OFFICE OF THE MANAGING DIRECTOR
ASSAM MEDICAL SERVICE CORPORATION LIMITED
SAIKIA COMMERCIAL COMPLEX, SRINAGAR PATH, CHRISTIANBASTI,
G.S ROAD, GUWHATI 781005

No: AMSCL-15/PROC/NABL-LAB/EMPANEL/17-18/ 109 **Date: 6/12/17**

CORRIGENDUM NO.1

e-Tender for empanelment of Analytical Testing Laboratory for testing of Drugs/Surgicals/Sutures/Chemicals/ Consumables/Linens

This is with reference to the TENDER NO: AMSCL-15/ PROC/ NABL-LAB/ EMPANEL/ 17-18/81, Dated. 20.11.17 for empanelment of Analytical Testing Laboratory for testing of Drugs/Surgicals/Sutures/Chemicals/ Consumables/Linens.

Some amendments are incorporated which must be considered prior to submission o the Tender.

1. Pt. 4: **Eligibility criteria**, clause D:- ISO 15189:2007 is hereby removed as eligibility criteria and may not require.

2. Pt. no 6 of **Techno commercial Bid**, clause D may be read as "Notarized copy of valid ISO 14001: 2004 Certificate should be enclosed. The license must have been duly renewed up to date. Original license should be produced if demanded for verification".

3. Pt. 4: **Eligibility criteria**, clause h:- may be read as "The laboratory should be **GLP** compliant under the provisions of Drugs and Cosmetics Act, 1940 and Rules there under and should hold schedule L-1 certificate or should have approval from Drug Control Department **or** NABL accreditation with proper scope of accreditation to undertake testing of drugs, surgical and sutures. GLP certificate should be clear and unambiguous.

4. Pt. 4: **Eligibility criteria : a new clause (U) is being incorporated "NON-CONVICTION CERTIFICATE " :** Notarized copy of Non-conviction Certificate issued by the Drugs Controller of the concerned state certifying that the firm has not been convicted in the last three years 2014-15, 2015-16, 2016-17 should be submitted.

5. **Pt. No. 5 , clause no xv "COMPLETE ANALYSIS & REPORTING CONDITIONS (Annexure-12)** may be read as below:

Delivery Period for collection of sample & delivery of reports to purchaser & Place of testing sample : The samples to be collected within 24 Hrs **with**

proper maintenance of **cold chain (if required)** & reports should be delivered within schedule mentioned in table from the date of receipt of sample. Consignee may change by direct Demanding Officer.

S. No.	Description	Sample collection Period	Testing Period of Sample	Delivery of analysis report of sample tested
1	Tablets, Capsules, Peccaries, Ointments, Powder and Liquid Oral Preparations etc	Within 24 Hrs	14 days	On same day or next day of testing period
2	Injection , I V Fluid	Within 24 Hrs	**24 days**	On same day or next day of testing period
3	Surgical **& Sutures**	Within 24 Hrs	**24 days**	On same day or next day of testing period
4	Surgical Non Drug	Within 24 Hrs	14 days	On same day or next day of testing period
5	Rubber articles	Within 24 Hrs	14 days	On same day or next day of testing period
6	Laboratory Chemical & Kits	Within 24 Hrs	14 days	On same day or next day of testing period
7	Suture All type	Within 24 Hrs	**24 days**	On same day or next day of testing period

6. Pt. 4-(x) "**INSTRUCTIONS TO BIDDERS"** SHOULD BE READ AS "AMSCL, Assam shall enter into a rate contract for a period mentioned in the tender i.e 31/12/2022 with the empanelled Lab.

7. TECHNO-COMMERCIAL BID EVALUATION PARAMETERS: **Pt. No. ii "Technical Evaluation Criteria", Clause no. "C"** should be read as below-

a) Each evaluated Proposal will be given a technical score (St) as detailed below. The maximum points/ marks to be given under each of the evaluation criteria are:

S. No.	Description	Marks (Documentation)
1.0	**Firm's capabilities to carry out the following Tests (Documentary evidence should enclose, certified by Competent Authority like Drug Controller/Inspector of Drugs)** **1. Chemical Test(27 marks)** ✓ **Dissolution Test= 4 marks Total** ❖ Dissolution Test (UV)=2 marks ❖ Dissolution (HPLC)= 2 marks	**50 marks**

S. No.	Description	Marks (Documentation)
	✓ **Content Uniformity=5 marks Total** ❖ Content Uniformity (HPLC)= 2 mark ❖ Filter Content=1 mark ❖ Sulphated ash content=2 mark ✓ **Identification=4 marks Total** ❖ Identification(UV)= 2 mark ❖ Identification(HPLC)= 2 mark ✓ **Test for Uniformity=4 marks Total** ❖ Dispersion Uniformity=2 mark ❖ Weight Uniformity=2 marks ✓ **ASSAY= 8 marks Total** ❖ ASSAY(TITRATION)=2 marks ❖ ASSAY(UV)= 2 marks ❖ ASSAY(AAS)= 2 marks ❖ ASSAY(HPLC)= 2 marks **2. Microbial Test(10 marks)** ✓ Antibiotic Assay=2 marks ✓ Microbial Limit Test=2 marks ✓ Preservative efficacy Test= 2 marks ✓ Contents of Bacterial/Yeast/Mould=2 marks ✓ Bacterial Endotoxin Test=2 marks **3. Instrumental Analysis(13 marks)** ✓ Related substance content=1 mark ✓ Related Substance (TLC)= 1 mark ✓ Organic impurities & residual solvent=2 marks ✓ IR for Finished product & raw materials=2marks ✓ UV absorption= 1mark ✓ **Disintegration time=6 marks Total** ❖ Disintegration for dispersion=2 mark ❖ Disintegration for uncoated=2 mark ❖ Disintegration for enteric coated=2 mark	
2.0	**EXECUTION OF SIMILAR CONTRACTS**	**20 marks**

S. No.	Description	Marks (Documentation)
	Minimum Rs. 25 lakhs per year from during the last 3 Financial Year i.e 2014-15, 2015-16, 2016-17 testing drugs /surgical/sutures/consumables for the Central/State Government organization/ programs sponsored by WHO, UNICEF, UNOPS, RITES (all order copies should enclosed and CA Certified) o For 25 lakhs per year= 10 marks o For more than 25-40 lakhs per year= 12marks o For more than 40-55 lakhs per year=14 marks o For more than 55-80 laks=16 marks o For more than 80 lakhs to 1 Cr=18 marks o For more than 1 Cr=20 marks	
3.0	**LIST OF SOPHISTICATED EQUIPMENT/INSTRUMENT/ APPARATUS AVAILABLE IN THE LAB** ✓ No. of HPCL equipment=4 marks i. 1 to 2= 1 mark ii. 3 to 4= 2 mark iii. 5 to 6= 3 mark iv. 7 and above= 4 mark ✓ No. of GC equipment=4marks i. 1 to 2= 1 mark ii. 3 to 4= 2 mark iii. 5 to 6= 3 mark iv. 7 and above= 4 mark ✓ No of Total Organic Carbon equipment= 2 marks i. 1 to 2 no= 1 mark ii. 3 no or above= 2 mark ✓ No of Automatic Absorption Spectrum equipment=2 marks i. 1 to 2 no= 1 mark ii. 3 no or above= 2 mark ✓ No of UV Spectrum equipment=2 marks i. 1 to 2 no= 1 mark ii. 3 no or above= 2 mark ✓ Weighing balance (4 digit with digital printer)=2 mark ✓ Weighing balance (4 digit without digital printer)=1 mark ✓ Weighing balance (5 digit with digital printer)=2 mark ✓ Weighing balance (5 digit without digital printer)=1 mark	**20 Marks**

S. No.	Description	Marks (Documentation)
4.0	**Name of the Technical Staff approved by State Licensing Authority along with his Designation** **<u>Minimum 3 Technical staff required in each category</u>** ***A.*** **<u>Technical Staff for NABL Scope for Microbiology</u> =4 marks (Qualification required: B.Sc Microbiology/M.Sc Microbiology; Minimum 3 Person required).** **i. For 3-5 Microbiologist= 2 mark** **ii. For 6 or more than 6 Microbiologist=2 mark** ***B.*** **<u>NABL Scope for Analytical testing</u>=4 marks** ***(Qualification required B.Sc Chemistry/B.Pharma/M.Sc Chemistry/M.Pharma)*** **i. For 3-5 *B.Sc Chemistry/B.Pharma/M.Sc Chemistry/M.Pharma= 2 mark*** **ii. For 6 *B.Sc Chemistry/B.Pharma/M.Sc Chemistry/M.Pharma= 2 mark***	**8 marks**
3.2	**Empanelment with other State Govt./Medical Service Corporation/Central or State Govt. Drug procuring agency**	**2 marks**

<u>TOTAL 100 MARKS</u>

8. **ANNEXURE –9 "**<u>To fill up the remark column of the enclosed Performa to access the existing facilities of your laboratories</u>" may be read as below:

(I) <u>Standard operating Procedures</u>

S.N.	Details of the requirement	Remark
1	Shall be written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instruments ;	
2	Shall have SOP manuals and have periodic Review.	

S.N.	Details of the requirement	Remark
3	Standard Operation Procedures for the followings are required (i) Sample handling and accountability ; (ii) Receipt identification, storage, mixing and method sampling of the test and control articles ; (iii) Record keeping, reporting, storage and retrieval of data ; (iv) Coding of different studies, handling of data including use of computerized data system : (v) Operation of technical audit personnel in performing and reporting audits, inspections and final report reviews ; (vi) Routing inspection of cleaning maintenance, testing, calibration and standardization of instruments ; (vii) Action to be taken in respect of equipment failure ; (viii) Analytical data methods (ix) Health and safety protection ; (x) Date handling and storage retrieval ; (xi) Health and safety protection ; (xii) Animal room preparations ; (xiii) Animal care ; (xiv) Storage and maintenance of microbial cultures ; (xv) Maintenance of sterility room (i.e. constant maintenance and monitoring of Aseptic condition room) ; (xvi) Use and storage of reference standards ; (xvii) Procurement of stores and equipment ; (xviii) Monitoring of testing of samples ; (xix) Method of retention of unexpended samples, their location, maintenance and disposal ; (xx) Document control ; (xxi) Redressal of technical complaints ; (xxii) House- keeping (xxiii) Corrective and preventive action ;	

S.N.	Details of the requirement	Remark
	(xxv) Calibration manual. (xxvi) Training manual.	
4	Protocols and specification archive :- List of all the pharmacopeias a file on patent and proprietary medicines (non- Pharmacopeia) test methods to specification prepared and validated by the manufacturer. The test methods shall be submitted to the concerned Drug Control Authority.	
5	Raw data - Date integrity and security shall be maintained Original entry must be saved and the system shall trail for all data.	
6	Storage and archival ; The residual sample shall be retained in proper storage condition for a period of one year after the final report.	
7	The laboratory must establish and maintain procedures for the identification collection, indexing, retrieval, storage, maintenance, and Disposal of all quality documents.	
8	All the raw date, documentation, SOP, protocols and final reports are the be retained and there shall be archives of orderly storage and expeditious retrieval of all raw data, documentation, protocols, interim and final report.	
9	The condition under which the original documents are stored must ensure their security and confidentiality.	
10	Raw data on thermal paper might fad away with time ; therefore, a photocopy of the thermal paper shall be retained in the archive.	

Above mentioned information corrects as per our record and if found incorrect, AMSCL may take action against our firm and reject our bid.

9. Some dates are here by re-scheduled

A. Last Date and Time of receipt of e-Tender : 16/12/2017 till 2.00 pm.
B. Start date of submission : 11/12/2017 from 3.00 pm.
C. Date and Time of opening e-Tender : 16/12/2017 at 3.00 pm.

All other terms and conditions of the above referred tender shall remain unchanged.

Sd/-

Managing Director, AMSCL, Assam