

Request for Information

from in vitro diagnostics manufacturers regarding multi-parameter point-of-care instruments for the detection of cardiometabolic markers in primary care settings

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FIND | Campus Biotech | Chemin des Mines 9 | 1202 Geneva, Switzerland T: +41 (0)22 710 05 90 | F: +41 (0)22 710 05 99 | www.finddx.org In collaboration with the World Health Organization (WHO), FIND is developing a technology landscape of available or in development in vitro diagnostic (IVD) instruments or tools for integrated multi-parameter detection of cardiometabolic markers which can identify people at high risk of cardiovascular disease and diabetes.

Background

Each year, over 40 million people die from noncommunicable diseases (NCDs) worldwide. Even though all age groups, regions and countries are affected by NCDs, 15 million of the total number deaths occur in people between 30 and 69 years of age. Over 85% (32 million) of these 'premature' deaths occur in low- and middle-income countries (LMICs). The WHO has prioritized four NCDs in its *Global action plan for the prevention and control of NCDs 2013-2020*: cardiovascular disease (CVD); diabetes; cancers; and chronic respiratory diseases (CRD). Cardiovascular diseases account for most NCD deaths, or 17.9 million people annually, followed by cancers (9.0 million), respiratory diseases (3.9 million), and diabetes (1.6 million) (<u>WHO key facts on NCDs</u>).

A crucial component of any health system is the capacity to screen, diagnose and monitor individuals with a given condition. For many NCDs, diagnostic tools are lacking within health systems in LMICs. Addressing the problem of access to and availability of tools to rapidly and correctly diagnose and monitor NCDs has wide development implications, with related impact on improving attainability of treatment regimens.

Innovation is needed to drive increased access to improved disease management, especially for vulnerable populations.

Several IVD manufacturers have developed solutions to address the need for comprehensive, integrated responses to cardiometabolic disease diagnosis and monitoring, and LMICs are increasingly looking to adopt them. However, since the available parameters and operational characteristics of the instruments vary, it is difficult for countries to decide which option best meets their needs.

Aim

The WHO and FIND aim to develop a technology landscape of multi-parameter point-of-care instruments for the detection of a range of cardiometabolic markers to support countries in their choice of fit-for-purpose technologies for diagnosis and monitoring of cardiometabolic diseases.

Call for information

With this call for information, we would like to hear from IVD manufacturers who have developed, or are currently developing, a multi-parameter cardiometabolic instrument that can be:

- used at the point-of-care in primary healthcare settings;
- handheld or operated as a small benchtop instrument.

Diagnostics tests to be covered include those that would routinely be used as part of a cardiometabolic panel to diagnose and monitor:

- Hypertension, hyperlipidaemia
- Diabetes
- Renal impairment
- Liver function

Point-of-care instruments for a cardiometabolic panel may include any of the following parameters (as single tests or combined in test cassettes):

Priority parameters

Lipoprotein (total cholesterol, LDL, HDL, triglycerides)

Plasma glucose

Haemoglobin A1c

Serum creatinine

Further parameters

Glycated albumin

Urine test: microalbuminuria, urine creatinine, urine ACR, ketones, glucose

Liver function and other tests: ALT, AST, ALP, GGT, Albumin, Bilirubin, Sodium,

Potassium, creatinine kinase, haemoglobin, haematocrit, troponin, blood gases

+ Other tests that might be available on a particular instrument

Information to submit

- 1. Operational characteristics
 - Evidence that the instrument can be used at the point-of-care in primary healthcare settings; e.g. instrument dimensions, power requirements, key features, robustness
 - Number of parameters that can be run on the instrument (NB: instruments should not be single parameter instruments such as glucose meters)
- 2. Parameters
 - A list of available or in development parameters that can be run on the instrument (with regulatory status if available)
 - Indication of test format, i.e., single test or multi-test cassettes/cartridges
 - Test matrices per parameter: serum/plasma/whole blood/urine

Please include anticipated timelines for in development instrument and parameters

- 3. Company information
 - Name of contact person
 - Company headquarter address

• Link to company website (if available)

Please submit your information to: info@finddx.org

Based on the submitted information, we will contact you for a more detailed review of the instrument and parameter characteristics. We will also inform you, should your submitted solution not currently meet the requirements of an integrated multi-parameter solution for cardiometabolic markers at the point-of-care.

Timelines

Please submit information by **10 August 2019**.

Should your company have a representation at <u>AACC 2019</u> (which is being held between 4-8 August 2019 in Anaheim, CA, USA) please let us know as soon as possible and we will evaluate the possibility for a face-to-face meeting.

About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control, and prevention. To learn more, visit www.finddx.org