

**National Center for Vector Borne Diseases Control**  
**Technical Specification for Rapid Diagnostic Test Kit for Kala-azar**

Approved on 01.02.2026 as per discussions held in TSC Meeting - 15.12.2025

**A. Description of the Test Kit**

- The rapid diagnostic test (RDT) kits for Kala-azar should comprise of immunochromatographic lateral flow rapid test and reagents including buffer solution in a dropping bottle.
- The test kit should be able to rapidly diagnose both VL and PKDL. The test should be based on the detection of antibodies to a recombinant antigen (rk-39) specific for VL in human whole blood.
- Each test kit should contain all the material required for performing the test. Test kit, lancet, swabs, capillaries, buffer solution should be available in the primary box. Procedural control line mandatory on test strip to validate test.
- One should be able to perform the test with the patient blood sample taken by finger prick on sample pad of the device.
- Information on the thermal stability data for the lab product should be available

**B. Type of RDT:**

- The RDT should be able to detect the presence of IgG antibodies against the recombinant antigen (rk-39) specific for Visceral leishmaniasis parasite in patients' blood.

**C. RDT performance criteria:**

The product should conform to ALL the following criteria (a-d)

- a) For the detection of VL/PKDL in all transmission settings, the product should have  $\geq 95\%$  sensitivity and  $>95\%$  specificity under field condition.
- b) The false positive rate should be less than 5%
- c) The invalid rate should be less than 5%
- d) Each lot of RDT should be have a PASS report generated by a designated ICMR laboratory such as ICMR-RMRIMS Patna at the time of delivery.

**D. Ease of Use:**

- Kits should allow the use whole blood for conducting the test.
- One should be able to perform the test with the patient blood sample taken by finger prick on the sample pad of the device.

**E. Content of Kits and Packaging:**

- Each kit box should contain individual test kits in hermetically sealed non-permeable pouch containing desiccant pouch. Not more than 25 such test kits 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 each individual kit.

*Handwritten signatures and initials:*  
 msh, h, Dufat, Lenu, Anur, Mestika, de, the, was, John, Insobol, Anant



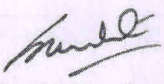
## National Center for Vector Borne Diseases Control

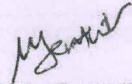
**J. Details regarding approval license:**

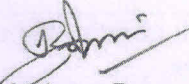
The product should be licensed by the competent authority defined under Drugs and Cosmetics Act 1940 and the Medical Devices Rules 2017 and amendments thereafter.


**K. 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 vehicle parked in the sun.

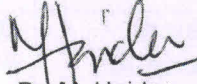
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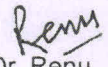
  
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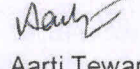
  
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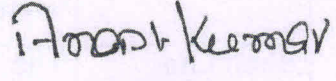
  
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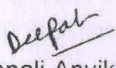
  
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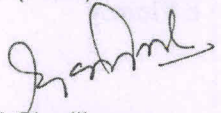
  
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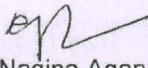
  
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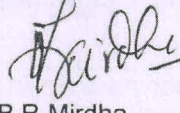
  
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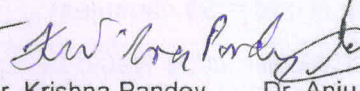
  
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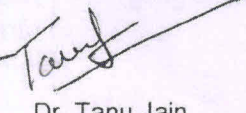
  
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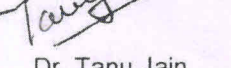
  
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Dr. Nagina Agarwal  
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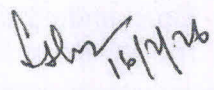
  
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