

ANNEX I
EXPRESSION OF INTEREST SUBMISSION FORM

WHO EVALUATION
OF
MOLECULAR ASSAYS FOR YELLOW FEVER VIRUS

CONTACT INFORMATION

Company details

Please 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	
	City	
	Postcode	
Telephone		
E-mail		
Web address		
Address of the legal manufacturer of the product		
Address(es) where test is manufactured and assembled (i.e. from raw materials through to finished product)		
Address where quality control testing is performed for product release		
Name of parent or legal organization if relevant		

Authorized contacts for the company

Name of PRIMARY authorized contact		
Authorized contact	Department	
Postal Address		
	Street Name and No	
	City	
	Postcode	
PRIMARY Contact Telephone	Fixed Line:	Mobile:
PRIMARY Contact E-mail		
Name of SECONDARY authorized contact		
Authorized contact	Department	
Postal Address		
	Street Name and No	
	City	
	Postcode	
SECONDARY Contact Telephone	Fixed Line:	Mobile:
SECONDARY Contact E-mail		

PRODUCT INFORMATION

Product Name	
Product code(s)/Catalogue number(s) and number of tests per kit	
Format of test	<input type="checkbox"/> RT-PCR <input type="checkbox"/> Isothermal (specify) <input type="checkbox"/> Other (specify)
Level of automation	<input type="checkbox"/> Fully (specimen added and results calculated) <input type="checkbox"/> Partially (all reagent addition etc) <input type="checkbox"/> Not automated
If not fully automated, please describe the extraction system/s that the assay has been validated to	
If not fully automated, please describe the thermocycler/s that the assay has been validated to	<input type="checkbox"/> ABI 7500 Real-Time PCR <input type="checkbox"/> ABI 7500 Fast Real-Time PCR <input type="checkbox"/> Qiagen Rotor-Gene Q <input type="checkbox"/> Cepheid Smart Cyclex <input type="checkbox"/> ABI 2720 Thermal Cyclex <input type="checkbox"/> Other (specify)
Analytical Sensitivity (Limit of Detection)	
Diagnostic Sensitivity (with 95% confidence intervals) N.B. If confidence intervals not available, please provide absolute numbers tested.	xx.x% (95% CI xx.x-xx.x%)
Positive Percent Agreement (PPA)	
Diagnostic Specificity (with 95% confidence intervals) N.B. If confidence intervals not available, please provide absolute numbers tested.	xx.x% (95% CI xx.x-xx.x%)

Negative Percent Agreement (NPA)	
Quality Control(s)	<input type="checkbox"/> Internal (specify) <input type="checkbox"/> Process/Extraction (specify) <input type="checkbox"/> External (specify)
Result Output	<input type="checkbox"/> Qualitative <input type="checkbox"/> Quantitative <input type="checkbox"/> Semi-quantitative (i.e. cut-off)
Time to Result (hours)	
Shelf-life – Closed Kit (time and temperature range)	
Shelf-life – Open Kit, including after component reconstitution if relevant (time and temperature range; note if all reagents have the same in-use storage or provide details of all differences)	
Transport Conditions (temperature, humidity, time and any other relevant information)	
On Instrument Stability (if applicable) (time and temperature range)	
Operating Specifications (temperature and humidity range)	
Kit Format	<input type="checkbox"/> All materials required for the procedure are contained in the kit including controls reagents and needed consumables (e.g., reagent grade water) <input type="checkbox"/> Other (specify).
Kit Throughput (Specimens, and Controls)	Number of tests per Kit – Number of Specimens per Kit – Number of Controls per Kit –
Batch Run Size – is it the Kit throughput flexible?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Is reagent reconstitution required? If yes, please provide details.	<input type="checkbox"/> Yes <input type="checkbox"/> No
List of items required but not provided, including any equipment	
Specimen transport conditions (as validated time/temperature range)	
Patient identification capability Please describe if there is the ability to track electronic identification of the patient either manually or by bar code.	
Result interpretation	<input type="checkbox"/> Manual (specify) <input type="checkbox"/> Automatic (specify output)
Training requirements	
Target list price USD	
Quality systems certification (ISO 13585, ISO 9001, MDSAP, etc.)	
Any other information that you feel is important for WHO to know	

ATTACHMENTS

Please provide a copy of the current Instructions for Use (IFU) for each NAT you are submitting. If these are not provided in paper format, please provide information on how these can be obtained.

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 03 March 2023 to:

Jean-François Lemaire,
VPD Surveillance and Risk Assessment team, Immunization Analysis and Insights (IAI) Unit, Department of Immunization, Vaccines & Biologicals (IVB), World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland

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.

AUTHORISED 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: _____