**UNFPA Questionnaire   
for *In vitro* Diagnostic products**

## 

## Part I. Submitter and Manufacturer Information 1.1 Submitter

Name of submitter: Click here to enter text.

Address: Click here to enter text.

Contact person’s name: Click here to enter text.  
Email: Click here to enter text.  
Phone: Click here to enter text.

Status of the submitter:

Legal manufacturer Yes  No   
 or

Distributor – Trader Yes  No

## 1.2 Legal manufacturer

|  |  |  |
| --- | --- | --- |
| 1.2.1 Name of manufacturer | Click here to enter text. | |
| 1.2.2 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. |
| 1.2.3 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. |
| 1.2.4 Manufacturer telephone | Click here to enter text. | |
| 1.2.5 Manufacturer email & web address | Click here to enter text. | |
| 1.2.6 Name of parent company | Click here to enter text. | |
| 1.2.7 List of all manufacturing  sites/addresses | Click here to enter text. | |

**Part II. Product Information**

## 2.1 Product name and product code

|  |  |  |  |
| --- | --- | --- | --- |
| 2.1.1 Product name: Click here to enter text. | | | |
| 2.1.2 Provide the product code for each kit size submitted for UNFPA evaluation: Click here to enter text. | | | |
| Contents of the kit[[1]](#footnote-1), including accessories: 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 kitsizes are available/offered.  Number of tests per kit:  Click here to enter text.  Product code:  Click here to enter text. |
| Insert name of one component per line.  Click here to enter text. | IndicateXx vial/device/bottle (xx volume)  Click here to enter text. | | Indicate Xx vial/device/bottle (xx 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 kit) | |
| 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. | |
|  |  |  | |
|  |  |  | |
|  |  |  | |

## 2.2 Current instructions-for-use and user manual[[2]](#footnote-2)

|  |  |
| --- | --- |
| 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. |

## 2.3 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. | | | | | |

**Part III. Product – Disease Category, Analyte and Method**

## 3.1 Disease category, type of analyte and IVD method of analysis

|  |  |
| --- | --- |
| 3.1.1 Disease category | Click here to enter text. |
| 3.1.2 Analyte - (Name and type of  analyte molecule: Antibody,  Antigen, NA, etc.) | Click here to enter text. |
| 3.1.3 IVD method of analysis | Click here to enter text. |
| 3.1.4 Other information | Click here to enter text. |

## 3.2 Specimen or sample type

|  |  |
| --- | --- |
| 3.2.1 Select the specimen type(s) to be used with the product | |
| **□** Serum | **□** Plasma |
| **□** Venous whole blood | **□** Capillary whole blood |
| **□** Oral fluid | **□** Dried blood spot |
| **□** Urine | **□** Stool |
| Other: Click here to enter text. | |

**Part IV. Product – Operation**

## 4.1 Assay controls

|  |  |
| --- | --- |
| 4.1.1 Does the assay include any form of control to indicate that the specimen has been added? | **□** Yes |
| **□** No |
| 4.1.2 For NAT assays, does the assay contain an internal (amplification) 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 of the test kit? If no answer is selected, no control specimens are assumed to be available. | **□** Within |
| **□** Separate |

**Part V. Regulatory and Commercial Status of the Product**

## 5.1 WHO Prequalification

|  |  |  |
| --- | --- | --- |
| 5.1.1Is the product WHO prequalified? | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 5.1.2Has the product undergone one of the following:  1) a WHO Emergency Use Evaluation and Listing of IVDs (EUAL), 2) an US FDA Emergency Use of Medical Products and Related Authorities (EUA), 3) an approval process from Stringent Regulatory Authority (SRA) designated by Global Harmonization Task Force (GHFT) Competent Authority. | **□** Yes | Name: Click here to enter text. Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 5.1.3Is the product for “Research use only” or “For export only”? | **□** Yes | |
| **□** No | |

|  |  |  |
| --- | --- | --- |
| 5.1.4 Provide details of any other current regulatory approvals for this product  (Do not include ISO 13485 certification details here. This is covered in question 6) | | |
| 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. |
|  |  |  |
|  |  |  |

**5.2 Is the product CE marked?**  Yes No

Nature of the EC certification (IVD 98/79/EEC, name annexes): Click here to enter text.

Identification of the Notified Body (+ identification number): Click here to enter text.

**5.3 Is the product FDA approved?**  Yes No

If the device is “510k cleared”, indicate the 510k clearance #: Click here to enter text.

If the device is “PMA cleared”, indicate the PMA clearance #: Click here to enter text.

**5.4**  Is the **product approved by National Regulatory Agency?**  Yes No

Nature of the approval/certification: Click here to enter text.

Name of the National Regulatory Agency: Click here to enter text.

**Part VI. Manufacturer – Quality Management System**

**6.1 Legal Manufacturer:**

1. ISO 9001 Yes  No 
   1. Certification body and number: Click here to enter text.
   2. Expiration date: Click here to enter text.
2. ISO 13485 Yes  No 
   1. Certification body and number: Click here to enter text.
   2. Expiration date: Click here to enter text.

**6.2 Submitter** (if the submitter is not the legal manufacturer):

1. ISO 9001 Yes  No 
   1. Certification body and number: Click here to enter text.
   2. Expiration date: Click here to enter text.
2. ISO 13485 Yes  No 
   1. Certification body and number: Click here to enter text.
   2. Expiration date: Click here to enter text.

**Part VII. Checklist of Required Documentation**

Documents to be submitted (**where applicable**) must be true and valid copies. All documents submitted must be in English or be accompanied with certified translation.

Copy of ISO 13485\* Certificate (for manufacturer and for trader and for possible subcontractor).

Copy of ISO 9001\* Certificate (for manufacturer and for trader)

Declaration of conformity stating compliance to the relevant standards.

Approval letter or certificate (National Regulatory Body) and/or CE certificate (European Notifying body), and/or 510k or PMA device letter (FDA).

Proof of WHO prequalification (If available, or other similar)

Photo of the product and packaging (at various angles if necessary).

Technical Sheet of the IVD product.

An English language version of the instructions-for-use for the IVD product. Instructions-for-use are also known as a package insert.

A certificate of analysis for at least one recently released batch.

UNFPA Questionnaire for Electrical or Battery Operated Equipment (*if applicable*).

\*) UNFPA accepts the versions of currently active standards, which are recognized by the International Organization for Standardization at the time of document submission.

1. [**ATTACHMENT:** Attach photographs of all kit components (packaged and individually.] [↑](#footnote-ref-1)
2. [**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-2)