



Expression of Interest Submission Form for Meningitis Rapid Diagnostic Tests (RDT)

Infectious Hazard Management (IHM) Department

1 Contact Information

1.1 Company details (indicate address of each site if more than one site in the manufacture of the tests to be assessed)

| | | | |
|---|------------------------|----------|--|
| Name of manufacturer | | | |
| Address | Street Name and No.: | | |
| | City: | | |
| | Postcode: | Country: | |
| Postal address | Street Name and No.: | | |
| | Postal Office Box No.: | | |
| | City: | | |
| | Postcode: | Country: | |
| Telephone | | | |
| E-mail | | | |
| Web address | | | |
| Address where test is assembled i.e. from raw materials through to finished product | | | |
| Address where quality control testing is performed prior to release to customers. | | | |
| Name of parent or legal organization if relevant | | | |

1.2 Authorized contacts for the company

| | | |
|---|----------------------|---------------|
| Name of <i>first</i> authorized contact | | |
| Authorized contact postal address | Department: | |
| | Street Name and No.: | |
| | City: | |
| | Postcode: | Country: |
| Authorized contact telephone | Fixed line: | Mobile phone: |
| Authorized contact e-mail | | |
| | | |
| Name of <i>second</i> authorized contact | | |
| Authorized contact postal address | Department: | |
| | Street Name and No.: | |
| | City: | |
| | Postcode: | Country: |
| Authorized contact telephone | Fixed line: | Mobile phone: |
| Authorized contact email | | |

Product Information

2.1 Description of the Meningitis RDT

| | |
|--|--|
| <i>Product name</i> | |
| <i>Product code(s)/Catalogue number(s) and number of tests per kit</i> | |

2.2 Assay format

| | |
|--|--|
| <i>Immunochromatographic (lateral flow)</i> | |
| <i>Immunofiltration (flow through)</i> | |
| <i>Agglutination</i> | |
| <i>EIA (Enzyme Immunoassay) in microtitre plate format</i> | |

2.3 Product Characteristics

| | <i>NmA</i> | <i>NmC</i> | <i>Nmw</i> | <i>NmX</i> | <i>NmY</i> | <i>Sp</i> | <i>Hib</i> |
|--|------------|------------|------------|------------|------------|-----------|------------|
| <i>Target detection</i> | | | | | | | |
| <i>Sensitivity with 95% confidence intervals</i> | | | | | | | |
| <i>Specificity with 95% confidence intervals</i> | | | | | | | |
| <i>Type of analysis (qualitative vs. quantitative)</i> | | | | | | | |
| <i>Reading system (visual or otherwise)</i> | | | | | | | |
| <i>Time to result (mins)</i> | | | | | | | |
| <i>Number of tests per hour</i> | | | | | | | |
| <i>Sample preparation requirements</i> | | | | | | | |

2.4 Product operational characteristics

| | | | |
|--|-------------------------|-----------------------|----------------------|
| <i>Shelf-life of reagents/kit</i> (months from date of manufacture) | | | |
| <i>Stability (conditions for transportation, storage and in-use stability of the test kit)</i> (indicate temperature and humidity ranges) | <i>Transport</i> | <i>Storage</i> | <i>In-use</i> |
| <i>Reagent reconstitution (need to prepare reagents prior to testing)</i> | | | |
| <i>Biosafety requirements (level of protection required for the operator and the specimens)</i> | | | |
| <i>List of items required but not provided including any equipment</i> | | | |
| <i>End-user profile (level of education of the operator in charge of the test)</i> | | | |
| <i>Training requirements</i> | | | |

2.5 Independent performance evaluations¹

Provide details of independent performance evaluations carried out for this product in the last five years regarding sensitivity, specificity and thermostability

| <i>Name of Independent Evaluation Centre</i> | <i>Physical Address of Independent Evaluation Centre</i> | <i>Date of Evaluation (Year)</i> |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

2.6 Product regulatory status

| <i>Name of Regulatory Authority</i> | <i>Type of Regulatory Approval</i> | <i>Period of Approval</i> |
|--|---|----------------------------------|
| | | |
| | | |
| | | |

¹ You may add peer reviewed published papers/conference abstracts from independently conducted studies.

2 Attachments

Please consider the list of attachments that are requested for the submission to be accepted as complete.

Attachments requested:

1. Copy of the current Instructions for Use (IFU) for the Meningitis RDT to be assessed (in English and French when available)
2. Copy of the manufacturer Quality Management System Certificate, ISO13485 or equivalent.
3. Copy of summary reports of independent evaluation studies and manufacturer verification/validation studies on sensitivity, specificity and thermostability
4. Copy of valid regulatory certificates or marketing authorizations (if available)
5. Any other document supporting the information provided in the submission form

3 Submission of the EOI Form and Attachments

One hard copy and one electronic copy of the completed EOI Submission Form and the above listed attachments must be posted before 31st October 2017 to:

World Health Organization
IHM/PAT/EVS (c/o Dr Olivier Ronveaux)
20 Avenue Appia
CH-1211, Geneva 27
Switzerland

4 Disclaimer

This Request for Expression of Interest is not a solicitation, and replying to it does not guarantee that a vendor will be invited to any solicitation by WHO. No further details of the planned solicitation will be made available to vendors prior to the issuance of solicitation documents. In the event of a solicitation for

the subject matter described herein, any Request for Proposal and any subsequent purchase order or contract will be issued in accordance with WHO's rules and procedures.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an Expression of Interest will exclusively be borne by the applicant. The application and selection process set forth in this document will not be subject to claims for financial compensation of any kind whatsoever.

WHO is acting in good faith by issuing this Request for Expression of Interest, however, this Request for Expression of Interest does not entail any commitment on the part of WHO, either financial or otherwise. WHO reserves the right to send solicitation documents to vendors identified by WHO through means other than this Request for Expression of Interest; reject any or all Expression(s) of Interest, without incurring any obligation to inform the affected applicant(s) of that decision or the grounds thereof; and/or change or cancel the procurement process at any time, including during the Request for Expression of Interest or formal solicitation processes.

5 Authorized Representative Declaration

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

I declare that

- I am authorized to represent the manufacturer specified in this EOI Submission form (the "Manufacturer") for the purposes of an assessment allowing eligibility for procurement by WHO of the product specified in this EOI Submission form (the "Product").
- Information stated in Section 3 of this questionnaire has been submitted as attachments.
- All the information provided in this form and its attachments is current, complete and correct.

Name of key authorized representative of the Company: _____

Signature: _____

Date: _____