

Call for Expression of Interest (EOI) from low-and-middle-income countries to procure blood glucose meters, test strips and lancets

BACKGROUND

FIND is the **Foundation for Innovative New Diagnostics**. We are a global non-profit organization driving innovation in the development and delivery of diagnostic tests to combat major diseases affecting the world's poorest populations. Diagnostics often do not exist, are inaccessible, or cost too much. They remain under-resourced and overlooked, despite being pivotal for guiding the best treatment for patients, preventing the spread of disease, and enhancing surveillance for early disease detection, screening and monitoring.

With the rise of diabetes and cardiovascular diseases, an increasing number of low- and middle-income countries (LMICs) are experiencing a double burden of infectious and noncommunicable diseases (NCDs). This puts tremendous strain on patients and healthcare systems, which is tragically highlighted by the ongoing COVID-19 pandemic and the increased morbidity and mortality of infected patients with NCD comorbidities. FIND is advocating for access to testing capacities that address risk factors, notably diabetes, by actively working on market interventions to drive equitable access for LMICs.

FIND is working with public and private partners to shape the diagnostic market ecosystem through providing market intelligence, preferential pricing, global roll out plans, technical and quality guidance for buyers, as well as setting up terms and conditions for product supply and support with buyers and suppliers.

Many LMICs have fragmented procurement systems, leaving each buyer (public and private) to negotiate prices with suppliers individually, resulting in uncontrolled end user prices. Buyers may only have the need for low volumes or lack knowhow and capacity, not allowing them to achieve reasonable prices of high-quality products with suppliers. FIND aims to aggregate demand across buyers to streamline and pool procurement of high-quality blood glucose monitoring commodities at preferential prices to address these challenges.

Commercial suppliers interested in participating in pooled procurement at affordable prices were identified through our recent Call to commercial suppliers of blood glucose meters, test strips and lancets (now closed).

FIND aims to obtain an understanding of LMIC <u>volume needs</u> for blood glucose meters, test strip and lancets and the interest of public and private buyers.

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OBJECTIVES

The objectives of this Expression of Interest (EOI) are to:

- 1. Identify buyers from **governments**, and the public and private sectors who would be interested to buy pre-selected high-quality blood glucose meters, test strips and lancets at preferential prices
- 2. Obtain an indication of product volumes and cycles of procurement (for example: where relevant private/public tender start dates and duration)
- 3. Understand additional requirements that buyers have, as well as evaluate interest in other blood glucose monitoring products

WHO CAN RESPOND TO THIS EOI?

Any public or private organization, institution or entity who buys (procures) blood glucose meters, test strips and lancets (for example: government departments, healthcare institutions, wholesalers, distributors, retail pharmacies).

BENEFITS

FIND is entering into discussions with suppliers of blood glucose meters, test strips and lancets, who have expressed interest in offering their products for pooled procurement. The aim is to secure sustainable access to pre-selected high quality, affordable blood glucose monitoring (BGM) products.

Participating buyers in pooled procurement would benefit from the following:

- BGM products approved by a stringent regulatory authority (for example: CE-IVD)
- BGM products meet EN ISO 15197:2015 accuracy criteria
- Preferential product prices
- Established product supply in country
- Customer support services and training materials available for patients and healthcare providers (maintenance, technical support, product training)
- Further technical requirements as outlined in Appendix 1

TIMELINES

It is anticipated that products will be available for procurement in Q3/Q4 of 2021.

CONDITIONS

Note that FIND does not provide procurement funds or purchases any products. Country buyers would use their regular financing mechanisms to purchase products. FIND's role will be in the facilitation of consolidating demand for procurement of the products at FIND pre-negotiated prices.

Responding to the EOI is neither a contract or a commitment between FIND and the responder.

EXPRESSION OF INTEREST DEADLINE AND DOCUMENTATION

Buyers who would like to express their interest in procurement of the pre-selected high-quality BGM products at pre-negotiated prices are requested to confirm their interest by completing the EOI <u>Data input</u> and returning the form to <u>NCDs@finddx.org</u> by **7 September 2020**.

Where submitters consider there is information that needs to remain confidential, FIND can provide its standard mutual Non-disclosure Agreement for execution.

FOR QUESTIONS AND SUBMISSIONS, CONTACT: NCDs@finddx.org

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APPENDIX 1: TECHNICAL SPECIFICATIONS FOR BLOOD GLUCOSE METERS, TEST STRIPS, LANCETS

General Category	Feature	Specifications
GMDN Meter: 30854 GMDN Test strips: 53302	Intended use	For quantitative determination of blood glucose levels
	Intended user	Patients (self-monitoring) and healthcare providers
Performance characteristics	System accuracy	Meets the requirements of EN ISO 15197:2015 accuracy criteria
	Sample type	Capillary (finger and other sites, e.g. palm, arm), venous and arterial whole blood
	Measuring range	20 - 600 mg/dl or 1,1 - 33,3 mmol/L
	Haematocrit range	30 - 55%
	Sampling volume	Less than 2 μl
	Measuring time	Less than 15 seconds
Test strip storage and handling	Storage temperature test strips	4–30°C
	Storage humidity test strips	10–90%
	Operating temperature range	8–45°C
	Operating humidity test strips	10–90%
	Shelf life of test strips once available in market	Unopened at least 12 months
Meter technical specifications	Memory capacity of the meter	At least 150 tests
	Coding of the meter	No coding
	Language options	Multiple languages (e.g. English, French, Spanish)
	Unit of measure	mg/dl and mmol/L; both available, separate meters
	Operating temperature range	8–45°C
	User defined target range settings	Potentially available*
	Pre-set meter settings date and time	Potentially available*
	User care	Can be cleaned with non-corrosive wipes, e.g. isopropyl alcohol 70%
	Meter blue tooth connectivity	Potentially available*
	Meter connection to PC via cable	Available
	Accessories included with meter kit	Spare battery(s), user manual, cable for connection to PC, lancing device and lancet samples (for home-use product configurations)
Lancing device & lancets	Lancet gauge	23–28G
	Lancing device	Available free of charge with the meter kit
	Lancing device depth settings	More than one depth setting available
	Shelf life of lancets once available in market	At least 12 months
Other features	Digital integration with applications	Potentially available*
	Software solution/platform to provide decision support	Potentially available*
	Ketone testing available on the meter (different ketone strips)	Potentially available*
Price benchmarks**	Test strips	USD 0,06–0,12 per test strip
	Blood glucose meters	USD <15.00/meter
	Lancets***	USD 0,01–0,03 per lancet
	Lancing device	Included with meter kit

GMDN: Global medical device nomenclature

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^{*}Potentially available: indicates that not all products have this feature

^{**} Prices are subject to final agreements with manufacturers; prices refer to landed-in-country (final Incoterms are to be determined)

^{***}Lancet types will vary, either for use with the lancing device or as individual lancets without lancing device