

Minutes of the meeting of Technical Specification Committee held on 19.03.2009 under the chairmanship of Dr. Shiv Lal, Special DGHS, Govt. of India to finalize technical specifications of Rapid Diagnostic Kits for Kala-azar

The following members were present :

1. Dr.D.Kanungo, Addl. DG (Stores), R.K.Puram, New Delhi.
2. Prof. K.D.Tripathi, (Rtd.), Deptt. of Pharmacology, MAMC, New Delhi.
3. Dr. Dinesh Srivastava, Consultant (Medicine), RML Hospital, New Delhi
4. Sh. A.K.Kamra, Director (Procurement), Dte. GHS, Nirman Bhawan, New Delhi.
5. Dr. Jagriti ~~Singh~~, <sup>Bhata, Pharmacology</sup> Clinical Microbiology Division, AIIMS, New Delhi. *Jagriti*
6. Dr. Neena Valecha, DD(SG), NIMR, New Delhi.
7. Sh. A.K.Pradhan, Asstt. Drugs Controller (I), GOI, New Delhi.
8. Dr.G.P.S. Dhillon, Director NVBDCP, Delhi.

Dr. V.K.Saxena, Joint Director & Head, Centre for Medical Entomology and Vector Management, NICD, Delhi and Dr. S.N.Sharma, Joint Director, National Vector Borne Disease Control Programme, Delhi assisted the committee.

There was only one agenda items w.r.t. the technical specification of rapid diagnostic kits for kala-azar to be procured under the National Vector Borne Disease Control Program, which was taken up by the technical specification committee for discussions.

Director, NVBDCP mentioned that the procurement of rapid diagnostic kits was made by NVBDCP through M/s RITES for the first time during 2005-06. This product was manufactured & supplied by Inbios USA being proprietary item. For the year 2007-08, UNOPS was requested to procure 2.11 lakhs of rK39 diagnostic kits for kala-azar with the same specifications as that of rK39 produced by Inbios USA. In the bid evaluation report (BER), UNOPS recommended NOA for all the four schedules to M/s Span diagnostics who manufacture rK16 diagnostic kits.

A representation was made by Inbios India dated 27<sup>th</sup> Feb. 2008 for the procurement of RDK for kala-azar addressed to UNOPS & copy endorsed to NVBDCP & MOH. It is mentioned that the Signal – KA Rapid diagnostic kits for kala-azar quoted by M/s Span Diagnostics do not match with the tender specifications of UNOPS. The specification were similar and very specific in view of the last purchase made through M/s RITES considering the item as proprietary

*Saxena*  
*Jagriti*  
*Tripathi*  
*A. Kanungo*  
*Kamra*  
*Valecha*  
*Pradhan*  
*Dhillon*

item. The standard of the product was also not known and quality assurance has not been tested under field conditions in programme mode. This product has also not been used in the programme earlier.

World Bank also intimated that advice from WHO has been sought and only rK39 – inbios product has been validated by WHO and recommended for the procurement of this product. MOH desired that the matter may be re-looked by the specification committee for final recommendations.

In view of the above, the technical committee deliberated on the matter at length during its meeting on 3.4.2008 and opined that there should be generic specifications to provide equal opportunities to all manufacturers presently available. But, there should not be any compromise with the quality of the product. Draft technical specifications of rapid diagnostic kits for kala-azar were also formulated.

Meanwhile, NICD branch Patna was requested to evaluate all the presently available rapid diagnostic kits for kala-azar in the market. The evaluation report submitted was put up to the committee on 19.3.2009 to examine the salient findings of the NICD, Branch Patna and to formulate technical specification of rapid diagnostic kit for kala-azar. After deliberations, all the committee members agreed upon to the following technical specifications for rapid diagnostic kit for kala-azar.

**Technical Specification for Rapid Diagnostic Kits for Kala-azar**

**Performance:**

The product should have sensitivity and specificity above 90% under field conditions.

**Ease of use:**

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

**Packaging:**

At least each rapid test strip should be individually packed in moisture proof pouch.

**Conditions of storage:**

The kit should be stable through its shelf life, when stored at a maximum of 30 degree Celsius.

[Handwritten signatures: Z. D., Gupta, Khanna, White, Singh, and others]

**Shelf life:**

A minimum of 12 months.

**Registration of the manufacturer :**

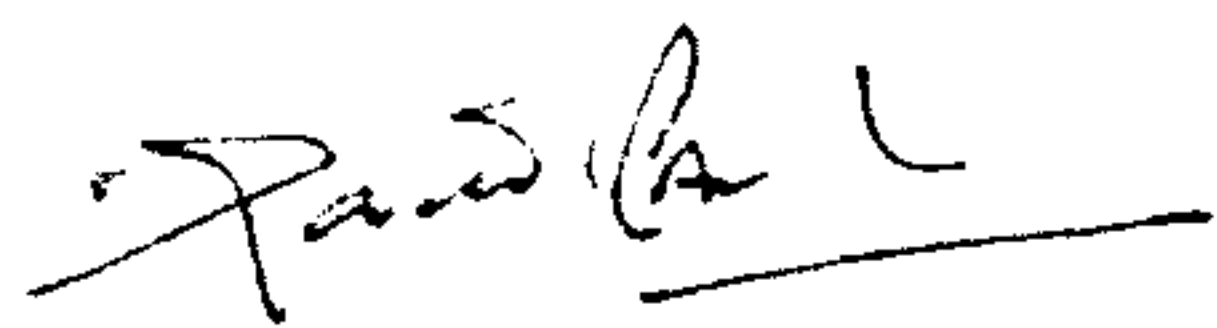
The product should be licensed for import / manufacture by DCG(I) / State drug controller under Drugs and Cosmetics Act 1940 and rules framed therein.

**Field Tested:**

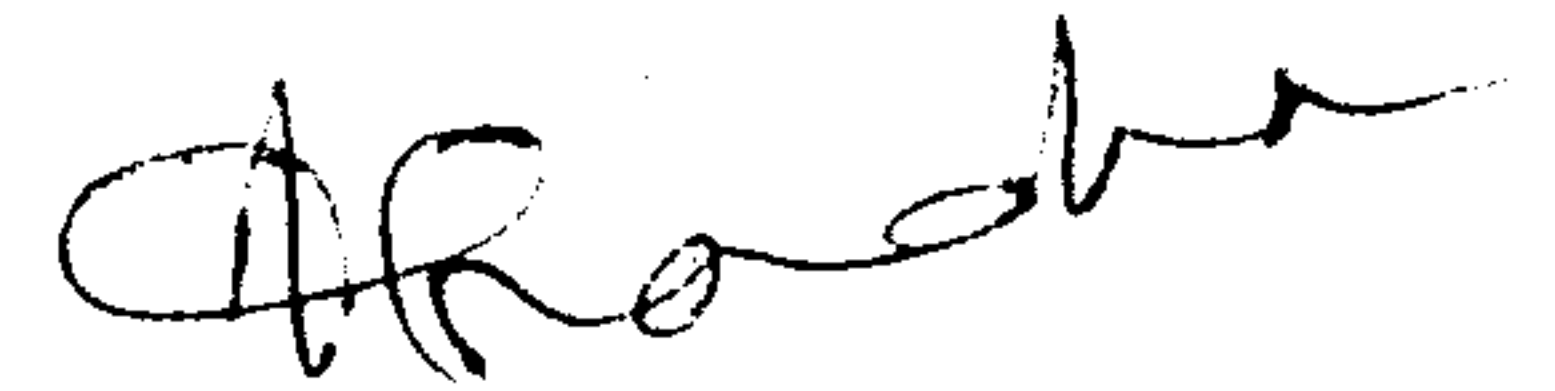
Satisfactory field tested report should have been generated through any institute designated by the programme.

**Labeling:**

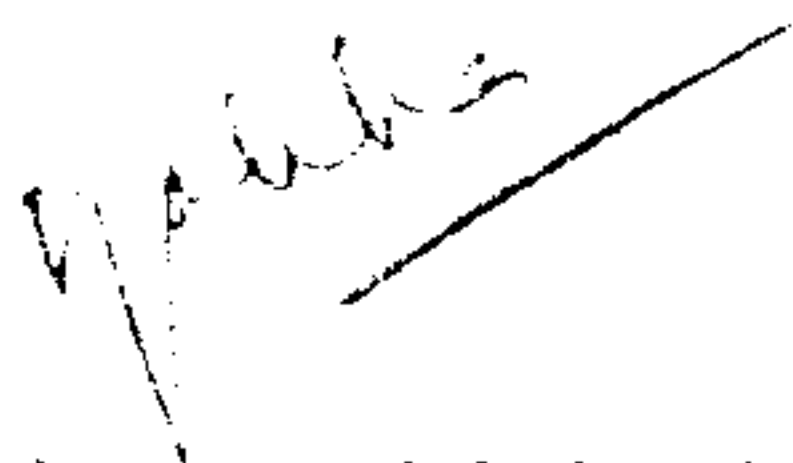
Each strip of the test should be labeled as NVBDCP Supply – Not for Sale.



Dr. G.P.S. Dhillon,  
Director NVBDCP



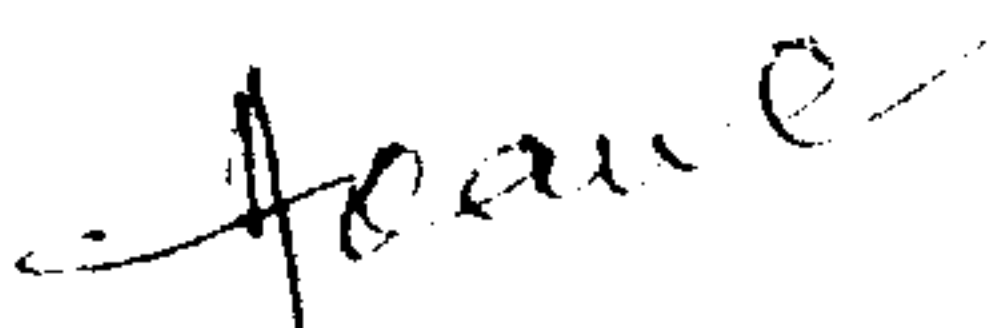
Sh. A.K. Pradhan,  
Asstt. Drugs Controller (I),



Dr. Neena Valecha,  
DD(SG), NIMR



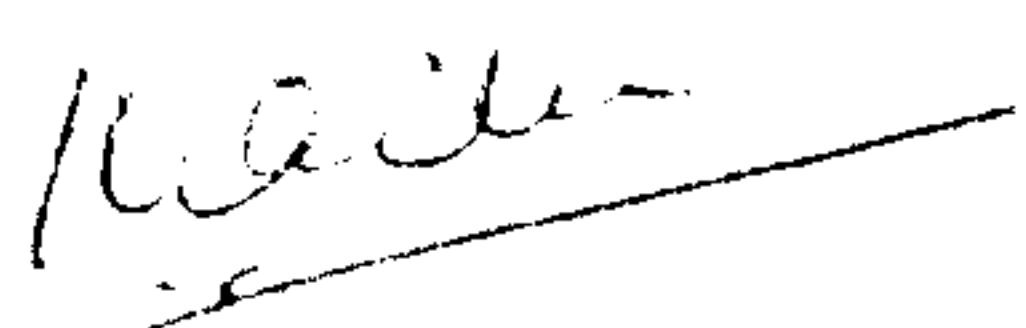
Dr. Jagriti Singh Bhatia  
Clinical Microbiology Division, Pharmacy,  
AIIMS



Sh. A.K. Kamra  
Director (Procurement)



Dr. Dinesh Srivastava  
Consultant (Medicine), RML Hospital



Prof. K.D. Tripathi, (Rtd.),  
Deptt. of Pharmacology, MAMC



Dr. D. Kanungo  
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Dr. Shiv Lal  
Special DGHS(PH)  
Chairperson