National Vector Borne Disease Control Programme

Technical Specification of Bivalent antigen-detecting rapid diagnostic tests (RDTs) for P. Falciparum and P. Vivax malaria under NVBDCP

Existing NCVBDC Technical Specifications for Bivalent RDT Malaria
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) only.
RDT Performance criteria:
The Products should conform to the following set of criteria (A-D) : (A) For the detection of Plasmodium falciparum (Pf) in all transmission settings the panel detection score (PDS) against Pf samples should be at least 95% sensitivity & specificity 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% sensitivity & 90 % specificity 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 ICMR laboratory 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 10 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 1/6th 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 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 evaluation by ICMR 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 be complied with ISO 13485:2016 or latest.

F. Marking /Labelling:

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

a. 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. NVBDCP, Dte.GHS 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 bidder must submit scientific study report of product testing at designated ICMR laboratory in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc.

(iii) Reports of proven performance of the offered product in conditions similar to Indian field conditions (room temperature up to 45°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. Ground Transportation

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

Approved as on 06/06/2022

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