

## Specifications of HLA Luminex Platform System for HLA Typing and DSA Detection / Multiplex array system (Luminex Platform for HLA Lab)/Fully Automated Multianalyte Profiling System Based on Multiplex Array Technology

### 1. Multiplexing Capability:

- **Assay Capacity:** Should have ability of multiplexing up to 500 individual analytes per sample in 96 well and 384 well plate format with automatic sampling.
- **Bead-based Assays:** Should be able to perform HLA typing, HLA Antibody detection, PRA, genotyping and all other test systems available for Luminex platforms.
- **TAT:** HLA typing kits should have a fast TAT of less than 2 Hours from DNA extraction to results.

### 2. Detection Technology:

- **Fluorescence Detection:** Should be capable of detecting and quantifying fluorescence signals emitted by the bead-bound antibodies.
- **Dual-Laser System:** Should be equipped with a dual-laser system to excite and detect fluorescence signals from different fluorochromes, allowing for multiplexing.

### 3. Assay Performance:

- **Sensitivity:** Should have high sensitivity to detect 500 fluorochromes per microsphere and reporter channel dynamic range should be 4.5 logs. samples.
- **Specificity:** Should have single antigen class 1&2 antibody detection test: shall detect antibodies specific for HLA A, B C, DR, DQ, DP and MICA antigens and shall be able to assign donor specific antibodies with high specificity and minimize false positives.
- **Dynamic Range:** Should have a wide dynamic range to accommodate a broad range of DSA concentrations in recipient samples.

### 4. Software and Data Analysis:

- **Dedicated Analysis Software:** Should come with user-friendly, latest OEM software designed for operation, data acquisition and analysing results of multiple product options like SSP, SSO, Single antigen, PRA. It should preferably have capability of performing virtual crossmatch. There should be provision for supply of free updates of the software.
- **Data Interpretation:** Should provide clear and concise interpretation of results, including qualitative and quantitative information.
- **Reporting:** Should generate comprehensive reports summarizing DSA results with customizable formats.

### 5. Workflow and Automation:

- **Calibration:** Should support automatic calibration, hands free start up, shut down, maintenance and validation procedure.
- **Automated Processes:** Shall Incorporate automated processes, such as sample handling, washing, and data acquisition, to minimize manual intervention and reduce hands-on time.

### 6. Hardware Features:

- **Instrument Design:** Should provide PC with 3.0 GHz intel core i7(or higher) along with 8GB RAM and 1TB hard drive space and Microsoft Windows 10 professional 64-bit operating system (or higher).
- All necessary accessories like UPS with at least 1 hour backup should be provided
- **Touchscreen Interface:** Should preferably have a touchscreen interface and high resolution screen for easy system control and monitoring.

#### **7. Additional Features:**

- **Quality Control:** Should include built-in quality control measures to ensure assay performance and reliability.
- **Calibration:** Should have mechanism for regular calibration and verification of the system to maintain accuracy.
- **Connectivity:** Provides options for data transfer and integration with laboratory information management systems (LIMS) or other data management platforms.
- **Maintenance and Support:** Installation and demonstration of equipment should be provided along with onsite training of technical staff.
- Starter kit including sheath fluid, calibration kit, performance verification kit and other reagents required for installation and maintenance should be provided.
- Availability of technical support, instrument maintenance with provision of CMC service contract for at least 5 years after expiry of standard warranty of 5 years/as per institutes guidelines to ensure continuous system performance.