# DETECT Rapid Diagnostics Open Call

Expression of Interest Form

**Organisation details**

Company name : _____

Contact person : _____

Contact person title : _____

Country : _____

Email Address : _____

Product name : _____

Briefly describe the intended use of your product : _____

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| **General** | | |
| 1 | Does the product require an instrument to generate results? [single] | ○ No instrument required (strip-based / direct readout)<br>○ Yes - portable instrument (handheld)<br>○ Yes - benchtop instrument (laboratory-based)<br>○ Yes - large automated platforms<br><br>Comments:_____ |
| 2 | If an instrument is required, is novel product development required or does the instrument already exist? [single] | ○ NA<br>○ Requires novel product development<br>○ Instrument already exists (Please list which instrument this test can run on: _____)<br><br>Comments:_____ |
| **Domain 1. Clinical scope and target pathogens** | | |
| 3 | What clinical specimen types are supported for this application? (Check all that applies) | ● Blood[1]<br>● Respiratory[2]<br>● Others |

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| | | Comments:_____<br><br>[1]whole blood, plasma, or serum<br>[2]sputum, tracheal/endotracheal aspirate, bronchoalveolar lavage |
| 4 | What is the required input sample type? [single] | ○ Direct clinical specimen with no processing (e.g. directly from whole blood draw, bypassing BACTEC bottles and agar plates)<br>○ Direct clinical specimen after sample processing (e.g. centrifugation, extraction)<br>○ Pre-cultured samples (e.g. requires incubation in blood culture broth such as BACTEC, or requires isolated colonies)<br><br>Comments:_____<br><br>[1]whole blood, plasma, or serum<br>[2]sputum, tracheal/endotracheal, BAL |
| 5 | What are the underlying detection and identification methodologies? [single] | ○ Polymerase chain reaction (PCR)<br>○ Isothermal amplification<br>○ Immunoassay/antigen detection<br>○ Biochemical identification<br>○ Other (please specify) :<br>_____<br><br>Comments:_____ |
| 6 | What pathogens can the product detect from a single sample? (Check all that applies) | ● *Escherichia coli*<br>● *Klebsiella pneumoniae*<br>● *Enterobacter spp.*<br>● *Pseudomonas aeruginosa*<br>● *Acinetobacter baumannii* |

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| | | • Other *Enterobacterales* not mentioned above<br>• *Staphylococcus aureus*<br>• *Streptococcus spp.*<br>• *Enterococcus faecium*<br>• *Candida spp.*<br>• Other (please specify) :<br>_____<br><br>Comments:_____ |
| 7 | Which genetic resistance determinants can the product detect? (Check all that applies) | • *blaKPC*<br>• *blaNDM*<br>• *blaOXA*<br>• *blaIMP*<br>• *blaVIM*<br>• Other carbapenemase genes<br>• *blaCTXM*<br>• *blaTEM*<br>• *blaSHV*<br>• MRSA markers (e.g. *mecA/mecC)*<br>• Other (please specify) :<br>_____<br><br>Comments:_____ |
| 8 | Does the product provide phenotypic antimicrobial susceptibility testing? [single] | ○ Yes – all the targeted antibiotics associated with the identified pathogens<br>○ Yes – only some of the targeted antibiotics associated with the identified pathogens<br>○ No phenotypic antimicrobial susceptibility testing<br><br>Comments:_____ |

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| **Domain 2. Operational and instrument characteristics** | | |
| 9 | Where is the product intended to be used? (Check all that applies) | ○ Community /outpatient setting<br>○ Primary care clinic<br>○ District hospital (non-lab setting)<br>○ Hospital laboratory<br>○ Home<br>○ Other (please specify) :<br>_____<br><br>Comments:_____ |
| 10 | What is the estimated training requirement for routine users? [single] | ○ No formal training required<br>○ ≤ 2 days of training<br>○ 3 days or more / certified training required<br><br>Comments:_____ |
| 11 | How many samples can be processed per run (i.e. per instrument cycle)? [single] | ○ 1-4 samples per run<br>○ 5-10 samples per run<br>○ >10 samples per run<br><br>Comments:_____ |
| 12 | What is the total time to result (including species identification and antimicrobial resistance detection)? [single] | ○ Less than 60 mins<br>○ 60 to 90 mins<br>○ 90 to 120 mins<br>○ More than 120 mins<br><br>Comments:_____ |
| 13 | How are the results reported and interpreted? [single] | ○ Fully automated digital output with interpretations<br>○ Semi-automated interpretation (requires operator confirmation)<br>○ Visual/manual readout (requires user judgement)<br><br>Comments:_____ |
| **Domain 3. Instrument cost, maintenance and support** | | |

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| 14 | If an instrument is required, what is the estimated cost of the instrument (in USD)? [single] | ○ Not applicable<br>○ < US $15,000<br>○ US $ 15,000 to US $ 30,000<br>○ > US $ 30,000<br><br>Comments:_____ |
| 15 | If an instrument is required, what is the expected mean time between failures / downtime? [single] | ○ Not applicable<br>○ < 24 months<br>○ 24-36 months<br>○ At least 36 months<br>○ Not known yet<br>○ Others (please specify) :<br>_____<br><br>Comments:_____ |
| 16 | What are the maintenance and servicing requirements of the instrument? [single] | ○ No routine maintenance required<br>○ Basic user-level maintenance only<br>○ Regular preventive maintenance required<br>○ Others:<br><br>Comments:_____ |
| 17 | Is there currently any local technical support available in LMIC settings? [single] | ○ Yes (regional support hubs)<br>○ No<br>○ In development<br><br>Comments:_____ |
| **Domain 4. Cost, consumables & supply chain** | | |
| 18 | What is the estimated cost per test at 100,000 tests per year (in USD, all consumable cost required for a single test)? [single] | ○ Less than 15 USD<br>○ 16 - 20 USD<br>○ 21 - 30 USD<br>○ More than 30 USD<br><br>Comments:_____ |
| 19 | How are the materials / consumables provided for a single test? [single] | ○ Fully self-contained kit without the need for external consumables<br>○ Kit-based system requiring basic generic consumables (e.g. pipette tips) |

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| | | ○ System requiring proprietary consumables supplied only by manufacturer or authorised distributor<br>○ System requiring externally sourced general laboratory consumables<br>○ Not known yet<br><br>Comments:_____ |
| 20 | What is the average shelf-life of these consumables? [single] | ○ <12 months<br>○ 12-18 months<br>○ >18 months<br>○ Not known yet<br><br>Comments:_____ |
| 21 | What are the storage and distribution requirements for these consumables? [single] | ○ Ambient storage and shipping (no cold chain)<br>○ Refrigerated storage/distribution (2–8°C)<br>○ Frozen storage/distribution (<0°C)<br>○ Mixed requirements across components<br>○ Not known yet<br><br>Comments:_____ |
| 22 | What are the power requirements for operating the product? [single] | ○ No external power required or battery-operable<br>○ Requires stable mains electricity but operable with backup power<br>○ Requires stable mains electricity<br>○ Not known yet<br><br>Comments:_____ |
| **Domain 5. Development and regulatory status** | | |
| 23 | What is the current technical validation status? [single] | ○ Concept /prototype<br>○ Analytical validation completed<br>○ Clinical validation completed<br>○ Fully validated (both analytical and clinical validation completed) |

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| | | Comments:_____ |
| 24 | What is the current commercial status? [single] | ○ Not commercialised<br>○ Pilot / limited deployment<br>○ Market available (Research-use only or in vitro diagnostics)<br><br>Comments:_____ |
| 25 | If the product has been distributed, where are the current distribution models? [single] | ○ Established LMIC distribution network<br>○ Some LMIC regional distributors<br>○ Only high-income distribution network currently<br>○ No distribution network established<br><br>Comments:_____ |
| 26 | What is the current regulatory status? [single] | ○ No regulatory pathway initiated<br>○ Regulatory strategy defined (pre-submission / preparation stage)<br>○ Submitted for regulatory review<br>○ Approved (e.g. CE-marked/CE-IVD, FDA approved or other relevant approvals from regulatory authority)<br><br>Comments:_____ |

**Supporting documents (where available)**

- Target Product Profile or equivalent product development profile
- Overview of the clinical workflow, including an actual or mock-up visual of the product.
- Instructions for use (IFU)
- Product specification / operational requirements sheet
- Performance reports(s) (e.g. analytical, clinical, validation studies)
- Regulatory documents or certification(s)
- Company profile and supporting documentation (e.g. company profile, organisational structure, regulatory and quality functions)

Any other relevant supporting material can also be attached.