ANNEX 1

SPECIFICATIONS: Automated Immunology Bench Top Analyzer

Description:

1. Brand New Benchtop Model to be installed and it should not be refurbished one.
2. Should not be a Point of care category Analyzer
3. Should be based on any one or a combination of the principle of chemiluminescence /Electrochemiluminescence, immunoassay technology, fluorescence immune assay technology, Immunoassay technology.
4. Performance: Very high sensitivity and linearity.
5. Test parameters required: proposed Analyzers shall have the following tests: AMH, Anti TPO, Anti CCP, IGE, Anti- Thyroglobulin, Procalcitonin, Free PSA, Growth hormone, ANA, Valporic acid and free BHCG. The supplier will have the flexibility to propose additional modules/equipment if one module/equipment cannot cover the tests listed.
6. Fully automated with a throughput of 20 to 50 tests or more per hour.
7. It should be able to detect concentrations: below and above the range of normal
8. clinical levels. Should report results in end point rather than a range. (Should not give results like ie: > 330ul/uL or < 200 iU/L).
9. The Analyzer shall be possible to analyze serum, plasma, urine, CSF and other body fluids.
10. The test types will include hormones, tumor markers, antibodies to infectious
11. diseases, auto immune diseases, allergy, cardiac, nutrition markers, markers of bone metabolism, reproductive markers and Triple markers.
12. Type of automation: fully automatic
13. Analyzer should have automatic carry over clot detection facility.
14. Use of disposable cups, cuvettes and tips to have minimum carry over.
15. There should be provision for onboard dilution with automatic calculation.
16. Reagents should have barcodes.
17. Provision for both bar code reading and manual entry.
18. Provision for running emergency STAT tests.
19. Operating system: windows or compatible.

20. Inbuilt printer or attachable printer with real time individual sample reporting facility.
21. Quality Control: minimum 2 quality control either same vendor or third party.
22. Should have quality assurance system with calibration.
23. Equipment should have automatic shutdown, startup and sample analysis.
24. Display: Touch screen or keyboard
25. Connectivity: Ethernet/USB
26. Memory: Program should have facilities for storage of data, report retrieval and report storage.
27. Network Integration to LIS available bidirectionally. HIS/LIS interface HL7.
28. Operating Environment: Temp: 20oC- 30oC. Relative Humidity 15- 85%
29. HIS/LIS Interface: RS232, Ethernet and or HL7.
30. Should be possible for Network Integration with LIS.
31. For external storage or Exporting data, USB ports should be available.
32. Printer: In-built or External (USB) printers should be available.
33. Online UPS should provide a minimum of 2 hours of backup.
34. Operating system should be compatible with our current LIS or future LIS for easy reporting.
35. If reagents need to be kept on analyzer overnight, there should be provision for on board refrigeration and stability of reagents for at least 15 days. If reagents to be loaded as required, there is no requirements for on board refrigeration.
36. Shall have an on-board reagent inventory management. (If Analyzer is having on board reagents).
37. **Reagent System: Single Unit strips, device or cups. (One test one Reagent System).**
38. The frequency of calibration for parameters should be limited only to lot changes.
39. Sample Volume: 10- 200uL
40. Foot Print: Small
41. The pack size of reagents should range from 20 to 200.
42. Analyzer Type: random and batch analysis
43. The reagents should be ready to use.
44. All supplied reagents should have a minimum shelf life of 6 months.

Standards and Requirements:

- USFDA, CE and or ISO certifications or relevant standards certification.
- Power requirement:250V, 50Hz.
- Conformity to electrical standards: IEC 61010-1, IEC 61010-2-081, IEC 61010-2-101 or BIS equivalent

Country of origin:

- Europe, UK, USA or Japan

Warranty & Service:

- The company should have service engineers who should be available 24/7 on phone & at site within 48 hours of reporting an error.
- Operator's manual and Service manual should be provided.
- All access codes to service mode shall be provided.
- Manufacturer's standard warranty with documents should be available.

Demonstration:

- All prospective bidders shall demonstrate the unit online before technical evaluation. This should include detailed explanation about reagents and consumables, operation, other accessories utilizations. And also, a short video of how the equipment works.

Samples:

- At the time of bid opening all bidders shall provide with samples of consumable sand reagents. Samples for diluents, cleaners, wash solutions which are bulky need not be submitted. Test kits for all parameters are also not mandatory. One test kit from any test parameter would suffice.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue (Soft & hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.
- Quotation with Details of all equipment price should be given.