Technical Specifications

Imaging & Analysis for **Cytogenetics**

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. The bidder must provide detailed discussion for requesting technical and functional support.

   1.5. Bidder must give detailed discussion on the support Bidder provides for the system, including coverage details, average downtime, and call response time.

   1.6. The 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.

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

2.1. The 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 • OS • Processor • RAM • Hard drive • Storage	• Microsoft Windows 11 or 10 64 Bit ENG Professional or Enterprise edition • Intel Core Processor i7-13700K • 16GB 3600MHz DDR4 or higher non-ECC • 512GB SSD • 2TB 7200 RPM	
• Minimal computer specifications -Manual Station • OS • Processor • RAM • Hard drive • Storage	• Microsoft Windows 11 or 10 64 Bit ENG Professional or Enterprise edition • Intel Core Processor i7-13700K • 16GB 3600MHz DDR4 or higher • 512 GB SSD • 2TB 7200RPM	
Minimal camera specifications • Resolution • Resolution (HxV) • Sensor Type • Frame Rate	• 5 MP • 2448px X 2048px • CMOS • 35fps • 12-bit	

• Pixel bit depth • Pixel Size (HxV) • Shutter • Interface	• 3.45µm X 3.45µm • Global shutter • USB 3.0	
Minimal monitor specifications • Resolution • Aspect ratio • Display size.	• Widescreen 2560 x 1440 • 16:9 • 25" Monitor or higher	
Microscopes for all Manual systems: • Vendor • Objectives	• Compatibility with any make of trinocular microscope • Subset of the following objectives based on included modules: o Objectives – 10X/0.3 or similar o Objectives – 60XOI/1.25 or similar o Objectives – 100XO2/1.3 or similar	
Motorized Microscopes for Scanning System • Vendor • Objectives • Focusing system • Step size • Fluorescence illuminator • Focus fine drive. • Control unit • Nosepiece • Filter turret • Light illuminator • True color BF light source • Fluorescent light source control	• Scanning Compatibility with Olympus BX61/BX63/Zeiss Z2 Axioimager microscopes • Subset of the following objectives based on included modules: o Objectives - 1.25X/0.04 o Objectives - 4X or 5X/0.16 o Objectives - 10X/0.3 o Objectives - 40X/ 1.4 o Objectives - 60X 1.42 / 63X /1.44 o Objectives - 100X/1.3 o Automatic Condenser for Karyotyping and FISH together • motorized nosepiece focusing system on 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. • Focus fine drive knobs with scaling. Control buttons around focus drive. Comes with a 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 wheels. 400 ms between neighboring positions. • Reflected light illuminator. • True color LED light source. • Optional control unit that automatically shuts down the FL light source to save lamp lifespan.	
Fluorescent Illuminator (FL Light source)	• LED based with minimal 20,000 work hours • Pad with continuous control of light intensity in 1% steps. • Pad control for differential intensity of green, red and DAPI for balanced review of fusion signals	
High Throughput Tray/Slide Loader specifications	• 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 (about 5.07 oz) reservoir.	
Scanning System • Stage capacity • Movement control	• 9 slides. • Joystick for stage movement control.	

KARYOTYPING

Automated Scanning and Metaphase Detection			
	Category	Technical/Description	Remarks
1.1	Slide definition	Automated slide definition by one-click assignment of common tests to slides.	
1.2	Panel definition	Automated panel definition by one-click definition of a panel, i.e., a test containing multiple slides.	
1.3	Sample types	Scanning and automatic metaphase detection for blood, bone marrow, amniotic fluid, or any other sample types.	
1.4	Staining types	Scanning and automatic metaphase detection of G-band, Q-band, R-band, DAPI and other staining types.	
1.5	Scanning program	Automated scanning program selection per barcode label.	
1.6	Unattended image acquisition	Fully unattended image acquisition from low magnification scanning through high magnification capture.	
1.7	Slide coverage	Full slide coverage - edge to edge scanning.	
1.8	Scanning progress indication	Real-time scanning progress display on mini slide viewer.	
1.9	Processed cells indication	Real-time processed cells indication display.	
1.10	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
1.11	Trays reloading	Continuous slide trays reloading during scanning.	Mandatory
1.12	Cover-slip detection and identification of amniotic fluid colonies	Rapid 1.25X automated scan for the detection of coverslip and identification of amniotic fluid colonies, followed by auto selection and 100X capture of n-best metaphases per colony.	
1.13	Exposure	Automated exposure adjustment for optimal image quality and metaphase detection.	
1.14	Metaphases detection	Machine learning algorithms based rapid 10X automated scan for detection of metaphases, including the most condensed metaphases in BM samples.	

1.15	Background reduction	Automatic removal of non-chromosomal objects and background reduction.	
1.16	Captured metaphases gallery	Real-time scanning progress indicator - displays gallery of captured metaphases.	
1.17	Metaphase grading	Automated metaphase grading during scan according to their quality.	
1.18	Automatic Metaphases selection for high magnification scanning	Automatic selection of highly graded metaphases for high magnification scanning.	
1.19	Interactive Metaphases selection for high magnification scanning	During slide scanning, allow user to interactively select desired metaphases for high magnification image acquisition (optional, otherwise selection is automatic).	Mandatory
1.20	Cell and micro nuclei detection	Algorithm for cell detection and MN (micro nuclei) detection and classification.	
1.21	Mitotic index calculation	Algorithm for cellular proliferation calculation during slide scanning.	

Automated Relocation to Cells and High magnification Image Acquisition			
	Category	Technical/Description	Remarks
2.1	Metaphase capture	Metaphase capture using x100 oil immersion objective for best image quality.	
2.2	Image resolution	Metaphase capture of 5M pixel resolution.	Mandatory
2.3	Field of view	Wide Field of view (FOV) of 22mm (about 0.87 in), to match the maximum FOV seen through the eyepieces.	
2.4	Automatic karyotyping at time of capture	AI-based chromosome segmentation and karyotyping per metaphase immediately after it is captured.	
2.5	Oil dispensing	Automated oil dispensing following 10x scan prior to high resolution capture of selected metaphases.	
2.6	Oil drop sensing	Automated oil drop sensing to achieve accurate oil amount and uniform oil spread.	
2.7	Focus	Automated focusing.	

2.8	Merge floating chromosomes	Ability to merge floating chromosomes to the metaphase within the scanning application.	Mandatory
2.9	Metaphase images display	Side by side display of low and high magnification metaphase images to ensure all chromosomes are included within the high magnification image.	Mandatory
2.10	Cells availability for review and analyze	Ability to start cells review and karyotyping of metaphases captured from a slide even if the slide is still undergoing scanning.	Mandatory
2.11	Capture of FISH metaphases	Automated metaphase finder and high magnification capture of FISH metaphases, including all FISH colors with optional Z-stack.	

Manual Metaphase Image Acquisition			
	Category	Technical/Description	Remarks
3.1	Image resolution	Metaphase acquisition of 5M pixel resolution.	Mandatory
3.2	Region of Interest adjustment	Adjustable Region of Interest in acquisition.	
3.3	Cell location visualization	Visualization of cell location on slide viewer.	
3.4	Merge floating chromosomes	Ability to merge unlimited number of floater chromosomes, including their automatic segmentation.	
3.5	Acquired metaphases gallery	Gallery of recently acquired metaphases available within the capture/ application window.	Mandatory
3.6	Workspace	Customizable workspace.	
3.7	Image enhancement	Automatic image enhancement.	
3.8	Spectral karyotyping	Optional image capture of 24-color-stained metaphases.	Mandatory

Chromosome Analysis and Karyotyping			
	Category	Technical/Description	Remarks
4.1	Case review by multiple users	Option for simultaneous reviewing of case by multiple users.	Mandatory
4.2	Case review and sign off	Documentation of the user performing analysis per cell.	
4.3	Third party system metaphase images analysis	Import and analyze metaphase images captured by third party system in standard image formats.	
4.4	Auto removal of non-chromosomal objects	Automatic removal of nuclei and non-chromosomal objects.	Mandatory
4.5	Automatic chromosome segmentation	AI-based chromosome separation, including overlapping, touching and clustered chromosomes with option for manual adjustment.	
4.6	Background vs. chromosome separation	Automatic threshold to separate between background and chromosomes.	
4.7	Interactive chromosome segmentation tool	Ability to perform all chromosome segmentation operations within a single tool.	Mandatory
4.8	Centromere detection	Auto centromere definition with option for user interaction.	
4.9	Chromosome classification and arrangement into karyogram	Highly accurate AI-DNN (Artificial Intelligence based on Deep Neural Network) karyotyping (or chromosomal assignment), including dedicated AI/DNN chromosomal orientation algorithm.	Mandatory
4.10	Chromosomes arrangement in karyotype table	Drag and drop chromosomes into karyotype table preserving visibility of the chromosome image while dragging (to enable real time check of matched bands).	
4.11	Editing within karyotype window	Ability to perform all contour editing and segmentation operations, including addition of missing telomere regions, in karyotype window.	Mandatory
4.12	Chromosomes counting	Automatic chromosomes counting based on contoured chromosomes.	
4.13	Indexing	Ability to index and annotate metaphase image.	
4.14	Band resolution	Automatic measurement of band resolution.	Mandatory
4.15	Chromosome Arm Ratio & Centromeric Index Indication	Ability to export chromosome arm ratio and centromeric index	Mandatory

		parameters for each indexed chromosome - providing additional chromosome structural and nomenclature information.	
4.16	Merge chromosome fragments	Ability to merge fragments into one chromosome.	
4.17	Chromosome boundaries resizing	Expand or shrink specific chromosome boundaries by keyboard short key.	
4.18	ISCN format	ISCN 2020 standard for 300, 400, 550, 700 and 850 band resolutions.	Mandatory
4.19	Auto ISCN text	Auto ISCN for chromosome enumeration, including aberrations written within the metaphase.	Mandatory
4.20	Sex chromosomes display	Incorporate the sex chromosomes within the count tool for display of both the model number and sex.	
4.21	Sex chromosomes mismatch notification	Optional notification in case of a mismatch between patient's gender entered in case details (database) and Karyotyping results derived from analysis.	
4.22	Chromosomes color-coding	Automatic color-coding of all segmented chromosomes.	
4.23	Text annotations	Free text annotation and markups, with assorted colors and shapes can be added to metaphase and karyogram images.	
4.24	Image enhancement tools	Enhancement tools (sharpening, contrast, staining etc.) always available globally and locally per chromosome.	
4.25	Keyboard shortcuts	Keyboard shortcut keys for main manual operations.	
4.26	Revert changes	Any undo operations are supported.	
4.27	Audit trail	Case, slide and cell audit trail.	
4.28	Overlapped chromosomes marking	Automatic marking and counting overlapped chromosomes.	Mandatory
4.29	Overlapped chromosomes tracking	Chromosome clearance tool for tracking of non-overlapped chromosome segments.	Mandatory
4.30	Multiple patients' chromosomes display	Side by side visualization of multiple patients' chromosomes.	Mandatory
4.31	Color probes	Availability of 24-color probes for analysis of complex cases.	
4.32	Color-stained metaphases	Optional image capture and analysis of 24 color-stained metaphases.	

4.33	Reference websites access	Single clicks access to customizable set of reference websites from the karyotyping application.	
4.34	Remote access	Remote review including full analysis capabilities and case sign out.	

Case Review and Reporting			
	Category	Technical/Description	Remarks
5.1	Case summary	Access to complete case summary from the database.	Mandatory
5.2	Chromosome overlap report	Digital Chromosome overlap report.	Mandatory
5.3	karyotype summary report	Case Report summarizing karyotype of all cell aberrations for immediate view of clones and common aberration.	Mandatory
5.4	Customizable ideograms	Customizable ideograms to represent any aberrant chromosome.	
5.5	Reports combining information from multiple cases	Ability to generate reports including chromosomes from multiple cases, normal and aberrant. ideograms, and annotations	Mandatory
5.6	Hide the sex chromosomes	Ability to hide sex chromosomes in cell reports.	Mandatory

FISH

Automated FISH Scanning & Image Acquisition			
	Category	Technical/Description	Remarks
6.1	Automatic scanning program assignment	Automated scanning program selection per barcode label.	
6.2	Scanning protocols and stop criteria	Versatile scanning protocols with configurable stop criteria.	Mandatory
6.3	Metaphase & Interphase detection	Simultaneous Metaphase & Interphase detection in a single scan, with ability to classify metaphases and interphases in separate cell galleries.	Mandatory
6.4	Sample types	Ability to scan both cell suspension and tissue samples.	
6.5	Cell suspension samples scanning	Fully automated scanning protocol for cell suspension.	
6.6	Tissue FISH samples scanning	Fully automated scanning protocol for tissue samples including: 1. 4X or 5X 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
6.7	Interactive scanning mode	Interactive scanning mode which enables the user to define the desired fields of view followed by automated scanning and image acquisition.	
6.8	Automatic cell number estimation	Automatic estimation and display of anticipated number of cells within user defined scanning path.	
6.9	Microscope control	Automatic control over the microscope components, filters turret, objective turret, Z axis and shutter.	
6.10	Acquisition parameters optimization	Intelligent acquisition parameters optimization.	
6.11	Support of all probe vendors	No limitation on sample type, probe vendor agnostic.	
6.12	Multi-region support	Support of multi-region, multi-probe slides.	
6.13	Exposure	Automated exposure adjustment for optimal image quality and cell detection.	

6.14	Pathologist defined regions scan	Automatic scanning based on pathologist-defined regions transferred from reference brightfield slides.	Mandatory
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.	Mandatory
6.16	Reset and rescan only selective regions of specific probes/tests on a slide.	Ability to reset and rescan specific regions of unsuccessful scans, without the need to rescan all regions/probes.	
6.17	Add tumor regions	Ability to scan newly added tumor regions without the need to rescan the original tumor regions.	Mandatory
6.18	Image resolution	Image acquisition of 5M pixel resolution.	Mandatory

Automated FISH Review & Analysis			
	Category	Technical/Description	Remarks
7.1	Cell detection	Automatic cell detection is based on cell morphology, size, shape, and intensity.	
7.2	Background removal	Automatic removal of background and debris.	
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, both through cells gallery and on the images/captured field of view.	
7.5	Cell reclassification	Ability to reclassify any cell to one of 15 cell-classes in a single key press.	Mandatory
7.6	Cell operations within captured field of view	Ability to select, add, delete cells from the captured field of view.	
7.7	Review modes	Versatile review modes, from automatic cell & signal detection and classification, through scanning without analysis, to scanning without classification.	Mandatory
7.8	Blinded review	Multiple users can review the cells of the same slide separately without revealing the analysis results of each user. Statistics are gathered digitally but cannot be seen by the next reviewer, for true double blinded process.	Mandatory

7.9	Supervisor mode	Supervisor review mode in case of results discordance between different users review and classification.	Mandatory
7.10	Remove readers	Ability to remove specific reader/s from overall statistics.	Mandatory
7.11	Region status indication	Status indication per region.	
7.12	Additional review indication per region	Ability to add indication for additional review per region.	Mandatory
7.13	Analysis approval notifications	Automatic notification in case application is closed without analysis approval.	Mandatory
7.14	Cells export to database	Ability to batch export cells from scanning application to database according to cell status.	Mandatory
7.15	FISH probes setup	Ability to define new FISH probes/kits without the need for vendor support.	Mandatory
7.16	Abnormal signal patterns detection	Automatic detection of abnormal signal patterns.	
7.17	Class allocation for abnormal signals	Automatic allocation of a new class for abnormal signal patterns, according to predefined threshold.	Mandatory
7.18	Multi-fusion probes detection	Algorithm for the detection and classification of multi-fusion FISH probes, including triple and quad-color fusions.	Mandatory
7.19	Cell editing tool	Single multi-tool for cell editing, free hand cell contour drawing, editing cell boundaries, deletion and more.	
7.20	Signal sensitivity adjustments	Ability to adjust the level of sensitivity of each signal layer for improved cell classification without the need to rescan.	Mandatory
7.21	Automatic image enhancement	Intelligent image enhancement algorithms for consistent signals appearance across sample.	Mandatory
7.22	Interactive image enhancement	Ability to change Image Enhancement settings of one image and if required apply to all cells/frames in the gallery.	Mandatory
7.23	Cell and signal detection parameters adjustments	Ability to adjust cell and signal detection parameters for reanalysis of cells from all originally analyzed frames.	Mandatory
7.24	Cells marking for supervisor review	Review bin allowing the user to mark questionable cells for later supervisor review.	

7.25	3D review	ability to review cells by seeing each of their Z-layers separately, simultaneously for any subset of the colors.	
7.26	Quality Control: 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
7.27	Color coded cells review	Ability to color each cell contour according to the signal pattern defined in class color	
7.28	Original vs. enhanced image display	Ability to toggle between the original images and the enhanced color image.	
7.29	Batch cell classification	Ability to change classification of entire group of cells simultaneously.	
7.30	Cell signal layers display	Ability to scroll between all signal layers of a cell.	
7.31		Ability to see all color layers of a cell side by side	
7.32	Probe vendor	Software should support automated imaging and analysis of all probe companies.	Mandatory
7.33	Classified cells display	Review of automatically classified cells from current field of view.	
7.34	Workspace	Multiple view modules within the software GUI: large FOV image, multi-color panel, zoom view.	Mandatory
7.35	Remote access	Remote review through the web, including all analysis and review capabilities available when working locally.	
7.36	Support **CTC** samples	Special scan and analysis options to support CTC samples of various technologies, like fluid chambers and more.	
7.37	Support **IF**, and combined **IF+FISH** stain protocols	Special scan and analysis options for immunofluorescent samples, including multi-color and combined with FISH signals	
7.38	Support research applications, like whole cell Telomeric and centromeric probes	Capable to detect hundreds of 3D signals (like telomers) per cell, with corresponding statistics and quantitative data per cell and per each signal (needed for research on aging, signals spatial arrangement and more)	

Manual FISH Imaging & Analysis			
	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	Karyotyping capabilities	Full Karyotyping capabilities within the basic FISH module.	Mandatory
8.6	Chromosome segmentation	Ability to perform chromosome segmentation operations within a single tool without additional keyboard strokes to switch to a different tool function (more than 10 different operations).	Mandatory
8.7	Signals intensity	Ability to view absolute value of signals intensity.	Mandatory
8.8	Probe definition	Pre-definition of probe text. Enables writing multi-lines with multiple colors to describe the probe.	
8.9	Digital Manual Counting Utility	Digital Cell scoring utility with double blinded concept and real time result statistics.	Mandatory
8.10	Automated FISH on manual microscopes (Cells detection and segmentation)	Support process of capture, automated cells detection and auto cells classification (based on signal-pattern) on fully manual fluorescent microscope.	Mandatory
8.11	Image resolution	Image acquisition at 5M pixel resolution.	Mandatory
8.12	Her2neu amplification	Her2neu auto ratio (amplification) calculation on manual microscope and manual stage.	
8.13	Manual scoring change indication	Ability to instantly review all cells that had a manual scoring change.	Mandatory

Database, Case, and Image Management

Database & Case Management			
	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 formal: jpg or tiff.	
9.5	Sample types	The database should manage all patient/sample demographics and images for all sample types analyzed.	
9.6	Database display	Instant view of case, slide and cells information and status.	Mandatory
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	Gallery view	Combined gallery views of all image types capture for a case, for side-by-side viewing.	Mandatory
9.10	Gallery sort	Variety of gallery images sorting criteria	
9.11	Search mechanism	Search mechanism by any case or slide field, or combination of any fields even when archived.	
9.12	Data entry fields	Ability to add and customize data entry fields.	
9.13	User access security level	Ability to assign levels of security for user access.	
9.14	Roles & permissions management	Ability to assign advanced roles & permissions management.	
9.15	Electronic records and signatures	Creation, and storage of electronic records, and application and maintenance of electronic signatures.	
9.16	Pending tasks notifications	User notification of pending tasks according to roles & permissions.	
9.17	Cell Status Management	Ability to pre-mark cells for actions like Count, Analyze and Karyotype, and view individual cell status upon action completion.	Mandatory

9.18	Case Status Management	Ability to view/track cases according to their status within the completion process.	
9.19	Case attachments	ability to scan patient info, document and incorporate into case view.	
9.20	Customize reports	Ability to customize reports and define the report structure, information and add laboratory logo.	
9.21	HIPAA compliance	Ability to meet or exceed HIPAA compliant security standards for protecting data information.	
9.22	Audit trail	Audit trails and logging for case, slide and cell status modification.	
9.23	Audit data interface	Audit data must be viewable through the user interface by an administrator with appropriate security permissions.	

Data Maintenance & Archiving		
	Category	Remarks
10.1	Automated data maintenance.	
10.2	Ability to Schedule the data maintenance automatically for less user intervention.	
10.3	Manual archiving of cases.	
10.4	Automatic archiving of completed cases based on user defined rules.	
10.5	Single click retrieval of archived cases.	
10.6	Store and query information of deleted archived cases, as well as import deleted archived cases back to Case Data Manager database.	

LIS Connectivity			
	Category	Technical/Description	Remarks
11.1	LIS interface	Ability to interface with a Laboratory Information System (LIS).	
11.2		System should have an 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			
	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	Case summary reports	Ability to create, view and save customizable summary reports for case statistics per sample type, period of interest and more.	Mandatory
12.3	Staff productivity reports	Ability to create, view and save customizable staff productivity reports per sample type, period of interest and more.	Mandatory
12.4	Turnaround time reports	Ability to create, view and save customizable turnaround time reports per sample type, period of interest and more.	Mandatory
12.5	Slides statistics reports	Ability to create, view and save customizable slides statistics reports.	Mandatory

Quality, Serviceability & Maintenance

Regulatory | Standards		
13	Category	Remarks
13.1	US FDA – 510K cleared	
13.1.1	• HiBand (karyotyping)	
13.1.2	• HiFISH	
13.1.3	• SpotScan, Her2neu FISH	
13.1.4	• SpotScan, ALK FISH	
13.1.5	• SpotScan, UroVysion FISH	
13.1.6	• SpotScan, CEP XY FISH	
13.1.7	• Complies with HIPAA Act	
13.2	EU Conformance (CE Marked)	
13.3	Complies with the requirements of EU in-vitro diagnostic medical devices regulation (EU IVDR 2017/746).	
13.4	Complies with the requirements of General Data Protection Regulation (GDPR) - EU 2016/679	
13.5	Registered with ARTG (Australia)	
13.6	Licensed with Health Canada	
13.7	Registered with UK MHRA	
13.8	Complies with IVD Electromagnetic Compatibility standard - Emission and immunity	
13.9	Complies with IVD safety standard	

Serviceability & Maintenance			
	Category	Technical/Description	Remarks
14.1	Service request response time	What is the response time for a service request during weekdays, weekends, or holidays? • 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?	