# Call for Partners
for
# Supply of point-of-care glycated hemoglobin (HbA1c) analysers and tests for low- and middle-income countries via the FIND DxConnect Marketplace

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## About FIND

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and save US$1 billion in healthcare costs to patients and health systems. We are co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, visit www.finddx.org.

## 1. Background

With the growing prevalence of diabetes and cardiovascular diseases, an increasing number of low- and middle-income countries (LMICs) are experiencing the double burden of infectious and non-communicable diseases, putting tremendous financial strain on healthcare systems and patients.

According to the World Health Organization, uncontrolled diabetes presents a serious risk to achieving the UN Sustainable Development Goal target 3.4, namely, to reduce premature mortality from NCDs by one-third [1]. A 2019 analysis of health system performance for diabetes in 28 LMICs showed that only 22.8% of people with diagnosed diabetes achieved control [2].

Glycated haemoglobin (HbA1c) testing plays a key role in the management of diabetes by providing information on a person's glycaemic control and risks of developing long-term complications. HbA1c values represent average glycaemic control over the past 2–3 months and regular HbA1c testing is recommended for all people living with diabetes [3]. The WHO 3rd edition of the Essential Diagnostics List recommends the availability of HbA1c testing in community settings and health facilities without laboratories to diagnose and monitor diabetes [4].

Access to and affordability of HbA1c testing in LMICs is limited. A review of 15 countries reported that HbA1c testing was not available at all in two countries and free in only one country. In 12 countries it required a co-payment, with 90% of families needing assistance with the cost [5]. In countries with HbA1c capacity, most testing is done in higher level hospitals or referral centres using laboratory-based analysers [6]. People with diabetes from remote rural areas have to travel extensive distances for HbA1c tests and therefore frequently skip them.

Point-of-care (POC) analysers mean that HbA1c testing can be carried out more easily for people with diabetes, regardless of the size of the healthcare facility in which they are receiving care. POC HbA1c testing has the potential to improve clinical outcomes and facilitates patient education and motivation [7,8]. It can also deliver cost and time savings for healthcare professionals and patients [9].

Despite these benefits, HbA1c POC testing is often not routinely implemented, and the high costs of tests and analysers are a considerable barrier to implementation.

Many LMICs have fragmented procurement systems for medical products, leaving each buyer (whether public or private) to negotiate with suppliers individually, often resulting in high end-user test prices.

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## 3. Objective of the partnership

FIND aims to partner with diagnostic manufacturers to support the procurement process by providing buyers in LMICs access to pre-negotiated product prices and supporting the liaison between buyers and suppliers to streamline demand.

Building on its work in bringing together buyers and suppliers of blood glucose test strips and meters, FIND is now seeking to do the same for buyers and suppliers of POC HbA1c analysers

FIND is looking to partner with manufacturers who are interested in:

a) supplying high-quality, easy-to-use POC HbA1c analysers and test cartridges/reagents appropriate for use in primary LMIC healthcare facilities;

b) offering all items at price points in line with LMIC requirements;

c) offering a comprehensive package to buyers comprising customer service, technical support, product training, and post-market surveillance.

FIND aims to enter into long-term agreements with manufacturers on product pricing and support to ensure consistent and sustainable supply of the products to LMIC buyers. Products will be listed in the FIND DxConnect Marketplace for access to approved buyers (see point 4.3 below).

## 4. Volumes, demand and the FIND DxConnect Marketplace

### 4.1 HbA1c volumes

FIND has modelled the total number of HbA1c tests forecasted to be needed in nine LMICs and estimates the need to be a minimum of 228 million HbA1c tests over 5 years across the estimated > 110 million people diagnosed and treated for diabetes[1] (see table 1). This reflects laboratory and point-of-care testing needs and while it is not possible to forecast how many tests will be needed at POC, the large total number needed indicates a growing opportunity for POC HbA1c testing. In 2020, market demand for POC HbA1c tests in India and South Africa was estimated to be around 1.3 million and 0.2 million tests, respectively[2].

Table 1: Needs forecast split across the public and private/out-of-pocket markets.

| | Public Market (thousands of tests) | | | | |
|---|---|---|---|---|---|
| '000 | 2021 | 2022 | 2023 | 2024 | 2025 |
| Bangladesh | 459 | 519 | 586 | 662 | 747 |
| Brazil | 5,184 | 5,858 | 6,618 | 7,478 | 8,450 |
| Ethiopia | 381 | 439 | 505 | 580 | 667 |
| India | 7,572 | 8,548 | 9,649 | 10,893 | 12,297 |
| Peru | 844 | 965 | 1,104 | 1,263 | 1,444 |
| Senegal | 23 | 26 | 30 | 34 | 38 |
| South Africa | 1,528 | 1,729 | 1,957 | 2,214 | 2,507 |
| Tanzania | 197 | 225 | 256 | 293 | 335 |
| Uganda | 57 | 66 | 76 | 88 | 101 |
| **Total need forecast** | **16,244** | **18,374** | **20,780** | **23,505** | **26,587** |

| | Private Market (thousands of tests) | | | | |
|---|---|---|---|---|---|
| '000 | 2021 | 2022 | 2023 | 2024 | 2025 |
| Bangladesh | 2,603 | 2,941 | 3,320 | 3,750 | 4,235 |
| Brazil | 1,296 | 1,464 | 1,654 | 1,870 | 2,112 |
| Ethiopia | 224 | 258 | 296 | 341 | 392 |
| India | 14,062 | 15,874 | 17,920 | 20,230 | 22,838 |
| Peru | 328 | 375 | 429 | 491 | 562 |
| Senegal | 24 | 28 | 32 | 36 | 42 |
| South Africa | 291 | 329 | 373 | 422 | 477 |
| Tanzania | 55 | 63 | 72 | 83 | 95 |
| Uganda | 38 | 44 | 50 | 58 | 67 |
| **Total need forecast** | **18,921** | **21,377** | **24,148** | **27,281** | **30,819** |

Source: FIND market model, IQVIA, IDF Atlas 2019

[1] Based on a minimum of two HbA1c tests per annum

[2] Maia Research, Absolute Reports 2021

### 4.2 Demand for POC HbA1c testing from FIND's current partners/buyers

Several of the current buyers of blood glucose monitoring supplies available through FIND have expressed interest in procuring POC HbA1c testing solutions in addition to glucose test strips and meters. Their presence is across different LMICs. They are convinced of the benefits of POC HbA1c testing and have plans to increase access if manufacturers can offer quality, affordable products.

### 4.3 DxConnect Marketplace

The FIND DxConnect Marketplace aims to drive access to quality diagnostics where there is a clear market gap, especially in LMICs. It draws on FIND's technology scouting and market intelligence expertise to target key product categories, identify manufacturers, and support negotiating terms for pricing and services where needed.

The DxConnect Marketplace will enable buyers in LMICs who may not have access to tests through traditional procurement channels to connect to manufacturers directly through a secure digital platform. The DxConnect Marketplace will play an active role in shaping a healthy diagnostic market to enhance LMIC access to quality diagnostics. Particular levers include:

- Access to quality diagnostics.
- Innovation: early market access for new tests in key priority segments.
- Aggregation of demand across buyers, in both the private and public sectors, supporting more efficient product delivery.
- Reliability: background checks for buyers and sellers, long-term agreements (LTAs) and governance of trades.

## 5. Eligibility criteria for responding to this Call for partners

FIND aims to identify 3–5 manufacturers interested in entering into a long-term agreement with FIND to supply **POC HbA1c analysers** via the DxConnect Marketplace. Products will need to meet the following criteria:

- **Stringent regulatory approval [SRA**], preferably FDA approval or CE certification.
- **International Federation of Clinical Chemistry [IFCC]** and/ or **National Glycohemoglobin Standardization Program (NGSP)** certification.
- The analyser is a **point-of-care device**, which means it can be performed where the patient is receiving care, carried out by a health professional, and giving results within minutes.
- Sample type: Needs to accept **capillary whole blood.**
- **Reagents**: No bulk reagents required; all liquids (including water) should be available in a self-contained test kit.
- **Product supply** in **low- and middle-income countries.**

Through customer and end-user research by FIND, it is apparent that POC devices which **offer other test parameters** in addition to HbA1c are beneficial. Therefore, even though the main focus is the HbA1c test, FIND would also be interested in reviewing submissions for POC instruments with multi-parameter testing capabilities, in addition to HbA1c, so long as they align with the minimum eligibility criteria described above.

All **proposals submitted in response to this Call for partners** will go through a **predefined selection process,** as explained in **section 7 and Appendix II.**

## 6. Proposal content and submission

The expected proposal content is outlined in Appendix I. Ahead of submission, clarifying questions may sent by email to NCDs@finddx.org. FIND will respond via email to any request submitted no later than five working days *before* the final submission deadline. A list of questions and responses will also be made available on the FIND website.

The submission deadline for the proposal is 4 **October 2021** at **23:59 CEST.**

Your proposal is to be submitted via FIND's Technology Scouting Submission Webform. Select "NCDs" as Disease Area and "Diabetes" as Disease Area Subtype on the form. Would you please upload your completed submission spreadsheet, PowerPoint presentation and additional materials as outlined in Appendix I. The submission spreadsheet can be downloaded from the submission portal.

FIND considers any proposal received as confidential. If required, FIND can sign a confidential disclosure agreement (CDA) with interested manufacturers before proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. The review of proposals will be carried out by a team comprising internal FIND authorities and independent external experts. External reviewers are under confidentiality agreements and are recused if found to have a potential conflict of interest. Any specific questions concerning confidentiality should be addressed to FIND.

## 7. Supplier selection process

The selection of proposals received in response to this Call will be based on key selection criteria laid out in Appendix II.
Proposals will be assessed, and partners selected through a systematic process designed to be objective, independent, and transparent to ensure that the most suitable manufacturers are selected, and potential conflicts of interest avoided.

- The evaluation of proposals will be conducted over a 4-week period following the close of the Call. Submissions will be assessed by a **minimum of two internal and two external** reviewers.
- **Up to five proposals** will be shortlisted: shortlisted applicants will be notified by 9 November 2021 and invited to **participate in a teleconference** with the internal and external review panel.
- The shortlisted products will undergo a **performance evaluation** based on the **CLSI EP-15** protocol at the **European Reference Laboratory for Glycohemoglobin (ERL)** Clinical Chemistry Department, Zwolle, The Netherlands**.** Manufacturers would need to provide **one instrument and 100 tests** free of charge and ensure they are delivered to the institute. FIND would cover the costs of the evaluation (but not the instrument and tests). The **results will not be published** and are only **used in the context of the proposal evaluation**. FIND will provide each manufacturer with the results for their respective analyser and a statement on result interpretation. Only products that **meet the acceptance criteria** in the evaluation will be **considered for long-term agreements with FIND.**

- A decision to enter into negotiations for long-term agreements will be made and communicated to applicants **no later than 13 December 2021***.

## 8. Timeline summary

| Date | Process step | Location / Contact |
|---|---|---|
| 3 September 2021 | Publication of Call for Proposals | FIND website |
| 20 September 2021 (23:59 CEST) | Deadline to submit questions | NCDs@finddx.org |
| 4 October 2021 (23:59 CEST) | Deadline for proposal submission | Submission spreadsheet and PowerPoint presentation uploaded to https://www.finddx.org/technology-review/webform/<br><br>Additional supporting documentation and links to NCDs@finddx.org |
| 5 November 2021 | End of proposal evaluation period | |
| 9 November 2021 | Notification of shortlisted manufacturers | Via individual email correspondence |
| 9–30 November | Meetings with shortlisted manufacturers<br><br>Performance evaluations | Online meetings<br><br>The European Reference Laboratory for Glycohemoglobin (ERL), location Isala, Clinical Chemistry Department, Zwolle, The Netherlands |
| 13 December 2021 | Notifications of selected candidates for long-term agreement negotiations* | Via individual email correspondence |

*Manufacturers not shortlisted or selected for long-term agreement negotiations will also be notified at the same time.
Note: Timelines may be subject to change and changes will be communicated accordingly.

## Appendix I: Expected proposal content

**Proposal submissions shall include the following important information and documentation:**

1. Submission spreadsheet (in Excel) containing the information requested in the ***Eligibility check, Technical and non-technical considerations, LMIC coverage, and Pricing worksheets***
2. A **PowerPoint presentation** that includes the following:
    - Introduction about the organization, including a brief history, corporate focus/mission, length of time active in diagnostics and / or diabetes care medical devices
    - Introduction to the product, evolution of the product since launch; include images and description of sample collection and cartridge loading process
    - Sales volume evolution globally and within LMIC's countries over the last two years (2020−2021)
    - Legal entity and corporate governance structure
    - Management structure
    - Biographies of the leadership team and senior management who will be directly responsible for the implementation of the partnership
    - Any current and past corporate social responsibility activities for diabetes supplies or other diagnostic devices in LMICs
    - List of any other diabetes-related diagnostics solutions provided by the organization, e.g.: blood glucose meters, continuous glucose monitors, etc.
    - Links to online product demonstration videos and peer-reviewed publications on the products, where available
3. **Additional materials to be provided:**

*Please note: These materials are to be sent as attachments to NCDs@finddx.org. The Excel and PowerPoint templates can be uploaded to the* **Technology Scouting Submission Webform.**

- A copy of the Instructions for Use (IFU) and User/Product Manual for the proposed product/s
- A copy of the latest NGSP and/IFCC certification (*preferred format .PDF certificate*)
- Proof of stringent regulatory authority approval (*preferred format .PDF certificate*)
- Examples of training resources available

## Appendix II: Assessment criteria

| Criterion | Description |
|---|---|
| Product quality and technical* specifications | Regulatory status; IFCC and/ NGSP certification & technical requirements |
| Product price | Unit pricing for tests/cartridges; analysers and control solution |
| Current coverage | List of LMIC countries where the product is registered and/or available for sale and/or has realised sales in 2020–2021 |
| Test procedure & training requirements | Time to result; training time |
| POC device & availability of other test parameters | Analyser meets the requirements for a point-of-care device.<br>Availability of other tests available on the same analyser. |
| Suitability for use in LMICs | Reagent shelf-life; reagent storage temperature; operating temperature; operating humidity |
| Customer support & maintenance | Educational and training support for healthcare providers; provision of in-country customer support and technical assistance |
| Company setup | Company strength and experience in the diabetes care business |

*Technical requirements are based on the WHO's preferred product profile for HbA1c tests [10, 11] as well as the target product profile for cardiometabolic point-of-care devices [12].

# Appendix III: Evaluation matrix

## First round eligibility assessment:

| FIRST ROUND - ELIGIBILITY ASSESSMENT | | | |
|---|---|---|---|
| | **Criterion** | **Description** | **Scoring Guideline** |
| **Eligibility** | Target parameter | Analyzer is designed to test for HbA1c<br>(**Q1**) | 0 = no<br>1 = yes |
| | Regulatory status | SRA approval has been obtained (list of SRAs is http://www.stoptb.org/assets/documents/gdf/drugsupply/list_of_countries_sra.pdf). Certificate(s) provided.<br>(**Q2**, **Q9** and supporting documentation - SRA certificate) | 0 = no evidence of SRA approval<br>1 = evidence of one or more SRA approvals |
| | IFCC and/or NGSP certification | IFCC and/or NGSP certification has been achieved. Certificate provided.<br>(**Q3**, **Q4** and supporting documentation - IFCC or NGSP certificate) | 0 = evidence of NEITHER IFCC certification NOR evidence of NGSP certification is available<br>1 = evidence of EITHER IFCC OR NGSP certification OR both is available |
| | End-user profile | End-user profile is not limited to trained laboratory professionals<br>(**Q5**) | 0 = end-use profile is limited to trained lab staff<br>1 = end-user profile includes general healthcare staff (and possibly lay-users) |
| | Sample type | Analyzer accepts capillary whole blood as a sample type for HbA1c testing<br>(**Q6**) | 0 = analyzer does not accept capillary whole blood<br>1 = analyzer accepts capillary whole blood |
| | Bulk reagents | The HbA1c test does not make use of bulk reagents (defined as any larger volume of reagent that requires measuring out by the user)<br>(**Q7**) | 0 = bulk reagents are required<br>1 = no bulk reagents are required |
| | Distribution in LMICs | In at least one low or middle-income country (https://data.worldbank.org/country/XO), the analyzer is registered with the relevant regulatory authority and there is a distributor agreement in place<br>(**Q8**) | 0 = There is no country in which the analyzer is registered AND in which there a distributor agreement in place<br>1 = There is at least one country in which the analyzer is BOTH registered AND in which there is a distributor agreement in place |

## Second round: Technical

| SECOND ROUND - TECHNICAL CONSIDERATIONS | | | |
|---|---|---|---|
| | **Criterion** | **Description** | **Scoring Guideline** |
| **HbA1c tests - additional details** | **Measurement range** | 4-15% (DCCT) or 20-140 mmol/mol (SI)<br>(**Q10**) | 0 = neither meets lower nor upper limit of measurement range of 4-15% / 20-140 mmol/mol<br>1 = meets or exceeds either the lower or the upper limit<br>2 = meets or exceeds both the lower and upper limits |
| | **Interference - Hb variants** | No interference from Hb variants. Identification of Hb variant.<br>(**Q11**, **Q12**, **Q13**, **Q14** and supplementary documention - instructions for use) | 0 = test method is known to be subject to interference from Hb variants. EITHER this analyzer has not been tested for interference OR it was tested but any interferences found are not listed in the instructions for use<br>1 = test method is known to be subject to interference from Hb variants. This analyzer has been tested and the interferences are listed in the instructions for use<br>2 = test method is not known to be subject to interference from Hb variants |
| | **Sample type** | Broader use-case opportunity<br>(**Q15**) | 0 = only accepts capillary whole blood<br>1 = accepts capillary and venous whole blood<br>2 = accepts whole blood and plasma/serum |
| | **Within run imprecision** | 3-5%<br>(**Q16**) | 0 = greater that 5% CV<br>1 = between 3% and 5% CV<br>2 = less than 3% CV |
| | **Between run imprecision** | 3-5%<br>(**Q17**) | 0 = greater that 5% CV<br>1 = between 3% and 5% CV<br>2 = less than 3% CV |
| | **Output - units** | % (DCCT)<br>mmol/mol (SI)<br>(**Q18**) | 0 = output is given in mmol/mol (SI)<br>1 = output is given in mmol/mol (SI) AND % (DCCT)<br>2 = output is given in mmol/mol (SI) AND % (DCCT) AND mg/dL estimated average glucose values |

| | Criterion | Description | Scoring Guideline |
|---|---|---|---|
| HbA1c tests - ease of use | Training requirement | For healthcare staff to operate the device (Q20) | 0 = more than one day<br>1 = between 2-8h<br>2 = less than 2h |
| | Sample volume | For easy collection of capillary whole blood volume (Q21) | 0 = greater than 50 micro litres per test<br>1 = equal to or less than 50 microlitres per test |
| | Sample loading in reagent cartridge/on test strip | Procedure and need for additional equipment (Q22, Q23) | 0 = sample cannot be loaded directly from the finger and no transfer device is provided (i.e. to be provided by facility)<br>1 = sample cannot be loaded directly from the finger but an adequate transfer device is provided (including tips in case of precision pipettes)<br>2 = sample can be loaded directly from the finger |
| | Number of steps up to sample loading | Additional steps between sample collection and sample loading into reagent cartridge/on test strips (Q24) | 0 = two or more steps<br>1 = one step<br>2 = zero steps |
| | Time to result | From reagent cartridge/test strip loading to result availability (Q25) | 0 = greater than 10 minutes<br>1 = between 5 and 10 minutes<br>2 = less than 5 minutes |
| | Biosafety requirement | For easy waste management at lower level healthcare facilities (Q26) | 0 = additional biosafety considerations beyond waste management and use of non-sterile gloves<br>1 = no additional biosafety considerations beyond waste management and use of non-sterile gloves |

| | Criterion | Description | Scoring Guideline |
|---|---|---|---|
| HbA1c tests - staorage and stability | Expiration date | Long shelf-life (Q27) | 0 = expiration date of less than 18 months<br>1 = expiration date of 18 or more months |
| | Unopened HbA1c tests - maximum storage temperature to maintain expiration date | Ease of storage for lower-level healthcare facilities (Q28) | 0 = refrigerated (2-8°C)<br>1 = up to 35°C<br>2 = up to 45°C<br>3 = above 45°C |
| | Unopened HbA1c tests - duration of storage at approved room temperature (RT) | Ease of storage for lower-level healthcare facilities (Q29, Q30) | 0 = unopened tests should be stored refrigerated<br>1 = up to 12 months<br>2 = longer than 12 months |
| | Transport conditions | Ease of transport and reduction of transport cost (Q31) | 0 = cold chain necessary<br>1 = cold chain recommended<br>2 = cold chain not necessary |
| | In-use stability | Ease of handling (Q32) | 0 = less than half an hour after opening the pouch<br>1 = at least half an hour after opening the pouch |
| | Criterion | Description | Scoring Guideline |
| HbA1c controls | HbA1c controls - storage and stability | Ease of storage for lower-level healthcare facilties (Q37, Q38) | 0 = opened control solutions remain stable only when refrigerated at 2-8°C and for up to 7 days<br>1 = opened control solutions remain stable at 2-8°C for longer than 7 days or remain stable at room temperature for up to 7 days<br>2 = EITHER opened control solutions remain stable at room temperarture for longer than 7 days OR controls are in a single-use test format |
| Add. Tests | Additional tests | Possibility to manage other cardiometabolic conditions (Q40, Q41, Q42) | 0 = no additional tests are available<br>1 = additional tests are available |
| Analyzer properties | Analyzer size | Size suitable for point-of-care (Q43) | 0 = at least 50x70x70<br>1 = smaller than 50x70x70 |
| | Display | Result reading independent of additional device (Q44) | 0 = the analyzer has no display<br>1 = the analyzer has a display |
| | Protection | Patient confidentiality protected (Q45) | 0 = no passcode protected access to results<br>1 = passcode protected access to results |
| | Connectivity | Ease of data transfer (Q47, Q48) | 0 = no connectivity, results need to be transferred manually<br>1 = EITHER data transfer via USB but no wireless connectivity OR wireless connectivity but no USB port<br>2 = USB port and wireless data transfer (Bluetooth, Wi-Fi, mobile network) |
| | Criterion | Description | Scoring Guideline |
| Operation | Operating conditions - temperature | Meeting of possible LMIC environmental conditions (Q52) | 0 = max. operating temperature is less than 35°C<br>1 = max. operating temperature is 35°C - 39°C<br>2 = max. operating temperature is at least 40°C |
| | Operating conditions - humidity | Meeting of possible LMIC environmental conditions (Q53) | 0 = max. operating humidity is less than 90% RH<br>1 = max. operating humidity is 90-97% RH<br>2 = max. operating humidity is at least 98% RH |
| Other considerations | Power requirements | Power source to operate the analyzer for 8 hours (Q54, Q55, Q56) | 0 = mains supply is needed, no battery<br>1 = can be battery-operated<br>2 = can be battery-operated for 8 hours or more |
| | Calibration | Calibration frequency (Q57, Q58, Q59) | 0 = regular calibration needed<br>1 = factory calibrated |
| | Maintenance by 3rd party | Requirement for a service provider (Q61, Q62, Q63, Q64) | 0 = EITHER servicing OR maintenance is required OR some parts have a limited lifespan and require replacement<br>1 = NEITHER servicing NOR maintenance is required AND no parts have a limited lifespan and require replacement |

## Second Round: Non-Technical

| SECOND ROUND - NON-TECHNICAL CONSIDERATIONS | | | |
|---|---|---|---|
| | **Criterion** | **Description** | **Scoring Guideline** |
| **Product price** | EXW price of analyzer | Ex-works price for analyzer is accessible for purchasers in LMICs<br>(Pricing worksheet) | 0 = analyzer cost is greater than $1000<br>1 = analyzer cost is between $250 and $1000<br>2 = analyzer cost is less than $250 |
| | Free of charge placement of the analyzer | HbA1c test throughput per month requirement, for a free of charge analyzer placement<br>(**Q80**, **Q81**) | 0 = No free of charge placements offered<br>1 = Monthly test throughput of >50<br>2 = Monthly test throughput of 30-50<br>3 = Monthly test throughput of <30 |
| | EXW price of HbA1c test | Ex-works price for HbA1c test is accessible for purchasers in LMICs<br>(Pricing worksheet) | 0 = HbA1c test cost is greater than $5<br>1 = HbA1c test cost is between $3 and $5<br>2 = HbA1c test cost is between $1 and $3<br>3 = HbA1c test cost is less than $1 |
| | Monthly cost for HbA1c control solutions (at 2 controls/week) | Ex-works price for running an HbA1c control is not excessive<br>(Pricing worksheet) | 0 = Greater than $10<br>1 = Less than $10 |
| | **Criterion** | **Description** | **Scoring Guideline** |
| **LMIC current coverage and access** | Registration of device/reagents | Supplier registration for sales in LMICs<br>(LMIC_coverage worksheet) | 0 = registration in only one LMIC<br>1 = registration in up to five LMICs AND all countries are in the same global region<br>2 = EITHER registration in up to five LMICs and those countries are in more than one global region OR registration in more than five LMICs and those countries are all in the same global region<br>3 = registration in more than five LMICs and those countries are in mor than one global region |
| | Distributors and sales | Supplier has distributor agreements in place for distribution and sales recorded<br>(LMIC_coverage worksheet) | 0 = distributor agreements not in place in all LMICs with registration<br>1 = distributor agreements in place in all LMICs with registration but sales not recorded in every country<br>2 = distributor agreements in place in all LMICs with registration and sales recorded in every country |
| | Registration in additional countries | Supplier is intending to register the device and make it available in additional countries<br>(LMIC_coverage worksheet) | 0 = Supplier not intending to register and make the analyzer available in additional countries<br>1= Supplier intending to register and make tha analyzer available in up to five countries<br>2 = Supplier intending to register and make the analyzer available in more than five countries |
| | FIND partner BGM sales | Nigeria, Kenya, Rwanda, South Africa, Lebanon, Syria, West Bank and Gaza, Iraq, Pakistan, India, Vietnam, Cambodia<br>(LMIC_coverage worksheet) | 0 = Registration not in place in any countries where BGMs under FIND partner agreements are sold or interest is registered<br>1 = Registration in place in some countries where BGMs under FIND partner agreements are sold or interest is registered<br>2 = Registration in place in the majority of countries where BGMs under FIND partner agreements are sold or interest is registered |

| | Criterion | Description | Scoring Guideline |
|---|---|---|---|
| Languages | Languages - product manual/instructions for use | Instructions for use are available in several languages (**Q66**) | 0 = only available in English<br>1 = available in English and French or Spanish<br>2 = available in English, French/Spanish and other languages |
| Customer support | Technical support - global level | Ease of access to product support by customers. The score reflects the option (LMIC-coverage worksheet) | 0 = technical support available via global call centre but not via a regional or in-country call centre<br>1 = technical support available via regional call centre but not via an in-country call centre<br>2 = technical support is available via in-country call centre<br>3 = technical support available via a manufacturer-approved repair centre or on-site visit |

| | Criterion | Description | Scoring Guideline |
|---|---|---|---|
| Company setup | Company strength | Company product portfolio (Powerpoint presentation) | 1 = Diagnostics company with limited diabetes portfolio OR Diabetes-care only with broad portfolio (including cardiometabolic disorders)<br>2 = Diagnostics company with broad portfolio across disease areas |
| | Product lead time for analyzers | Time from ordering to release for shipping (**Q68, Q69, Q70**) | 1 = on-demand manufacturing with 45 day lead time<br>2 = global product warehouses with low lead time for orders up to 100 analyzers |
| | Post-market surveillance | Supplier has a post-market surveillance concept in place (**Q74**) | 0 = no post-market surveillance concept<br>1 = post-market surveillance concept |
| | Quality system | Supplier has a certified quality management system in place (**Q75** and supportimg documentation - quality standard certificate) | 0 = quality system in place without certification<br>1 = certified quality system in place<br>2 = ISO 13485 and/or FDA Quality System Regulation certification in place |

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## References


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