**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-2)**

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

**Tick all that apply**

|  |  |
| --- | --- |
| G6PD deficiency |  |
| Malaria rapid diagnostic tests |  |
| STI (C. trachomatis, N. gonorrhoeae, T. vaginalis) NAT |  |
| STI (C. trachomatis, N. gonorrhoeae) RDT |  |
| TB NAT |  |
| TB LAM |  |

# 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) |
| **Title of certificate** | **Issue date** | **Expiry date** | **Issuing organization**  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| Activities  |
| General description of the laboratory/organization (legal status) |  |
|  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.  |  |
| Experience with evaluation of in vitro diagnostics |
| Describe the experience of the laboratory in evaluation of in vitro diagnostics (number of studies initiated in the past 5 years and status of studies) |  |
| If applicable, describe how data management and analysis for studies is handled (internal or external) |  |
| Number of staff with certificates on GCP and/or ethics for clinical studies |  |
| 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 [ ]  STI Ag RDT [ ] Malaria RDT [ ]  | HPV NAT [ ]  TB LAM [ ] STI NAT [ ]   |
| Reference method(s) |
| List the validated reference method(s) used for this analyte (corresponding SOP and method verification/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. A copy of the Quality Manual (in English)
 |  |  |
| 1. Specific testing method verification/validation protocol
 |  |  |
| 1. Specific testing method verification/validation report
 |  |  |
| 1. Standard operating procedures of the relevant testing method(s)
 |  |  |
| 1. The final external quality assessment (EQA) summary performance reports of the relevant testing method(s) for the past year
 |  |  |
| 1. Organigram
 |  |  |
| 1. Minutes of the last management review (local language acceptable)*a*
 |  |  |
| 1. Internal audit summary report (local language acceptable)*a*
 |  |  |

*a If the documents are provided in the local language, an on-line translator will be used for translation to English*

# Submission of the EOI form and attachments

All submission must be sent through ePQS portal, please follow the steps:

1. Request registration the [ePQS portal](https://who.my.site.com/ePQS/s/login/) by completing the form available at <https://who.my.site.com/ePQS/s/login/> and sending to diagnostics@who.int.
2. You will receive an email with an invitation to access the ePQS portal. We will also send you an email providing guidance for first access and for submitting a PEL application through the wizard.
3. Submit a completed expression of interest form and the required annexes in the WHO ePQS portal through the application wizard using the guidance document provided in the portal. Additional information on the use of the ePQS portal may be on the webpage below. <https://extranet.who.int/prequal/epqs-portal>
4. Please send an email to diagnostics@who.int to inform of the submission.

# 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-2)