

**Technical Specification of Bivalent Rapid Diagnostic Test kits for detecting
P. falciparum and P. vivax Malaria under NVBDCP**

A. Description of the Test Kit

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

The test kit should be able to conduct the rapid diagnosis for 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 material required for conducting 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 required packing standards and labeling should meet the Good Manufacturing Practices (GMP) standards. The manufacturer should have 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 Real-time stability for the lab product and accelerated stability for the purchased lot should be available.

Each batch of RDK should be tested during time of delivery to ensure sensitivity and specificity as follows:

(i) For Pf:

Sensitivity and Specificity should be minimum 95% at parasite density level of 200 asexual parasites/ul of blood.

(ii) For Pv:

- Sensitivity: $\geq 75\%$ at density of 200 parasites/ul of blood
- Specificity : $\geq 90\%$

Type of RDT- Only Histidine-Rich Protein 2 (HRP2) and Parasite lactate dehydrogenase (pLDH) based RDTs to be used and **not aldolase based ones**.

B. Content of Kit:

Each kit should be hermetically sealed and non-permeable pouch and should have moisture absorbent material. 10 such test cards (cassette) should be packed in a box containing the reagents and the test plates. Adequate literature detailing the components, methodologies, validity criteria.

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 day to expiry date should be at least 2 years and it should not pass more than 1/6th 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 Test kits will be made good by the firm at their cost.

D. Quality Assurance:

The product should be complied with ISO 13485.

E. Marking /Labeling:

- (i) Each card (cassette) should have space for patients particulars and date of the test
- (ii) The large carton (containing 5 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 content
 - f. Storage conditions
 - g. Handling procedures
 - h. Disposal instruction for the box and its contents
 - i. **NVBDCP Supply – NOT FOR SALE**

F. Details regarding approval of license

- (i) Manufacturing and Marketing License for manufacturing of Rapid Malaria Diagnostic Kits 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 sensitivity and specificity of the offered product from an institution recognized for the purpose. **RDK should be stable up to 40⁰ C**. Claim should be supported by actual shelf life studies.
- (iii) Reports of proven performance of the offered product in conditions similar to Indian field conditions (room temperature up to 40⁰ 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 condition for storage (e.g. room temperature) and shelf life should clearly be mentioned on the label of RDK.

G. Shipping from manufacturers

Before shipping: The manufacturer contacts consignees with 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) is 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 initiates shipment only when the consignee confirms the shipping notification is received.

Consignees then arrange to have customs agents or other personnel on site to receive materials. Shipments are moved immediately to moderate temperature storage (less than 30°C if possible). Avoid leaving materials on airport tarmacs, in customs sheds, or in vehicles.

H. Ground transportation

Ground transportation during any stage of delivery is carried out without delay and with attention to ambient temperature while the vehicle is moving and if parked. Avoid leaving RDTs in vehicles parked in the sun.