National Center for Vector Borne Diseases Control, Delhi

Technical Specifications of Rapid Diagnostic Test kit for Kala-Azar

14.06.2024

A. Performance:

The product (IgG - an Antibody based test) should have at least 95% and above specificity and sensitivity for wider competition under field conditions.

B. Ease of Use:

Kits should allow for the use whole blood/serum for conducting the test.

C. Packaging & labeling:

Each kit should be hermetically sealed in non – permeable pouch and should have desiccant pouch / canister. 25 such test kits or lesser quantities as required by the programme should be packed in a box. Adequate literature detailing the kit components, principles, methodologies, and validity criteria should be provided as the kit insert with the test kit.

- Each test kit should have space for recording particular of the patients, time, and date of the test.
- · Storage conditions, expiry dates and limitations of the test should be provided.
- The large carton (containing 10 small boxes) and small boxes (containing 25 test kits) should have the following markings; Name of the test, Lot/Batch number, Manufacturing and expiry date. Name of manufacturer and address, Details of content, storage conditions, Handling procedures, Disposal instruction for the box and its content.
- · The cartoon should be sealed with sealing tape.
- NVBDCP Dte. GHS, Govt. of INDIA supply NOT FOR SALE.

The product insert/leaflet should have the pictorial representation of the test procedure/methodology and the product label should comply with Chapter VI of Medical Devices Rules, 2017 or latest.

D. Condition of uses:

The test should have thermal stability for use in areas with very high ambient temperatures as per evaluation after 60 days of storage at 30 to 45 degrees Celsius.

The cumulative time temperature indicator technology may be used along with the product package to monitor recommended storage conditions during storage & transportation of the kits.

E. Shelf life:

Shelf life from manufacturing date to expiry date should be at least 2 years and it should not have lost more than 1/6th of its effective life from the date the date at the time material is offered for inspection. In case of losses due to premature deterioration as a result of biological and other activities during the life of potency of the test, it will be made good by the supplying firm at their own cost.

F. Quality Assurance:

The product should comply with BIS/ ISO 13485:2016 standards or the latest.

Each lot may be tested at the designated laboratory before being used by the program division.

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Registration of Product:

The product should be licensed for import/ manufacture by DCG (I) / State drug controller under Drugs and Cosmetics Act 1940 and the rules framed therein.

Field tested: H.

Satisfactory field tested reports should have been generated through designated institute(s) such as ICMR - RMRIMS, Patna.

Above Technical Specification of Rapid Diagnostic Test kit under NVBDCP approved by Technical Specification Committee in the meeting held on 06.05.2024.

(Ms. Akansha Jain) AGM(QA), CMSS

(Dr. Sambit Pradhan)

(Dr. T. Sonai Rajan) Asst. Director, CIB&RC

(Dr. Shahwar Kazmi) NPO-VL, WHO

Jt. Director, NCDC

Asst. Director, NCVBDC & Member Secretary

(Dr. Rinku Sharma) Jt. Director, NCVBDC (Dr. Annam Visala) JDC(I), CDSCO

(Dr. Prashanta Saini) Scientist C. VCRC

(Dr. Mehvash Haider) Asst. Prof., VMMC-SJH

(Dr. M.P.S. Chawla) Cons. Prof. & HoD(Med.) ABVIMS& RML H

(Dr. Mala Chhabra) Cons. (Microb.) ABVIMS & RMLH

Aryind Kumar) Addi. Prof. (Med.) AIIMS

Spoul Supti (Dr. Sparsh Gupta), Prof. (Pharm.), VMMC-

SJH

th hladhawar (Dr. Preeti Wadhawan) CMO(SAG), I/c, MSO

(Dr. Sagar Borker) Asst. Prof. (PSM), ABVIMS & RMLH

Dr. Kanika Jain Asst. Prof. (Hosp.) AIIMS

(Dr. S.C.Sarangi) Addl. Prof. (Pharm.) **AIIMS**

Dr. Ajay Kumar Sci. B, RMRIMS, Patna

(Dr. Roshan K Topno) Sci. E, RMRIMS, Patna

(Dr. Abhinav Sinha) Scientist F, NIMR, Delhi

Ym (Dr. Neelima Mishra), Scientist G, ICMR

(Sh. Rakesh Kumar) DDG(Stat.), Dtc. GHS (Dr. Rupak Chatterjee) Advisor, MSO

(Dr. Tanu Jain) Director, NCVBDC

Prof. (Dr.) Atul Goel Director General, Dte. GHS & Chairperson