

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device & Diagnostics Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

F. No. 29/Misc/4/2013-DC (52)

Date :

14 FEB 2014

To

The Director,
✓ National Institute of Biological,
A-32, Sector -62 (Institutional Area)
Noida-201309

SUB: "Specification" and "Criteria for acceptance" for test performed on Syphilis Rapid and ELISA Kits- Regarding

Sir,

Please refer to your letter no I/DIR.OFF/2012-13/NIB/1100 dated 25-07-13 and letter no. 1-14/Lab Corroes /IDKL dated 06-02-2014 received by this office vide FTS 8371 dated 07-02-2013 on the subject matter.

In this connection this office has constituted a Experts Committee to examine the "specification" and "criteria for acceptance" for the test performed on Syphilis Rapid and ELISA Kits. Said meeting was held on 07-10-2013 at this office, minutes of meeting is enclosed herewith for your kind perusal.



Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (I)

Encl:-

Copy of the minutes of the meeting of the Experts committee to examine the Specification and Criteria for acceptance for test performed on Syphilis Rapid and ELISA Kits held at CDSCO, FDA Bhavan, Kotla Road, New Delhi-110002

Minutes of the meeting of the Experts Committee to examine the 'Specifications' and 'Criteria for acceptance' for Tests performed on Syphilis Rapid and ELISA Kits' held on 07 Oct 2013 at CDSCO, FDA Bhavan, Kotla Road, New Delhi-110002.

Name of the Experts attended the meeting:

1. Dr. Reba Chhabra, Scientist –II
National Institute of Biologicals (NIB), Noida
2. Dr. Charu Mehra Kamal., Scientist III
National Institute of Biologicals (NIB), Noida
3. Mr. Pankaj Sharma, Junior Scientist
National Institute of Biologicals (NIB), Noida
4. Dr. A. R. Risbud., Scientist – F
National AIDS Research Institute, Pune
5. Dr. Nupur Gupta
Non-Teaching Specialist (Microbiology)
Division of Microbiology
National Center for Disease Control (NCDC),
New Delhi

Name of the Expert absent for meeting:

1. Dr. Padmakar S. Sathe, Scientist –E
National Institute of Virology
2. Dr. J. C Samantaray
Head, Department of Microbiology; AIIMS

Invitees

1. Federation of Indian Chambers of Commerce and Industry (FICCI)

- I. Mr Alok Soni, Head RA and Quality System; Siemens Ltd.
- II. Ms Jay lande, Executive RA, BD, INDIA
- III. Mr. Gaurav Mendiratta, Assistant Director, FICCI

2. Confederation of Indian Industry (CII)

- I. Mr Bivash Chakraborty- Biomerieux
- II. Mr. Virendra Verma - Abbott

3. The Association of Diagnostics Manufacturers of India (ADMI)

- I. Mr Pradeep Desai, Span Diagnostics

Officers form CDSCO (HQ):

1. Dr. S. Eswara Reddy, Deputy Drugs Controller (India), CDSCO HQ, New Delhi
2. Dr. Ravi Kant Sharma, Assistant Drugs Controller (India), CDSCO HQ, New Delhi
3. Sh. Sanjay Kumar Agrawal, Drugs Inspector, CDSCO HQ, New Delhi
4. Sh. Ashish Kumar Rai, Drugs Inspector, CDSCO HQ, New Delhi
5. Sh. Sella Senthil, Drugs Inspector, CDSCO HQ, New Delhi.
6. Mr. Saurabh Jain, Drugs Inspector, CDSCO HQ, New Delhi.
7. MS. Nisha Kaushik, Drugs Inspector, CDSCO HQ, New Delhi.
8. Mr. Hari Babu, Drugs Inspector, CDSCO HQ, New Delhi.

The DDC (I) welcomed the members and briefed the agenda. The objective of the meeting was to establish specifications and criteria for acceptance for tests performed on Syphilis Rapid and ELISA Kits proposed by NIB, Noida based on WHO Guidelines.

Ms. Charu Mehra Kamal, Scientist III, National Institute of Biologicals (NIB), Noida gave brief presentation on the 'Specifications', 'Criteria' for acceptance and panel preparation for Tests performed on 'Syphilis Rapid and ELISA Kits'.

Mr. Pradeep Desai, ADMI also gave brief presentation on the basic principles, procedure and technologies used for the diagnosis of syphilis and explained about the advantages and limitations of Treponemal and Non-Treponemal diagnostic test.

After the deliberation in the meeting and discussion with Experts and stakeholders (members of FICCI, CII and ADMI) following decisions were made:-

1. Specifications and criteria for acceptance of the tests performed on Syphilis Rapid and ELISA kit in terms of sensitivity and specificity parameter based on WHO guidelines proposed by NIB were accepted.
2. It was decided that before grant of Import license for Syphilis Rapid and ELISA kit, evaluation report of 3 batches conducted by NIB, Noida needs to be submitted along with the application for the grant of import licence. For this propose 6 months transition period may be given to the stakeholders. Till that implementation the current practice of accepting Evaluation report from the NABL accredited Lab shall be continued.



3. National Institute of Biologicals (NIB), Noida, informed that they required total no. of 500 tests per batch/lot for the evaluation of the Syphilis Rapid and ELISA kit and the reports shall be released within 30 days from the submission of the samples.
 4. It was also recommended that 3 batches of the product Syphilis Rapid and ELISA kit manufactured by Indigenous manufacturers shall also be tested at NIB, Noida before grant of marketing authorisation in the country in addition to the random samples from the market. In this regard all the State Licensing Authorities will be informed to forward the samples of Syphilis Rapid and ELISA kits manufactured indigenously to NIB, Noida for evaluation.
 5. Experts from the NARI and members of FICCI, CII and ADAMI suggested that in future the NIB may prepare separate specification with respect to both Treponemal and Non-Treponemal test for the better quality control.
 6. Members of FICCI, CII and ADAMI also requested the CDSCO to inform the final proposed specification to NACO for their information and implementation.
 7. CDSCO and members of FICCI, CII and ADAMI requested the NIB to prepare a checklist for each of the Diagnostic Kits/Reagent tested at NIB (Like quantity of test required, Fees, Documents requirements etc) shall be circulated to all stakeholders and CDSCO and website of NIB.
 8. Members of FICCI, CII and ADAMI also requested the CDSCO to conduct such meetings/ interaction with industry stakeholders in future also
- The meeting ended with the vote of thanks to the chair.



BACKGROUND NOTE

The In Vitro Diagnostic Kits for Syphilis (Rapid and ELISA) are being imported from foreign manufactures by various firms for marketing in the Country. Few manufacturers are also manufacturing indigenously the said kits under the manufacturing licence issued by State Licensing Authority.

In order to assess the quality and performance of kit it is necessary to formulate the specification in terms of the sensitivity and specificity.

The Syphilis Rapid and ELISA kits for detection of Syphilis are being tested at the National Institute of Biological since 2009. In view of the NABL certification for evaluation of the these kits i.e Syphilis Rapid and ELISA kits the criteria used for evaluating the kit in terms of Sensitivity and Specificity parameter based on WHO Guidelines is given below

S.No.	Name of Kit	Sensitivity	Specificity
1.	Syphilis Rapid	≥85%	≥93%
2	Syphilis ELISA	≥85%	≥93%

Experts may kindly give their opinion in this regard.