**Fast Track Procurement Questionnaire**

**for *In vitro* Diagnostic Products (IVD)**

## Part I. Manufacturer Information Bidder (if not manufacturer): Click here to enter text.

**Manufacturer:** Name of manufacturer: Click here to enter text.  
 Country: Click here to enter text.  
 Address (office): Click here to enter text.  
 Address (manufacturing site(s)): 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.

**Part II. Product Information**

## 2.1 Product name and product code

|  |  |
| --- | --- |
| 2.1.1 Product name: Click here to enter text. | |
| 2.1.2 Manufacturer’s **product code** as it appears in the label and catalog (reference number):   Click here to enter text. | |
| 2.1.3 Product details, or individual contents of the IVD kit[[1]](#footnote-1), including accessories | 2.1.4 Number of tests per box/kit  (if different kit sizes are available, complete one form per each kit) |
| *Insert name of one component per line, add more rows if needed.* Click here to enter text. | *Indicate units,**X tests/vials/devices/ bottles (a volume)*  Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| 2.1.5 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: Click here to enter text. | |
| 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.  Click here to enter text. | |

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

|  |  |
| --- | --- |
| 2.2.1 Name of the disease, category | Click here to enter text. |
| 2.2.2 Analyte - (Name and type of  analyte molecule: Antibody,  Antigen, DNA, RNA, etc.) | Click here to enter text. |
| 2.2.3 IVD method of analysis (e.g. PCR,  POCT, immunoassay, ELISA,etc.) | Click here to enter text. |
| 2.2.4 Other information | Click here to enter text. |

## 2.3 Specimen/sample type

|  |  |
| --- | --- |
| 2.3.1 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 |
| 2.3.2 Other information (e.g. sample volume or quantity, requirements for sample collection, specify acceptable blood sample anticoagulants, etc.): Click here to enter text. | |

## 2.4 Transport, storage and operating temperatures

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 2.4.1. List transport, storage and operating temperatures and shelf life (add more rows if needed). | | | | | |
| 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. |
|  |  |  |  |  |  |
| 2.4.2. Describe any other storage conditions that are applicable to this product:  Click here to enter text. | | | | | |

**Part III. Regulatory Status**

|  |  |  |
| --- | --- | --- |
| 3.1Is the product WHO prequalified? | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 3.2Has 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 (GHTF) Competent Authority. | **□** Yes | Name of body: Click here to enter text. Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 3.3Is the product for “Research use only” or “For export only”? | **□** Yes, specify Click here to enter text. | |
| **□** No | |

|  |  |  |
| --- | --- | --- |
| 3.4Is the product CE marked (IVDD 98/79/EC)?  Certification body and number: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 3.5Is the product FDA approved?  510k clearance #: Click here to enter text.  PMA clearance #: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 3.6 Is the product approved by National Regulatory Agency or Department?  Name of agency and type of approval: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| 3.7 Provide details of any other current regulatory approvals for this product.  Name of jurisdiction and type of approval: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |

3.8 Manufacturer QMSISO 9001 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

3.9 Manufacturer QMS ISO 13485 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

**Part IV. Checklist of Required Documentation**Documents to be submitted must be true and valid copies. All documents submitted must be in English or be accompanied with a certified English translation.

☐ Copy of ISO 13485\* Certificate  
☐ A signed and dated Declaration of Conformity according to ISO 17050 stating compliance to critical ISO standards and directives, and which has reference to the offered product.  
☐ Approval letter or certificate (National Regulatory Body) and/or EC certificate (European Notifying body), and/or 510k or PMA device letter (FDA).   
☐ Proof of WHO prequalification (If product is not prequalified, a proof of approval by one of the other regulatory bodies in section 3.2 is mandatory)  
☐ Evidence that the product is registered in the country of intended use.  
☐ Certificate of analysis for at least one recently released batch.  
☐ Photos of the finished IVD product and labeling.  
☐ A certificate of analysis for at least one recently released batch.

\*) 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)