UTTAR PRADESH MEDICAL SUPPLIES CORPORATION LTD.

(A Government of Uttar Pradesh Undertaking)

Regd. Office: SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226 010

Corrigendum-4 dated 03.11.2020

With reference to tender no. UPMSCL/Drugs-**062/241** dated 16 September, 2020 a corrigendum is being issued as follows:

Sr. No.	Reference of tender document	Existing	Revised/ clarification
1	**Last Date and Time for Online Submission of Tender**	05 November, 2020, UPTO 15:00 Hrs	10 November, 2020, UPTO 15:00 Hrs
2	**Date and Time of Opening of Technical BID-COVER 'A'**	05 November, 2020 at 15:30 Hrs at UPMSCL Office	10 November, 2020 at 15:30 Hrs at UPMSCL Office

Following amendment in **Annexure-A** has been done:

Sr. No.	DRUG CODE	Reference of tender document-(Annexure-A)	Existing	Revised/ clarification
01	**RDT (HEPA-B)**	**Rapid Diagnostic Kit For Hepatitis-B**	Specification given on page no 35-36 of tender document	As per Specification given on page no **2** of this corrigendum.
02	**RDT (HEPA-C)**	**Rapid Diagnostic Kit For Hepatitis-C**	Specification given on page no 37-38 of tender document	As per Specification given on page no **3-5** of this corrigendum.
03	**ELISA KIT (HEPA-B)**	**ELISA Kit for Hepatitis-B**	Specification given on page no 39-40 of tender document	As per Specification given on page no **6-7** of this corrigendum.
04	**ELISA KIT (HEPA-C)**	**ELISA Kit for Hepatitis-C**	Specification given on page no 41-42 of tender document	As per Specification given on page no **8** of this corrigendum.
05	**POC**	**POC KIT FOR syphilis**	Specification given on page no 43 of tender document	As per Specification given on page no **9** of this corrigendum.
06	**ELISA KIT (HIV)**	**ELISA Kit for HIV**	Specification given on page no 45 of tender document	As per Specification given on page no **10** of this corrigendum.

1- Rapid Diagnostic Kit For Hepatitis-B

1. The test should be lateral flow technology based on sandwich principle
2. The membrane should be coated with highly purified antibodies directed against immune dominant 'a' epitope of HBsAg.
3. The assay time should not be more than 30 mins
4. The assay should be able to detect all major genotypes of HBsAg.
5. The test should have clinical sensitivity and specificity more than 99%, the analytical sensitivity of HBsAg kit for Surface antigen detection should be < 0.05 IU/ml with 2nd International WHO Standard (00/588).
6. Rapid qualitative, two side sandwich immune assay.
7. Hetetrophile blocking reagent should be used to minimize the interference of heterophile antibodies.
8. The pack size should be 25T or 100T suitable for less and bulk use.
9. The test should have analytical sensitivity better than 0.5 mg/ml
10. The analytical sensitivity of the test should be evaluated with WHO reference panel
11. Storage should be at room temperature.
12. The test should have a valid manufacturing license.
13. The shelf life should be upto two years after the date of manufacturing
14. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
15. The test Kit should detect infection at all stages.
16. The manufacturer/ authorized agent should ensure maintenance of adequate temperature during storage & transport the kits at 2- 30 °C.
17. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**
18. The manufacturer should ensure maintenance of cold chain items during storage & transportation as per label claimed
19. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**
20. **Reagents needs to be colour coded with OD norms for reagents addition verification on automation as well as manual processing.**

2- Rapid Diagnostic Kit For Hepatitis-C

Requirements:

1. Should be solid phase/particle coated with recombinant and / or synthetic peptide antigens for Core, NS3, NS4 and NS5.
2. Kit needs to be able to detect both antibodies (capsid, NS3 and NS4) and antigen (Capsid) against/of Hepatitis C Virus.
3. Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions. Limitation of assays, manufacturing &expiry dates should be provided with each Kit.
4. The Kit should have approval of the statutory authority form the country of origin.
5. In case of Imported kits it should be registered and licensed by the DCG(I) .
6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG (I).
7. The kit should have minimum 5/6 th or more of the shelf life at the port of discharge of consignees.
8. The time required for performing the test should not be more than 30 minutes.
9. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.
10. The assay should have sensitivity of > 99 % and specificity of > 99 %.
11. The manufacturer should ensure maintenance of cold chain items during storage & transportation as per label claimed.
12. The pack size should not be more than 50 test wherein each test is individually packed.
13. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
14. The test Kit should detect infection at all stages. .
15. Reagents needs to be colour coded with OD norms for reagents addition verification on automation as well as manual processing.

Inspection & Tests:

- Deleted

Product and Package Specifications:

1. The required packing standards and labelling must meet the requirements given in this Technical Specification and Part.
2. Not only the Goods but also the packaging components should also meet specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tampered-proof.
3. All labelling and packaging inserts shall be in the language requested by the Purchaser or English if not otherwise stated
4. Goods requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.
5. Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Purchaser may request

Product Information:

1. The following information will be required for each pharmaceutical product offered by the Bidder:

i) International Non-Proprietary Name (INN), if applicable;
ii) Brand Name (if it appears on label);
iii) Name and address of the manufacturer;
iv) Country of origin; and
v) Compendia standards

2. Upon award, the supplier shall, on demand, provide a translated version in English, of the prescriber's information for any specific product, the Purchaser may request.

3. Failure to include any of this information, at the discretion of the Purchaser, may render the bid non-responsive.

Expiration Date:

All products must indicate the dates of manufacture and expiry

Recalls:

If products must be recalled because of problems with product quality as a result of quality check carried out during the life span of the drug or adverse reactions to the pharmaceutical, the supplier will be obligated to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals, or withdraw and give a full refund if the product has been take off the market due to safety problems.

Labelling Instructions:

1. The label for each Goods shall include: (a) the Purchaser's logo and code number and any specific color coding if required (b) content per pack (c) instructions for use (d) special storage requirements (e) batch number (f) date of manufacture and date of expiry (in clear language, not code) (g) name and address of manufacture with license number
(h) any additional cautionary statement.
2. The outer case or carton should also display the above information
3. Details of Packing/Cases
4. All cases should prominently indicate the following:
i) The generic name of the product;
ii) Date of manufacture and expiry (in clear language not code);
iii) Batch number
iv) Quantity per case.
5. No case should contain drugs from more than one batch.
6. Unique Identifier
7. The Purchaser shall have the right to request the Supplier to imprint a logo on the containers used for packaging and in certain dosage forms such as tablets and this will be indicated in Part A of the Technical Specifications. The design of such logo shall be provided to the supplier at the time of Contract award.

Qualifications of Manufacturer:

The bidder shall furnish a certificate from the competent FDRA that the manufacturer of the pharmaceutical or vaccine product covered by this

Standards and Quality Assurance Requirements:

1. All products must:
(a) Meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin;
(b) Conform to all the specifications contained herein; and
(c) Must undergo strict raw material inspection, in process checks, appropriate material handling to eliminate cross contamination (of molecules) and final

product testing to ensure quality and consistency of the products.

2. The Bidder is required to furnish to the Purchaser:

(a) With each consignment, a certificate of quality assurance test results concerning quantitative assay, chemical analysis and other tests, as applicable to the product being supplied and Part A of these Specifications.

(b) Assay methodology of any or all tests if requested.

(c) Evidence of basis for expiration dates and other stability data on the offered package (as per climatic conditions prevalent in India) concerning the commercial final package upon request.

(d) Package integrity test results.

3. The Bidder will also be required to provide the purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished Goods.

4. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**

3- ELISA Kit for Hepatitis-B

Hepatitis B Surface Antigen ELISA Kits (3rd generation)

1. Microplate ELISA Coated with monoclonal antibodies to HBsAg (murine and human)

2. The assay should be able to detect surface antigen to Hepatitis B virus.

3. Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each Kit.

4. The Kit should have approval of the statutory authority from the country of origin and by CDSCO and declared of "Standard Quality" by NIB (Noida)

5. In case of Imported kits it should be registered and licensed by the DCG (I) .

6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centers approved by the DCG (I)

7. The kit should have minimum 5/6 th or more of the shelf life at the port of discharge of consignees.

8. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.

9. The assay should have sensitivity of > 99 % and specificity of >99%. The analytical sensitivity of HBsAg kit for Surface antigen detection should be < 0.05 IU/ml with 2nd International WHO Standard (00/588).

10. The assay should have analytical sensitivity of detecting < 0.1ng/ml.

11. The manufacturer should ensure maintenance of cold chain items during storage & transportation as per label claimed.

12. The pack size should be 96 tests/kit.

13. The Kit Should be compatible to both semi automated and fully automated Elisa analyzers.

14. The volume of all the chemicals used should be adequate enough (not less than 1 litre) for automated Elisa analyzer. The volume should cover the dead volume for automated ELISA system.

15. Shelf life of the Kits should be not less than 12 months.

Each batch supplied should be accompanied with quality assurance test result from NABL approved lab as well as in house lab.

Specific Requirement of the Kits

1. The supplier should supply 96 tests x 2 sets along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification.

2. A “Cold Chain indicator” is to be supplied with the kits with the following specification:

a. A cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2-8 degree C

b. The cumulative time-temperature indicator technology used should be prequalified by WHO

c. The indicator should change colour uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters.

d. The colour change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.

e. Each batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.

3. Each test Kit should contain all the materials required for performing the test. 4. The test Kit should detect infection at all stages. .

4. Reagents needs to be colour coded with OD norms for reagents addition verification on automation as well as manual processing.

4-ELISA Kit for Hepatitis-C

TECHNICAL SPECIFICATIONS FOR HCV (ELISA) TEST KITS

HCV (ELISA) TEST KITS OF 3rd Generation

1. Micro plate ELISA coated with recombinant and / or synthetic peptide antigens for Core. NS3, NS4 and NS5.

2. Kit needs to be able to detect both antibodies (capsid, NS3 and NS4) and antigen (Capsid) against/of Hepatitis C Virus.

3. Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each Kit.

4. The Kit should have approval of the statutory authority from the country of origin.

5. In case of Imported kits it should be registered and licensed by the DCG (I) .

6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG (I).

7. The kit should have minimum 5/6 th or more of the shelf life at the port of discharge of consignees.

8. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.

9. The assay should have sensitivity of > 99 % and specificity of > 99 %.

10. The manufacturer should ensure maintenance of cold chain items during storage & transportation as per label claimed.

11. Shelf life of the Kits should be not less than 12 months.

12. The pack size should be 96 tests/ kit.

13. The Kit Should be compatible to both semi automated and fully automated Elisa analyzers. The volume of all the chemicals used should be adequate enough (not less than 1 litre) for automated Elisa analyzer. The volume should cover the dead volume for automated ELISA system.

14. Reagents needs to be colour coded with OD norms for reagents addition verification on automation as well as manual processing.

15. Each batch supplied should be accompanied with quality assurance test result from NABL approved lab as well as in house lab.

5-Detail Specifications of POC test kit for Syphilis:-

1- The assay should have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens.
2- The assay may be based on any of the rapid test principles: (Immunoconcentration/Dot blot immunoassay (vertical flow), dip stick and comb assay.
3- The assay should have an in-built positive and negative control for testing the validity 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 5/6th 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 32 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. 32 Screening for Syphilis during Pregnancy 42 .
11- Reagents needs to be colour coded with OD norms for reagents addition verification on automation as well as manual processing.
12- The manufacturer should ensure the following:
a. The test should be packed such that there is a provision to conduct single test at a time.
b. The pack size of test kits should be in 50 (for peripheral health levels).
c. The manufacturer should ensure maintenance of cold chain items during storage and transportation as per label claimed.
d. Total procedure time should not be more than 20 minutes.

6. ELISA Kit for HIV

The kit should be of 4th Generation.

1. Should be solid phase microplate coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies.
3. Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each Kit.
4. The Kit should have approval of the statutory authority form the country of origin.
5. In case of Imported kits it should be registered and licensed by the DCG(I) .
6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG(I)
7. The kit should have minimum 5/6 th or more of the shelf life at the port of discharge of consignees.
8. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.
9. The assay should have sensitivity of > 99 % and specificity of > 99%. Kit should detect both Ab and Ag with an analytical Sensitivity of < 1.0 IU/ml for p24 Ag (WHO HIV P24 Antigen standard (90/636).
10. The manufacturer should ensure maintenance of cold chain items during storage & transportation as per label claimed.
11. Shelf life of the Kits should be not less than 12 months.
12. The pack size should be 96 tests/ kit.
13. The Kit Should be compatible to both semi automated and fully automated Elisa analyzers. The volume of all the chemicals used should be adequate enough (not less than 1 litre) for automated Elisa analyzer. The volume should cover the dead volume for automated ELISA system.
14. Reagents needs to be colour coded with OD norms for reagents addition verification on automation as well as manual processing.
15. Each batch supplied should be accompanied with quality assurance test result from NABL approved lab as well as in house lab.

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

MANAGING DIRECTOR
UPMSCL