NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME

TECHNICAL SPECIFICATIONS OF BIVALENT ANTIGEN-DETECTING RAPID DIAGNOSTIC TESTS (RDTs) FOR *P. FALCIPARUM* AND *P. VIVAX* MALARIA UNDER NVBDCP

A. Description of the Test Kit

The Bivalent Rapid Diagnostic Test (RDT) for Malaria should comprise of test card (cassette) and reagents including buffer solution in a dropping bottle.

The test kit should be able to rapidly diagnose both *P. falciparum* and *P. vivax*. The test should be based on the principle of capture of parasite antigen from blood using monoclonal antibodies specific for antigen targets.

Each test kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, heparinized capillary tubes (diameter -1 mm) with relevant markings and reaction tubes with stand / wells as required.
The manufacturer should have specified International Organization for Standardization [ISO] certification. One should be able to perform the test with the blood taken by finger prick of the patient.

Temperature stability data: information on thermal stability data for the lab product should be available

Type of RDT – The RDT should be able to detect *P.falciparum* Histidine-Rich Protein-2 (HRP2) and *P. vivax* Lactate Dehydrogenase (pLDH) **and not aldolase**.

RDT Performance criteria:

The Products should conform to the following set of criteria (A-D), based on the results of the evaluation of the WHO Malaria RDT Product Testing:

(A) For the detection of *Plasmodium falciparum* (Pf) in all transmission settings the panel detection score (PDS) against Pf samples should be at least 75% at 200 parasites/μL.

(B) For the detection of *Plasmodium vivax* (Pv) in all transmission settings the panel detection score (PDS) against Pv samples should be at least 75% at 200 parasites/μL.

(C) The false positive rate should be less than 10%

(D) The invalid rate should be less than 5%

Each lot of RDT should be tested at a designated lot testing laboratory by using WHO protocol at the time of delivery. Only those lots with **PASS** report will be accepted for delivery.

B. Content of Kit and Packaging :

Each kit should be hermetically sealed in non-permeable pouch and should have moisture absorbent material.10 such test cards (cassette),or lesser quantity as required by the Programme should be packed in a box containing the reagents and the test plates. Adequate literature detailing the test kit components, principle, methodologies and validity criteria as specified under 'RDT performance criteria' should be provided in the kit inserts with the test kits.

Storage conditions, expiry dates and limitations of test should be provided. The small box should be packed in bigger cardboard carton containing 5 such small boxes. The carton should be sealed with a sealing tape.

C. Shelf Life:

Shelf life from manufacturing date to expiry date should be at least 2 years and the RDTs should not have lost more than $1/6^{th}$ of their effective life from the date at the time the material is offered for inspection. Losses due to premature deterioration as a result of biological and other activities during the life of potency of the Rapid Diagnostic Tests will be made good by the firm at its own cost.

D. Stability requirements at temperatures of intended storage, transport and use:

RDTs should have high thermal stability for use in areas with very high ambient temperatures as per the evaluation by WHO Malaria RDT Product Testing against a single cultured *P. falciparum* isolate at 200 parasites/μL at baseline and after 60 days of incubation at room temperature, **35 °C and 45 °C.**

E. Quality Assurance:

The product should comply with ISO 13485.

F. Marking /Labeling:

(i) Each card (cassette) should have space for recording particulars of patients, time and date of the test

(ii) The large carton (containing 10 small boxes) and small box (containing 10 tests) should have the following markings :

a. Name of the test
b. Lot number
c. Manufacturing and expiry date
d. Name of the manufacturer with address
e. Details of the contents
f. Storage conditions

g. Handling procedures
h. Disposal instruction for the box and its contents
i. GOI, NVBDCP Supply – NOT FOR SALE

G. Details regarding approval of license

(i) Manufacturing and Marketing License for manufacturing of Rapid Malaria Diagnostic Tests should have been obtained from the concerned Regulatory authority in the country by the manufacturer.

(ii) The Bidders must submit scientific study report in support of their claim of performance criteria of the offered product, i.e. WHO FIND report mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc. Claim should be supported by reports of actual shelf life studies.

(iii)Reports of proven performance of the offered product in conditions similar to Indian field conditions (room temperature up to 40^0 C) with certification of no adverse report for the offered product from the end users during the last five years must be submitted with the bid.

(iv)The Bidders must submit a sample of their product (for example as two kits to Procurement Agent for assessment of user friendliness by Procurement Agent.

(v) Recommended conditions for storage (e.g. room temperature) and shelf life should clearly be mentioned on the label of RDT.

H. Shipping from manufacturer

Before shipping: The manufacturer should provide to the consignees the details of airway bill numbers, airline carrier, flight number, numbers of containers, expected arrival time. These details should be sent by email and followed up by fax.

The shipper (air carrier) should be notified of temperature storage requirements by the manufacturer in writing and by clear markings on cartons and related documents. (Stowage of the shipment close to the skin of some aircraft may result in freezing.)

The manufacturer should initiate shipment only when the consignee has confirmed the receipt of shipping notification.

Manufacturer should ensure / arrange to have customs agents or other personnel on site to receive materials. Shipments should be moved immediately to moderate temperature storage places (less than 30°C). Leaving materials on airport tarmacs, in customs sheds, or in vehicles should be avoided.

I. Ground transportation

Ground transportation should be carried out during any stage of delivery without delay, maintaining temperature requirements while the vehicle is moving and is parked. Avoid leaving RDTs in vehicles parked in the sun.

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