**Expression of Interest Submission Form for Performance Evaluation Laboratories**

WHO Prequalification of In Vitro Diagnostics

**Indicate if submission is for List 1 or List 2 evaluating laboratory[[1]](#footnote-1)**

|  |  |
| --- | --- |
| List 1 |  |
| List 2 |  |

**Tick all that apply**

|  |  |
| --- | --- |
| G6PD deficiency |  |
| HPV NAT |  |
| TB NAT |  |

# Contact Information

## Laboratory details (indicate address of each site if more than one site must be assessed)

|  |  |  |
| --- | --- | --- |
| **Name of Department/ Laboratory** |  | |
| **Name of parent or legal organization** |  | |
| Address | Street Name and No.: | |
| City: | State/Province: |
| Postcode: | Country: |
| Postal address | Street Name and No.: | |
| Postal Office Box No.: | |
| City: | State/Province: |
| Postcode: | Country: |
| Telephone |  | |
| E-mail |  | |
| Website |  | |

## Authorized contacts for the laboratory

|  |  |  |
| --- | --- | --- |
| **Name of *first* authorized contact** | Salutation (Dr, Mr, Mrs, Miss, Prof) |  |
| First Name |  |
| Middle Name |  |
| Last Name |  |
| Authorized contact job title |  | |
| Authorized contact postal address | Department: | |
| Street Name and No.: | |
| City: | State/Province: |
| Postcode: | Country: |
| Authorized contact telephone | Fixed line: | Mobile phone: |
| Authorized contact e-mail |  | |
|  |  | |
| **Name of *second* authorized contact** | Salutation (Dr, Mr, Mrs, Miss, Prof) |  |
| First Name |  |
| Middle Name |  |
| Last Name |  |
| Authorized contact job title |  | |
| Authorized contact postal address | Department: | |
| Street Name and No.: | |
| City: | State/Province: |
| Postcode: | Country: |
| Authorized contact telephone | Fixed line: | Mobile phone: |
| Authorized contact email |  | |

# General Information about the laboratory

|  |  |  |  |
| --- | --- | --- | --- |
| Certification/Accreditation (Quality Management System or other including Biosafety level) | | | |
| **Title of Certificate** | **Issue Date** | **Expiry Date** | **Issuing Organization** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| Activities | |
| General description of the laboratory/organization (status and mission) |  |
| Main functions of the laboratory (tick all that apply) | Routine pathology service  Reference laboratory  Research laboratory  Other  If other, specify: |
| Disciplines of testing of the laboratory (tick all that apply) | Serology  Molecular biology  Flow cytometry  Microbiology  Other  If other, specify: |
| Number of full-time or equivalent technical staff members who are currently employed in the laboratory? Include their technical expertise. |  |
| Biobanking capacities | |
| Does the laboratory have a biobanking capacity?*If yes, please provide the information below* |  |
| What is the capacity available for storage and at what temperature (-20°C/-80°C) |  |
| How are the freezers monitored? |  |
| Describe the specimen inventory system |  |

# Analyte-specific information

**Please complete one per analyte selected (copy and paste the table for additional analytes)**

|  |  |  |
| --- | --- | --- |
| Analyte (please tick only one, that the information below relates to) | G6PD deficiency  TB NAT | HPV NAT |
| Reference method(s) | | |
| List the validated reference method(s) used for this analyte (corresponding SOP and method validation protocol and report shall be provided in attachment) |  | |
| Capacity to acquire and store analytical and clinical specimens | | |
| Is a panel of specimens already available for this analyte? (Yes/No) |  | |
| If yes, please provide details about the panel (origin, number of positive/negative specimens, type of specimens, approximate volume, characterization) |  | |
| Is it possible to collect specimens prospectively for this analyte? (Yes/No) |  | |
| Describe availability of prospectively collected specimens relevant for this analyte, including: specimen types (e.g. venous whole blood, capillary whole blood, plasma, sputum, etc.), possible sources of collection (e.g. on-site, or collaborating clinic/hospital), the approximate number of specimens per month (positive/negative) and whether these are left-over specimens from routine collection or should be collected specifically for the evaluation | |  |  |  |  | | --- | --- | --- | --- | | Specimen Type | Source(s) of collection | Approximate number per month | Left-over or purposefully collected | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | |
| Has the laboratory performed independent performance evaluations of IVDs for this analyte? (Yes/No) |  | |
| If yes, provide an overview including the objective (250 words) anda link to the publication(s), if any. |  | |

# Attachments

**Attachments requested:**

|  |  |  |
| --- | --- | --- |
| **Attachment** | **Provided? (Y/N)** | **Comments** |
| 1. Copy of the current Quality Management System Certificate(s) and scope of testing (annex to the Certificate of Accreditation) |  |  |
| 1. Specific testing method validation protocol |  |  |
| 1. Specific testing method validation report |  |  |
| 1. Standard Operating Procedures of the specific testing method which is being applied for. |  |  |
| 1. The final External Quality Assessment performance reports of the specific testing method for the past year, that is being applied for approval. |  |  |
| 1. A copy of the Quality Manual (in English). |  |  |
| 1. Organigram. |  |  |
| 1. Floor plan of the laboratory |  |  |

# Submission of the EOI Form and Attachments

Please submit all documentation **by electronic copy only** by any of the following means:

1. **To the email address** [**diagnostics@who.int**](mailto:diagnostics@who.int) **(the default combined file size limit is 10 MB)**
2. **Uploading a compressed folder format (i.e. .zip) to the dropbox folder**

[**https://fileinbox.com/diagnostics**](https://fileinbox.com/diagnostics)  (please ensure that the folder is clearly identified and send an email to [diagnostics@who.int](mailto:diagnostics@who.int) to inform of the submission)

1. **Save your file to a cloud service and share a link**

# Authorized Representative Declaration

The undersigned key authorized representative of the laboratory makes the following declarations on behalf of the laboratory and, in signing this form, declares that he/she has the authority to establish working agreement with WHO.

I declare that

* I am authorized to represent the laboratory specified in this questionnaire that supports the EOI from the laboratory.
* Information stated in Section 4 of this questionnaire has been submitted as attachments.
* All the information provided in this form and its attachments is current and correct.

Name of Authorized Contact Person for the Laboratory: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Authorized Contact Person for the Laboratory: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. List 1 will include laboratories that will work directly with WHO during the evaluation process

   List 2 will be laboratories that will work directly with the manufacturers during the evaluation process [↑](#footnote-ref-1)