

Invitation to manufacturers of Meningitis rapid tests to submit an expression of interest

Infectious Hazard Management, WHO Health Emergencies Programme, WHO Geneva

20 September 2017

IHM Department invites manufacturers of Meningitis Rapid Diagnostic Tests (RDT) to submit an Expression of Interest (EOI) for WHO assessment allowing eligibility for procurement by WHO services.

Aim

The invitation is to encourage manufacturers to submit an application for assessment against WHO requirements and international standards for Meningitis RDTs. Products that meet the established requirements will be eligible for procurement by WHO, UN agencies, and affiliated partner organizations.

Background for this invitation

The IHM team aims at selecting the best quality products for procurement of Meningitis RDTs and making them available to the WHO Member States at risk for Meningitis outbreaks. This invitation refers to an assessment which will be conducted by WHO/IHM department following an abbreviated process compared to a full or abridged WHO Prequalification assessment. If and when the scope of WHO Prequalification assessment is extended to in vitro diagnostics for detection of Meningitis, the products selected through the present assessment process will be automatically eligible for prequalification assessment.

This initiative is launched in a context where Meningitis outbreak management is challenged by the difficulty to diagnose the serogroup of meningococcal meningitis. Hence the RDTs should be planned for use as a surveillance tool guiding public health control measures -the vaccine response- during outbreaks of meningococcal meningitis. At individual level, the RDT should also be used as an easy to use method to aid the diagnosis of bacterial meningitis. The expected scale of manufacture is between 15 000 and 30 000 tests per year for the African Meningitis belt countries.

Conditions related to the application

- Participation in this assessment process is voluntary
- The manufacturer of the Meningitis RDT must share its Quality Management System certificate for review
- Only submissions by original manufacturers will be considered, submissions by distributors/agents/re-branders will not be eligible for assessment
- This invitation is not limited to any particular type of rapid test format. However, WHO reserves the right to prioritize products with attributes as defined after a consultation with the WHO collaborating centres for Meningitis
- The products to be submitted for evaluation should meet the specifications outlined below:

Target Population/Patient

Patient meeting the suspect case of Meningitis clinical definition presenting to health care facility and on whom a lumbar puncture is performed

Target use setting

- Decentralized health care facilities with no laboratory infrastructure available. The test is performed at point of care where suspect cases are presenting
- Decentralized laboratory where a cerebrospinal fluid sample from a suspect patient is brought within one hour from the time of collection

Scope of testing and test performance

Key features	Desired	Acceptable
Target pathogens	Neisseria meningitidis serogroup A, B, C, X, Y and W Streptococcus pneumoniae Haemophilus influenzae	Neisseria meningitidis serogroup A, B, C, X, Y and W
Sample type	CSF	CSF
Type of analysis	Qualitative	Qualitative
Reading system	Visual reading by the operator	Visual reading by the operator
Level of differentiation	Species and serogroup	Serogroup
Sensitivity (under lab conditions, reference test: quantitative PCR assay)	> 90% for each pathogen	> 90% for each pathogen
Specificity	> 95% for each pathogen No cross reaction	> 90% for each pathogen No cross reaction
Limit of detection	0.5 ng of the corresponding capsular polysaccharide or 10 ² CFU/ml	1 ng of the corresponding capsular polysaccharide or 10 ³ CFU/ml

Test procedure and operational characteristics

Key features	Desired	Acceptable
Number of steps	1	1
Precision pipetting	Not required	Not required
Specimen preparation	Not required	Not required
Time to result	< 10 minutes	< 20 minutes
Shelf-life	18 months at 2-30°C and 80% humidity	12 months at 2-30°C and 80% humidity
Reagent reconstitution	All reagents ready to use	Reconstitution acceptable if very simple, all liquids including water included in the test kit
Biosafety requirements	None in addition to waste management and use of non- sterile gloves	None in addition to waste management and use of non- sterile gloves
Need for additional equipment	None	Simple equipment, table top device, portable
End-user profile	Any level of health care worker	Any level of health care worker
Training requirements	Operator able to run the test after a brief review of IFU – Job-aid provided in the kit	Half a day training - Job-aid provided in the kit

Submission of an EOI

All information must be submitted before 31st October 2017. Manufacturers interested in having their product assessed under this procedure must provide WHO with the completed EOI submission form with all the requested attachments.

Assessment process following submission of an EOI by a manufacturer

The assessment process of the Meningitis RDTs by WHO/IHM consists of the following steps:

1. Receipt of the EOI
2. Stage 1 audit – assessment of EOI and specific quality management system certificate
3. Stage 2 audit – performance evaluation of the submitted product at a laboratory designated by WHO
4. Listing of eligible products for procurement of Meningitis RDTs by WHO

Outcome of the assessment process

If the assessment demonstrates that an RDT for Meningitis meets WHO requirements, it will be listed as WHO eligible Meningitis RDT for procurement for a time period specified by WHO. Once a product is listed, post market surveillance will be established. WHO may delist a WHO eligible Meningitis RDT when there is evidence of non-compliance with WHO requirements.

If you have any questions relating to the procedure, please contact Dr Ronveaux meningitis@who.int