



INDIAN INSTITUTE OF TECHNOLOGY BOMBAY

MATERIALS MANAGEMENT DIVISION

Powai, Mumbai - 400076

PR No. 100035813

Rfx No. 6100001553

**Technical Specification for Fully Automated Computerized Archival System**

| Sr. No. |                                 |   | Qty | Compliance (Yes/No) | Vendor's Remark |
|---------|---------------------------------|---|-----|---------------------|-----------------|
| 1       | Purpose :                       | High-performance microscopy-based automatic slide scanner system for animal tissue that supports normal microscopy glass slides. The system should be equipped with various high-performance objectives, support both brightfield and fluorescence samples with dedicated cameras, and be integrated with easy-to-use software and web-based database (to allow imaging sharing, annotations, and analyses over several users) for imaging and analysis of animal and human tissue samples.   | --  | --                  | --              |
| 2       | Microscope or Scanner Unit Box: | <ol style="list-style-type: none"><li>1. High-quality optics with the latest Infinity Colour Corrected System for high Brightness, High contrast, and color correction.</li><li>2. All optics coated with anti-reflection / anti-fungal treatment.</li><li>3. Tray concept (complete slide frame to be loaded on to imaging region to avoid dropping of slides, slides with coverslips should be loaded without any contact with coverslip) for slide with varying thickness (all types on conventional microscope slides eg: 1"x3", 2"x3" and 3"x4" slides) useful for data archiving.</li><li>4. Slide loading capacity should be minimum 9 or above glass slides with automated loading.</li><li>5. User should be free to give certain slides priority to be scanned first.</li><li>6. Complete specimen area should accessible for detection and scanning, including corners. The system should be able to detect tissues, specimen area without using fluorescence mode to avoid bleaching of sensitive fluorescence samples.</li><li>7. The system should be able to detect multiple slices/sections in the same slide automatically.</li><li>8. The system should be able to scan complete slides and still resolve sub cellular structures.</li><li>9. Preferably the system should be able to</li></ol> | 1   |                     |                 |



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|    |   | achieve the desired image resolution with minimal scanning time.<br>10. Please mention the scan speed of your system along with achievable resolution.<br>11. Workable with brightfield and Fluorescence slide                        |          |  |  |
| 3  | Nose Piece:   | Seven or more position Motorized objective nosepiece with DIC/ polarizer attachment slot.   | 1        |  |  |
| 4  | Objectives:   | 1. Plan Semi Achromat 4X/0.13.<br>2. Plan Semi Achromat 10X/0.3.<br>3. Plan Semi Achromat 20X/0.50.<br>4. Plan Achromat 40X/0.95.<br>5. Plan Achromat 60X/1.42<br>6. Plan Achromat 100X/1.43  | One Each |  |  |
| 5  | Condenser:  | Condenser with NA of 0.8 or better  | 1        |  |  |
| 6  | Fluorescence Attachment & Reflected Light Fluorescence: | Motorised Eight or more position fluorescence/ FISH Filter turret.  | 1        |  |  |
| 7  | Mechanical Stage:.                                      | XY Motorized scanning stage with adapter for 9 or above slides at a time or better.   | 1        |  |  |
| 8  | Condenser:  | Motorized condenser for all microscopy techniques with 8-position turret for optical elements, with motorized polarizer in/out. Polarizer is freely rotatable (360 degrees). Motorized in/out top lens.                               | 1        |  |  |
| 9  | Illumination:   | High color reproducing LED light source with an average life of at least 20,000 hours or better. White LED Reflected Light Illumination direct fir for better transmission with life of atleast 25,000 hours better.                  | 1        |  |  |
| 10 | Filters:  | 1. Single bandpass DAPI filter (Ex: 350/30, Em: 460/50).<br>2. Single bandpass Green filter (Ex: 495/25, Em: 537/29).<br>3. Single bandpass Orange filter (Ex: 546/22, Em: 590/33).<br>4. Single bandpass Red filter (Ex: 580/25, Em: | One Each |  |  |



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|    |                       | 625/30).<br>5. Single bandpass Aqua filter (Ex: 436/20, Em: 480/30).<br>6. Single bandpass Gold filter (Ex: 546/10, Em: 572/23).  |   |  |  |
| 11 | Camera Specifications | 1.Color.<br>2. Resolution: 5 MP.<br>3. Resolution (HxV) – 2448px X 2048px.<br>4. Sensor Type: CMOS.<br>5. Frame Rate: 35fps.<br>6. Pixel bit depth: 12-bit.<br>7. Pixel Size (HxV): 3.45µm X 3.45µm.<br>8. Shutter: Global shutter.<br>9. Interface: USB 3.0.   | 1 |  |  |
| 12 | Other Requirements:   | 1. Acquisition of imaging using software should be automated. It should be able to but not limited to automatically scan all the loaded slides with minimal operation.<br>2. System should have automated user-friendly feature to set up imaging and scanning parameters that encompasses hardware settings including scan area, z-stack settings, multichannel, etc., such that the system can be used by users with minimal training. The system should have a feature to store such settings and recall these user specific settings.   | 1 |  |  |
| 13 | Database Management:  | 1. Single database for all applications.<br>2. Modern paperless laboratory design management software.<br>3. View full-case summary status from the database management station.<br>4. Workflow oriented database user interface, includes all the information about the patient demographics, images, results, etc.<br>5. Microsoft SQL server based database for maximum security and scalability.<br>6. All images stored should be of conventional formal: jpg or tiff.<br>7. The database should manage all patient / sample demographics as well as images for all sample types analyzed.<br>8. Better control on flow and data protection by | 1 |  |  |



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|    |                    | <p>temporal lock of data as needed.</p> <p>9. Ability to assign levels of security for user access.</p> <p>10. Ability to assign advanced roles &amp; permissions management.</p> <p>11. User notification of the next “To Do” item according to roles &amp; permissions.</p> <p>12. Automated data maintenance.</p> <p>13. Automatic archiving of completed cases and based on user defined rules.</p> <p>14. Single click retrieval of archived cases.</p> <p>15. Single database can support multi-site installations without the need to transfer data between workstations.</p>  |   |  |  |
| 14 | LIS Connectivity:  | <p>1. System should have open interface for LIS, implemented worldwide with various LIS systems.</p> <p>2. Ability to import/export patient demographic data from/to hospital LIS system.</p> <p>3. Automatic Import of patient information and test protocol from LIS.</p> <p>4. Automatic export of results, images and reports to LIS.</p>   | 1 |  |  |
| 15 | Report Generation: | <p>1. Result reporting through the application must have customizable reports with direct reporting formats (PDF, MS Word, etc.) without the need to go through a third party software before reporting.</p> <p>2. Ability to create and organize customized report in accordance to application in use.</p> <p>3. Obtain statistics across any subset of cases according to desired parameters.</p> <p>4. Ability to create, view and save customizable summary reports for case statistics per sample type, period of interest (day/week/month/quarter) and more, for CAP Guidance compliant reporting.</p> <p>5. Ability to create, view and save customizable turnaround time reports per sample type, period of interest (day/week/month/quarter) and compare performance year on year to make data driven decisions.</p> <p>6. Summarize case results - normal, abnormal,</p> | 1 |  |  |



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|    |  | <p>failed - and review per specimen type.</p> <p>7. Ability to create, view and save customizable slides statistics reports.</p> <p>8. Ability to create, view and save customizable staff productivity reports per sample type, period of interest (day/week/month/quarter) and more.</p>   |   |  |  |
| 16 | <p>BRIGHTFIELD WHOLE SLIDE IMAGING:<br/>Digital scanning IHC stains:</p> | <ol style="list-style-type: none"> <li>1. Open Microscope-based system, to enable any objective and illumination model, C-mount control, 8 filters for IF.</li> <li>2. Fully automated, walk-away operation for 9 slides and high efficiency.</li> <li>3. Ability to scan IHC full slides in 20x in parallel with ability to review under eyepieces.</li> <li>4. Pre-scanning with low magnification for up to 4x for easy determination and digital marking of regions of interest.</li> <li>5. Automatic tissue detection for IHC stained slides.</li> <li>6. Ability to manually adjust automatic tissue detection results, add and delete regions prior to high magnification scanning.</li> <li>7. Whole slide image acquisition and review of IHC stained slides at 10x.</li> <li>8. Whole slide image acquisition and review of IHC stained slides at 20x.</li> <li>9. Multi-focal plane scanning of whole slide for optimal and uniform image quality.</li> <li>10. Automatic exposure algorithm for optimized scanning time and image quality.</li> <li>11. Real-time graphical display of scanning progress.</li> <li>12. Automatic and semi-automatic scanning modes for IHC stained slides.</li> <li>13. Real-time image file generation and storing to, in parallel with scanning.</li> <li>14. Scanning of IHC and IF slides in the same scanning session on same system.</li> </ol> | 1 |  |  |
| 17 | <p>Image view &amp; Annotation for IHC stained slides:</p>               | <ol style="list-style-type: none"> <li>1. Fast and easy viewing and navigation through the digital slide (WSI).</li> <li>2. Tumor marking tools, distance and area measurements and annotations for pathologist on IHC scanned images.</li> <li>3. Quantitative measurements and cell counting</li> </ol>  | 1 |  |  |



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|    |   | <p>for cancer grading and stage determination.</p> <p>4. Image enhancement tools including contrast and brightness controls for optimal image display.</p> <p>Digital zoom for up to 80x magnification.</p> <p>5. Fast navigation to the desired area from mini slide viewer.</p> <p>6. Intuitive workflow with designated tab for each of the pathologist's tasks.</p> <p>7. Viewing and navigation through the IHC stained slide regions of interest, annotation and tumor markings.</p> <p>8. Review of all slides and creation of case reports.</p> <p>9. Snapshots of images for later review and reporting.</p> <p>10. Synchronized navigation through up to four selected panel slides following co-registration.</p> <p>11. Flexible selection of display configuration for display and review of individual or multiple panel slides.</p> |   |  |  |
| 18 | IHC Analysis:   | <p>1. Computer aided evaluation system for immune-histo-chemistry (IHC).</p> <p>2. Algorithm for IHC membrane and nuclear analysis on individual frames.</p> <p>3. Real-time graphical display of results and statistics for complete slide or specific region of interest.</p> <p>4. Sensitivity control – ability to enhance the system classification without exiting the application.</p> <p>5. Capable to produce high-quality, repeatable, reproducible and managed results.</p>   | 1 |  |  |
| 19 | IMMUNOFLUORESCENCE (IF): Automated IF Scanning & Image Acquisition: | <p>1. Fully automated, walk-away operation for 9 slides and high efficiency.</p> <p>2. Automatic control over the microscope components, filters turret, objective turret, Z axis and shutter.</p> <p>3. Fully automated scanning protocol for cell suspension and tissue samples.</p> <p>4. User defined scan mode which enables the user to define the desired fields of view followed by automated scanning and image acquisition.</p>  | 1 |  |  |



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|    |                          | <p>5. Ability to scan slide by descending order of cell density, defined co-ordinates or user-defined area. It should come with basic scanning patterns like Spiral &amp; line by line.</p> <p>6. Low magnification pre-scan with up to 4x magnification for fast view of the slide, automatic tissue detection or slide matching.</p> <p>7. High magnification scanning with 40x or 60x/63x/100x for image acquisition of FOV's.</p> <p>8. System notifies the user of expected number of cells during the Interactive definition of FOV (fields of view).</p> <p>9. Built-in safe guards for coordinates that are overlapping or outside of the defined tumor regions during the Interactive definition of FOV.</p> <p>10. User can define scanning stop condition based on number of cells found, FOV captured, time limit.</p> <p>11. System can scan multiple regions on slide with different probe for each of the regions.</p> <p>12. System can perform Z-stacking based on user defined number of layers and distance between layers.</p> <p>13. Automated exposure adjustment for optimal image quality and cells/tissue detection.</p> <p>14. Ability to reset Scan for specific regions of unsuccessful scans.</p> <p>15. Ability to scan newly added tumor regions without the need to rescan the original tumor regions.</p> |   |  |  |
| 20 | Digital Tissue Matching: | <p>1. Tissue matching and registration of a reference IHC slide with consecutive tissue cuts stained with DAPI for the purpose of accurate IF scanning and analysis on tumorous areas only.</p> <p>2. Ability to add new tumor areas after IF scan completed without the need to rescan the whole slide.</p> <p>3. Review of the IF results in a way that enables examination of each captured field of view and each cell, verifying their location on the reference slide (IHC) to ensure that relevant tumor region/cells were analyzed.</p>  | 1 |  |  |
| 21 | Automated IF Analysis    | <p>1. Compatible for Suspension and FFPE samples on same system.</p>   | 1 |  |  |



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|  | <p>&amp;Review :</p> | <ol style="list-style-type: none"> <li>2. Software should support automated imaging and analysis of all probe companies.</li> <li>3. Single click image acquisition with automatic switch of filters.</li> <li>4. Ability to see all color layers of a cell side by side.</li> <li>5. Automatic cells detection based on cell morphology, size, shape, intensity.</li> <li>6. Automatic cells classification based on pre-defined signal pattern.</li> <li>7. User can select, add, delete cells from the captured field of view. User can select, add, delete cells from the captured field of view.</li> <li>8. On-screen review of automatically detected and classified cells, both through cells gallery and on the images/captured field of view.</li> <li>9. Single multi-tool with multiple cell editing functions, free hand cell contour drawing, editing cell boundaries, deletion and more.</li> <li>10. Single multi-tool with and multiple cell editing functions, free hand cell contour drawing, editing cell boundaries, deletion more.</li> <li>11. Ability for user to change Image Enhancement settings of one image and if required apply to all cells/frames in the gallery.</li> <li>12. User can review cells by seeing each of their Z-layers separately, simultaneously for any subset of the colors in 3D Mode.</li> <li>13. Ability to scroll between all signal layers of a cell.</li> <li>14. Multiple view modules within the software GUI: large FOV image, multi-color panel, zoom view.<br/>Color coded on-screen cells review: each cell contour is colored according the signal pattern defined class color.</li> <li>15. Ability to reclassify any cell to one of 15 cell-classes in a single key press.</li> <li>16. Ability for user to adjust cell and signal detection parameters for reanalysis of cells from all originally analyzed frames.</li> <li>17. Review bin allowing the user to mark questionable cells for later supervisor review.</li> <li>18. Blinded review: multiple users can review the cells of the same slide separately without</li> </ol> |  |  |  |
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|    |                     | <p>revealing the analysis results of each user. Statistics is gathered digitally but cannot be seen by the next reviewer, for true double blinded process.</p> <p>19. Ability to provide quantitative graphical data from FISH scanning, including cell area, signals intensity and SNR. This should be used in evaluating probes and wet lab quality control.</p> <p>20. Ability to change classification of entire group of cells simultaneously.</p> <p>21. Original Image display – Ability to display the original images in addition to the enhanced color image.</p> |          |  |  |
| 22 | QUALITY STANDARDS : | <p>1. CE Certified for Microscope.</p> <p>2. FDA clearance for Microscope.</p> <p>3. CE Marked for IHC Scoring.</p> <p>4. FDA cleared IHC algorithms for analysis of Breast Panel IHC HER2, ER, PR, Ki-67.</p> <p>5. All the modules of s/w should be from same vendor and should be incorporated into the database.</p>  | 1        |  |  |
| 23 | COMPUTER:           | <p>1. OS Windows 10 Professional 64 Bit ENG.</p> <p>2. Processor Intel Xeon 6-Core W-2133 (8.25M Cache, 3.6GHz,) .</p> <p>3. RAM 64GB 2666MHz DDR4.</p> <p>4. System HDD 2TB 7200 RPM SATA 6Gb/s 64MB Cache.</p> <p>5. Storage 2TB 7200 RPM SATA 6Gb/s 64MB Cache.</p>  | 1        |  |  |
| 24 | MONITOR:            | <p>1. Widescreen 2560 x 1440 resolution.</p> <p>2. Aspect ratio 16:9.</p> <p>3. 25" Monitor or higher.</p>  | 1        |  |  |
| 25 | UPS                 | 3 KVA USB with at least 30 minutes of backup.   | 1        |  |  |
| 26 | OTHER ADDITIONS:    | <p>1. MS Office should be provided with the system.</p> <p>2. Antivirus for 1 year to be provided with the system.</p> <p>3. 2 TB external HDD for backup to be provided with the system.</p> <p>4. Anti-vibration table to be provided with the</p>  | One Each |  |  |



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|    |          | system.<br>5. Offline system should be provided for image analysis. |   |  |  |
| 27 | Warranty | 3 years   | 1 |  |  |