Specifications for Bench Top Clinical Flowcytometer

1. Bench Top Flow Cytometer should have 3 lasers (red, blue and violet) with and should be capable of 10 parameter analysis (8 fluorescent plus forward and side scatter). System should have upgradable features up to 12 or more. The company should mention laser power output and minimum laser power received at the flow cell at the time of sample acquisition, for all lasers in the offer.
2. Should have sample acquisition rate of at least 20,000 events per second or more.
3. Pulse Height, Area and Width information available for all parameters to be able to discriminate doublets based on size, granularity & nucleic acid content.
4. The system should have threshold settings option on multiple channels/ parameters for a single sample run.
5. Must have compensation capability between all fluorescence channels manually and through auto compensation.
6. The system software should be capable of establishing baseline settings of system performance and be able to adjust for instrument variability thereby automating instrument setup.
7. The equipment should have analogue/ digital signal processing with dynamic range of at least 18bit data acquisition or more in order to get the clear resolution.
8. Optical filters should be easily changeable by user without having to call service engineers.
9. Sample Carry-over of the fluidics (cells) of the system should not be more than 0.1%.
10. The company should provide standard software for complete plot and graphical analysis of flow files with facilities such as back gating.
11. The instrument should be capable of performing daily QC and of maintaining monthly quality assurance data for monitoring performance of the instrument.
12. Must have automated loader with minimum of 30 tubes or more.
13. Must have provision for integrated bar code reading to identify carousel number & tube location.
14. System should be CE–IVD approved for maximum parameters used in analysis.
15. Instrument software should have capability for automated gating strategy following ISHAGE guidelines for accurate measurement of CD34+ stem cells
16. The data management system should have PC workstation with at least processor, 160 GB hard disk drive, DVD/CD writer (combo drive), 22" monitor and colour laser jet printer. System must have LIS compatibility.
17. On-line UPS with at least 30 minutes backup should be quoted with the system and should be supplied with the equipment.
18. The company should provide multiple time to time free trainings to the users as per their requirement during setting up of flow lab and later for up gradation.
19. Participating company should have direct presence in India with relevant application and service specialist for anytime support.
20. The company should have proven capability demonstrated in the past in after-sale-service and application support in the field of flow cytometry instrumentation in India.
21. Accepts any company 5mL (12 x 75mm) polystyrene and polypropylene and micro centrifuge 1.5mL and 2mL.

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22. Rates for all the reagents needed to run the assay to be quoted. Complete list of primary antibodies for immunophenotyping of lymphoma panel, myeloid and lymphoid leukemia a panel, multiple myeloma panel, MRD panel, CD 34 assay, HLA B 27 assay, PID panel to be provided with rate quotes.
23. Document supporting track record and satisfactory performance from Institutes of national importance (minimum three) should be provided.
24. 5 years warranty followed by 5 years CMC.
25. The company should provide IQ/PQ and OQ documents at the time of installation.

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3. **Technical Specifications**

AIIMS Bhatinda Specified (Proprietary-BD)

Technical Specifications

1. The system must be equipped with 3 solid state lasers (488nm Blue & 633-642nm Red) having a minimum 12 fluorescence parameter output. All the lasers & detectors should be fixed aligned for data consistency and reliability on a day-to-day basis.

2. **The system should be US-FDA / CE-IVD (IVDR) complied for all colours for clinical reporting and should have US-FDA/CE-IVD approved template for clinical reporting of assay like CD4/CD8 and CD34 (Stem Cell Enumeration.)**

3. The equipment should have dedicated beam-spots for each laser. All the fluorescence detector channels, and side scatter channel must be designed with photo multiplier tube (PMT) for voltage optimization with stabilized CV & minimal electronic noise contribution for achieving best resolution even for dimly stained population.

4. **Pulse Height, Area, and Width information available for all parameters simultaneously to be able to discriminate doublets based on size, granularity & nucleic acid content.**

5. Digital signal processing should allow threshold to be set on all available channels simultaneously in any combination of all available parameters during sample acquisition.

6. For high throughput, the analysis speed should be at least 30000 events per second or better with all the parameters available. The system apart from offering low, medium & high flow rates, should also offer high sensitivity fluidics aspiration mode, which can result in higher fluorescence signal resolution for dim stained population.

7. The System should have sample carry over of <0.1% or better with cells for rare cell populations discovery and novel marker identification.

8. The system generated compensation should be valid for a minimum of 60days and updated with daily QC. The system software should be able to do single fluorochrome addition to an existing setting from panel of reagents and recalculate the spillover matrix by running a single tube.

9. The system should also allow parallel data acquisition & analysis from two different experiment.

10. This system must be capable of standardization and collaboration between inter-lab/intra-lab through assay portability feature to maintain consistency in data quality.

11. Instrument software must be capable of exporting data as FCS file per population. In addition, system software must allow data overlay of tubes in the same experiment & different experiment.

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12. The instrument should support bi-directional LIS connectivity to eliminate transcription errors.

13. The system should be in a single tube acquisition format & upgradable in future to universal plate and tube loader platform which can accommodate minimum 30/40 tubes rack as well as 96 & 384 well plates directly for complete walk away automation.

14. **A detailed list of various single-color makers and IVD approved kit for CD4/CD8 & Stem Cell Enumeration Assay along with their current list prices should be quoted.**

15. The system should be offered with suitable workstation and UPS having minimum of 30mins backup.

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