a Saúde	IDIS, in partnership with the social organizations BSocial and Movimento Bem Maior, raised USD 8.14 million in 5 months, directly benefiting 59 hospitals, a research centre and a social organization. The funds raised by the campaign were used to purchase hospital equipment, personal protective equipment (EPI) for health professionals, medicines, and IVD tests for COVID-19. The fund earmarked USD 18 400 to purchase 962 RDTs for COVID-19 and 500 RT-PCR tests. Website: https://www.idis.org.br/en/	Institute for the Development of Social Investment (IDIS)

Key takeaways:

- Understanding the discussions and initiatives around diagnostics makes it possible to identify opportunities for collaboration in this arena.

FIND

IX

STAKEHOLDERS RELATED TO DIAGNOSTICS

IX
STAKEHOLDERS RELATED TO DIAGNOSTICS

Government bodies

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Ministry of Health	In conjunction with the National Health Council, the MoH is the national SUS manager that formulates, regulates, inspects, monitors and evaluates health policies, campaigns and programmes (including those related to diagnostics and disease management). Despite the lack of solid coordination during the pandemic, it is the main stakeholder in healthcare and is responsible for the national purchasing of IVD tests. Within the MoH, the department accountable for managing the National Network of Health Surveillance Laboratories (responsible for defining which IVD tests can be used in the network) is the Health Surveillance Secretariat (SVS).
State Health Secretariats (SES)	The SESs formulate health policies, campaigns and programmes (including those related to diagnostics and disease management), provide support to municipalities, and participate in the Bipartite Interagency Commission (CIB) to approve and implement state-level health plans. The SESs have played an essential role in managing the COVID-19 epidemic in their geographic domain and promoting initiatives related to IVD tests.
Municipal Health Secretariats (SMS)	SMSs plan, organize, control, evaluate and execute health programmes, services and campaigns in conjunction with the municipal council and the state to approve and implement health plans at city levels. The Municipal Health Secretary is responsible for managing diabetes and collecting IVD tests and samples for COVID-19 testing in the public health system.
National Council of Health Secretariats (CONASS)	A representative entity composed of state health secretariats. They are responsible for leading initiatives in the country and lobby the MoH to promote testing-related and other protective health policies.
National Council of Municipal Health Secretariats (CONASEM)	A representative entity of municipal health secretariats. In partnership with CONASS, they launched a Guide for Coping with the COVID-19 Pandemic in the Healthcare Network (*Guia Orientador para o enfrentamento da pandemia COVID-19 na Rede de Atenção à Saúde*). The guide reinforced public health measures in primary healthcare, especially for people with chronic diseases. It was developed in partnership with the Albert Einstein Hospital, one of the leading private hospitals in Brazil.
National Supplementary Health Agency (ANS)	The National Supplementary Health Agency (ANS) is the regulatory agency linked to the MoH that is responsible for the health insurance sector in Brazil. The agency defines the list of health procedures that health plans are required to offer.
Northeast Consortium	The Northeast Consortium was created by a collaboration among the States of Alagoas, Bahia, Ceará, Maranhão, Paraíba, Pernambuco, Piauí, Rio Grande do Norte and Sergipe, all located in the northeast region of Brazil. It was established in 2019 to be the legal, political and economic instrument for integrating the nine states in the northeast of Brazil. The Consortium aims to attract investments and leverage joint projects and governance agreements. It can implement regional public policies regarding testing and perform joint purchases.

Public laboratories

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Oswaldo Cruz Foundation (Fiocruz)	The Oswaldo Cruz Foundation is a dedicated public health research institution in Latin America. It is the National Reference Laboratory in the Influenza Surveillance Program and is accredited by WHO as a National Influenza Center, forming part of their global surveillance network. It has developed IVD tests for COVID-19 and trained the state laboratories (LACEN) to detect the SARS-CoV-2 virus.
Adolfo Lutz Institute (IAL)	The Adolfo Lutz Institute contributes to planning epidemiological, sanitary and environmental surveillance actions in Brazil. It is one of the Regional Reference Laboratories for influenza surveillance and part of the WHO global surveillance network. It is one of the centres responsible for carrying out RT-PCR molecular tests.
Evandro Chagas Institute (IEC)	The mission of the Evandro Chagas Institute is scientific research, surveillance and teaching to produce and disseminate knowledge and technological innovations to motivate health policies. It is a regional reference laboratory for influenza surveillance and, since the beginning of the COVID-19 pandemic, it has been one of the reference centres for the molecular detection of pathogens. It is also part of the WHO global surveillance network.
Instituto Butantan	Instituto Butantan is a public laboratory in the state of São Paulo and the leading immunobiological producer in Brazil. It develops studies in the areas of biology and biomedicine related to public health. Since the beginning of the COVID-19 pandemic, it has coordinated a portal with data from the Laboratory Platform for Coronavirus Diagnosis in São Paulo, which provides information on testing activities carried out to detect COVID-19 throughout the state.

Private laboratories

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Dasa	Dasa is the leading company in diagnostic medicine in Brazil and Latin America and the fifth largest globally, focusing mainly on clinical analysis, imaging diagnostics and genomics. During the COVID-19 pandemic, the laboratory partnered with the MoH to expand the testing capacity for coronavirus.
Fleury	Founded in 1926, Grupo Fleury performed more than 82 million tests during 2019 (in clinical analysis, radiology, imaging diagnostics and pathological anatomy). Alongside the “Todos pela Saúde” (“All on behalf of health”) initiative, the laboratory helped conduct COVID-19 prevalence surveys in the city of São Paulo.
Sabin	Sabin is specialized in clinical analysis, imaging diagnostics, vaccinations and executive check-ups. It has 296 units in Brazil and treats more than 5 million patients each year. It is recognized for fostering and supporting technical and scientific research and the development of new diagnostic methods.
Albert Einstein Diagnostic Medicine	Albert Einstein Diagnostic Medicine is a non-profit civil society organization active in supplementary and public health activities. Its structure of supplementary health services includes 38 units in Brazil. It performs clinical analysis, imaging diagnostics, pathological anatomy, and genetic testing for more than 6.5 million patients each year in supplementary health laboratory and imaging tests and more than 3 million through SUS. Albert Einstein Diagnostic Medicine is also a reference health entity in Brazil.

B2B marketplace

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Bionexo	Bionexo is a health technology company that offers health sector buyers the possibility of concentrating all purchases (hospital equipment and medicines, office supplies, cleaning products, disposables, food, clothing and others) in a single system to manage stock demand processes. The company contributes to time savings, greater productivity and easier access to information through an automated solution for supply managers. According to the company, its marketplace accounts for more than 10 000 sellers of medicines and hospital supplies in Brazil, Argentina, Colombia and Mexico. Approximately 1700 Brazilian hospitals use the system, which performs transactions worth an average of USD 2.4 billion per year.[51] In March 2021, Bionexo filed a request for registration with the Securities and Exchange Commission (CVM), the regulatory and supervisory body in the Brazilian capital market.[52] Its initial public offering (IPO) prospect declared 34,000 clients, including hospitals, health insurance companies, supplies sellers and buyers, from Brazil, Argentina, Colombia and Mexico. In 2020, the company had a net revenue of USD 18 million, an increase of 17.3% compared with 2019. Since 2018, Temasek, Singapore's sovereign wealth fund, has been one of Bionexo's shareholders. The IPO involved selling new shares to improve Bionexo's cash capacity for acquisitions and R&D. Additionally, Bionexo created, alongside the Economic Research Institute Foundation (FIPE), the Drug Price Index for Hospitals (IPM-H), to provide information regarding the behaviour of drug prices traded in Bionexos's marketplace. The index does not include IVD tests. Website: Home - Bionexo
Plataforma Síntese (Synthesis Platform)	Síntese began its operations as a purchasing and specialized consulting centre for hospital supplies. In 2017, it launched a purchasing platform as the first module of a global supply management system, including supply planning, marketplace, orthotics, prosthetics and special materials (OPME), delivery monitoring and business intelligence. Via the platform, purchasers can negotiate directly with Brazilian suppliers from all over the country. Initially operating exclusively in Pernambuco, Síntese expanded its activities to the entire Brazilian territory in 2018. In 2020, they launched the OPME Synthesis Platform, which controls the flow of materials and integrates all aspects, such as surgery scheduling, doctors, pharmacies, buyers, suppliers, health plans (which authorize a procedure) and the hospital financial sector in the same tool/platform. In 2020, it declared that it has handled transactions worth more than USD 200 million on the platform. The company states that it has access to around 8000 suppliers and more than 400 purchasing entities. In June 2021, Síntese received a capital injection of USD 1.8 million for business expansion. Website: Síntese B2B - For Health(1) (plataformasintese.com)

Health professional associations

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Brazilian Association of Collective Health (ABRASCO)	ABRASCO gathers prominent specialists and researchers in public health in conjunction with government agencies. Several of its participating members are representatives of public institutions and former ministers of health. During the COVID-19 pandemic, it advocated for SUS and recommended testing strategies.
Brazilian Society of Diabetes (SBD)	The Brazilian Society of Diabetes (SBD) is a medical foundation dedicated to people who have diabetes. It promotes periodic awareness campaigns that include advocating for diagnostics. SBD produces technical reference materials and is involved in discussions regarding public policies and protocols for diabetes.
Brazilian Society of Endocrinology and Metabolism (SBEM)	The Brazilian Society of Endocrinology and Metabolism (SBEM) is a recognized stakeholder that includes diabetes as an essential theme in its awareness campaigns.
Brazilian Society of Pneumology and Phthisiology (SBPT)	The Brazilian Society of Pneumology and Phthisiology (SBPT) brings together specialists in pulmonology and physiology. They have launched a portal that contains information about coronaviruses.
REDE-TB	The Brazilian Network for Research in Tuberculosis (REDE-TB) is a non-profit, private NGO that participates in the development of new diagnostic tests and TB control strategies. It is recognized for validating technological innovations before they are commercialized in the country. REDE-TB is very vocal regarding COVID-19 in Brazil and recognizes testing as a critical resource with which to fight the disease.

Industrial associations

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Brazilian Association of Pharmacies and Drugstores (ABRAFARMA)	The Brazilian pharmaceutical retail representative entity Abrafarma (has drugstores that sell COVID-19 and other POCTs among its members. Portal Abrafarma
Brazilian Association for Diagnostic Medicine (ABRAMED)	The Brazilian Association for Diagnostic Medicine (ABRAMED) represents the leading institutions in the diagnostic medicine market and is the most significant sectoral representative. Its members are responsible for 56.4% of the market share for supplementary health tests. Home - Abramed
Brazilian Chamber of Laboratorial Diagnostics (CBDL)	The Brazilian Chamber of Laboratorial Diagnostics (CBDL) is an organization that engages in advocacy to strengthen links within the health value chain. It focuses on the ways and means to improve access to quality IVD products. CBDL has a list of associated companies, which can be found at: Associados | CBDL – Câmara Brasileira de Diagnóstico Laboratorial – CBDL – Câmara Brasileira de Diagnóstico Laboratorial
Brazilian Federation of Hospitals (FBH)	The Brazilian Federation of Hospitals (FBH) was created in 1966 to represent and develop the hospital sector. It brings together more than 6000 hospitals in the country. Home - FBH - Federação Brasileira de Hospitais
National Association of Private Hospitals (ANAHP)	The National Association of Private Hospitals (ANAHP) is an entity that represents the most important private hospitals in the country that are accredited at the level of excellence and has more than 1,300 members. It is an essential stakeholder as it plays a strategic role in the political and institutional arenas, especially regarding topics vital to the system's sustainability. Website: https://www.anahp.com.br
Brazilian Association of Laboratory Information System Developers (LIS Brasil)	The Brazilian Association of Laboratory Information System Developers (LIS Brasil) is a reference group for the information technology industry that works to develop and promote initiatives to strengthen diagnostic medicine. Its associates are responsible for processing more than 60% of all laboratory tests performed in the national territory. https://www.lisbrasil.org.br

Civil society

Stakeholder	Why the stakeholder is relevant in the diagnostics context
National Federation of Diabetes Associations and Entities (FENAD)	The National Federation of Diabetes Associations and Entities (FENAD) is a non-profit organization that coordinates diabetes associations around Brazil to improve patients' quality of life. It develops activities for the early detection of diabetes, guidance, education and prevention of complications. Website: www.fenad.org.br
National Social Mobilization Network (COEP)	The National Social Mobilization Network (COEP) is a network of communities and organizations created in 1993 that brings together 33 public and private organizations to articulate and implement public interest initiatives. Due to its reach and credibility, COEP became a Rio de Janeiro Federal University partner in a Technology and Citizenship laboratory. It has a dedicated webpage to provide coronavirus information, including testing information. Link for the initiative related to diagnostics: https://coepbrasil.org.br/iniciativas-da-sociedade-civil-no-combate-ao-coronavirus/
Brazilian Interdisciplinary AIDS Association (ABIA)	The Brazilian Interdisciplinary HIV Association (ABIA) is an organization that promotes advocacy around monitoring public policies, designing education projects and HIV prevention. Together with ten other civil society organizations, it created the "Testes Para Todxs" – testing for all – campaign to push for the adoption of a broad national policy on diagnostic tests to fight COVID-19. In 2020, the group published a letter for new institutions to adhere to, based on the WHO recommendations for wide-ranging testing. Links for the initiative related to diagnostics: http://bit.ly/testeparatodxs and https://abiaids.org.br/COVID-19-onze-organizacoes-da-sociedade-civil-lancam-carta-de-adesao-por-politica-nacional-de-testagem-para-todos/33915
Articulation of Indigenous Peoples of Brazil (APIB)	The Articulation of Indigenous Peoples of Brazil (APIB) is a national reference body for the indigenous peoples' movement in Brazil. It fights threats and aggressions against indigenous rights, bringing together regional organizations and strengthening indigenous peoples' unification. It has created an emergency plan to fight COVID-19 and advocates for mass testing among the indigenous population. In March 2021, the Federal Court determined "the prioritization of the RT-PCR test, for indigenous peoples, and planning and specific logistics, aimed at this end, using alternative testing if necessary." Despite this Federal Court decision, however, testing of the indigenous population remains deficient. Link for the initiative related to diagnostics: Plano-Indígena-de-Enfrentamento-ao-COVID-19-Versão-final.docx.pdf (apib.info)

International/regional organizations

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Pan American Health Organization (PAHO)	PAHO is the specialized international health agency for the Americas. It works with countries throughout the region to improve and protect people's health. It has supported initiatives from the MoH in response to COVID-19 since the beginning of the pandemic. These initiatives include training in laboratory diagnosis and the purchase of 10 million RT-PCR tests. Link for the initiative related to diagnostics: https://www.paho.org/pt/covid19/apoio-da-opas-ao-brasil-durante-pandemia-COVID-19
Latin American Alliance for the Development of In Vitro Diagnostics (ALADDiV)	The Latin American Alliance for the Development of In Vitro Diagnostics (ALADDiV) is a non-profit organization interested in promoting the convergence of diagnostics-related themes. It was created to design a new model to expedite the adoption of testing policies and to guarantee access to diagnostics for all Latin American countries. https://www.aladdiv.org.br/?lang=en
International Diabetes Federation (IDF)	Initiatives from the International Diabetes Federation (IDF) in relation to diabetes care and prevention often inspire local campaigns in Brazil. https://idf.org/

Distributors

Stakeholder	Why the stakeholder is relevant in the diagnostics context
Brazilian Association of Importers and Distributors of Products for Health (ABRAIDI)	The Brazilian Association of Importers and Distributors of Products for Health (ABRAIDI) was launched in 1992 to represent the interests of healthcare product importers and distributors, in relationships with both government agencies and other entities in the sector. It has around 300 associates and has members on the board of the Brazilian Alliance of Innovative Health Industry (ABIIS). www.abraidi.com.br

Key takeaways:

- Although this list is not exhaustive, the stakeholders identified are some of the key actors involved in diagnostics focused on diabetes and COVID-19. Understanding their general position in the public debate can help in understanding their influence and impact on the healthcare system and policy formulation.

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FINAL CONSIDERATIONS (DIAGNOSTICS IN GENERAL, PLUS DIABETES AND COVID-19)

X
FINAL CONSIDERATIONS
(DIAGNOSTICS IN GENERAL, PLUS DIABETES AND COVID-19)

KEY CHALLENGES

- According to CBDL, the main challenges for the diagnostics market in Brazil are:
  - The reimbursement value for the purchase of reagents sold to the public sector is below market value and has not changed since 1996, with no adjustment for inflation.
  - New technologies take time to be incorporated into SUS or ANS lists. With SUS, the incorporation of requests is continuous, but the entire process takes approximately 120 days, while with ANS it occurs every two years.
  - The market demands increasingly sophisticated equipment but is unwilling to pay for it; thus, the diagnostic products industry must spend more on investments.
  - The market has become more vertical; healthcare operators have their own hospitals and laboratories, giving them an advantage in negotiations.
  - The consolidation of smaller laboratories is likely to reduce/eliminate small- to medium-sized players, leading to a reduction in manufacturers and distributors in the market.
  - Technologically mature products continue to be considered as "commodities" in purchase orders.
  - There are distortions in purchase contract agreements, mainly in the public sector, such as a lack of a guarantee of payment and non-compliance with agreed payment terms. Distortions caused by the "price registration" modality, in which the buyer does not have to guarantee the purchase of the volume stated in their bid, affects suppliers that depend on more accurate sales forecasts to justify the investments required to meet the contract.
- Interviews with three C-Level executives of top-tier private hospitals and laboratories and a government relations and access director from a civil society association revealed that there is a lack of continuity in public health policies, which has been aggravated by the COVID-19 pandemic. As one of them said: *"there is a big challenge within the IVD market, which is to demonstrate 'the value' of each test for each clinical situation; that is what will guide policymakers. The choice of what medical products will be available for the population depends on public policy definitions. It is not a well-resolved issue in Brazil, and we need more studies than we have now"*.
- Additionally, Brazilian decision-makers lack adequate public policy awareness and do not have enough information to understand that diagnostic tools can save future public health expenditure. According to a C-Level executive from a sectoral association: "*some people think about it, but there is no interaction between public health and this type of intelligence*".
- Related to diabetes, the government relations and access director indicated that diagnostics such as antibody titers, which assess rarer forms of disease, are still challenging to obtain in the public health system; they are available, in small quantities, for patients in the supplementary health network and through health insurance organizations.
- The lack of organization of logistics related to IVD tests purchased by the Ministry of Health was also an issue. An example was the approximately seven million COVID-19 tests purchased by the federal government that remained in storage, close to their expiration date, without being distributed to the state level.[53] This situation occurred in 2020 and again in 2021.[54]

KEY OPPORTUNITIES

- One interviewee, a C-Level executive from a top-tier private hospital, declared in relation to IVD test suppliers, "*multinational companies with a presence in Brazil currently control the market. They import inputs and equipment from abroad, nationalize these products, and then sell them in the national market. Because global manufacturers directly import their products, buyers have limited access to small companies abroad. As a result, we don't have access to small manufacturers and startups that might be developing disruptive technologies*". From this interviewee's perspective, the Brazilian market could likely benefit from a marketplace in which local buyers are able to connect with innovative suppliers.

- Society-organized groups (sectoral and patient associations, disease networks and professional alliances, among others) are conducting critical discussions regarding the importance of preventive health measures and the need to expand the adoption of diagnostics. These stakeholders have already identified the country's main challenges and FIND can present itself as an ally in addressing these challenges.

- The number of IVD tests for diabetes used in the country can be increased, as demonstrated by the interviewees' responses.

- The use of IVD tests for COVID-19 needs to be expanded in Brazil due to the arrival of the Delta variant. Representatives of the legislative branch, CONASS and CONASEMS, are currently discussing the need to create a new testing protocol to investigate the prevalence of viral sub-lineages among the Brazilian population.

- There is room to engage with state governments due to recent genomic surveillance initiatives and expansion of testing to identify and control the circulation of new variants of SARS-CoV-2.

- There are opportunities to establish partnerships with the Northeast Consortium. This entity would be able to perform joint purchases and implement integrated public health policies. A network of public universities in the northeast of Brazil is interested in resuming R&D activities. They may be able to consolidate the budgets from each state to build a more robust funding capacity. In the short term, there is great interest in developing business intelligence capacity to guide public policies.

- FIND can support the Articulation of Indigenous Peoples of Brazil (APIB) achieve the Federal Court's goal of prioritizing COVID-19 testing for indigenous people.

RECOMMENDATIONS

- Conduct more research into the IVD test distributors and their outreach into the remote regions of Brazil.
- Start engaging with stakeholders from associations that represent the healthcare industry to identify collaborative opportunities for advocacy and problem-solving.
- Start engaging with associations that represent the private sector, such as private laboratories and private hospitals, to introduce FIND products and identify partnership opportunities.
- Establish connections with civil society groups working on diabetes to identify diagnostic access challenges and patient groups' needs.
- Contribute to national initiatives to strengthen actions to control the COVID-19 epidemic and encourage testing while engaging in ongoing discussions.
- Promote FIND's marketplace among industry associations and private laboratories.
- Establish connections with CONASS and CONASEMS to introduce FIND and identify potential areas for collaboration with the public sector, especially at the state level.
- Establish partnerships with both public and private universities to finance research, support findings and build an evidence base.
- Define a strategy to request the incorporation of new health technology at CONITEC.
- Evaluate technology transfer initiatives.
- Implement a pilot project in which buyers will be able to test, for a period of six months, IVD products purchased from FIND's marketplace:
    - Consider offering the opportunity to an industry association (e.g. ABRAMED), a nongovernmental organization (e.g. Articulation of Indigenous Peoples of Brazil - APIB) or a health professionals' association (e.g. Brazilian Society of Diabetes - SBD).
    - Consider making a public call via a trade outlet, presenting FIND's marketplace, and providing a link for buyers to register on the platform.
    - Define key performance indicators and register the pilot project to collect data and build a business case for the Brazilian market for IVD tests.

FIND

SWOT MATRIX

SWOT MATRIX

STRENGTHS

1. The Brazilian market is highly professionalized but still does not have a B2B marketplace for diagnostics
2. Strong Trade and Professionals Associations are willing to discuss and open to partnerships
3. Organized stakeholders are already advocating towards the importance of diagnostics
4. Any person or institution can request CONITEC's analysis to incorporate new health technologies

WEAKNESSES

1. There is a current lack of national coordination regarding the implementation of health policies (primarily related to Covid-19)
2. National R&D initiatives conducted in Public Universities were harmed by recent public budgets shortage

OPPORTUNITIES

1. Disclosure of science-based studies to Brazilian media and influencers to promote public conversations about preventive medicine and the importance of diagnostics
2. Support stakeholders that are already vocal with cases, data and information
3. Define a Brazilian spokesperson to be FIND's local ambassador

THREATS

1. Highly regulated market regarding prices definition
2. Presidential and State Elections in 2022 may interfere in all public conversations
3. Big pharma players might try to block FIND attempts to approach most relevant laboratories

FIND

APPENDIX

APPENDIX

A. Official databases

Database	Description
ANS Procedures	https://www.ans.gov.br/planos-de-saude-e-operadoras/espaco-do-consumidor/o-que-o-seu-plano-de-saude-deve-cobrir/verificar-cobertura-de-plano-de-saude
Federal Legislation	http://www4.planalto.gov.br/legislacao/
National Health Secretariats Council	https://www.conass.org.br/painelconasscovid19/
Anvisa Power BI	https://consultas.anvisa.gov.br/#/
Health Products Price Panel Anvisa	MICROSOFT POWER BI
Complete list of IVD products submitted to Anvisa for analysis	MICROSOFT POWER BI

B. Tier 1 media references

Database	Description
BBC News Brazil	BBC Brazil is the subsidiary of the BBC in Brazil. As a provider of world news in Portuguese and a news agency, BBC Brazil has physical offices in São Paulo and Rio de Janeiro. https://www.bbc.com/portuguese
UOL	UOL is a Brazilian web content, products and services company. It belongs to the Grupo Folha enterprise. According to Ibope Nielsen Online, UOL is Brazil's largest internet portal, with more than 50 million unique visitors and 6.7 billion page views every month. www.uol.com.br
O Estado de São Paulo	O Estado de S. Paulo, also known as Estadão, is a Brazilian newspaper published in the city of São Paulo since 1875. It is a reference newspaper in Brazil. www.estadao.com.br
Época Negócios	Época Negócios is the business and economy magazine of Grupo Globo, the largest mass media group in Latin America. https://epocanegocios.globo.com/
G1	G1 is a Brazilian news portal maintained by Grupo Globo. www.G1.globo.com

C. Registration requirements for the importation of health products

Database	Description
1. Sanitary permit and operating licence	This is an authorization issued by the Secretary of the Department of Public Health or their duly authorized representative to any person or persons who have met the requirements of the sanitary regulations and are allowed to operate a business establishment. It must follow the procedures established by the Municipality where the business is located. The permit must allow the import, storage and distribution of health and related products. Further details are available after the definition of the Municipality where the business will be established.

Database	Description
2. **Company registration**	Companies that provide products or services that may be regulated, supervised or sanitarily inspected by Anvisa and/or by the State or Municipal bodies must register with Anvisa as a "Private Company". Company registration – available via the website: https://www9.anvisa.gov.br/recadastramento/Login.asp?SID=751149046 User registration and management through the Security System – available via the website: https://www1.anvisa.gov.br/segurancaLogin/execute/startLogin?urlSolicitado=/segurancaWeb/execute/startMenu
3. **Petitioning system**	The Companies Registration System also requests the entry of the company's users responsible for accessing other Anvisa systems. According to the following profiles, these users can be registered: legally responsible person, the responsible person for technology, legal representative and security manager. Anvisa provides a step-by-step guide for registration: https://www.gov.br/anvisa/pt-br/sistemas/cadastros/cadastro-de-empresas/passo-a-passocadastro-de-empresa-2021-01-08.pdf
4. **Operating permit – health products (AFE)**	The Company Operation Authorization (AFE) falls under Anvisa's competence. It allows the operation of companies or establishments by complying with the technical and administrative requirements contained in the RDC n. 16/2014. An AFE is required for companies that carry out activities of storage, distribution, packaging, shipping, export, extraction, manufacture, fractionation, import, production, purification, repackaging, synthesis, transformation and transportation of health products. An interested company must make an AFE request through the Petitioning System: https://www.gov.br/anvisa/pt-br/sistemas/peticionamento A GRU document (*Guia de Recolhimento da União* - official federal payment document) will be generated to pay the Health Surveillance Inspection Fee at the end of the petition process. After payment of the GRU, the interested party must gather all the documentation requested in the RDC n. 16/2014: • Social contract; • CNPJ (Cadastro Nacional de Pessoa Jurídica, equivalent to IEN - Individual Employer Identification Number); • Municipal permit (sanitary permit); • Accounting and tax documents to prove the company's size. Minimum deadline for analysis: 30 days. The AFE will be valid only after its publication in the Federal Official Gazette (DOU), which will prove the company has been registered. Once the AFE has been published, the issuance of the AFE Certificate must be requested through petitioning of the Coordination of Sanitary Surveillance of Ports, Airports, Borders, and Bonded Areas of the State that has granted the AFE. Validity: The AFE is valid for as long as the Operating Permit, so there is no need to renew or apply for a new AFE certificate every year. However, if there are any changes in the company's name or address, a new certificate should be requested. Certificate of Good Distribution and/or Storage Practice (CBPDA) (not mandatory but recommended) 1. **What is the Certificate of Good Distribution and/or Storage Practice (CBPDA)?** The CBPDA is a document issued by Anvisa attesting that a given establishment complies with the good distribution and storage practices required by the legislation in force. 2. **To whom does the CBPDA apply?** The CBPDA applies to companies located in the national territory that store, distribute and import medicines, health products, and pharmaceutical supplies.

Database	Description
	3. Is the CBPDA mandatory for the operation of a company? No. Companies that produce products subject to sanitary surveillance are obliged to comply with Good Practices, following the procedures and practices established in specific Anvisa standards. However, companies do not need to have a CBPDA for their regular operations. The basic documentation required is: • Business operation authorization (AFE), sanitary permit, documentation from the person responsible for technology, state and municipal registration • A request via Anvisa's petition system
5. Product registration with Anvisa	The registration, or market approval, issued by Anvisa is the authorization required for the manufacturing and marketing of a drug in Brazil. After authorization, a product must be registered. Anvisa approves a product for the market by evaluating the legal–administrative and technical–scientific compliance related to a product's efficacy, safety and quality. Anvisa categorizes medical devices into four types: medical devices, materials for health use, orthopaedic implants and in vitro diagnostics. According to Anvisa RDC n. 185/2001, the term "medical devices" covers a wide range of health or medical instruments used directly or indirectly in medicine, dentistry, physical therapy and laboratory practice for diagnostic, rehabilitation, therapeutic, monitoring and aesthetic purposes. According to Anvisa RDC n. 206/2006, "in vitro diagnostic products" are reagents, calibrators, standards, controls, sample containers, materials and instruments used individually or in combination, with their purpose determined by the manufacturer, for the in vitro analysis of samples derived from the human body or of animal origin, exclusively or mainly to provide data for the purposes of diagnosis, monitoring and screening, or to determine the compatibility of potential recipients of blood, tissues and organs. The usual period for registering a product with Anvisa is around 6 to 12 months.
6. RADAR -synchronization with Brazil Federal Tax Authority	Before starting any import or export operation in Brazil, it is necessary to obtain authorization for such activities from the Federal Tax Authority. RADAR is a licence that grants access to the SISCOMEX system (Integrated System of External Commerce) within the Federal Tax Authority.

D. Request of shipping documentation to the exporter

After a commercial agreement has been made between an importer and an exporter, the exporter must provide and issue:

- A commercial invoice, according to the guidelines sent by the Brazilian importer
- A packing list
- A product analysis certificate
- A product quality certificate
- Proof of product sterility for sterile products
- Bill of lading: to be issued by the contracted international cargo agent

Note: It is the exporter's responsibility to check their country's sanitary and customs requirements to obtain an export authorization. Additionally, it is critical and mandatory to pay attention to Brazilian labelling rules and information that must be present in Portuguese on the packaging.

Before shipment, completed documentation (as mentioned above) must be sent to the importer/customs agent for approval. It is not recommended to ship any goods before this approval has been granted.

The expected time to complete this process depends on the exporter and the customs and sanitary clearance rules in the country of origin.

Contract international cargo agent for international freight

The negotiation of Incoterms (international commercial terms) will define the responsibility of who will contract the

international freight. If this is the responsibility of the Brazilian importer, it is recommended that the cargo agent is an AEO company (Authorized Economic Operator Program – OEA certification).

Request authorization for shipment to the customs broker contracted in Brazil

On its own or through its Customs Broker, the importer will be responsible for authorizing the exporter to carry out the shipment. This authorization will occur after analysis of the shipping documents sent by the exporter to the importer/ customs broker to check the need for prior approval from Anvisa.

Estimated time/deadline term: Usually, companies in Brazil authorize shipment within 24 hours after receiving the documentation from the exporter. If the product requires a prior licence fromAnvisa, it usually takes an average of 5 working days for Anvisa to issue this authorization. However, this timeline depends on Anvisa's internal processes, which may take longer in some cases.

Submit import licence registration to the Brazilian government

Once the importer/customs broker has authorized a shipment, the import licence registration procedure must be carried out, and the electronic petition should be prepared for submission to Anvisa, and then payment of the inspection fee must be made.

The health surveillance inspection rate varies according to the number of items to be imported and the classification of the company's size byAnvisa. These amounts range from USD 23.45 to USD 709.16 per import licence; the actual value can only be defined after receipt of the commercial invoice with the number of items to be imported.

The electronic petition and payment of the inspection fee, the product, and the company documentation to be presented to Anvisaare as follows:

- Commercial invoice
- Packing list
- Bill of lading
- Certificate of analysis and warranty
- Sterilization certificate (if required)
- Operating authorization - AFE
- Sanitary permit
- Product registration

Anvisa will analyse all documentation presented and schedule the physical inspection of the material where they will verify/certify:

- Product conditions (e.g. product defects, malfunctions, whether it is temperature-controlled)
- Validity
- Lot number
- Labelling guidelines (compliance)
- If the shipped product corresponds to the imported product registered

Once the goods have been confirmed to conform to Anvisa standards, it will approve the issuance of an import licence.

Estimated time/deadline timeline: The average timeline for analysis and approval of an import licence is approximately five working days from the date of submission. The petition can only be presented once the cargo has arrived at the terminal, where the customs clearance process occurs.

Payment of clearance costs and taxes/ duties to customs

Upon receipt of the shipping documents, the customs agent will request the automatic debit payment, listing the estimated costs of the process. The purpose of the automatic debits request is to inform the importer of the total estimated amount to release the cargo. Federal taxes and State Tax on Goods and Services (ICMS) are paid upon registration of the import declaration, and other expenses are paid as the process moves on.

Usually, payment includes:

- Federal taxes

- ICMS
- Anvisa inspection fee (according to the company's size and number of imported items)
- Cargo agent expenses in Brazil (according to negotiation with the contracted cargo agent)
- AFRMM (Additional Freight for Renewal of the Merchant Marine) tax – modal shipment: maritime transport.
- Customs broker fees (according to negotiation with the contracted customs agent/broker)
- Storage cost (variable value, according to the terminal where the clearance will occur; for estimation purposes only, consider this to be around 1% of the customs value)
- International freight (according to negotiated Incoterms)
- Internal/domestic road transport (departure from the port/airport after customs clearance until arrival at the importer's warehouse)
- Other expenses may be involved, depending on each process.

Calculation of federal taxes plus ICMS

Federal taxes are calculated on a customs value basis of the import operation. The customs value can be obtained according to each situation by a valuation method provided by a customs valuation agreement called the AVA-GATT (Acordo de Valoração Aduaneira). In general, the customs value assigned to imports of common goods can be found from the following values:

- Merchandise value
- The cost of transportation of the imported goods to the customs port or airport of unloading or the customs border point where the formalities for entry into the customs territory must be completed
- Expenses related to loading, unloading and handling associated with the transport of the imported goods, until arrival at the port or airport of destination
- The cost of international insurance of the goods (international insurance is not mandatory, but it is recommended to minimize economic losses)

Example of how taxation is applied in Brazil:

- II (*Imposto de Importação* - import tax) = x% * customs value
- IPI (*Imposto Produtos Industrializados* – federal tax on industrial products) = x% * (customs value + II)
- PIS (*Programa de Integração* Social - Federal social integration programme tax) = x% * customs value
- Cofins (*Contribuição para o Financiamento da Seguridade Social* - Social security financing federal tax) = x% * customs value

ICMS = (customs value + II + IPI + PIS + Cofins + fees + Expenses incurred until customs clearance) / (1 - x%)

To indicate and define tax rates, it is necessary to have the product's fiscal classification (NCM – harmonized system code), which will determine the tax rates for each product. The NCM is established after receiving the technical product specification.

ICMS tax rate is defined by the state where the company is established; some tax benefits may apply. Considering the worst-case scenario, the tax rate for ICMS can be as high as 18%.

Below are the estimated tax rates for selected products:

Material	II%	IPI%	PIS %	COFINS %	ICMS %
Glucometer	14.0	-	2.10	9.65	18.0
Reagent strips for the determination of blood glucose, on strip support, for direct use	2.0	-	2.10	9.65	18.0
Lancets for use in glucometers	-	-	2.10	9.65	18.0
IVD test kits for diabetes	-	-	2.10	9.65	18.0
Test kits for COVID-19, based on polymerase chain reaction (PCR) nucleic acid test	-	-	2.10	9.65	18.0
Test kits for Covid-19, based on immunological reactions	-	-	-	-	18.0

Example of a tax calculation for a glucometer (USD)	
Merchandise value	160
International freight value	24
International insurance value	16
Customs value	200
II = USD 200 x 14%	28
IPI = 0%	0
PIS = USD 200 x 2.10%	4.2
COFINS = USD 200 x 9.65%	19.3

ICMS = 200 + 28 (II) + 0.00 (IPI) + 4.2 (PIS) + 19.3 (COFINS) + 30.85 Expenses (which varies from state to state; in this example we considered only the SISCOMEX rate of 1 addition)

Calculation basis: USD 282.35

Registration of import declaration with full payment of federal taxes plus ICMS (state tax)
After the approval of the import licence and presentation of automatic debit receipts, the import declaration can be registered, and the payment of federal taxes and SISCOMEX can be made.

A SISCOMEX fee is charged for each import declaration registered. This fee varies according to the number of additions (usually separated by NCM – harmonized system code).

The SISCOMEX fee varies from USD 30.85 (one addition or just one type of product) to a limit that is impossible to determine, as the fee varies according to the number of additions. For example, one import declaration could involve:

- Glucometer
- Reagent strips for use in the glucometer
- Lancets
- Reagents for IVD tests for diabetes
- Reagents for IVD tests for COVID-19

In this example, there are five additions, so the value of the SISCOMEX fee would be USD 57.06. If there was only one product, the value would be USD 30.85.

The DI (*Declaração de Importação* - import declaration) and the DUIMP (*Declaração Única de Importação* - single import declaration) are the official documents for the regularization of the entry of imported goods in Brazil and the system through which importing companies pay taxes. Companies can only register the DI or DUIMP with a RADAR licence and if the legal representative (customs agent/broker) is registered for this purpose.

After registering the DI or DUIMP, SISCOMEX selects the registered documents for one of the following customs clearance channels:

- **Green:** automatic merchandise clearance. Documental examination and physical inspection will not be done by RFB (Receita Federal - Brazilian Federal Revenue). The selected DI for the green channel on SISCOMEX may be subjected to a physical or documental examination if RFB identifies any evidence of irregularity.
  - Estimated release/clearance time: up to 24 hours after DI or DUIMP registration

- **Yellow:** documental examination only. If no irregularity is found, customs clearance is carried out with no physical inspection of the goods. In the event of an incomplete description of the merchandise described in the DI, for example, RFB will require a physical examination to confirm if the declared NCM is correct. RFB may require documental examination and physical inspection of the merchandise if there is any evidence of errors or incorrections.
  - Estimated release/clearance time: up to five business days after DI or DUIMP registration

- **Red:** merchandise will only be cleared after documental examination and physical inspection.
  - Estimated release/clearance time: up to eight business days after DI or DUIMP registration

- **Grey:** documental examination, physical inspection and application of a special customs control procedure to identify evidence of fraud, including the declared price of the merchandise.
  - Estimated release time: up to 16 business days after DI or DUIMP registration

Note: The estimated time for customs clearance depends on the flow of each customs department, which may be longer than the times indicated above.

Issuance of Brazilian invoices ("*nota fiscal*")

After RFB have issued the import receipt (CI - a document that proves that goods were released by the Federal Revenue of Brazil – RFB) and the release of the ICMS visa by the Department of Finance of the state where the company is located, it is necessary to proceed with the issuance of the internal Brazilian domestic invoice of entry *Nota Fiscal*). This invoice must be issued following the rules established by the state where the company is located. The number of the import declaration must be included in this document. Once this invoice has been issued, the domestic freight carrier is authorized to collect the products from where the customs clearance was performed. After issuing the domestic invoice of entry and receipt of materials, the fiscal/accounting department of the company must carry out the procedures required by the legislation to regularize their entry into their stock.

Estimated time/deadline time: this depends on the company's tax and accounting department; it usually takes place within 24 hours after the issuance of the import receipt, as this document is mandatory for internal transportation in Brazil.

E – A brief overview of other diseases

The following paragraphs provide some insights beyond the primary focus of this report (COVID-19 and diabetes) that the specialists who were interviewed shared in our conversations.

Dengue and Zika virus disease

Dengue has been an endemic disease in Brazil for more than 27 years. Its vector, the *Aedes* mosquito, is considered by entomologists to be an urban pest that is very difficult to eradicate. A researcher from Universidade de Pernambuco who was interviewed for this study has recently submitted, in collaboration with the Department of Biomedical Sciences at Universidade de São Paulo (USP), a manuscript to the *Journal of Infectious Diseases*, about the development of a diagnostic methodology to serologically differentiate Zika virus and Dengue virus. The Zika and Dengue viruses are closely related; they are both flaviviruses with similar molecular and genetic structures. The objective of the research was to establish an efficient testing methodology to distinguish Dengue from Zika virus infections. In pregnant women infected with Zika virus, the virus can cross the placenta and cause congenital disease, including microcephaly and other skeletal defects. Hence, if a pregnant woman develops a skin rash, it is critical to determine whether she has Dengue or Zika virus infection, as there can be serious consequences from a misdiagnosis.

Tuberculosis (TB)

Some of the equipment used in public facilities to diagnose TB is very expensive. GeneXpert, for instance, provides a rapid result and information about antibiotic resistance but is very costly. GeneXpert also requires a laboratory that is close to a *nível de biossegurança* 3 (NB3) level, which is rare in Brazil, especially in the public health framework. The GeneXpert test increased the detection of TB cases but did not reduce the number of patients or the time-lapse between diagnosis and treatment. Even the Cepheid test, which uses a single module and a battery and thus does not require electricity, must still be maintained, and most signed contracts do not include maintenance.

Brazil is interested in purchasing the Quantiferon-TB Gold, which can detect latent TB infection. It is an expensive test that requires a robust laboratory structure. In Brazil, the effectiveness of Quantiferon, compared with that of Tuberculin test, is questionable and still needs to be assessed for its potential impact.

As well as testing, there are a series of other obstacles to remove. One TB researcher who was interviewed said: "My dream is to have an equipment-free diagnostic, a real point-of-care test that delivers results in less than 2 hours, costs less than USD 4, and is easy to perform." He believes that Brazil can become successful in developing its own technology and innovation, as there is great potential to transform knowledge into products.

Hepatitis

Hepatitis C is an underreported disease, and we do not have a culture of testing for it in Brazil. Some people have said that if we tested the Brazilian population for hepatitis C, the health system would collapse because it would be unable to support treatment demands.

F - Composition of the sub-network of the National Public Health Laboratory System (Sistema Nacional de Laboratórios de Saúde Pública - SISLAB), by definition and competencies

National Network of Public Health Laboratories (SISLAB) Subnets	Definition	Competencies
Collaborating Centers (CC)	Laboratory units specialized and trained in specific areas to develop more complex activities, teaching and research (Art. 9th, PC 4/2017)	I - assist the national manager in monitoring, normalizing, standardizing techniques and evaluating laboratory activities; II - collaborate in the scientific and technological development of the network's units and training of human resources; III - perform high complexity* laboratory procedures for diagnostic complementation and analytical quality control; IV - develop studies, research and teaching; and V - submission of periodic reports to provide the national manager with information regarding laboratory activities
National Reference Laboratories (LRN)	Laboratory units of highly specialized technical excellence (According to art. 10, PC 4/2017)	I - assist the national manager in the monitoring, standardization of techniques and evaluation of laboratory activities; II - technically coordinate the laboratory surveillance network under his/her responsibility; III - perform highly complex laboratory procedures, to complement diagnosis and control the analytical quality of the entire network; IV - develop studies, diagnostics and research, in conjunction with non-profit technical-scientific societies and with research and development centres, which bring together skills and technical training in critical areas of interest; V - promote human resources training in areas of interest for the development of laboratory credibility and reliability, stimulating partnerships with the laboratories that are part of the system and with training centres with specific skills' interest, aiming at improving the quality of laboratory diagnosis; VI – provide national managers with technical and management periodical reports with information on laboratory activities; and VII - participate in national and international exchanges and agreements, aiming to promote the improvement of the system.
Regional Reference Laboratories (LRR)	Laboratory units qualified to develop more complex activities, organized by diseases or programmes, that provide technical-operational support to those units defined for their geographical area of coverage (According to art. 11, PC 4/2017)	I - advise, monitor, and evaluate the laboratory activities performed in the units; II - develop and perform analytical techniques of greater complexity necessary for the laboratory diagnosis of diseases and other health problems, as well as providing technical support to State Reference Laboratories, promoting technical and operational conditions in the execution of actions; III - support laboratory units by carrying out more complex analysis, complementing diagnosis, quality control, human resources training, as well as supervision and technical advice; IV - periodically evaluate, together with the National Reference Laboratory, the performance of state laboratories; V - implement and promote mechanisms for inter- and intra-laboratory quality control; VI - forward inconclusive samples to the National Reference Laboratory, as well as those for the completion of the diagnosis and others destined for analytical quality control; and VII – provide periodic reports with information related to laboratory activities.

National Network of Public Health Laboratories (SISLAB) Subnets	Definition	Competencies
State Reference Laboratories (LRE)	Laboratory units linked to the state health departments, with a geographical area of state coverage	I - coordinate the network of public and private laboratories that carry out public health interest analysis; II - forward inconclusive samples to the Regional Reference Laboratory for diagnostic complementation and analytical quality control; III - perform the analytical quality control of the state network; IV - perform laboratory procedures of greater complexity to complement diagnosis; V – enable, in line with specific legislation, which laboratories will be integrated into the state network; VI - promote the training of the laboratory network human resources, and VII – produce periodic reports to inform national managers about laboratory activities.
Municipal Reference Laboratories (LRM)	Laboratory units linked to the municipal health departments, with a geographic area of municipal scope (According to art. 13, PC 4/2017)	I - define, organize and coordinate the municipal network of laboratories; II - supervise and assist the laboratory network; III - promote human resources training in the laboratory network; and IV - enable the laboratories to be integrated into the municipal network, informing the state manager.
Local Laboratories (LL)	Laboratory units that are part of the state or municipal network of public health laboratories (According to art. 14, PC 4/2017)	I - perform basic and/or essential analysis; II - forward inconclusive samples, and those destined to the analytical quality control, to the respective Municipal or State Reference Laboratory, to complement the diagnosis; and III – submit periodic reports with information of laboratory activities to the Municipal or State Reference Laboratory.
Frontier Laboratories (LF)	Laboratory units located in border regions for the diagnosis of etiologic agents, vectors of communicable diseases, and other public health issues, and promotion of analytical control for sanitary quality of provided services and products (According to art. 15, PC 4/2017)	I - strengthen epidemiological, environmental health and sanitary surveillance regarding laboratory actions in border areas; II - assist in the activities developed by the State Reference Laboratories; and III - collaborate to fulfil the International Agreements in the areas of prevention and control of diseases. Being strategically located, these laboratories must report to the national manager of the specific network and the state manager.

* Laboratory procedures that require Authorization of High Complexity Outpatient Procedures (APAC): CD4/CD8 (lymphocyte count), HIV viral load and HCV quantitative genotyping (hepatitis). All of these are taught by LACENs.

G - Test kits developed and manufactured by official Brazilian Pharmaceutical Laboratories

Product	Official Pharmaceutical Laboratory (LFO)
Antígeno Mitsuda – Prognóstico Hanseníase (Mitsuda Antigen - Leprosy Prognosis)	CPPI
Antígeno de Montenegro – Diagnóstico da Leishmaniose tegumentar americana (Montenegro Antigen – Diagnosis of American Tegumentary Leishmaniasis)	CPPI
Antígeno – Diagnóstico da Paracoccidioidomicose e Esteriteste (Antigen - Diagnosis of Paracoccidioidomycosis and Steritest)	CPPI
Ensaio Sorológico de Leishmaniose Humana (Human Leishmaniasis Serological Assay)	Biomanguinhos
Ensaio Sorológico de Doença de Chagas (Serological Test for Chagas Disease)	Biomanguinhos
Kit Molecular ZDC - Zika, Dengue e Chikungunya (Molecular Kit ZDC (Zika, Dengue and Chikungunya)	Biomanguinhos
Kit NAT HIV/HCV/HBV	Biomanguinhos
Teste Parasitológico – método Kato-Katz (Parasitological Test - Kato-Katz method)	Biomanguinhos

Product	Official Pharmaceutical Laboratory (LFO)
Teste Rápido Febre Amarela NS1 (Yellow Fever Quick Test NS1)	Bahiafarma
Teste Rápido Leishmaniose (Leishmaniasis Quick Test)	Bahiafarma
Teste Rápido Hepatite B (Hepatitis B Rapid Test)	Bahiafarma
Teste Rápido Hepatite C (Hepatitis C Rapid Test)	Bahiafarma
Teste Rápido Febre Amarela IgC/IgM (Yellow Fever IgC/IgM Rapid Test)	Bahiafarma
Teste Rápido HIV (HIV Rapid Test)	Bahiafarma
Teste Rápido Dengue NS1 (Dengue NS1 Rapid Test)	Bahiafarma
Teste Rápido Dengue IgC/IgM (Dengue IgG/IgM Rapid Test)	Bahiafarma
Teste Rápido de Sífilis (Syphilis Rapid Test)	Bahiafarma
Teste Rápido Zika Vírus NS1 (Zika Virus NS1 Quick Test)	Bahiafarma
Teste Rápido Chikungunya IgM (Chikungunya Rapid Test IgM)	Bahiafarma
Teste Rápido DPP® HIV – ½ (DPP® HIV Rapid Test - ½)	Biomanguinhos
Teste Rápido HIV-Sífilis Combo (HIV-Syphilis Combo Rapid Test)	Biomanguinhos
Teste Rápido Imunoblot Rápido DPP (DPP Rapid Immunoblot Rapid Test)	Biomanguinhos
Teste Rápido DPP Sífilis (DPP Syphilis Quick Test)	Biomanguinhos
Teste Rápido DPP Sífilis Duo (DPP Syphilis Duo Quick Test)	Biomanguinhos
Teste Rápido DPP® Leishmaniose Visceral Canina (DPP® Rapid Test Canine Visceral Leishmaniasis)	Biomanguinhos
Teste Rápido Zika IgG/IgM Combo (Zika IgG/IgM Combo Rapid Test)	Bahiafarma
kit de diagnóstico molecular (Molecular diagnostic kit)	Biomanguinhos
Kit Molecular SARS-CoV-2 (EDx) (Molecular Kit SARS-CoV-2 (EDx)	Biomanguinhos
Kit Molecular SARS-CoV-2 (E/RP) (Molecular Kit SARS-CoV-2 (E/RP))	Biomanguinhos
Teste Rápido DPP® COVID-19 (IgM/IgG) (DPP® COVID-19 Rapid Test (IgM/IgG))	Biomanguinhos
Teste Rápido TR COVID-19 (IgM-IgG) (TR COVID-19 Rapid Test (IgM-IgG))	Biomanguinhos
Teste Rápido DPP® COVID-19 AG (DPP® COVID-19 AG Rapid Test)	Biomanguinhos

Source: Anvisa Microsoft Power BI[55]

H - Sanitary requirements for importing health-related products:

The following section explains the importation and registration requirements for diagnostic products in Brazil. If these products are imported, another partner company must be registered for this operation, and this partner company must have authorization to import from third parties. It is recommended to hire a company that specializes in product registration with Anvisa for greater flexibility in the registration process.

Test strips – self-test for the determination of capillary blood glucose:

- Registration with Anvisa.
- Only the importer of the manufacturer can perform the registration.
- The product registration process with Anvisa may take between 6 and 12 months.
- Many documents will be required, depending on each individual product.
- Classified as Class III: products with high risk to the individual and/or medium risk to public health.
- Payment of the Health Surveillance Inspection Fee may vary according to the company's size and request type.
- Requirement of import licence before shipment – procedure 4 Anvisa:
  - Payment of the Health Surveillance Inspection Fee
  - Sanitary and AFE permits
  - Proof of product sterility for sterile products
  - Product registration with Anvisa. If another company has already registered the product, it will be necessary to present a Detaining Letter in which the registration holder will authorize another company to carry out the import

- Shipping documentation (commercial invoice, packing list, quality certificates – according to each product):

  Packaging must include:

  - Description in Portuguese
  - Quantity of strips in each box
  - Indication of which device (glucometer) can be used
  - Expected result time
  - Usage mode
  - Manufacturing date (day/month/year)
  - Validity date (day/month/year)
  - Disposal method
  - Indication whether it is a single-use product
  - Manufacturer and country of origin
  - Registration holder and importer/distributor data
  - A responsible technician with their respective record (CRF, for example)
  - Anvisa registration
  - Lot
  - Model
  - Serial number (when applicable)
  - Customer service
  - It is recommended that the packaging be labelled in Portuguese

Glucose meter kit – glucometer (blood glucose monitoring system):

- Registration with Anvisa
- Only the importer of the manufacturer can perform the registration
- Product registration process with Anvisa may take between 6 and 12 months
- Many documents will be required, depending on each individual product
- Classified as Class III: products with high risk to the individual and/or medium risk to public health
- Payment of the Health Surveillance Inspection Fee may vary according to the company's size and request type
- Requirement of import licence before shipment – procedure 4Anvisa:
  - Payment of the Health Surveillance Inspection Fee
  - Sanitary and AFE permits
  - Product registration with Anvisa. If another company has already registered the product, it will be necessary to present a Detaining Letter in which the registration holder will authorize another company to carry out the import
- Shipping documentation (commercial invoice, packing list, quality certificates – according to each product):

  Packaging must include:

  - Description in Portuguese
  - Usage mode
  - Manufacturing date (day/month/year)
  - Validity date (day/month/year) – if applicable
  - Manufacturer and country of origin
  - Registration holder and importer/distributor data
  - A responsible technician with their respective record (CRF, for example)
  - Anvisa registration
  - Batch
  - Model
  - Serial number (when applicable)
  - Customer service

- It is recommended that the packaging be labelled in Portuguese
- Other usage guidelines must be in Portuguese

Lancet for launchers or auto lancet:

- Registration with Anvisa
- Only the importer of the manufacturer can perform the registration
- The product registration process with Anvisa may take between 6 and 12 months
- Many documents will be required, depending on each individual product
- Classified as Class II: products with medium risk to the individual and/or low risk to public health
- It is recommended to hire a company specialized in product registration with Anvisa for greater flexibility in the registration process
- Payment of the Health Surveillance Inspection Fee may vary according to the company's size and request type
- Requirement of import licence before shipment – procedure 4Anvisa:
  - Payment of the Health Surveillance Inspection Fee
  - Sanitary and AFE permits
  - Proof of product sterility for sterile products
  - Product registration with Anvisa. If another company has already registered the product, it will be necessary to present a Detaining Letter in which the registration holder will authorize another company to carry out the import
- Shipping documentation (commercial invoice, packing list, quality certificates – according to each product):

  Packaging must include:
  - Description in Portuguese
  - Usage mode
  - Manufacturing date (day/month/year)
  - Validity date (day/month/year)
  - Disposal method
  - Indication whether it is a single-use product
  - Manufacturer and country of origin
  - Registration holder and importer/distributor data
  - A responsible technician with their respective record (CRF, for example)
  - Anvisa registration
  - Lot
  - Model
  - Serial number (when applicable)
  - Customer Service
  - It is recommended that the packaging be labelled in Portuguese

In vitro reagents for diabetes diagnosis to be used in fasting, postprandial glucose testing and glycated haemoglobin (HbA1c) laboratory tests:

- Registration with Anvisa
- Only the importer of the manufacturer can perform the registration
- The product registration process with Anvisa may take between 6 and 12 months
- Many several documents will be required, depending on each individual product
- Classified as Class II: products with medium risk to the individual and/or low risk to public health
- It is recommended to hire a company specialized in product registration with Anvisa for greater flexibility in the registration process
- Payment of the Health Surveillance Inspection Fee may vary according to the company size and with the request type

- Requirement of import licence before shipment – procedure 5.5Anvisa:
  - Payment of the Health Surveillance Inspection Fee
  - Sanitary and AFE permits
  - Proof of product sterility for sterile products
  - Product registration with Anvisa. In case the product has already been registered by another company, it will be necessary to present a Detaining Letter Where the registration holder will authorize another company to carry out the import
  - Product analysis certificate issued by the exporter
- Shipping documentation (commercial invoice, packing list, quality certificates – according to each product):

  Packaging must include:
  - Description in Portuguese
  - Usage mode
  - Manufacturing (day/month/year)
  - Validity (day/month/year)
  - Disposal method
  - Form of conservation (if it is necessary to keep at refrigerated temperatures, which temperature etc.)
  - Manufacturer and country of origin
  - Anvisa registration
  - Batch
  - Model/Brand
  - It is recommended that the packaging be labelled in Portuguese.

In vitro diagnostic reagents for the detection of neutralizing antibodies against sars-cov-2 virus (covid-19) in laboratories:

RT-PCR

Serology

Rapid tests (i) antigens; (ii) antibodies

Rapid molecular test

- Registration with Anvisa
- Only the importer of the manufacturer can perform the registration
- The product registration process with Anvisa may take between 6 and 12 months
- Many several documents will be required, depending on each individual product
- Classified as Class II: products with medium risk to the individual and/or low risk to public health
- It is recommended to hire a company specialized in product registration with Anvisa for greater flexibility in the registration process
- Payment of the Health Surveillance Inspection Fee may vary according to the company size and with the request type
- Requirement of import licence before shipment – procedure 5.5Anvisa:
  - Payment of the Health Surveillance Inspection Fee
  - Sanitary and AFE permits
  - Proof of product sterility for sterile products
  - Product registration with Anvisa. In case the product has already been registered by another company, it will be necessary to present a Detaining Letter, where the registration holder will authorize another company to carry out the import
  - Product analysis certificate issued by the exporter
- Shipping documentation (commercial invoice, packing list, quality certificates – according to each product):

  Packaging must include:
  - Description in Portuguese

- Usage mode
- Manufacturing (day/month/year)
- Validity (day/month/year)
- Disposal method
- Form of conservation (if it is necessary to keep at refrigerated temperatures, which temperature etc.)
- Manufacturer and country of origin
- Anvisa registration
- Batch
- Model/Brand
- Customer service
- It is recommended that the packaging be labelled in Portuguese.

I – Grupo Fleury and Hospital Israelita Albert Einstein Suppliers requirements

Grupo Fleury

Grupo Fleury has a Supplier's Manual used to inform suppliers of essential processes and routines, to promote good business relationships between sellers and the Fleury Group. The goal of the manual is to eliminate operating problems caused by a lack of information, guide suppliers about the purchasing department practices, ensure the quality of good supplied and maintain the integrity and transparency of buying processes.

The purchasing department makes all products available through a bidding process, in which the supplier receives a request for quotation/RFP (request for proposal). After a technical/commercial evaluation and completion of negotiations, the supplier will receive from the purchasing department the information that it has won the competition, in the form of a purchase order or a signed contract.

All suppliers must be registered on the Nimbi portal. After the first homologation, the supplier is responsible for keeping their documents updated on the platform.

There are two ways that a supplier can ensure their registration at Grupo Fleury:

A. Directly through the Nimbi website: (1) access the website https://login.nimbi.com.br/ (2) register on the platform (or log in if they are already registered), (3) access the menu *Certifica* and go to *Meus Clientes*, (4) search for Grupo Fleury and request connection.

   The purchasing department will evaluate the supplier and send a form via the Nimbi portal to request the attachment of necessary documents and provide specific information.

B. Through an invitation sent by Grupo Fleury: (1) click on Connect at the invitation, (2) register on the platform (or log in if they are already registered), (3) access the menu *Certifica* and go to *Meus Clientes*, (5) search for Grupo Fleury, fill in the required information and attach any necessary files.

Evaluation process

Grupo Fleury's suppliers are evaluated each quarter through the Supply Chain Relationship Excellence Program (PERC). Among the criteria that PERC considers are the degree of environmental risk and business continuity risk of the supplier.

To evaluate the quality of suppliers, Grupo Fleury uses Service Provider Performance Assessments, Delivery Timeliness, RNC - Non-Compliance Reports and Supplier Assessment Reports. Sellers are also evaluated based on their payment terms to their suppliers, current contracts, and savings.

Grupo Fleury demands that all suppliers accept the General Terms and Conditions for Supply, Anti-Corruption and Sustainability, and Citizenship documentation through the Nimbi portal. These terms address compliance with all laws and regulations relating to the environment, compliance with all legal requirements of occupational safety and medicine, the non-use of child or slave labour, and undertakings not to adopt or support harmful or injurious discrimination practices related to ethnicity, sex, religion, sexual orientation or any other personal characteristic of its professionals. It also mentions all of a supplier's obligations concerning any commercial relationships between the parties.

Albert Einstein (Brazilian Israeli Beneficent Society Albert Einstein - SBIBAE)

To be an SBIBAE supplier, the seller must be up to date with their fiscal responsibilities, comply with the Supplier Registration Policy, and be technically approved, according to the purchasing department's criteria. The supplier registration, approval and qualification process is the responsibility of the Supply and Logistics Department, which analyses the possibility of new partnerships and whether they meet commercial and legal prerequisites.

The documents required for registration vary. When requesting registration, the supplier receives a list of the necessary documents by email. The list includes the CNPJ Card, Federal Debt Clearance Certificate - Social Security (INSS), Clearance Certificate of Municipal and State Debts, FGTS Collection Certificate, Certificate of Good Manufacturing and Storage Practices, Certificates of Technical Responsibility, Sanitary Surveillance License, Company Operating Permit, Term of Acknowledgment of the Ethics Manual http://www.einstein.br/Documentos%20Compartilhados/manual_conduta_etica.pdf, and details of the tax regime, among others.

The approval and qualification of suppliers is the responsibility of the Supply and Logistics Department, which analyzes new partnership alternatives based on commercial and legal requirements. Once the bidder requests registration, the approval process begins, and specific documents are requested. For materials and medications (a category that includes diagnostics), the following documentation will be requested: certifications, payment terms, DIFOT, price, quality indicators, batch, validity, labelling in Portuguese and temperature requirements, among others.

When the Albert Einstein Israeli Beneficent Society receives the documentation from the supplier, an analysis of the materials is carried out. If the documents comply with the legal standards, the approval process begins. If any documents are missing, the supplier will be alerted about the files in question.

All communication regarding new suppliers is carried out via email.

J – Remote and point-of-care testing available at pharmacies

Supplier	Test type
ABBOTT	COVID-19 IgG/IgM COVID-19 Antígeno (Swab Nasofaringe) COVID-19 Antígeno (Swab Nasal)
BD	COVID-19 Antígeno (Swab Nasal)
BIOSYNEX	COVID-19 IgG/IgM
CHEMBIO	COVID-19 Anticorpos Anti-Spike Teste IgM/IgG Anticorpos Anti-Proteína S COVID-19 Antígeno (Swab Nasal) COVID-19 IgG/IgM
ECO	Ácido Úrico Beta-HCG Chikungunya IgG/IgM Covid/Flu A/B Ag COVID-19 Ag (Swab Nasal) Covid Ag Oral Eco Detect (Saliva) COVID-19 Anticorpos Anti-Spike (ECO Teste Ab Plus) COVID-19 IgG/IgM Eco Teste COVID-19 IgA/IgG/IgM Dengue IgG/IgM/NS1 Dímero-D Estreptococos Grupo A Antígeno Glicemia HCV Ab Hemoglobina Glicada A1c Hemoglobina Hb HIV/Sífilis Anticorpos HIV Ab HIV Ab Anti-HIV 1/2/O (HIV 4 Line)

Supplier	Test type
	Hormônio Luteinizante – LH Influenza A/B Antígeno Lactato Malária Antígeno PCR – Proteína C Reativa Perfil Lipídico PSA – Antígeno Prostático Específico Rubéola IgG/IgM Sífilis Anticorpos Toxoplasmose IgG/IgM Vírus Sincicial Respiratório – RSV Antígeno Zika IgG/IgM
EINCOBIO	COVID-19 IgG/IgM
MEDLEVENSOHN	Antígeno Prostático Específico (PSA) Chikungunya Anticorpo IgM Chikungunya IgG/IgM Colesterol Total COVID-19 Anticorpos Anti-Spike (Medteste COVID-19 Anticorpos Anti-Proteína S) COVID-19 Antígeno (Nasofaringe) COVID-19 IgG/IgM Dengue Antígeno NS1 Dengue IgG/IgM Dengue IgG/IgM + NS1 – Combo Dímero-D Glicemia H. pylori Hemoglobina Glicada A1c Hepatite B Hepatite B Antígeno HbSAg Hepatite C HIV HIV/Sífilis Combo Influenza A+B (H1N1) Malária Antígenos Mioglobina Perfil Lipídico PSA Sífilis Anticorpos Zika IgG/IgM
ROCHE	COVID-19 Antígeno (Swab Nasofaringe) COVID-19 IgG/IgM
VYTTRA	COVID-19/Flu A/B Ag COVID-19 Anticorpos Anti-Spike (Smart Test COV nAb) COVID-19 Antígeno (Swab Nasal) COVID-19 IgG/IgM

Source: Abrafarma and Clinicarx

FIND

REFERENCES AND FOOTNOTES

REFERENCES AND FOOTNOTES

1. Brazilian Institute of Geography and Statistics. https://www.ibge.gov.br/ - Accessed on September 2021

2. GDP: Gross Domestic Product; GNI: Gross National Income; PPP: Purchasing Power Parity

3. World Development Indicators - Economy. The World Bank. WDI - Economy (worldbank.org) - Accessed on September 2021

4. The Brazilian Institute of Geography and Statistics. https://www.ibge.gov.br/ Accessed in September 2021

5. Unified Health System (SUS). http://www.planalto.gov.br/ccivil_03/leis/l8080.htm - Accessed on September 2021

6. DECREE No. 7,508 OF JUNE 28, 2011. Brazil Ministry of Health. http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/decreto/d7508.htm -Accessed on September 2021

7. **Tripartite Interagency Commission (CIT):** Negotiation forum and agreement between federal, state and municipal managers regarding the operational aspects of SUS. It comprises representatives from the Ministry of Health (MoH), the National Council of Health Secretaries (CONASS) and the National Council of Municipal Health Secretaries (CONASEMS). **Bipartite Interagency Commission (CIB):** Negotiation forum and agreement between state and municipal managers regarding operational aspects of SUS. It is composed of representatives of the State Councils of Municipal Health Secretaries (COSEMS).

8. Flow of incorporation of technologies in the SUS follows careful steps. Ministry of Health. https://www.gov.br/saude/pt-br/assuntos/noticias/fluxo-de-incorporacao-de-tecnologias-no-sus-segue-etapas-criterio-sas - Accessed on September 2021

9. Flow of incorporation of technologies in the SUS follows careful steps. Ministry of Health. https://www.gov.br/saude/pt-br/assuntos/noticias/fluxo-de-incorporacao-de-tecnologias-no-sus-segue-etapas-criterio-sas - Accessed on September 2021

10. Flow of incorporation of technologies in the SUS follows careful steps. Ministry of Health. https://www.gov.br/saude/pt-br/assuntos/noticias/fluxo-de-incorporacao-de-tecnologias-no-sus-segue-etapas-criterio-sas - Accessed on September 2021

11. RESOLUTION - RDC No. 36, OF AUGUST 26, 2015, Ministry of Health / NATIONAL HEALTH SURVEILLANCE AGENCY / COLLEGIATE BOARD. https://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/32421597/do1-2015-08-27-resolucao-rdc-n-36-de-26-de-agosto-de-2015-32421440 - Accessed in September 2021

12. QR Consulting Relatorio-de-Atividades-COVID-19.pdf

13. Documents will be valid until the expiration date of the registration of the product, except when the registration or sanitary registration is revoked, in which case the certificate will also be invalidated.

14. A foreign manufacturer must have a local subsidiary or commercial representative, which must obtain an operating authorization, a sanitary licence and marketing authorization for each imported product.

15. Anvisa conducts international inspections to verify Good Manufacturing Practice is being observed by companies that manufacture drugs, medical devices, and APIs (active pharmaceutical ingredients) to be imported and marketed in Brazil. A valid GMP certificate is a requirement for Anvisa to issue a market authorization for these products.

16. CMED's Council of Ministers is composed of representatives from the Ministry of Health (MoH), the Ministry of Justice, the Ministry of Finance, the Ministry of Industry, Foreign Trade and Services, and the Cabinet of the President of the Republic. Anvisa is the Council's executive secretariat.

17. The medical devices in the list will be selected gradually and incrementally.

18. The operational structure of CONITEC comprises two bodies: the Plenary and the Executive Secretariat. The Plenary has thirteen members, including representatives from the seven secretariats of the Ministry of Health, Anvisa, ANS, CONASS, CONASEMS, civil society, the Federal Council for Medicine (CFM) and the National Council of Health (CNS).

19. Technology Incorporation Flow in SUS, CONITEC. http://conitec.gov.br/fluxo-de-incorporacao-de-tecnologias-no-sus - Accessed in September 2021

20. National Supplementary Health Agency. https://www.gov.br/ans/pt-br - Accessed in August 2021.

21. The National System of Public Health Laboratories. http://www.castelo.fiocruz.br/vpplr/laboratorio_referencia/portarias/PORTARIA_2031.pdf - Accessed in September 2021

22. PORTARIA GM-MS nº 2031, de 23-09-2004.doc (fiocruz.br)

23. Ministry of Health - Office of the Minister ORDINANCE NO. 264, OF FEBRUARY 17, 2020. https://bvsms.saude.gov.br/bvs/saudelegis/gm/2020/prt0264_19_02_2020.html - Accessed in June 2021

24. DATASUS. http://tabnet.datasus.gov.br/cgi/tabcgi.exe?cnes/cnv/estabbr.def - Accessed in September 2021

25. As explained in the SUS Managers Support Manual, it may not be feasible or advisable to structure laboratories for all municipalities in the country. To serve the population living in small municipalities, with less than 25 000 inhabitants, for example, it may be more advisable to refer them to a laboratory located in another nearby municipality. For this reason, the organization of laboratory networks in several units of the federation requires structured planning, jointly by the municipalities, to guarantee the population's access to services, either by the municipality or in a regionalized manner.

26. SUS Managers Support Manual Organization of the Clinical Laboratory Network. https://bvsms.saude.gov.br/bvs/publicacoes/apoio_sus.pdf - Accessed in September 2021

27. Diagnose to care - Vigilance, Epidemiological and Laboratory Strategy. https://www.gov.br/saude/pt-br/coronavirus/publicacoes-tecnicas/guias-e-planos/diagnosticar-para-cuidar_estrategia-nacional-de-vigilancia-epidemiologica-e-laboratorial_versao-preliminar.pdf - Accessed in September 2021

28. STRATEGY FOR VIGILANCE EPIDEMIOLOGICAL AND LABORATORY. https://www.gov.br/saude/pt-br/coronavirus/publicacoes-tecnicas/guias-e-planos/diagnosticar-para-cuidar_estrategia-nacional-de-vigilancia-epidemiologica-e-laboratorial_versao-preliminar.pdf - Accessed in September 2021

29. Epidemiological data on DM in Brazil - Department of Epidemiology, Economics and Public Health – Brazilian Society of Diabetes - SBD 2018 – 2019 Accessed in August 2021 https://diabetes.org.br/wp-content/uploads/2021/06/SBD-_Dados_Epidemiologicos_do_Diabetes_-_High_Fidelity.pdf

30. According to the regionalization of healthcare services, municipalities with less than 25 000 inhabitants may refer patients or tests to a laboratory located in another municipality, which can be a reference laboratory for nearby municipalities.

31. BRAZIL. Ministry of Health. Strategies for the care of people with chronic diseases: diabetes mellitus. Brasília: Ministry of Health, 2013. (Primary Care Notebooks, n. 36). https://aps.saude.gov.br/biblioteca/visualizar/MTIxMw== - Accessed in September 2021

32. Sao Paulo city health. AMG - Glycemic Self-Monitoring Program. Medicines and Supplies for comprehensive care for people with chronic diseases. https://www.prefeitura.sp.gov.br/cidade/secretarias/saude/programas/index.php?p=6070 - Accessed in June 2021

33. CONASS. Panel COVID-19 Data. https://www.conass.org.br/painelconasscovid19/ - Accessed in September 2021

34. COVID-19 Git Hub Data. https://coronavirusbra1.github.io/ - Accessed in October 2021

35. SCTIE - Secretariat of Science, Technology, Innovation and Strategic Health Inputs. Guidelines for Diagnosis and Treatment of COVID-19. https://portalarquivos.saude.gov.br/images/pdf/2020/May/08/Diretriz-Covid19-v4-07-05.20h05m.pdf - Accessed in October 2021

36. Brazil Agency. https://agenciabrasil.ebc.com.br/saude/noticia/2020-07/saiba-como-fazer-o-teste-diagnostico-de-covid-19-pelo-plano-de-saude - Accessed in October 2021

37. Guidelines for treatment and diagnosis of COVID-19. Ministry of Health. https://saude.rs.gov.br/upload/arquivos/202004/14140600-2-ms-diretrizes-covid-v2-9-4.pdf - Accessed in October 2021

38. Guidelines for treatment and diagnosis of COVID-19. Ministry of Health. https://saude.rs.gov.br/upload/arquivos/202004/14140600-2-ms-diretrizes-covid-v2-9-4.pdf - Accessed in October 2021

39. Insufficient and disorganized tests leave Brazil in the dark to control pandemic. https://noticias.uol.com.br/ultimas-noticias/bbc/2021/05/20/testes-insuficientes-e-desorganizados-deixam-brasil-no-escuro-para-controlar-pandemia.htm?cmpid= - Accessed in July 2021

40. http://abramed.org.br/2230/agora-o-maior-desafio-e-economico/ - Accessed in July 2021Mordor Intelligence - 2021 In-Vitro Diagnostics Market Size, Share & Growth | Industry Trends 2021 to 2026 Accessed in September 2021

41. Mordor Intelligence - 2021 In-Vitro Diagnostics Market Size, Share & Growth | Industry Trends 2021 to 2026 - Accessed in September 2021

42. CBDL | Livro Branco - Accessed in July 2021

43. CBDL | Livro Branco - Accessed in July 2021

44. CBDL | Livro Branco - Accessed in July 2021

45. CBDL | Livro Branco - Accessed in July 2021

46. QR Consulting. Activity-Report-COVID-19.pdf (qrconsulting.com.br) - Accessed in July 2021

47. Covid-19: diagnostic products panel. Anvisa Power BI. https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/covid-19-painel-de-produtos-para-diagnostico - Accessed in June 2021

48. Anvisa Power BI. https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/covid-19-painel-de-produtos-para-diagnostico - Accessed in June 2021

49. Abrafarma (2021). Profile of COVID-19 in Brazil in 2021: results of mass testing in pharmacies.

50. Federal Council of Pharmacy. https://www.cff.org.br/pagina.php?id=801&titulo=Dados 2018 - Last accessed on 2 July 2021

51. Bionexo will open its marketplace to smaller hospitals for free. Estadao Economy and Business. https://economia.estadao.com.br/blogs/coluna-do-broad/bionexo-vai-abrir-gratuitamente-seu-market-place-a-hospitais-menores/ - Last accessed on 2 July 2021

52. Negocios. Software producer for hospitals Bionexo requests registration for IPO. https://epocanegocios.globo.com/Empresa/noticia/2021/03/epoca-negocios-produtora-de-software-para-hospitais-bionexo-pede-registro-para-ipo.html - Last accessed on 2 July 2021

53. Politico. Brazil has 6.8 million Covid-19 tests about to expire on deposit. Brasil tem 6,8 milhões de testes de COVID-19 prestes a vencer em depósito, diz jornal | Política | G1 (globo.com) - Accessed in September 2021

54. More than 2 million Covid tests are stopped in the Ministry of Health's shed in SP. Globo G1 Welfare. https://g1.globo.com/bemestar/coronavirus/noticia/2021/04/23/mais-de-2-milhoes-de-testes-de-covid-estao-parados-em-galpao-do-ministerio-da-saude-em-em-cumbica.ghtml - Accessed in September 2021

55. Anvisa Power BI. https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/covid-19-painel-de-produtos-para-diagnostico - Accessed in June 2021

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