Rajasthan Medical Services Corporation Limited, Jaipur

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No. F -8 (15) RMSC/EPM/M-5/15-16/NIB-139/ 758 **Dated:** 27/2/16

CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject :- Amended technical Specifications, date extension of Bid document for (1) Treponemal-Specific Rapid (Point-of-Care) Diagnostic Test for Syphilis and (2) HIV (Rapid) Whole Blood Finger Prick Test Kits under NIB No. F-8(15) RMSC/EPM/M-5/2015-16/NIB-139/57 Dated 07.01.2016.

In Reference to above cited subject and NIB-139, The technical specification are examined by the competent authorities. The following Clarification/Corrigendum/Addendum is issued for inclusion in bid document & Technical Specification of items as below:-

(a) Revised Technical Specifications of Treponemal-specific Rapid (Point-of- Care) Diagnostic Test for Syphilis :-

1. The assay may be based on any of the rapid test principles: (immunoconcentration/ immunofiltration/immunochromatography).
2. The assay should quantitatively detect total anti-treponemal antibody (IgG and IgM) in whole blood, serum or plasma for serological diagnosis of syphilis in all stages of infection.
3. The assay should have an in-built procedural control in form of band or dot for validation of the test kits.
4. The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size).
5. The kit should have $5/6^{th}$ of the shelf life or 12 months before expiry (whichever is more) at the time of receipt by the consignee.
6. Adequate literature detailing the principle, components, methodologies, validity criteria, bio-safety, performance characteristics, storage conditions, limitation of assay, manufacture and expiry dates and methods of disposal should be provided with each kit.
7. The imported rapid kit should have approval of the statutory authority in its country of origin. The imported kits should have been registered and licensed in India by the Central Drugs Standard Control Organization (CDSCO).
8. In case of indigenous manufacturers they should have a valid license issued by the competent authority defined under Drugs and Cosmetics Act, 1940, after appropriate evaluation by the centres approved by the CDSCO.
9. The assay should have sensitivity of 90% or more and specificity of 95% or more and the same should be supported by statements in kit insert and certificate from National Institute of Biological Sciences.
10. The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from the manufacturer.
11. Test procedure should be user friendly (can be performed with few simple steps with minimum training)
12. The manufacturer should ensure the following:
    - Test should be equipment free. Result should be visualised with nacked eye.
    - The test should be packed such that there is a provision to conduct single test at a time.
    - The pack size of test lots should be in 50 (for peripheral health levels) and 100 tests per kit (for secondary and tertiary health care level) but not more than 100 tests per kit.
13. The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2°C to 8°C in form of transtracker on every kit.
14. Total procedure time should not be more than 30 minutes.

(b) In Reference to above cited subject and NIB-139, the last date for sale of bid, receipt of bid and date of opening of technical bid is hereby extended as below:-

Existing Date			Extended date		
Last Date for Sale of Bid Form	**Last Date of Receipt of Bid Form**	**Date of Opening of Technical Bid**	**Last Date for Sale of Bid Form**	**Last Date of Receipt of Bid Form**	**Date of Opening of Technical Bid**
26-02-2016 11:00 AM	26-02-2016 01:00 PM	26-02-2016 03:00 PM	08-03-2016 11:00 AM	08-03-2016 01:00 PM	08-03-2016 03:00 PM

Note: Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of the bid document. This corrigendum/ addendum should be signed and annexed with bid document.

All other terms and conditions of bid shall remain the same.

This bears the approval of M.D., RMSCL, Jaipur

Executive Director (EPM)
RMSCL, Jaipur