

Technical Specifications

Imaging & Analysis for Pathology

Company details:

Technical/Description	
Manufacturer/Supplier	
Contact Information	
Name of Distribution Partner	

1. Licensing, Maintenance, and Support. Bidder’s proposal must include a detailed discussion regarding the following requirements:

- 1.1. Bidder’s proposal must provide the system’s licensing package, including, but not limited to, structure, options, and cost.
- 1.2. Bidder’s proposal must detail all modules in the proposed advancement solution and whether each is required or optional, as well as whether it is included in Bidder’s stated pricing.
- 1.3. Maintenance and support services, including all regular updates /upgrades to software and hardware.
- 1.4. Bidder must provide detailed discussion for requesting technical and functional support.
- 1.5. Bidder must provide detailed discussion on the support Bidder provides for the system, including, but not limited to, coverage details, average downtime, and call response time.
- 1.6. Bidder’s proposal should include detailed discussion regarding annual system upgrades, at a minimum.
- 1.7. Bidder must provide detailed discussion on any specific performance procedures required on a daily/weekly/monthly/annual basis as part of the upkeep and management of the system.
- 1.8. Bidder’s proposal should provide a detailed discussion as to the requirements needed for personal computers and servers to adequately run the system for licenses. Requirements include, but are not limited to, the following:
 - 1.8.1. Windows operating system (OS) Version;
 - 1.8.2. Computer Processor Unit (CPU) Speed;
 - 1.8.3. Display Properties;
 - 1.8.4. Screen Resolution;

- 1.8.5. Disk Space;
- 1.8.6. Networking Software;
- 1.8.7. Networking Hardware;
- 1.8.8. IOS/Driod Operating System Version(s); and

2. Implementation and Training. Bidder’s proposal must include a detailed discussion regarding its capabilities to meet the following requirements:

2.1. Bidder must provide a detailed implementation plan. The plan should include, but is not limited to, descriptions of roles with skill levels required and the estimated amount of time per role that must be committed to the implementation of Bidder’s system. MANDATORY

- 3. Bidder’s proposal must provide the estimated amount of effort (hours, % of FTE, etc.) that will be required for the implementation of Bidder’s system.
- 4. Bidder must provide a detailed list of technical skills required to maintain the proposed system.
- 5. Costs associated with training must be included in Bidder’s cost proposal.
- 6. Bidder’s proposal must provide its proposed plan for data migration of historical data to Bidder’s system.

7. System Requirements

Category	Technical/Description	Remarks
Minimal computer specifications - Scanning Station <ul style="list-style-type: none"> • Operating system (OS) Version • Computer Processor Unit (CPU) Speed • RAM • Hard drive • Storage 	<ul style="list-style-type: none"> • Windows 10 Professional 64 Bit ENG • Intel Core Processor i7-13700K • 64GB 2666 MHz DDR4 • SSD 2TB 7200 RPM SATA 6Gb/s 64MB Cache • 2TB 7200 RPM SATA 6Gb/s 64MB Cache 	
Minimal computer specifications - Manual Stations <ul style="list-style-type: none"> • Operating system (OS) Version • Computer Processor Unit (CPU) Speed • RAM • Hard drive • Storage 	<ul style="list-style-type: none"> • Windows 10 Professional 64 Bit ENG • Intel Core i5-12500 • 16GB • 512GB SSD • 2TB 7200 RPM SATA 6Gb/s 64MB Cache 	
Minimal camera specifications <ul style="list-style-type: none"> • Resolution • Resolution (HxV) • Sensor Type • Frame Rate • Pixel bit depth 	<ul style="list-style-type: none"> • 5 MP • 2448px X 2048px • CMOS • 35fps • 12-bit • 3.45µm X 3.45µm 	

<ul style="list-style-type: none"> • Pixel Size (HxV) • Shutter • Interface 	<ul style="list-style-type: none"> • Global shutter • USB 3.0 	
<p>Minimal monitor specifications</p> <ul style="list-style-type: none"> • Resolution • Aspect ratio • Display size 	<ul style="list-style-type: none"> • Widescreen 2560 x 1440 • 16:9 • 25" Monitor or higher 	
<p>Microscopes for all Manual systems</p> <ul style="list-style-type: none"> • Vendor • Objectives 	<ul style="list-style-type: none"> • Compatibility with any make of trinocular microscope • Subset of the following objectives based on included modules: <ul style="list-style-type: none"> ○ Olympus <ul style="list-style-type: none"> ▪ 4x/0.16NA ▪ 20x/0.5NA ▪ 60x/1.4NA ○ ZEISS <ul style="list-style-type: none"> ▪ 5x/0.16NA ▪ 20x/0.5NA ▪ 63x/1.25NA 	<p>60X/63X objectives are required for Tissue FISH samples</p>
<p>Motorized Microscopes for Scanning System</p> <ul style="list-style-type: none"> • Vendor • Objectives • Focusing system • Step size • Fluorescence illuminator • Focus fine drive • Control unit • Nosepiece • Filter wheel • Light illuminator • True color light source • Fluorescent light source 	<p>Motorized Microscopes for Scanning System</p> <ul style="list-style-type: none"> • Scanning Compatibility with Olympus BX61/BX63/Zeiss Z2 Axioimager microscopes • Subset of the following objectives based on included modules: <ul style="list-style-type: none"> ○ Olympus <ul style="list-style-type: none"> ▪ 4x/0.16NA ▪ 10x/0.3NA ▪ 20x/0.5NA ▪ 40x/1.3NA ▪ 60x/1.4NA ○ ZEISS <ul style="list-style-type: none"> ▪ 5x/0.16NA ▪ 10x/0.3NA ▪ 20x/0.5NA ▪ 40x/1.3NA ▪ 63x/1.25NA • motorized nosepiece focusing system in combination fixed stage to reduce potential sources of vibrations, for improved quality of image acquisition • Step size of the focusing drive: < 50nm., Reproducibility: +/-30 nm • Microscope fluorescence illuminator equipped with a Fly's-eye lens to provide uniform illumination 	<ul style="list-style-type: none"> • 4x/0.16NA/ 5x/0.16NA objectives are optional, required for Tissue FISH samples only • 40X objective is optional for high magnification Tissue FISH scan

	<ul style="list-style-type: none"> • Focus fine drive knobs with scaling. Control buttons around focus drive. Comes with fine drive knob and fine drive disk • Focus, objectives and filter control unit can be removed from the microscope and attached anywhere on the microscope, enabling the operator to create a working environment of his/her own • Nosepiece 7X motorized. • 8 position filter wheel. 400 ms between neighboring positions • Reflected light illuminator • True color LED light source • Fluorescent light source – Metal halide control unit that automatically shuts down the FL light source to save lamp lifespan 	
<p>High Throughput Tray/Slide Loader specifications</p>	<ul style="list-style-type: none"> • Minimum slide capacity of 99 slides • Continuous slide replacement for effectively infinite capacity • Uninterrupted loading during system operation • Tray prioritization option • Barcode Reader: code 128 or QR code • Barcode Printer • Oil Dispenser minimum 150 ml reservoir 	
<p>Scanning System</p> <ul style="list-style-type: none"> • Stage capacity • Movement control 	<ul style="list-style-type: none"> • 9 slides • Joystick for stage movement control 	

Brightfield WSI Scanning for H&E and IHC Stains			
1	Category	Technical/Description	Remarks
1.1	Whole slide image acquisition	Whole slide image acquisition of H&E and IHC stained slides at 10x	
1.2		Whole slide image acquisition of H&E and IHC stained slides at 20x	Mandatory
1.3	Combined scanning of various slide staining techniques	Scanning of H&E, IHC and FISH slides in the same scanning session	Mandatory
1.4	Scan modes	Automatic and semi-automatic scanning modes for H&E and IHC stained slides	
1.5	Scan in parallel to Microscope review	Ability to scan H&E and IHC slides in 20x in parallel with ability to review under eyepieces	
1.6	Automatic tissue detection	Automatic tissue detection for H&E and IHC stained slides	Mandatory
1.7	Tissue detection adjustments	Ability to manually add and/or delete detected tissue regions prior to high magnification scanning	Mandatory
1.8	Multi-focal plane scanning	Multi-focal plane scanning of whole slide image	Mandatory
1.9	Automatic exposure	Automatic exposure algorithm	
1.10	Scanning progress indication	Real-time graphical display of scanning progress	
1.11	Scan status monitoring	Real time scan status monitoring, including slide search by case or slide details or by scan status. Optional filtering by lab and scanner. Ability to export scan history	Mandatory
1.12	Image generation and storage	Real-time image file generation and storing	

Scanner-Agnostic Capabilities			
2	Category	Technical/Description	Remarks
2.1	Third-party scanners conversion and import	Ability to convert and import images acquired on third-party scanners into ASI's WSI format for later case and slide management.	
2.2	Acceptable file formats for conversion	<ul style="list-style-type: none"> • NDPI • SVS 	
2.3	Visualization of H&E or IHC images	Visualization of H&E or IHC images from multiple formats (ASI and third-party scanners)	
2.4	Quantitative analysis of nuclear and membranous stain	Quantitative analysis of nuclear and membranous stain on any brightfield image	
2.5	Registration of H&E or IHC images	Registration of any H&E or IHC image with ASI FISH scan	

WSI Review			
3	Category	Technical/Description	Remarks
3.1	Pathology Imaging and Analysis Suite	Single environment for complete pathologists workflow, including intuitive viewing and navigation through the digital slide (WSI)	
3.2	Digital pathology workflow	Graphic representation of workflow steps	Mandatory
3.3	Digital zoom	Digital zoom for up to 80x magnification	Mandatory
3.4	Slide viewer	Fast navigation to the desired area from mini slide viewer	Mandatory
3.5	Image enhancement	Image enhancement tools including contrast, brightness and color controls	
3.6	Comparative review	Comparative review of scanned WSI vs. low magnification slide image	Mandatory
3.7	Reference slide	Reference slide selection	
3.8	Region marking	Region marking tools, including geometric and free-style shapes	
3.9	Region marking editing	Ability to edit marked regions of interest	
3.10	Control Sample	Ability to analyze, document and monitor control samples	Mandatory
3.11	Regions navigation	Navigation between regions of interest	
3.12	Annotation tools	Image annotation tools, including distance and area measurements and text annotations	
3.13	Multi Slide Panel Display	Flexible selection of display configuration for display and review of individual or multiple panel slides	
3.14	Snapshots	Snapshots of images for later review and reporting	

Digital Tissue Matching			
4	Category	Technical/Description	Remarks
4.1	Reference slide	Co-registration of a reference brightfield slide with multiple consecutive tissue cuts stained with H&E/IHC/DAPI	
4.2		Ability to select a reference slide for tissue matching from multiple H&E/IHC slides	

4.3	Region of Interest transfer to matched slides	Automatic ROI transfer from reference slide to matched slides	
4.4	Synchronized viewing of matched slides	Synchronized viewing of matched slides, including navigation through ROIs	
4.5	Continuous region adding	Ability to add new regions after FISH scan completed without the need to rescan the whole slide	Mandatory

IHC Analysis			
5	Category	Technical/Description	Remarks
5.1	IHC analysis	Algorithms for analysis of IHC membrane and nuclear stains on individual frames and WSI	Mandatory
5.2	Control regions analysis	Ability to assign and analyze control regions independently from clinical sample regions.	Mandatory
5.3	Results display	Real-time graphical display of results and statistics for complete slide/frame or specific region of interest	Mandatory
5.4	Heterogeneous tumors analysis	In-depth analysis of heterogeneous tumors. Region-by-region navigation and analysis	
5.5	Cell classification overlay marking	On/off toggle of cell classification overlay marking	
5.6	Sensitivity control	Ability to enhance the system classification without exiting the application	
5.7	PDL-1 NSCLC analysis	Dedicated analysis and classification for PDL-1 NSCLC cases	Mandatory
5.8	Global IHC scores display	Configurable calculation and display of widely accepted global IHC scores (H-score, M-score, TPS)	Mandatory
5.9	CISH classification	Automated algorithm for CISH cell segmentation, signal detection and classification	

FISH Tissue Imaging			
6	Category	Technical/Description	Remarks
6.1	Automatic scanning program assignment	Automated scanning protocol selection according to slide barcode	
6.2	Scanning protocols and stop criteria	Versatile scanning protocols with configurable stop criteria	
6.3	Microscope control	Automatic control over the microscope components, filters turret, objective turret, Z axis and shutter	
6.4	Sample types	Scanning of tissue and cell suspension samples with one system	Mandatory
6.5	Tissue FISH samples scanning	Fully automated scanning protocol for tissue samples including <ol style="list-style-type: none"> 1. 4x scan of entire slide in DAPI with background uniformity correction 2. Tissue detection 3. High magnification tissue scans with all colors and multiple focal planes 	Mandatory
6.6	Tissue detection on fluorescent samples	Deep learning-based tissue detection directly on fluorescent samples	Mandatory
6.7	Interactive scanning mode	Interactive scan mode which enables the user to define the desired fields of view followed by automated scanning and image acquisition	
6.8	Magnification	High magnification scanning with 40x/60x/63x/100x	
6.9	Z-stack	Z-stacking based on user defined number of layers and distance between layers	
6.10	Pathologist defined regions scan	Automatic scanning based on pathologist-defined regions transferred from reference brightfield slides	Mandatory
6.11	Automatic cell number estimation	Automatic estimation and display of anticipated number of cells within user defined scanning path.	
6.12	Multi-region support	Support of multi-region, multi-probe slides.	
6.13	Acquisition parameters optimization	Intelligent acquisition parameters optimization	
6.14	Exposure adjustment	Automated exposure adjustment for optimal image quality and cells/tissue detection	
6.15	Scan status monitoring	Real time scan status monitoring, including slide search by case or slide details or by scan status. Optional filtering by lab and scanner. Ability to export scan history.	
6.16	Reset scan	Ability to reset scan for specific regions of unsuccessful scans	

6.17	Add tumor regions	Ability to scan newly added tumor regions without the need to rescan the original tumor regions	Mandatory
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Automated FISH Review & Analysis			
7	Category	Technical/Description	Remarks
7.1	Probe analysis	Automated analysis of any probe and any probe vendor	
7.2	Cell detection	Automatic cells detection based on cell morphology, size, shape, intensity	
7.3	Cell classification	Automatic cells classification based on pre-defined signal pattern	
7.4	Detected and classified cells display	On-screen review of automatically detected and classified cells	
7.5	FISH analysis relative to H&E tumor marking	Pathologist can review the FISH analysis of cells and the location of FOV captured relatively to the H&E tumor marking	
7.6	Cell reclassification	Ability to reclassify any cell to one of 15 cell-classes in a single key press	Mandatory
7.7	Cell operations within captured field of view	Ability to select, add, delete cells from the captured field of view	Mandatory
7.8	Review modes	Versatile review modes ranges from computer assisted image analysis for cell/signal classification to manual signal classification	Mandatory
7.9	Remove readers	Ability to remove readers from overall statistics	Mandatory
7.10	Region status indication	Status indication per region	Mandatory
7.11	Additional review indication per region	Ability to add region indication for additional review	Mandatory
7.12	Analysis approval notifications	Automatic notification in case application is closed without analysis approval	Mandatory
7.13	Cells export to database	Ability to batch export cells from scanning application to database according to cell status	Mandatory
7.14	On-screen analysis/review	User pre-defined classes and short keys to support for on-screen analysis/review of cells within the gallery	
7.15	FISH probes setup	Ability to define new FISH probes/kits of any probe vendor and probe type without the need for probe vendor support	Mandatory

7.16	Abnormal signal patterns detection	Automatic detection of abnormal signal patterns	
7.17	Multi-fusion probes detection	Algorithm for the detection and classification of multi-fusion FISH probes, including triple and quad-color fusions	Mandatory
7.18	Cell editing tool	Single multi-tool for cell editing, free hand cell contour drawing, editing cell boundaries, deletion and more	
7.19	Signal sensitivity adjustments	Ability to adjust the level of sensitivity of each signal layer for improved cell classification	
7.20	Interactive image enhancement	Ability to change Image Enhancement settings of one image and if required apply to all cells/frames in the gallery	Mandatory
7.21	Cell and signal detection parameters adjustments	Ability to adjust cell and signal detection parameters for reanalysis of cells from all originally analyzed frames	Mandatory
7.22	Cells marking for supervisor review	Review bin allowing the user to mark questionable cells for later supervisor review	
7.23	3D review	Ability to review cells by seeing each of their Z-layers separately, simultaneously for any subset of the colors	
7.24	Quantitative graphical data	Ability to provide quantitative graphical data from FISH scanning, including cell area, signals intensity and SNR. Useful in evaluating probes and wet lab quality control	Mandatory
7.25	Color coded cells review	Ability to color all cell contours according to the signal pattern defined in class color	
7.26	Original vs. enhanced image display	Ability to display the original images in addition to the enhanced color image	
7.27	Batch cell classification	Ability to change classification of entire group of cells simultaneously	
7.28	Cell signal layers display	Ability to scroll between all signal layers of a cell	
7.29		Review of automatically classified cells from field of view	
7.30	Workspace	Multiple display layouts	
7.31	Results display	<ul style="list-style-type: none"> • Ability to toggle display of FISH frames indications on the Brightfield scan or FISH prescan image • Slides, regions and frames display configuration 	

		<ul style="list-style-type: none"> FISH slide results table and graph formats 	
7.32	Annotations	Ability to annotate FISH scan results	
7.33	Case and slide notes	Ability to fill out case final results, slide notes and technical notes	
7.34	Snapshots review	Ability to review captured snapshots	
7.35	FDA clearance	FDA clearance for HER2 FISH, ALK, UroVysion probes	Mandatory
7.36	Remote access	Remote review through the web, including all analysis and review capabilities that are available when working locally	

Manual FISH Imaging & Analysis			
8	Category	Technical/Description	Remarks
8.1	Z stack	Ability to Z-Stack on manual microscopes	Mandatory
8.2	Region of Interest adjustment	Adjustable region of Interest in acquisition	
8.3	Contrast control	Ability to control contrast locally per each region/cell/chromosome in the image.	
8.4	Auto contrast schemes	Multiple user-defined auto contrast schemes	
8.5	Signals intensity	Ability to view absolute value of signals intensity	
8.6	Probe definition	Pre-definition of probe text: one click enables writing multi-lines with multiple colors to describe the probe	
8.7	Digital FISH cell counter utility	Digital FISH cell counter with real time result statistics	Mandatory
8.8	Cells detection and segmentation	Support process of capture and automated cells and signal-pattern analysis on fully manual fluorescent microscope	
8.9	Her2neu amplification	Her2 auto amplification calculation on manual microscope and manual stage	
8.10	Manual scoring change indication	Ability to reclassify any cell to one of 15 cell-classes in a single key press	Mandatory

Database & Case Management			
9	Category	Technical/Description	Remarks
9.1	Database information	Workflow oriented database user interface, includes all the information about the patient demographics, images, results, etc.	
9.2	Server type	Microsoft SQL server-based database for maximum security and scalability	
9.3		Database can be installed in hospital SQL server	
9.4	Image format	All images stored should be of conventional format: jpg or tiff	
9.5	Sample types	The database should manage all patient / sample demographics as well as images for all sample types analyzed	
9.6	Database display	Instant view of case, slide and cells information and status	
9.7	Data protection/ lock mechanism	Control on workflow and data protection by temporal lock mechanism of cell/slide/case as needed.	
9.8	Multi-site connectivity	Single database can support multi-site installations without the need to transfer data between workstations	
9.9	Search mechanism	Search mechanism by any case or slide field, or combination of any fields even when archived	
9.10	Data entry fields	Ability to add and customize data entry fields	
9.11	User access security level	Ability to assign levels of security for user access	
9.12	Roles & permissions management	Ability to assign advanced roles & permissions management	
9.13	Electronic records and signatures	Creation, and storage of electronic records, and application and maintenance of electronic signatures.	
9.14	Pending tasks notifications	User notification of pending tasks according to roles & permissions	
9.15	Case Status Management	Ability to view/track cases according to their status within the completion process	
9.16	Case attachments	Ability to scan patient info, document and incorporate into case view	
9.17	Customize reports	Ability to customize reports and define the report structure, information and add laboratory logo	

9.18	HIPAA compliance	Ability to meet or exceed HIPAA compliant security standards for protecting data information	
9.19	Audit trail	Audit trails and logging for case, slide, and cell status modification	
9.20	Audit data interface	Audit data must be viewable through the user interface by an administrator with appropriate security permissions	

10	Data Maintenance & Archiving	Remarks
10.1	Automated data maintenance	
10.2	Automatic Scheduling of maintenance without the need for user intervention	
10.3	Manual archiving of cases	
10.4	Automatic archiving of completed cases and based on user defined rules	
10.5	Single click retrieval of archived cases	

LIS Connectivity and Remote Access			
11	Category	Technical/Description	Remarks
11.1	LIS interface	Ability to interface with a Laboratory Information System (LIS)	
11.2		System should have open interface for LIS, implemented worldwide with various LIS systems	
11.3	LIS connectivity file format	Connectivity to LIS through HL7 FHIR/ XML/txt file exchange	
11.4	LIS information import	Automatic Import of patient information and test protocol from LIS	
11.5	Export information to LIS	Automatic export of results, images and reports to LIS	
11.6	Barcode connectivity	automated barcode reading of LIS barcodes for slide detection	
11.7	Transfer stored images	Ability to transfer stored images from current system to a new system.	
11.8	Import/export patient demographic	Ability to import/export patient demographic data from/to hospital LIS system	

Reporting			
12	Category	Technical/Description	Remarks
12.1	Customizable reports formats	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	
12.2	Customizable reports formats per application	Ability to create and organize customized report in accordance to application in use	
12.3	Case summary reports	Ability to create, view and save customizable summary reports for case statistics per sample type, period of interest and more	Mandatory
12.4	Staff productivity reports	Ability to create, view and save customizable staff productivity reports per sample type, period of interest and more	Mandatory
12.5	Turnaround time reports	Ability to create, view and save customizable turnaround time reports per sample type, period of interest and more	Mandatory
12.6	Slides statistics reports	Ability to create, view and save customizable slides statistics reports	Mandatory

13 Quality Standards		Remarks
13.1	CE Marked	
13.2	FDA - State 510K	
13.2.1	<ul style="list-style-type: none"> • Karyotyping 	
13.2.2	<ul style="list-style-type: none"> • FISH 	
13.2.3	<ul style="list-style-type: none"> • Her2neu FISH 	
13.2.4	<ul style="list-style-type: none"> • ALK FISH 	
13.2.5	<ul style="list-style-type: none"> • UroVysion FISH 	
13.2.6	<ul style="list-style-type: none"> • CEP XY FISH 	
13.2.7	<ul style="list-style-type: none"> • FDA cleared algorithms for analysis of Breast Panel IHC HER2, ER, PR, Ki-67 	Mandatory
13.2.8	<ul style="list-style-type: none"> • 21 CFR Part 11 	
13.3	Electromagnetic Compatibility - Emission	
13.4	Electromagnetic Compatibility - Immunity	
13.5	EU Conformance	
13.6	Australian ATG Conformance	
13.7	Canada Health Conformance	
13.8	UK Conformance	
13.9	HIPAA and GSPR Compliance	

Service Ability & Maintenance			
14	Category	Technical/Description	Remarks
14.1	Service request response time	What is the response time for a service request during weekdays, weekends or holidays? <ul style="list-style-type: none"> • Telephone • On-Site 	
14.2	Critical failure response time	What is the response to a failure of a critical component of the system, including what the response time would be to ensure continuous operation of laboratory functions?	
14.3	Call-in technical support	Is call-in technical support available? If yes, what hours are they available? Is there a charge for this support? If so, see Pricing section	
14.4	System remote monitoring	Provide information on how your system is monitored remotely to identify potential problems?	
14.5	Parts delivery time	What is the average parts delivery time?	
14.6	Warranty	State what is covered and what is not covered under the warranty. What does the agreement include regarding upgrades, parts and labor	
14.7	Preventative maintenance	How many preventative maintenance schedules are included in the annual preventive maintenance service?	

14.8		Provide complete preventative maintenance details and schedules	
14.9	Software upgrades	Will future software upgrades be performed at no additional cost?	
14.10	Onsite setup	State who is responsible for the onsite setup, configuration and pre-testing of any software and all hardware peripherals	
14.11	System delivery time	From the time of contract signature, what is the guaranteed delivery time & installation for all software and hardware peripherals?	