Queries raised By M/s Instrumentation Laboratory India (P) Ltd.

1. As we understand, the above tender is for only rate contract of reagents to be used on CA-1500 Coagulation Analyzer. Either we quote reagents that are compatible for use on CA-1500 Analyzer or we quote reagents along with equivalent analyzers. Is our understanding correct?
2. If our Understanding is correct, what features or specifications would constitute an equivalent analyzer of CA-1500? What would you consider as equivalent: throughput, features, special technology, foot print etc?
3. In the scope of work mentioned on page 16, there are rates mentioned as applicable in CGHS, AIIMS Delhi. Are these indicative CPRT rates? Are these rates mentioned as applicable in AIIMS Bhopal? How many controls per day (one level or two levels per day) have been considered for calculation of CPRT?
4. Do we have to quote on CPRT basis or per kit basis? or quoting on kit basis indicating CPRT is enough?
5. Are all mentioned rates, for quantitative results? (Eg:D-Dinner)

Queries raised by M/s Transasia Bio-medical Limited

In the tender it is mentioned as below:
Rate contract of 3 year for various tests of coagulation on Cost Per Reportable test basis (CPRT Basis) for Automated Coagulation Analyzer of AIIMS Bhopal, Make —Sysmex, Model CA -1500 reagents or on equivalent/upgraded quality equipment (US FDA approved) made available by the bidder for Department of Pathology & Lab Medicine AIIMS Bhopal/2020-21/137, Dated :24/11/2020.

Please note that in the above tender it is mentioned as requirement of USFDA approved Equipment. Kindly note that as per circular No. P-45021/12/2017-Public Procurement BE-11 regarding clear guidelines issued by the Director of Ministry of commerce & Industry (Public Procurement Section) categorically informing that government agencies must ensure that their tenders do not include restrictive and discriminatory conditions against local Manufacturer/ suppliers.

Please find attached the copy of, Circular No: P-4502 1/21/2018-BE-11,P-45021/12/2017- Public Procurement (BE-11) issued by the Director of Ministry of commerce & Industry (Public Procurement Section), Copy of letter of Principal Secretary of Prime Minister, December, 2017, Copy of Advisory Letter of Add. Secretary (H), MOH&FW dt : 18.07.2016, Copy of Dept. of Pharmaceuticals Final Guidelines for implementation of Public Procurement — May, 2018, Copy of Letter no F.No.Z.28018/67/2017-EPW dated 05.11.2020. Looking at above guidelines issued by the Director of Ministry of commerce & Industry (Public Procurement Section), we would appreciate if you would kindly consider not having a "US-FDA Clause. We request you to consider amending Technical Specifications and add ISO 13485 / CE / ICMED 13485 Certifications as alternatives so that the Bid can become nonrestrictive if a Manufacturer has either one of the Certifications of Quality and Manufacturers all Over the World other than American Manufacturers can participate in this Tender. This will enable you to get more Competitive Bids.

In the tender document in the Scope of work — table 2 — page no 16 of 33, following list of reagent are asked. These reagents are not common reagent used in any hospital having veil low stability and these reagent belongs to one particular company and are very expensive and workload for the below reagent is also very less as mentioned in the tender.

Sr. no. 13 Plasminogen Assay
Sr.no. 15 Alpha 2 Antiplasmin Assay
Sr.no 18 Heparin assay
Sr.no. 20 VWF activity

We request you to delete the above reagent from the scope of work/BOQ or alternative it can mentione as option category not be in included L1 Pricing.

Looking at above, We would appreciate if you would kindly consider Not having a "US-FDA Clause an request you to consider ISO 13485 / CE / ICMED 13485 Certifications as alternatives so that the Bid ca become nonrestrictive if a Manufacturer has either one of the Certifications of Quality and Manufacture all Over the World other than American Manufacturers can participate in this Tender. This will enable yo to get more Competitive Bids also request you to provide the quality control frequency which is also no mentioned in the tender to quote the correct CPRT in the tender. In turn you will be benefitted with mo competitive quotes and lower operational cost in long run resulting in savings for governmer organization and affordable patient care.

Clarifications:

M/s Instrumentation Laboratory India (P) Ltd.-Clarifications

1. No. The tender is not for reagents only.
It is asking for rates on" Cost per Reportable Test Basis" which means the price quoted should include the complete cost of each test(as on the price list of any pathology laboratory)
The Institute will not pay for any extras (i.e. Equipments, controls, peripherals, human resource etc.), whether our machine is used or some equivalent machine is brought in by the vendor.
The payments shall only be done on the number of tests performed multiplied by the rates agreed upon in the contract. No. of test would be verified by Department of Pathology and Lab Medicine.
2. The definition of equivalence would be as for a fully automated analyzer, which is capable of performing
all the tests(Under Coagulation Profile) listed in the tender document. The other important parameters on which equivalence would be measured are:
i)Throughput-Approx. 120 Tests PT/hour.
Approx. 80 Tests PT,APT/hour simultaneously
ii)Bar code capability for reagents, samples, control, calibrator
iii)Sample Handling-Flexible mixing of sample cups and various primary sample tubes: capped and uncapped. Automated sample and standard predilution.
Bar Code identification: Automatic positive sample identification. Continuous loading of sample racks.
iv) Operation-Calibration: Automatic predefined
v) Quality Control-X control, Levy Jennings control, multi rule (Westgard rule) monitoring.
vi)Work station-Built in PC
vii)Display-Built in touch screen

3. As per current Govt. of India directives "No" bids will be considered qualifying wherein the equipment to be used in manufactured or originating from China.

4. The rates Quoted in the scope of work are indicative rates only.

5. The controls shall be strictly put as per the current NABL Guidelines

6. Quotes should be on CPRT basis and NOT kit basis

7. The requirement is for Quantitative tests.In matter of Quality or equivalence CA-1500 would be a broad bench mark.In all such matters decision of technical committee would be final.

Transasia Clarifications

1. **The assessment by the technical committee will be done as per prevailing Govt. of India rules, regulation.**
2. **The tests (list given in the tender) are as per requirement of AIIMS Bhopal.**
3. **The use of controls will be as per currently applicable NABL standards.**

Deepak Seth Harilal Panwar