Uttar Pradesh Medical Supplies Corporation Limited

(A Govt. of Uttar Pradesh Undertaking)
GSTIN: 09AACCU2250P1ZZ CIN: U85310UP2018SGC102425
Registered Office : SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226002
E-Mail: drugs@upmsc.in Website: www.upmsc.in Contact Number: 0522-2838102

Corrigendum-1 date 17/09/2024

With reference to tender no. **UPMSCL/Drugs-217/09** dated 28.08.2024 a corrigendum is being issued as follows:

A- Technical Corrigendum

Sr. No.	Reference of tender document	Existing conditions/specifications	Revised Conditions/Specifications
1	Annexure- A Schedule of Requirement	***Note-*** *Bidder(s) will be qualified only after evaluation by govt. hospital(s) for efficacy, accuracy & specificity of test as per specifications mentioned in the tender, of samples of above mentioned kits. If, found up to the mark. Samples (**10 packs of each as per packing specification mentioned below for the respective item)** need to be submitted to UPMSCL (SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226010(UP) India) up to **15:30 Hrs, 18 September, 2024** with Test report of sample batch from Government laboratory/NABL and proper labeling for* *a. Firm name* *b. Sample name* *c. Tender ref. no.* *d. Contact no of bidder/authorized person*	***Note-*** *Bidder(s) will be qualified only after evaluation by govt. hospital(s) for efficacy, accuracy & specificity of test as per specifications mentioned in the tender, of samples of above mentioned kits. If, found up to the mark. Samples (**5 boxes of secondary packing for RDT kits)** need to be submitted to UPMSCL (SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226010(UP) India) up to **15:30 Hrs, 30 September, 2024** with Test report of sample batch from Government laboratory/NABL and proper labeling for* *a. Firm name* *b. Sample name* *c. Tender ref. no.* *d. Contact no of bidder/authorized person*
2	Annexure- A Schedule of Requirement **3. Specification of Rapid Diagnostic Kit for Hepatitis- C**		Enclosure- 1

B- Date Extension Corrigendum

S.N	Reference of tender document	Existing	Revised/ clarification
1	Last Date and Time for Online Submission of Tender	18 September, 2024 UPTO 15:30 Hrs.	30 September, 2024 UPTO 15:30 Hrs.
2	Date and Time of Opening of Technical BID-COVER 'A'	18 September, 2024, UPTO 16:00 Hrs	30 September, 2024 UPTO 16:00 Hrs.

All other terms & conditions of the tender document shall remain same.

MANAGING DIRECTOR
UPMSCL

(Enclosure-1)

Specification of Rapid Diagnostic Kit for Hepatitis-C

4) Anti-HCV Antibody (Rapid Test)

1. Should utilize recombinant and /or synthetic peptide antigens for core, NS3, NS4 and NS5.
2. The assay should detect total anti HCV antibodies
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
9. The total procedure time shall not be more than 30 minutes.
10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)which may be provided along with the kits if not a part of the kit.
11. The assay should have sensitivity more than or equal to 99%and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No 29/Misc./4/2016-DC(65) dated 12/7/2017
12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specification of Anti HCV antibody (rapid test)