Pre-submission form

Prequalification of in vitro diagnostics, October 2025 update

How to complete this form:

This form has been designed to assist WHO capture necessary information about a product submitted for WHO prequalification assessment. The information provided by the manufacturer in this form assists WHO in determining whether a product is eligible for WHO prequalification assessment and, if so, the type of assessment (full or abridged) that the product will undergo. The information in this form is also used in the planning of each of the elements of the prequalification assessment. Therefore, the manufacturer must complete the form with accuracy and completeness.

To complete this form, refer to guidance document entitled, "PQDx 017 Instructions for the completion of the pre-submission form", which is available in the WHO website at the following location https://extranet.who.int/prequal/vitro-diagnostics/prequalification-guidance.

Type in text or tick boxes (☐) as required for each field. Where information is not available or the field is not applicable, type in N/A.

The manufacturer should submit this form as a searchable PDF file. In this case, sign the Manufacturer Declaration electronically.

(This document version supersedes any previous document versions)

Pre-submission form - Prequalification of in vitro diagnostics, October 2025 update

Regulation and Prequalification department, Health Systems Division

WHO/MHP/RPQ/PQT/2025.4

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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 & web address	Click here to enter text.	
1.1.6.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 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 people are authorized to represent the manufacturer for the purposes of prequalification of this product.]

2. Product - Information

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

2.1.1. State product name: Click here to enter text.		
2.1.2. Provide the product code for each kit size submitted for WHO prequalification:		
Contents of the kit[2], including accessories	Number of tests per kit: *Click here to enter text.* Product code: *Click here to enter text.*	Number of tests per kit: Click here to enter text. Product code: Click here to enter text. *Complete if multiple kit sizes are available
Kit component (one per line). Click here to enter text.	**Indicate** vial/device/bottle (include volume) Click here to enter text.	**Indicate** vial/device/bottle (include volume) 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.	Click here to enter text.

2.1.3. 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 reagent for each 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.

2.1.4. 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] [**ATTACHMENT:** Attach photographs of all kit components (packaged and individually)]

2.1.5. Is the regulatory version submitted for WHO prequalification commercially available? (See section 5 below)	□ Yes Date product[3] was initially placed on the market: Click here to enter text.
	□ No Product[3] expected to be commercialized by: Click here to enter text.

2.2. Current instructions for use and user manual[4]

2.2.1. 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)	Click here to enter text.
2.2.2. If applicable, the user manual(s) version number for dedicated instrumentation	Click here to enter text.

2.3. Transport, storage and operating temperatures

2.3.1. List transport, storage and operating temperatures and shelf life

Product name (If more than one box, provide the name for each reagent box)	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)
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. Specimen type

3.1.1. Select the specimen type(s) to be used with the product	
☐ Serum	☐ Plasma

[3] Refers to the regulatory version of the product submitted for WHO prequalification

[4] [**ATTACHMENT:** Attach the English language version of the instructions for use (also referred to as a package insert)]

☐	Venous whole blood	☐	Capillary whole blood
☐	Dried blood spot	☐	Concentrated sputum sediments
☐	Raw sputum	☐	Cerebrospinal fluid
☐	Bronchial alveolar lavage	☐	Lymph node aspirate
☐	Stool	☐	Urine
☐	Cervical swab/specimen	☐	Oral fluid
☐	Nasopharyngeal swabs	☐	Oropharyngeal swab
☐	Nasal swabs	☐	Buccal/oral swab
Other: Click here to enter text.			

3.2. HIV

3.2.1.	Select HIV sub-type		
☐	HIV-1/HIV-2 discriminatory detection	☐	HIV-1/2 combined detection
☐	HIV + another analyte	Specify:	Click here to enter text.
3.2.2.	Select HIV analyte		
☐	Antibody	☐	Antigen
☐	Ab/Ag combined detection	☐	Ab/Ag discriminatory detection
☐	Nucleic acid – qualitative	☐	Nucleic acid - quantitative
☐	Surrogate marker for viral load		

3.3. Malaria

3.3.1.	Select malaria species		
☐	*P. falciparum*	☐	*P. vivax*
☐	*P. ovale*	☐	*P. malariae*
☐	*P. knowlesi*	☐	PAN - all malaria species
3.3.2.	Select malaria analyte		
☐	HRP2	☐	pLDH Specify: Click here to enter text.
☐	Aldolase	☐	Multiple/other: Specify: Click here to enter text.
3.3.3.	Select type of detection		
☐	One line	☐	Two or more lines

3.4. Hepatitis

3.4.1.	Select hepatitis C (HCV) analyte		
☐	Antibody	☐	Antigen
☐	Ab/Ag combination	☐	Nucleic acid
3.4.2.	Select hepatitis B (HBV) analyte		
☐	Surface antigen	☐	Nucleic acid

3.5. G6PD detection

3.5.1. Select measurement type	
☐ G6PD qualitative	☐ G6PD quantitative
☐ G6PD semiquantitative	

3.6. Human papilloma virus

3.6.1. Select human papilloma virus (HPV) analyte	
☐ HPV 16, 18	☐ All high-risk HPV
☐ Other combination of high-risk genotypes	Specify: Click here to enter text.
3.6.2. Select method of analysis	
□ Genotype discrimination	☐ Non-discrimination of genotypes

3.7. Cholera

3.7.1. Select *V. cholerae* analyte	
☐ *V. cholerae* O1	☐ *V. cholerae* O1 / O139

3.8. Syphilis

3.8.1. Select syphilis analyte	
☐ Antibodies to *T. pallidum*	☐ Antibodies to *T. pallidum* in combination with antibody detection to non-treponemal antigens

3.9. Tuberculosis

3.9.1. Select TB analyte	
☐ DNA of MTB or MTBC species	☐ DNA of MTBC species and detection of MTBC genomic changes associated with resistance to one or more anti-TB drugs
☐ MTBC genomic changes associated with resistance to one or more anti-TB drugs	☐ Mycobacterial lipoarabinomannan (LAM) antigen

3.10. SARS-CoV-2

3.10.1. Select SARS-CoV-2 analyte	
☐ Antigen	☐ Nucleic acid

3.11. Diabetes

3.11.1. Select measurand	
☐ Blood glucose	☐ HbA1c (Glycated haemoglobin)

3.12. Anaemia (haemoglobin detection)

3.12.1. Select measurand	
☐ Haemoglobin	

3.13. CD4 counting technology[5]

3.13.1. Select the best description of the CD4 count instrument/method.	
☐ Double platform flow cytometer	☐ Single platform flow cytometer
☐ Point-of-care technology	☐ Other: Click here to enter text.
3.13.2. Select the appropriate electricity power requirement	
☐ Alternating current (110-220V)	☐ Direct current (battery, solar power)
3.13.3. Select the type of results obtained	
☐ CD4 counts only	☐ CD4 counts and percent
☐ CD4 counts and hematology	☐ CD4 counts, percent and hematology
☐ CD4 counts semiquantitative	☐ CD4 counts semiquantitative
☐ CD4 qualitative	☐ Other: Click here to enter text.

3.14. Assay format

3.14.1. Select the assay format for serology and nucleic acid testing technologies	
☐ Immunochromatographic (lateral flow)	☐ Immunofiltration (flow through)
☐ Agglutination	☐ EIA (Enzyme immunoassay)
☐ Recombinant immunoblot	☐ Western blot
☐ Antigen neutralization	☐ Immunofluorescence
☐ Nucleic acid test	Specify:
	☐ Nucleic acid test (qualitative) ☐ Nucleic acid test (quantitative)
☐ Reverse hybridization/line probe assay	☐ LAMP
☐ Other: Click here to enter text.	
3.14.2. Assay format/method for blood glucose monitors, HbA1c analysers, and haemoglobin analysers	
☐ Specify: Click here to enter text.	

[5] Section 3.12 applies only to CD4 technologies and should be left blank for other types of products.

3.15. Other disease categories

3.15.1. Specify:Click here to enter text.

4. Product - Operation

4.1. Assay controls

4.1.1. Does the assay include a control line/dot?	□	Yes
	□	No
4.1.2. For nucleic acid test assays, does the assay contain an internal control?	□	Yes
	□	No
4.1.3. Are control specimens (also called test-kit controls) such as positive, negative, low or high controls, supplied within the test kit or available separate from the test kit? If no answer is selected, no control specimens are assumed to be available.	□	Within
	□	Separate

4.2. Product usage

4.2.1. How long does it take to obtain a test result (time required from specimen collection to the final result being read)?	Click here to enter text. Minutes	
4.2.2. State the minimum and maximum number of specimens (excluding controls) that can be tested in a single run	Click here to enter text. Minimum	Click here to enter text. Maximum

4.2.3. If instrument-based, select the technology 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

4.3. 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

5.1.1. Provide the manufacturer's performance characteristics for this product, for each analyte (please 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.

5.2. Specifications for CD4 technologies

5.2.1. Provide the manufacturer's performance characteristics for this product	
Analytical range for CD4 absolute count	Click here to enter text.
Analytical range for CD4%	Click here to enter text. %
Precision (CV%)	Click here to enter text. %
Bias (%)	Click here to enter text. %
If qualitative, state sensitivity and specificity	Sensitivity: Click here to enter text. **%** 95% confidence interval: (Click here to enter text. **to** 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.) **%**

5.3. Specifications for nucleic acid tests

5.3.1. 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	Sensitivity: Click here to enter text. **%** 95% confidence interval: (Click here to enter text. **to** Click here to enter text.) **%**
Clinical/Diagnostic specificity	Specificity: Click here to enter text. **%** 95% confidence interval: (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. **%**

5.4. Specifications for blood glucose monitors, HbA1c point of care analysers, and haemoglobin analysers

5.4.1. Provide the manufacturer's performance specifications for this product, for each measurand	
Packed cell volume (haematocrit) range (for BGM)	Click here to enter text. **%**
Precision (CV%)	Click here to enter text. **%**
Bias (%)	Click here to enter text. **%**
Trueness	Click here to enter text.
Linear range	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 version of the product submitted for prequalification
(Please tick and enter the approval period)[6]: Click here to enter text.

Name of jurisdiction	Type of regulatory status	Product name Product code Period of approval: Start (DD/MM/YY) - Expiry (DD/MM/YY)
Rest of world version	☐ The product submitted for prequalification is not approved in any of the jurisdictions listed below. (Please provide information of any approvals under section 6.1.2)	
European Economic Community (CE-mark) IVDR 2017/746	☐ Certificates issued under Annex IX of Regulation 2017/746 ☐ Certificates issued under Annex X and XI of Regulation 2017/746 ☐ Other Click here to enter text.	Click here to enter text.
European Economic Community (CE-mark) Directive 98/79/EC	☐ Self-declared CE-mark, Annex III	Click here to enter text.
	☐ Full quality assurance certificate, Annex IV.3	Click here to enter text.
	☐ Product design examination certificate, Annex IV.4	Click here to enter text.
	☐ Type examination certificate, Annex V	Click here to enter text.
United States of America (FDA)	☐ 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 (Health Canada)	☐ Medical device license and summary report for a Class III IVD	Click here to enter text.

[6] If more than one regulatory version exists, and at least one regulatory version has undergone stringent regulatory assessment (see Abridged Prequalification Assessment document PQDx_173), please complete Annex 1 to determine if the product can undergo the abridged WHO prequalification assessment.

	☐ 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 (TGA)	☐ 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 (JMHLW)	☐ 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 (HSA)	☐ 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.

6.1.2. Provide details of <u>any other</u> current regulatory approvals for this product
(Do <u>not</u> 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.

6.2. Commercial agreements and re-branding[7]

6.2.1. Do you sell or supply this product or any of the components for re-branding[7]?	☐ Yes
	☐ No
6.2.2. Is this product or any of the major 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.	

6.3. WHO history of product

6.3.1. Has WHO previously assessed this product?	☐ Yes	Date Click here to enter text.
	☐ No	
6.3.2. Has WHO previously assessed this product under a different name?	☐ Yes	Date Click here to enter text.
	☐ No	
If you answered yes to 6.3.2, please provide the name, product code, and PQDx number of the previously assessed product: Click here to enter text.		

7. Manufacturer - Quality Management System

Does the manufacturer have 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.

8. Manufacturer – Quality Management System Certification

Please 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 13485:2016	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.

9. Manufacturer - Sites of Product Manufacture

9.1. Sites of manufacture

Please provide the address where manufacturing occurs. If multiple manufacturing locations are involved, please complete table 9.1.1.

Manufacturing address	Street Name and No.: Click here to enter text.

[7] Applications for WHO prequalification of IVDs are accepted only from the legal manufacturer of the product.

	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.

9.1.1. List <u>all</u> 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 (e.g. device pouch for RDTs)	Click here to enter text.	Click here to enter text.
Secondary packaging (e.g. box of 25 RDTs)	Click here to enter text.	Click here to enter text.
Labelling (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.

9.2. Contact person(s) for inspection

Should WHO determine that an inspection of the manufacturing site(s) is required, please provide below the details of the authorized contact(s) to allow for inspection planning. If there are multiple manufacturing sites, you may provide one contact per site.

Inspection authorized contact		
9.2.1 Name	Click here to enter text.	
9.2.2 Postal address	Site: Click here to enter text.	
	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.
9.2.3 Telephone	Fixed line: Click here to enter text.	Mobile phone: Click here to enter text.
9.2.4 E-mail	Click here to enter text.	
9.2.5 Contact has ePQS access?	☐ Yes	☐ No, to be requested

9.3. 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

9.4. Key suppliers

9.4.1 List **all** key suppliers which 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	Name of supplier	Physical address of supplier
Click here to enter text.	Click here to enter text.	Click here to enter text.

10. Performance evaluation pathway

10.1. Performance evaluation option

Choose one of the two performance evaluation options:	
☐ Option 1	Performance evaluation **commissioned by WHO** and carried out at an evaluating site listed by WHO.

☐ Option 2	Performance evaluation **commissioned by the manufacturer** and carried out at an evaluating site listed by WHO.

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-submission form, 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 prequalification pre-submission form (the "Manufacturer") for the purposes of WHO diagnostics prequalification of the product specified in this pre-submission form (the "Product").
- All the information provided in this form is current, complete and correct.
- Any changes to the information provided in this form will be readily communicated by the Manufacturer to WHO.
- The Manufacturer holds data in support of all claims made in this pre-submission form.
- The Manufacturer understands and agrees that, in the event that WHO agrees to undertake prequalification assessment of the Product: (i) the Manufacturer must complete and sign a Letter of Agreement with WHO relating thereto, and must pay WHO the prequalification fees; (ii) WHO will have absolute, exclusive, unfettered control over the manner in which the prequalification assessment process is carried out (including the performance evaluation and/or the publication of results of the prequalification assessment, regardless of the outcome); and (iii) WHO reserves the right to share the results of the prequalification assessment and the full assessment and inspection reports, including any drafts thereof and including (subject to appropriate obligations of confidentiality) any confidential information to which WHO may gain access in the course of the prequalification process, with the relevant authorities of any interested Member State and with relevant intergovernmental organizations.
- The Manufacturer understands and agrees that the purpose of the WHO prequalification 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 prequalification assessment, the participation in the WHO prequalification assessment process, the inclusion of any product in the WHO list of prequalified IVDs 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 prequalification status is dependent on the fulfilment of post-qualification requirements including:
    - prequalification commitments;
    - annual reporting;
    - reporting of changes;
    - post-market surveillance obligations;
    - receiving re-inspection; and
    - ongoing compliance with WHO prequalification technical specifications.

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.

12.Annex 1: Eligibility for abridged prequalification assessment.

Fill in the following table comparing the differences between regulatory versions in order to assess eligibility for abridged assessment		
A1 – 1 Product details	Regulatory version to be WHO prequalified	Stringent regulatory version(s)[8] (add column, if more than one)
A1 – 2 Product name, product code	Click here to enter text.	Click here to enter text.
A1 – 2.1 The intended use of the IVD, including:	Click here to enter text.	Click here to enter text.
a. what is detected (i.e. analyte).	Click here to enter text.	Click here to enter text.
b. the function of the product (e.g. screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease).	Click here to enter text.	Click here to enter text.
c. the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate.	Click here to enter text.	Click here to enter text.
d. whether the product is automated or not.	Click here to enter text.	Click here to enter text.
e. whether the test is qualitative or quantitative.	Click here to enter text.	Click here to enter text.
f. the type of specimen(s) required (e.g. serum, plasma, venous whole blood, capillary whole blood, dried blood spot, oral fluid, sputum, urine, CSF).	Click here to enter text.	Click here to enter text.
g. the intended testing population.	Click here to enter text.	Click here to enter text.
h. the intended user (e.g. professional or lay user).	Click here to enter text.	Click here to enter text.
A1 – 2.2 A general description of the principle of the assay method or instrument principles of operation.	Click here to enter text.	Click here to enter text.
A1 – 2.3 A description of the components of the test kit (e.g. microtiter plate, test device, reagents, assay controls and calibrators, etc.) for each test kit configuration.	Click here to enter text.	Click here to enter text.
A1 – 2.4 A description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers).	Click here to enter text.	Click here to enter text.

[8] Where stringent assessment means: CE: Class C and Class D (IVDR), FDA: PMA or BLA, Health Canada: Class III or IV, TGA: Class 4, Japan; Minister's approval; Singapore: Class C or D.

A1 – 2.5 A description of the specimen collection and transport materials provided with the product or descriptions of specifications recommended for use.	Click here to enter text.	Click here to enter text.
A1 – 2.6 For instruments of automated assays: a description of the appropriate assay characteristics or dedicated assays.	Click here to enter text.	Click here to enter text.
A1 – 2.7 For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation.	Click here to enter text.	Click here to enter text.
A1 – 2.8 If applicable, a description of any software to be used with the product.	Click here to enter text.	Click here to enter text.
A1 – 2.9 If applicable, a description of the accessories (consumables, equipment) that are required but not provided within the test kit.	Click here to enter text.	Click here to enter text.
A1 – 3 Design and manufacturing information	Click here to enter text.	Click here to enter text.
A1 – 3.1 List design differences between regulatory versions.	Click here to enter text.	Click here to enter text.
A1 – 3.2 List manufacturing process differences between regulatory versions.	Click here to enter text.	Click here to enter text.
A1 – 3.3 List differences for in-process and finalised product quality control between regulatory versions, including QC panel composition.	Click here to enter text.	Click here to enter text.
A1 – 3.4 List differences in sites of manufacture.	Click here to enter text.	Click here to enter text.
A1 – 3.5 List differences in key suppliers.	Click here to enter text.	Click here to enter text.
A1 – 4 Labelling (labels and IFU)	Click here to enter text.	Click here to enter text.
A1 – 4.1 Submit most recent English version of instructions for use for each regulatory version, as an attachment.	Click here to enter text.	Click here to enter text.