WHO-EN-BW-H

**Pre-submission form**

Prequalification of in vitro diagnostics, April 2024 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/pqweb/vitro-diagnostics/procedures-and-fees-prequalification> .

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.

WHO/MHP/RPQ/PQT/2024.2

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2. Manufacturer Information
   1. Legal manufacturer

|  |  |  |
| --- | --- | --- |
| * + 1. Name of manufacturer | Click here to enter text. | |
| * + 1. 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. 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. Manufacturer telephone | Click here to enter text. | |
| * + 1. Manufacturer e mail & web address | Click here to enter text. | |
| * + 1. Name of parent company | Click here to enter text. | |

* 1. Authorized contacts for the manufacturer[[1]](#footnote-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. 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. Authorized contact telephone | Fixed line: Click here to enter text. | Mobile phone: Click here to enter text. |
| * + 1. Authorized contact email | Click here to enter text. | |
| * + 1. Authorized contact job title | Click here to enter text. | |
| * + 1. 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. 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. 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. | |

2. Product - Information
   1. Product name and product code/catalogue number for WHO prequalification assessment

|  |  |  |  |
| --- | --- | --- | --- |
| * + 1. State product name: Click here to enter text. | | | |
| * + 1. Provide the product code for each kit size submitted for WHO prequalification: | | | |
| Contents of the kit[[2]](#footnote-3), 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. |
|  |  | |  |
| * + 1. 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. | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
| * + 1. 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. | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
| * + 1. Is the regulatory version submitted for WHO prequalification commercially available? (See section 6 below) | | **□** Yes  Date product[[3]](#footnote-4) was initially placed on the market:  Click here to enter text. | |
| **□** No  Product3 expected to be commercialized by: Click here to enter text. | |

* 1. Current instructions for use and user manual[[4]](#footnote-5)

|  |  |
| --- | --- |
| * + 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. |
| * + 1. If applicable, the user manual(s) version number for dedicated instrumentation | Click here to enter text. |

* 1. Transport, storage and operating temperatures

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| * + 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. |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| * + 1. Describe any other storage conditions that are applicable to this product:   Click here to enter text. | | | | | |

1. Product - Disease Category, Analyte and Method
   1. Specimen type

|  |  |
| --- | --- |
| * + 1. Select the specimen type(s) to be used with the product | |
| **□** Serum | **□** Plasma |
| **□** 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. | |

* 1. HIV

|  |  |
| --- | --- |
| * + 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. |
| * + 1. Select HIV analyte | |
| □ Antibody | □ Antigen |
| □ Ab/Ag combined detection | □ Ab/Ag discriminatory detection |
| □ Nucleic acid – qualitative | □ Nucleic acid - quantitative |
| □ Surrogate marker for viral load |  |

* 1. Malaria

|  |  |  |  |
| --- | --- | --- | --- |
| * + 1. Select malaria species | | | |
| □ P. falciparum | | □ P. vivax | |
| □ P. ovale | | □ P. malariae | |
| □ P. knowlesi | | □ PAN - all malarial species | |
| * + 1. Select malarial analyte | | | |
| □ HRP2 | □ pLDH | | □ pLDH- *Pf* specific  □ pLDH-PAN  □ pLDH- *Pv* specific (non-HRP2) |
| □ Aldolase | □ Multiple/other:  Specify: Click here to enter text. | | |
| * + 1. Select type of detection | | | |
| □ One line (one species detection) | □ One line (combine detection of 2 or more species) | | □ 2 or more lines (discriminatory detection of 2 or more species) |

* 1. Hepatitis

|  |  |
| --- | --- |
| * + 1. Select hepatitis C (HCV) analyte | |
| □ Antibody | □ Antigen |
| □ Ab/Ag combination | □ Nucleic acid |
| * + 1. Select hepatitis B (HBV) analyte | |
| □ Surface antigen | □ Nucleic acid |

* 1. G6PD detection

|  |  |
| --- | --- |
| * + 1. Select measurement type | |
| □ G6PD qualitative | □ G6PD quantitative |
| □ G6PD semiquantitative |  |

* 1. Human papilloma virus

|  |  |
| --- | --- |
| * + 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. |
| * + 1. Select method of analysis | |
| □ Genotype discrimination | □ Non-discrimination of genotypes |

* 1. Cholera

|  |  |
| --- | --- |
| * + 1. Select *V. cholerae* analyte | |
| □ V. cholerae O1 | □ *V. cholerae* O1 / O139 |

* 1. Syphilis

|  |  |
| --- | --- |
| * + 1. Select syphilis analyte | |
| □ Antibodies to *T. pallidum* | □ Antibodies to *T. pallidum* in  combination with antibody detection to non-treponemal antigens |

* 1. Tuberculosis

|  |  |
| --- | --- |
| * + 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 |  |

* 1. SARS-CoV-2

|  |  |
| --- | --- |
| * + 1. Select SARS-CoV-2 analyte | |
| □ Antigen | □ Nucleic acid |

* 1. Diabetes

|  |  |
| --- | --- |
| * + 1. Select measurand | |
| □ Blood glucose | □ HbA1c (Glycated haemoglobin) |

* 1. CD4 counting technology[[5]](#footnote-6)

|  |  |
| --- | --- |
| * + 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. |
| * + 1. Select the appropriate electricity power requirement | |
| □ Alternating current (110-220V) | □ Direct current (battery, solar power) |
| * + 1. 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. |

* 1. Assay format

|  |  |
| --- | --- |
| * + 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. | |
| * + 1. Select the assay format/method for blood glucose monitors and HbA1c analysers | |
| □ Enzymatic | □ Capillary electrophoresis |
| □ Boronate affinity | □ Immunoassay |
| □ Glucose oxidase method | □ Glucose dehydrogenase method |
| □ Hexokinase method |  |

* 1. Other disease categories

|  |
| --- |
| * + 1. Specify: Click here to enter text. |

1. Product - Operation
   1. Assay controls

|  |  |
| --- | --- |
| * + 1. Does the assay include any form of control (flow or specimen addition)? | **□** Yes |
| **□** No |
| * + 1. For nucleic acid test assays, does the assay contain an internal (amplification) control? | **□** Yes |
| **□** No |
| * + 1. 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 |

* 1. Product usage

|  |  |  |  |
| --- | --- | --- | --- |
| * + 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 | |
| * + 1. 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 |
| * + 1. 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 | | |

* 1. 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 |

1. Product – Performance Characteristics
   1. Performance characteristics for serology EIAs and RDTs

|  |  |  |
| --- | --- | --- |
| * + 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. |

* 1. Specifications for CD4 technologies

|  |  |
| --- | --- |
| * + 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.) **%** |

* 1. Specifications for nucleic acid tests

|  |  |
| --- | --- |
| * + 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. **%** |

* 1. Specifications for blood glucose monitors and HbA1c point of care analyzers

|  |  |  |
| --- | --- | --- |
| * + 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. |

1. Regulatory and Commercial Status of the Product
   1. Regulatory status of product

|  |  |  |  |
| --- | --- | --- | --- |
| * + 1. State the regulatory version of the product submitted for prequalification   (Please tick and enter the approval period)[[6]](#footnote-7): 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. |
| **□** 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. |
| * + 1. Provide details of any 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. |

* 1. Commercial agreements and re-branding[[7]](#footnote-8)

|  |  |
| --- | --- |
| * + 1. Do you sell or supply this product or any of the components for re-branding 7? | □ Yes |
| □ No |
| * + 1. 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. | |

* 1. WHO history of product

|  |  |  |
| --- | --- | --- |
| * + 1. Has WHO previously assessed this product? | **□** Yes | Date Click here to enter text. |
| **□** No | |
| * + 1. 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. | | |

1. 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. |

1. 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 13485:2003  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. |
|  |  |  |

1. Manufacturer - Sites of Product Manufacture
   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. | |
| 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. 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 | Click here to enter text. | Click here to enter text. |
| (list the site(s) manufacturing each of the critical raw materials; e.g. assay buffer) |
| Assembly of device | Click here to enter text. | Click here to enter text. |
| (if multiple sites are involved, detail which step(s) occur at each site; e.g. nitrocellulose card lamination) |
| In-process quality control (QC) | Click here to enter text. | Click here to enter text. |
| (if multiple sites are involved, detail which incoming QC step(s) occur at each site; e.g. nitrocellulose card lamination). |
| Primary packaging | Click here to enter text. | Click here to enter text. |
| (e.g. device pouch for RDTs) |
| Secondary packaging | Click here to enter text. | Click here to enter text. |
| (e.g. box of 25 RDTs) |
| Labelling | Click here to enter text. | Click here to enter text. |
| (e.g. lot number, expiry date, IFU) |
| 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. |

* 1. 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. | |

* 1. Production

|  |  |
| --- | --- |
| 9.3.1How many lots do you manufacture per year? | Click here to enter text. per year |
| 9.3.2What is the average size of a lot? | Click here to enter text. |
| 9.3.3How many of this test/device in total do you manufacture per year? | Click here to enter text. tests/devices per year |
| 9.3.4How many instruments in total do you manufacture per year? | Click here to enter text. instruments per year |

* 1. Key suppliers

|  |  |  |
| --- | --- | --- |
| 9.4.1List **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. |
|  |  |  |
|  |  |  |
|  |  |  |

1. Performance evaluation pathway
   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. |

1. 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.

1. 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 | | |
| * 1. Product details | Regulatory version to be WHO prequalified | Stringent regulatory version(s)**[[8]](#footnote-9)**  (add column, if more than one) |
| * 1. 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. |
| 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. |
| * 1. 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. |
| * 1. 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. |

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.] [↑](#footnote-ref-2)
2. [**ATTACHMENT:** Attach photographs of all kit components (packaged and individually.] [↑](#footnote-ref-3)
3. Refers to the regulatory version of the product submitted for WHO prequalification [↑](#footnote-ref-4)
4. [**ATTACHMENT:** Attach the English language version of the instructions-for-use to this application form. Instructions-for-use are also known as a package insert.] [↑](#footnote-ref-5)
5. Section 3.12 applies only to CD4 technologies and should be left blank for other types of products. [↑](#footnote-ref-6)
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. [↑](#footnote-ref-7)
7. Applications for WHO prequalification of IVDs are accepted only from the legal manufacturer of the product. [↑](#footnote-ref-8)
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. [↑](#footnote-ref-9)