Invitation to Manufacturers

Of rapid IVD products for bacterial meningitis, to submit an Expression of Interest (EOI) to Gavi for product evaluation by the WHO Expert Review Panel for Diagnostic Products

Publication Date: 22/11/2023

Closing Date: 05/01/2024

Reference of the ERPD round: 23-GAVI-0001

Concerning: Bacterial Meningitis Rapid IVD Tests for the detection and differentiation of *Neisseria meningitidis* (Nm) serogroups

A. Background

The Gavi Alliance (Gavi), in partnership with the World Health Organization (WHO), is working to improve the availability of fit-for-purpose diagnostic tests so that the use of Gavi-supported targeted vaccines can be made more effective, efficient and equitable. This project aims to accelerate the availability of rapid *in vitro* diagnostics (IVDs) for enhanced disease surveillance for several vaccine-preventable diseases including bacterial meningitis, to enable Gavi-supported country procurement and introduction.

The vision of the Defeating Meningitis by 2030 Global Roadmap is "Towards a world free of meningitis" carried by three visionary goals: (i) elimination of bacterial meningitis epidemics; (ii) reduction of cases of vaccine-preventable bacterial meningitis by 50% and deaths by 70%; and (iii) reduction of disability and improvement of quality of life after meningitis.

The global road map, developed through iterative multidisciplinary consultations, paves the way to achieve this through strategic goals, key activities and milestones across five pillars: prevention and epidemic control; diagnosis and treatment; disease surveillance; support and care for people affected by meningitis; and advocacy. The diagnosis and treatment goals, which are focused on rapid confirmation of acute bacterial meningitis at all levels of care through the development and access to diagnostics assays, are placed high on the roadmap's agenda.

Bacterial meningitis is the most serious type of meningitis and is largely preventable through vaccination. The bacterium *Neisseria meningitidis* (Nm), commonly known as meningococcus, causes the majority of bacterial meningitis outbreaks. With the introduction of the meningococcal A conjugate vaccine, epidemics from serogroup A have largely been eliminated across the African meningitis belt. However, outbreaks due to other meningococcal serogroups have continued and have become more prominent in the meningitis belt. To enable an appropriate vaccination response to an outbreak, it is critical to quickly identify the causative pathogen and Nm serogroup to inform whether a response is relevant and which vaccine to deploy from the emergency stockpile given the availability of multivalent vaccines. In addition, routine surveillance for other bacterial causes of meningitis is important for monitoring meningitis burden and potential pneumococcal meningitis outbreaks.

Access to high-quality, high-performing and affordable diagnostics is critical to achieving the targets set out in the Defeating Meningitis by 2030 Global Roadmap. In support of the attainment of the roadmap goals, Gavi is partnering with WHO on this invitation to manufacturers. Gavi collaborates with UNICEF to list and coordinate procurement of commodities for its programs and requires that procurement be restricted to products that have been reviewed and endorsed by WHO, including WHO Pre-Qualification (PQ) and/or

Expert Review Panel for Diagnostic Products (ERPD). Recognizing that bacterial meningitis *in vitro* diagnostics (IVDs) are not yet covered by WHO PQ, Gavi has engaged with the ERPD program coordinated by the WHO PQ team. The ERPD program provides recommendations for procurement decisions and facilitates the supply of quality IVDs specifically intended for meningitis surveillance. This collaborative effort between Gavi, the WHO meningitis team and WHO PQ team seeks to ensure that Gavi can provide access to countries to reliable and quality diagnostic products, supporting collective goals in meningitis control and elimination.

B. The Expert Review Panel for Diagnostic products

The ERPD is an independent advisory body of technical experts, coordinated by WHO PQ. The role of the ERPD is to assess the risks and benefits associated with procurement of IVDs that may have a high public health impact but are not yet prequalified or that are not currently eligible for prequalification. The risks of procurement and use of the products are considered in a specific binding context to determine their quality assurance risk category. The assessment is based on a desk review of available evidence of compliance to transparent criteria and will provide advice for decisions regarding time-limited procurement in specific conditions. ERPD Members are technical experts in the field of IVD performance, quality and safety; and/or with extensive scientific knowledge and experience of diagnostic procedures in the relevant settings and disease area. The complete process involves Gavi publishing an "Invitation to Manufacturers to Submit an Expression of Interest for Product Evaluation." Subsequently, manufacturers submit a diagnostic product questionnaire to Gavi. The WHO PQ team will coordinate the ERPD review. The results of the review are then communicated to the manufacturers by Gavi.

C. Scope of the present Invitation to Manufacturers

The present invitation focuses on: **Bacterial Meningitis rapid IVDs**

The purpose of this document is to invite manufacturers to submit an EOI for the product evaluation of urgently needed IVDs by Gavi. The invitation specifically pertains to rapid tests for the detection and differentiation *of Neisseria meningitidis* (Nm) serogroups. Additionally, the document provides the required specifications or quality assurance criteria for these IVDs (see section D below).

Manufacturers whose IVDs are intended for ***Nm serogroup detection and differentiation*** are encouraged to apply by completing a product submission form and providing necessary supporting documentation to Gavi. WHO PQ team will coordinate the ERPD review process and provide recommendations for procurement decisions and facilitate the supply of IVDs by Gavi.

D. Eligibility criteria

To be eligible for ERPD reviews, manufacturers must meet the following criteria:

D.1. Quality assurance criteria

i. Quality management system: The manufacturer should provide evidence that the considered products are designed and manufactured under a relevant quality management system, such as ISO 13485 or equivalent standard.
ii. Operational capabilities: The manufacturer should provide evidence of their ability to support design, manufacturing, distribution, sales and post-market activities such as customer support, control of vigilance activities, in and for all WHO Member States involved in the management of meningitis.
iii. The application is limited to manufacturers who commit to submit their product to PQ (when eligible) or a stringent regulatory agency for approval.

D.2. Technical criteria

To be eligible for ERPD review, the products must:

i. Meet the specific criteria defined in section D.1. above.
ii. Be a rapid test format and/or technologies that can be used at or near point-of-care, like primary health care settings including health posts (Level 1 and above) that have the necessary equipment and trained staff to perform lumbar punctures for cerebrospinal fluid (CSF) collection.
iii. Demonstrate clinical performance with clinical samples of CSF in intended populations (i.e., suspected meningitis cases in the African meningitis belt region).
iv. Identify and differentiate with minimal cross-reactivity Nm serogroups A, C, X, Y and W and no cross-reactivity with Nm serogroup B, Spn and Hib.
v. Demonstrate product stability with real time and accelerated stability data.

E. Submission of documents for ERPD review

All manufacturers interested in submitting applications for review by the ERPD are kindly requested to submit the following information:

1. A cover letter expressing interest (Expression of Interest or EoI) in submitting the product to the ERPD for review. The cover letter should also indicate the authorized contact for the manufacturer.
2. One of the following documents, substantiated by the most recent inspection reports:
    - An ISO 13485 certificate covering the product manufacturing activities; or
    - A certificate ensuring that the IVD (device, reagents, and associated equipment) is manufactured at a site that is compliant with ISO 13485 requirements; or
    - An equivalent quality management system recognized by a stringent regulatory authority of the Founding Members of the Global Harmonization Task Force (GHTF); or
    - A letter from WHO ensuring that the manufacturing site has undergone inspection by the WHO Prequalification of In Vitro Diagnostics Program and has been found compliant with WHO prequalification requirements.
3. ERPD questionnaire, including all relevant attachments and evidence supporting product claims (refer to Annex 1).

Please ensure that all available evidence and requested documents and information are included. In case any of these are absent or incomplete, please provide a justification. Incomplete Expressions of Interest and Expressions of Interest submitted after the Closing Date will, in principle, be disregarded, unless Gavi decides otherwise, at its sole discretion.

F. Confidentiality

All information provided by manufacturers will be received by Gavi and shared with the WHO ERPD coordinator for the purpose of facilitating their review of the submission and provision of advice to Gavi. All parties involved will operate under a confidentiality agreement with WHO PQ as the coordinating entity. The outcomes of the ERPD review, as well as the advice provided in the review report, in connection with this Expression of Interest, will be shared with and used by Gavi and the following partners as the basis for procurement decisions: WHO PQ, ERPD, WHO meningitis technical team, FIND and UNICEF Supply Division.

G. Instruction for submission

Submission should be submitted by electronic means (either via email or web-based download service) to diagnostics@gavi.org by the specified deadline.

Annex 1

Diagnostic Product Questionnaire for product evaluation

by the WHO Expert Review Panel for Diagnostic Products (ERPD)

ERPD ASSESSMENT TEAM (PQT)

EXTERNAL DOCUMENT

WHO PQT - ERPD Questionnaire		**Document No**: ERPD_ PROCURER_ROUND_23-GAVI-0001
Effective Date: 20 July 2023	**Replaces:** Version 1.0 30 January 2017	**Version No:** 2.0 **Pages: 23**

World Health Organization

Product Questionnaire

Product Evaluation by the

Expert Review Panel for Diagnostic Products

How to complete this form

This questionnaire has been designed to assist the WHO to capture necessary information about a product submitted for evaluation by the WHO Expert Review Panel for Diagnostic Products (ERPD). The information provided by the manufacturer in this form assists WHO to determine whether a product is eligible for WHO ERPD assessment. Therefore, the manufacturer must complete the form with accuracy and completeness.

When completing the form, type in text or tick boxes (□) as required for each field. Where information is not available or the field is not applicable, type N/A. The manufacturer should submit this form as a searchable PDF file and sign the Manufacturer Declaration electronically. Completed ERPD Questionnaires and all relevant documentation must be submitted to the following email address: diagnostics@gavi.org

Contents

1. Manufacturer Information

1.1. Legal manufacturer

1.1.1.Name of manufacturer	Click here to enter text.	
1.1.2.Manufacturer physical address	Street Name and No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
1.1.3.Manufacturer postal address	Street Name and No.: Click here to enter text.	
	Postal Office Box No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
1.1.4. Manufacturer telephone	Click here to enter text.	
1.1.5. Manufacturer e-mail	Click here to enter text.	
1.1.6. Manufacturer web address	Click here to enter text.	
1.1.7. Name of parent company	Click here to enter text.	

1.2. Authorized contacts for the manufacturer[1]

1.2.1. Name of first authorized contact	Salutation	Click here to enter text.
	First Name	Click here to enter text.
	Middle Name	Click here to enter text.
	Last Name	Click here to enter text.
1.2.2. Authorized contact postal address	Department: Click here to enter text.	
	Street Name and No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
1.2.3. Authorized contact telephone	Fixed line: Click here to enter text.	Mobile phone: Click here to enter text.
1.2.4. Authorized contact email	Click here to enter text.	
1.2.5. Authorized contact job title	Click here to enter text.	
1.2.6. Name of the second authorized contact	Salutation	Click here to enter text.
	First Name	Click here to enter text.
	Second Name	Click here to enter text.
	Last Name	Click here to enter text.
1.2.7. Authorized contact postal address	Department: Click here to enter text.	
	Street Name and No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
1.2.8. Authorized contact telephone	Fixed line: Click here to enter text.	Mobile phone: Click here to enter text.
1.2.9. Authorized contact email	Click here to enter text.	
1.2.10. Authorized contact job title	Click here to enter text.	

[1] **ATTACHMENT:** Attach a signed letter from the manufacturer stating that the above two contacts are authorized to represent the manufacturer for the purposes of ERPD assessment of this product.

2. Product - Information

2.1. Product name and product code/catalogue number for WHO ERPD assessment

2.1.1. Product name: Click here to enter text.		
2.1.2. Tests per kit*	Number of tests per kit: Click here to enter text.	Product code: Click here to enter text.
**add lines if multiple kit sizes are available*	Number of tests per kit: Click here to enter text.	Product code: Click here to enter text.

2.1.3. Kit contents, including accessories. Provide the product code for each kit size submitted for WHO ERPD evaluation.

Kit component and product code (one per line)	Type of component (vial/device/bottle). Include volume.	Number per kit
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

2.1.4. If reagents are supplied in more than one box, provide the reagent name, product code/catalogue number, and number of tests for each box of reagents.

Name of reagents per box	Product code/catalogue number	Reagent box size (number of tests per box)
Click here to enter text.	Click here to enter text.	Click here to enter text.

2.1.5. Packaging formats

Pack name	Pack size / number of units	Catalogue number / code	Dimensions L x H x W (cm)	Weight (kg)

2.1.6. Does this product require dedicated instrumentation? If so, please provide the instrument or component name, product code/catalogue number, and other relevant information.

Name of instrument or component	Product code/catalogue number	Other

Click here to enter text.	Click here to enter text.	Click here to enter text.

2.1.7. Is the regulatory version submitted for WHO ERPD evaluation commercially available? (See section 6 below)	☐ Yes Date product[2] was initially placed on the market: Click here to enter text.
	☐ No Product[3] expected to be commercialized by: Click here to enter text.

Please provide in ANNEX A any Material Safety Data Sheets (MSDS) relating to the product.

Please provide in ANNEX E copies of all the packaging labels, including labels and component labels of primary, secondary and tertiary/transportation package.

2.2. Product instructions for use and user manual

2.2.1. Provide a short narrative of the intended use/intended purpose.	Click here to enter text.
2.2.2. Describe the principle of operation of the assay.	Click here to enter text.
2.2.3. Instructions-for-use (IFU) version number (if different IFUs are provided with different kit sizes, please include each, and identify which product code applies to which IFU) [5]	Click here to enter text.
2.2.4. If applicable, the user manual(s) version number for dedicated instrumentation [5]	Click here to enter text.
2.2.5. List the languages for which the IFU and users manual, if applicable, are available.	Click here to enter text.

Please provide in ANNEX D the English language version of the instructions for use (IFU) / product insert and, if applicable, the user manual for dedicated instrumentation.

2.3. Transport, storage and operating temperatures

2.3.1. List transport, storage and operating temperatures, as well as the product shelf life.					
Product name (If more than one box, provide the	Transport temperature range (min °C - max °C)	Storage temperature range (min °C - max °C)	Operating temperature range (min °C - max °C)	Shelf-life upon manufacture (months)	Indicative shelf life upon delivery (months)

[2] Refers to the product holding the regulatory version submitted for WHO ERPD assessment.

name for each reagent box)					
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

2.3.2. Describe any other storage conditions that are applicable to this product.

Click here to enter text.

3. Product - Disease Category, Analyte and Method

3.1. Disease category and analyte

3.1.1. Indicate the disease category to be diagnosed with the product.	
3.1.2. Specify the analyte detected by the product.	

3.2. Specimen type

3.2.1. Select the specimen type(s) to be used for this IVD.			
☐	Serum	☐	Plasma
☐	Venous whole blood	☐	Capillary whole blood
☐	Oral fluid	☐	Dried blood spot
☐	Raw sputum	☐	Concentrated sputum sediments
☐	Bronchial alveolar lavage	☐	Cerebrospinal fluid
☐	Stool	☐	Lymph node aspirate
☐	Urine	☐	Other: Click here to enter text.
☐	Cervical swab/specimen		

3.3. Assay format for serology and nucleic acid testing technologies

3.3.1. Select the assay format			
☐	Immunochromatographic (lateral flow)	☐	Immunofiltration (flow through)
☐	Agglutination	☐	EIA (Enzyme immunoassay)
☐	Recombinant immunoblot	☐	Western blot
☐	Antigen neutralization	☐	Immunofluorescence
☐	NAT (nucleic acid testing)	Specify NAT methodology:	
		☐	NAT (qualitative)

		☐	NAT (quantitative)
☐	Reverse hybridization/line probe assay	☐	LAMP
☐	Other: Click here to enter text.		

4. Product - Operation

4.1. Sample collection and transport materials

4.1.1. Details of sample collection.	
4.1.2. List all the materials required / supplied for sample collection.	

4.2. Assay controls

4.2.1. Does the assay include any form of control (flow or specimen addition)?	☐	Yes
	☐	No
4.2.2. For NAT assays, does the assay contain an internal (amplification) control?	☐	Yes
	☐	No
4.2.3. Are control specimens (also called test-kit controls) such as positive, negative, low or high controls, supplied within the test kit or available separate of the test kit? If no answer is selected, no control specimens are assumed to be available.	☐	Within
	☐	Separate

4.3. Other accessories required

Accessories (*e.g.* lancet, pipettes, swabs, etc.)	Code	Provided by (*i.e.* as part of the kit, separately by the manufacturer, or by another manufacturer)

4.4. Product usage

4.4.1. Time required to obtain a test result from specimen collection to the final result being read (in minutes)	Click here to enter text.	
4.4.2. State the minimum and maximum number of specimens (excluding controls) that can be tested in a single run	Minimum Click here to enter text.	Maximum Click here to enter text.
4.4.3. If instrument-based, select the throughput per day		
☐ 0-20 tests/day per operator	☐ 20-50 tests/day per operator	
☐ 50-100 tests/day per operator	☐ > 100 tests/day per operator	

4.5. Indicative cost

Indicate the approximate cost per Test (reagent)	Click here to enter text. USD
Indicate the approximate instrument(s) cost, if applicable	Click here to enter text. USD

5. Product – Performance Characteristics

5.1. Performance characteristics for serology EIAs and RDTs

Provide the manufacturer's performance characteristics for this product, for each analyte (add rows for each analyte as required).	
Sensitivity	Analyte: Click here to enter text. Sensitivity: Click here to enter text. **%** 95% confidence interval: (Click here to enter text. **to** Click here to enter text.) **%**
Specificity	Analyte: Click here to enter text. Specificity: Click here to enter text. **%** 95% confidence interval: (Click here to enter text. **to** Click here to enter text.) **%**
Invalid rate (RDTs)	Click here to enter text. **%**
Other relevant performance characteristics	Click here to enter text.
5.1.1. If some of the studies mentioned above were conducted on other design versions of the product, please provide details of design changes.	
Click here to enter text.	
Click here to enter text.	

5.2. Analytical performance studies

5.2.1. Provide an overview of the study conducted. For each study, please provide in Annex H as specified below with study protocols and related study reports. Clearly specify the methods used.			
Study type	Yes	No	Specimen type(s)

Specimen Stability	☐	☐	Click here to enter text.
Accuracy of measurement:			
- Trueness of measurement	☐	☐	Click here to enter text.
- Precision of measurement	☐	☐	Click here to enter text.
Analytical sensitivity:			
- LOB / LOD / LOQ	☐	☐	Click here to enter text.
- Detection of variants	☐	☐	Click here to enter text.
Analytical specificity:			
- Interference studies/cross-reactivity	☐	☐	Click here to enter text.
Measuring range	☐	☐	Click here to enter text.
Other	☐	☐	Click here to enter text.
5.2.2.If some of the studies mentioned above were not conducted, please provide a justification below why.			
Click here to enter text.			
5.2.3. If some of the studies mentioned above were conducted on other design versions of the product, please provide details of design changes.			
Click here to enter text.			
Click here to enter text.			

Please provide in ANNEX H the analytical study protocols and reports relating to the analytical performance studies conducted with the product.

5.3. Clinical performance studies

5.3.1.Clinical performance data should be collected on samples taken from two different production lots of the finished product manufactured under a "final" validated production scale, except justified by the innovative aspects of the device. Independent studies are conducted without involvement from the manufacturer, although the reagents and instruments for the study may have been provided free of charge for the study. For each evaluation, please provide in Annex I and J study protocols and related study reports as specified below.			
Clinical evaluation	Yes	No	Clinical specimen type(s) and number of unique specimens tested.
By the manufacturer	☐	☐	
Independent #1	☐	☐	
Independent #2	☐	☐	
5.3.2.If some of the clinical studies mentioned above were not conducted, please provide a justification below why.			
Click here to enter text.			

5.3.3. If some of the studies mentioned above were conducted on other design versions of the product, please provide details of design changes.
Click here to enter text.
Click here to enter text.

Please provide in ANNEX I the protocols and reports of clinical studies conducted by the manufacturer.

Please provide in ANNEX J the protocols and reports of independent clinical studies conducted in the intended use setting.

5.4. Product stability studies

Study type	Yes	No	Specimen type(s)
Transport	☐	☐	Click here to enter text.
Shelf-life	☐	☐	Click here to enter text.
In-use stability	☐	☐	Click here to enter text.
If some of the studies mentioned above were conducted on other design versions of the product, please provide details of design changes.			
Click here to enter text.			
Click here to enter text.			

Please provide in ANNEX G the protocols and reports of stability studies conducted with the product.

5.5. Specifications for nucleic acid tests

5.5.1. Provide the manufacturer's performance specifications for this product, for each analyte/measurand* *Please add rows as required for each analyte/measurand	
Clinical/Diagnostic sensitivity % (95% confidence intervals)	Click here to enter text. **%** (Click here to enter text. **to** Click here to enter text.) **%**
Clinical/Diagnostic specificity % (95% confidence intervals)	Click here to enter text. **%** (Click here to enter text. **to** Click here to enter text.) **%**
Precision (CV%)	Click here to enter text. **%**
Bias (%) for quantitative assays	Click here to enter text. **%**

Analytical sensitivity (Limit of detection (LOD))	Click here to enter text.
Linear range for quantitative assays	Click here to enter text.
Invalid rate	Click here to enter text. **%**

6. Regulatory and Commercial Status of the Product

6.1. Regulatory status of product

6.1.1. State the regulatory versions of the product submitted for WHO ERPD assessment (please tick and enter the approval period): Click here to enter text.		
Name of jurisdiction	Type of regulatory status	Product name Product code Class of the device Period of approval: Start (DD/MM/YY) - Expiry (DD/MM/YY)
Performance evaluation device version	☐ The product is labeled for performance evaluation.	Click here to enter text.
Non SRA version	☐ The product is approved by the jurisdictions listed below. (Please provide information of any approvals under section 6.1.2)	Click here to enter text.
European Union	☐ Self-certification	Click here to enter text.
European Union	☐ Certificates issued under Regulation 2017/746: please specify the annex: Click here to enter text.	Click here to enter text.
	☐ Certificates issued under Regulation 2017/746: please specify the annex: Click here to enter text.	Click here to enter text.
	☐ Certificates issued under Regulation 2017/746: please specify the annex: Click here to enter text.	Click here to enter text.

European Union	☐ Self-declared CE-mark, Annex III IVDD Directive 98/79/EC	Click here to enter text.
	☐ Full quality assurance certificate, Annex IV.3 IVDD Directive 98/79/EC	Click here to enter text.
	☐ Product design examination certificate, Annex IV.4 IVDD Directive 98/79/EC	Click here to enter text.
	☐ Type examination certificate, Annex V IVDD Directive 98/79/EC	Click here to enter text.
	☐ Type examination certificate, Annex VII IVDD Directive 98/79/EC	Click here to enter text.
United States of America	☐ Premarket Approval (PMA)	Click here to enter text.
	☐ 510(k) clearance	Click here to enter text.
	☐ Certificate of Exportability to Foreign Government	Click here to enter text.
	☐ Non-clinical Research Use Only Certificate	Click here to enter text.
	☐ Other: Click here to enter text.	Click here to enter text.
Canada	☐ Medical device license and summary report for a Class III IVD	Click here to enter text.
	☐ Medical device license and summary report for a Class IV IVD	Click here to enter text.
	☐ Manufacturer's Certificate to Cover Export of Medical Devices (MCE)	Click here to enter text.
	☐ Other: Click here to enter text.	Click here to enter text.
Australia	☐ Australian Register of Therapeutic Goods (ARTG) Number (aka Medical Device Inclusion Number) Number	Click here to enter text.
	☐ Conformity Assessment - Full quality assurance certificate	Click here to enter text.

	☐ Conformity Assessment - Production quality assurance certificate	Click here to enter text.
	☐ License for manufacturer	Click here to enter text.
	☐ Other: Click here to enter text.	Click here to enter text.
Japan	☐ Recognized foreign manufacturer	Click here to enter text.
	☐ Minister's approval	Click here to enter text.
	☐ Other: Click here to enter text.	Click here to enter text.
Singapore	☐ Listing on the Singapore Medical Device Register (SMDR) as Class C IVD	Click here to enter text.
	☐ Listing on the Singapore Medical Device Register (SMDR) as Class D IVD	Click here to enter text.

6.2. Provide details of other current regulatory approvals for this product

(Do not include ISO 13485 certification details here. This is covered in question 7)

Name of regulatory authority/jurisdiction	Type of regulatory approval	Product name Product code Period of approval: Start (DD/MM/YY) - Expiry (DD/MM/YY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

6.3. Commercial agreements and rebranding[3]

6.3.1. Do you sell or supply this product or any of the components for rebranding [7]?	☐ Yes ☐ No
6.3.2. Is this product or any of the critical components sourced from another manufacturer?	☐ Yes ☐ No
If you have answered yes to 6.2.1 or 6.2.2, please provide details: Click here to enter text.	

7. Manufacturer - Quality Management System

7.1. Quality Management System

Is a quality management system in place for the design, development, and production of this product?	☐ Yes ☐ No
Does this quality management system meet the requirements of ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes?	☐ Yes ☐ No
Does the quality management system meet the requirements of other similar standards e.g. those required by other jurisdictions? If yes, please provide details.	Click here to enter text.

7.2. Quality Management System Certification

Provide details regarding any certification held in respect to the quality management system used for the manufacture of this product.

Type of QMS e.g. ISO 13485:2003 ISO 13485:2016	Name of certification body	Current period of certification Start (DD/MM/YY) - Expiry (DD/MM/YY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

Please provide in ANNEX R the ISO

7.3. Quality Management System of the site of the manufacture

Provide details regarding QMS of manufacturing site of the submitted product if different from 7.1 above.

Is a quality management system in place for the design, development, and production of this product?	☐ Yes ☐ No

[3] Applications for WHO ERPD round of IVDs are accepted only from the legal manufacturer of the product.

Does this quality management system meet the requirements of ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes?	☐ Yes ☐ No
Does the quality management system meet the requirements of other similar standards e.g. those required by other jurisdictions? If yes, please provide details.	Click here to enter text.

7.4. Quality Management System Certification

Provide details regarding any certification held in respect to the quality management system used for the manufacture of this product if different from 7.2 above.

Type of QMS e.g. ISO 13485:2003 ISO 13485:2016	Name of certification body	Current period of certification Start (DD/MM/YY) - Expiry (DD/MM/YY)
Click here to enter text.	Click here to enter text.	Click here to enter text.
Add lines if required		

Please provide in ANNEX Q the Quality Manual of the manufacturer.

Please provide in ANNEX R the ISO 13485 certificate(s)

Please provide in ANNEX S audit/inspection reports associated with certification.

7.1. Claimed standards and applicable standards Certification

Provide details regarding any claimed standard or certification held in respect to any standard applicable to the in vitro diagnostic medical devices system used for the manufacture of this product if different from 7.2 above.

Type of standard e.g. EN 61010-2- 101:2002	Name of certification body	Current period of certification Start (DD/MM/YY) – Expiry (DD/MM/YY)
Click here to enter text.	Click here to enter text.	Click here to enter text.
Add lines if required		

Please provide in Annex N a list of standards and indicate the level of compliance.

8. Risk Management

Was a risk analysis conducted to identify possible hazards for the IVD medical device, and to address and control the risks to an acceptable level?

Was a risk analysis conducted to identify possible hazards for the IVD medical device, and to address and control the risks to an acceptable level?	☐ Yes ☐ No
Provide he standard/guideline that was followed.	Click here to enter text.

Please provide in ANNEX F the specific risk report, risk-analysis, risk management plan and risk control for the product.

Please provide in ANNEX W the procedure for handling complaints from customers and other stakeholders.

Please provide in ANNEX X the recall procedure for recalling products from the market.

Please provide in ANNEX Y a description of the customer support mechanisms available for the product.

9. Manufacturer – Sites of Product Manufacture

9.1. Product design, manufacturing flowchart and lot release procedure

9.1.1. Overview of the Design and Development Records specific to the product including design and development plan and report.	Click here to enter text.
9.1.2. Provide a process flow chart describing the manufacturing processes and control processes with relevant parameters.	Click here to enter text.
9.1.3. Please provide a copy of the procedure for quality control of the lot release. Provide rationale for the definition of lot release testing criteria.	Click here to enter text.

Please provide in ANNEX L the manufacturing flowchart, and Certificates of Analysis for the last three lots released.

Please provide in ANNEX M the procedure for design changes.

Please provide in ANNEX V the procedure of quality control of lot release and a copy of the certificates of analysis for the last 3 lots released.

9.2. Manufacturing capability

9.2.1. Indicate the number of tests sold/per year for the last three years.	Year	Number of tests sold
	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.

9.2.2. Current manufacturing capacity (number of tests per year)	Click here to enter text.
9.2.3. Planned manufacturing capacity (scale up potential/year)	Click here to enter text.

9.3. Sites of manufacture

Please provide the address where manufacturing occurs. If multiple manufacturing locations are involved, please complete table 9.3.2.

9.3.1.Manufacturing Address	Street Name and No.: Click here to enter text.	
	Postal Office Box No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.

9.3.2. List all sites that are involved in each and every step of the manufacture of this product.		
Description of the stage of manufacture	Name of site	Physical address of site
Design & Development	Click here to enter text.	Click here to enter text.
Raw materials (list the site(s) manufacturing each of the critical raw materials; e.g. assay buffer)	Click here to enter text.	Click here to enter text.
Assembly of device (if multiple sites are involved, detail which step(s) occur at each site; e.g. nitrocellulose card lamination)	Click here to enter text.	Click here to enter text.
In-process quality control (QC) (if multiple sites are involved, detail which incoming QC step(s) occur at each site; e.g. nitrocellulose card lamination).	Click here to enter text.	Click here to enter text.
Primary packaging	Click here to enter text.	Click here to enter text.

(e.g. device pouch for RDTs)		
Secondary packaging (e.g. box of 25 RDTs)	Click here to enter text.	Click here to enter text.
Labeling (e.g. lot number, expiry date, IFU)	Click here to enter text.	Click here to enter text.
Lot release QC	Click here to enter text.	Click here to enter text.
Warehousing of finished products	Click here to enter text.	Click here to enter text.
Release for supply	Click here to enter text.	Click here to enter text.
Customer complaints	Click here to enter text.	Click here to enter text.
Technical support	Click here to enter text.	Click here to enter text.

9.4. Production

9.3.1. How many lots do you manufacture per year?	Click here to enter text. Per year
9.3.2. What is the average size of a lot?	Click here to enter text.
9.3.3. How many of this test/device in total do you manufacture per year?	Click here to enter text. Tests/devices per year
9.3.4. How many instruments in total do you manufacture per year?	Click here to enter text. Instruments per year
9.3.5. How many personnel are employed as full-time equivalents at the site of the manufacture?	Click here to enter text.
9.3.6. What is the work area of the manufacturing activity (in square meters)?	Click here to enter text.
9.3.7. What other products are manufactured at the site (brief list)?	Click here to enter text.

9.5. Key suppliers

	9.4.1 List **all** key suppliers and subcontractors who supply products/components/services for the manufacture of this product (e.g. raw materials, enzymes, key components, bulk chemicals and reagents, instruments, etc.)		
Description of the component/product/service supplied	Product code	Name of supplier	Physical address of supplier
Click here to enter text.		Click here to enter text.	Click here to enter text.

Please provide in ANNEX O a flow diagram describing the manufacturing and control processes with relevant parameters.

Please provide in ANNEX P a list of key components and reagents, including supplier name and address.

Please provide in ANNEX T the procedure for the evaluation of key suppliers.

Please provide in Annex U the procedure for quality control of received critical reagents and components.

10. Rationale on the product and the submission

Please provide a rationale for the product's suitability according to the specifications outlined in the Invitation to Manufacturer.

11. Manufacturer Declaration

The undersigned duly authorized representative of the Manufacturer makes the following declarations on behalf of the Manufacturer and, in signing this pre-Questionnaire, declares that he/she has the power and authority to bind the Manufacturer.

I declare that:

- I am authorized to represent the manufacturer specified in this ERPD assessment pre-Questionnaire (the "Manufacturer") for the purposes of WHO diagnostics ERPD assessment of the product specified in this pre-Questionnaire (the "Product").
- All the information provided in this form is current, complete and correct.
- The Manufacturer holds data in support of all claims made in this Questionnaire.
- The information in this questionnaire may be shared confidentially amongst WHO and WHO appointed experts.

- The Manufacturer understands and agrees that the purpose of the ERPD assessment of IVDs is to provide guidance to interested UN agencies and WHO Member States in their procurement decisions. In this regard, the results of the ERPD assessment, the participation in the ERPD assessment process, the ERPD Category of an IVD and/or the WHO name and emblem, may not be used by manufacturers or any other party for commercial and/or promotional purposes.

- The Manufacturer understands and agrees that the validity of the ERPD assessment Category is dependent on the fulfillment of post-assessment requirements including:
    - no changes to the product version, intended use, key suppliers and components listed in 9.5 or to any manufacturing processes or facilities
    - fulfilling post-market surveillance and reporting obligations.
    - and an ongoing compliance with WHO ERPD criteria and expression of interest.

Name of the Duly Authorized Representative of the Manufacturer: Click here to enter text.

Signature of the Duly Authorized Representative of the Manufacturer: _____

Date: Click here to enter text.

Checklist of annex documents to submit with the ERPD questionnaire.

Annexe			Justification if not provided
•	Annex A	Hazardous classification: including Material Safety Data Sheets (MSDS).	Click here to enter text.
•	Annex B	Copy of the WHO ERPD assessment of Diagnostics signed letter of agreement mentioning the No for this specific product and/or copy of product license/approval/registration emitted by the SRA.	Click here to enter text.
•	Annex C	Terms of the contract between the applicant and the OEM related to access to the technical documentation, complaints management, vigilance and recall.	Click here to enter text.
•	Annex D	Instructions for Use (IFU).	Click here to enter text.
•	Annex E	Labeling & packaging: Labels artwork /copy of labels, description and composition of primary, secondary and tertiary (outer shipping) packaging materials.	Click here to enter text.
•	Annex F	Risk analysis, risk management plan and risk control including a) for production and b) end user considerations.	Click here to enter text.
•	Annex G	Stability studies (real time, accelerated, include protocol): shelf life, in-use stability, transportation.	Click here to enter text.
•	Annex H	Analytical studies: analytical performance characteristics including specimen types validation studies.	Click here to enter text.
•	Annex I	Clinical performance studies: By the manufacturer.	Click here to enter text.
•	Annex J	Clinical performance studies (in intended use settings): Independent.	Click here to enter text.
•	Annex K	Other studies performed to demonstrate product performances.	Click here to enter text.
•	Annex L	Design and manufacturing information: design overview including biological safety, if available design and development plan and design and development report	Click here to enter text.
•	Annex M	Procedure for design changes.	Click here to enter text.
•	Annex N	List of standards should include the name of standard organization, standard number, standard title, year/version, and if full or partial compliance.	Click here to enter text.
•	Annex O	Manufacturing processes: flow diagram describing the manufacturing and control processes with relevant parameters.	Click here to enter text.
•	Annex P	List of key components and reagents, including specifications and criteria of acceptance, and suppliers (including for DBS suppliers, if not provided) including supplier name and address.	Click here to enter text.

•	Annex Q	Quality Manual.	Click here to enter text.
•	Annex R	ISO 13485 certificate(s) related to this diagnostic product at this manufacturing site(s).	Click here to enter text.
•	Annex S	Audit/Inspection reports associated with certification (SRA or MDSAP, or CE or USFDA approval if relevant): two most recent and valid surveillance reports and the most recent valid recertification report. Include the list of findings associated with each report.	Click here to enter text.
•	Annex T	Procedure for the evaluation of key suppliers.	Click here to enter text.
•	Annex U	Procedure for quality control of received critical reagents and components.	Click here to enter text.
•	Annex V	Procedure for quality control of lot release including a copy of the certificate of analysis for the last 3 lots released.	Click here to enter text.
•	Annex W	Procedure for handling complaints from customers and other stakeholders.	Click here to enter text.
•	Annex X	Recall Procedure, for recalling products from the market.	Click here to enter text.
•	Annex Y	Description of customer support mechanisms: training (including materials); technical support, customer feedback mechanisms.	Click here to enter text.
•	Annex Z	Any other relevant information.	Click here to enter text.