tech. guide

Anatomic and Digital Pathology Instruments and Tools

	Applied Spectral Imaging CA, USA (760) 929-2840 https://spectral-imaging.com	**Aurora mScope** Montreal, Canada www.aurorainteractive.com info@aurorainteractive.com	**BioGenex** Fremont, CA (510) 824-1400 www.biogenex.com
1. What is the brand name of your company's product for anatomic or digital pathology?	PathFusion, HiPath Pro	Aurora mScope Clinical	NanoVIP
2. What is the latest version of your named product; what year was this version first released to market?	First released in 2015, Latest version v8.3.1 in 2022	The latest version is 4.2. The first version was released in 2004.	FDA IVD Class I, 2019
3. What is the intended use or primary function of the product?	Digital slide review, Analysis, diagnosis, reporting and various research applications both in BF and FL.	Aurora mScope is an image management system (IMS) designed for digital pathology, with case management, workflow, reporting, and auditing functionality built-in.	FISH, ISH, immunohistochemistry, multiplex immunofluorescence staining - OPAL Protocol & RNA Scope.
4. What types of specimen/ sample does the product employ?	FFPE, cell suspension, and smear slides.	Vendor-agnostic; supports viewing, annotating, and measuring using slides scanned in the proprietary file formats of all major manufacturers, as well as DICOM.	FFPE blocks, cyto-preparations, cytospins, and smear slides.
5. What types of diseases, conditions, or analytes does the product detect?	Cancer and genetic aberrations	N/A	Mapping genetic abnormalities in tissue and cells, spatialtemporal patterns of protein-biomarkers, multi-omics with spatial proteomics & genomics
6. What level of magnification can be achieved; what level of image resolution is captured?	From 1.25x up to 100X optical magnification (resolution down to 0.069µ/pixel)	All magnification levels supported by the chosen scanner are supported in mScope; up to 100x magnification.	N/A
7. Under ideal conditions, what is the time to first result; how are the test results made available?	Scan may last one to few minutes. Results are typically available in realtime, parallel to scan.	Digital slides are available within mScope within minutes of the slide being output by the WSI scanner.	Execution of protocol in 2.5 hours to 24 hours with display device. Support for printing or LIMS.
8. What are the product's maximum capacity (eg, number of slides) and throughput under ideal conditions (limit 150 characters, with spaces)?	ASI's trayloader highthroughput system capacity is 99 slides with special design that allows you to add and replace trays while system is scanning making it a continuous scanner.	Maximum capacity is limited only by available server storage space. Aurora mScope can support 100s of simultaneous users.	Maximum 10 slides with STAT or continuous protocols.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Automatic IHC and FISH analysis of marked tumor areas with tissue matching between H&E, IHC, and FISH successive cuts. Complete remote access solution, enabling HIPAA-compliant access, review, analysis and sign-off cases from any location.	Automatically transfer slides to applicable AI algorithm, automatic assignment of cases to pathologist (or group) and case prioritization. Integration with LIS and health record systems.	Fully automated slide staining including hybridization and stringency wash.
10. What is the typical training time for the product?	Typical installation and training is one week. ASI's collaborate with the lab pre and post installation to verify smooth integration with lab workflow.	Online training is typically done over 2-3 hours.	1-3 days.
11. What types of technical support are available?	Remote and onsite technical support is available	Online support (English and French) is available depending on SLA, up to 24/7 support.	User manual,onsite, phone, and email support, product demo, training, and protocol optimization.
12. What capabilities, features, or accessories distinguish this product from others on the market?	End-to-end workflow for digital pathology, including scanning and analysis, bridging the gap between brightfield pathology and FISH, combining Whole Slide Imaging, digital FISH analysis and digital tissue matching of FISH with H&E/IHC samples. Highly accurate results under real conditions and slide variabilities for both clinical and research app.	Supports file formats of all major scanner manufactures, and can be integrated with EHR, LIS, and AI systems. This vendor-neutral approach allows health systems to choose best-of-breed scanners, AI, storage, and other systems, and to use Aurora mScope to present a unified user interface to its pathologists and lab staff.	Fully automated only benchtop system for FISH technique. Accurate temperature control over individual slides. Runs spatial proteomics and genomics inclusive of OPAL protocol, and RNA Scope.

	Gestalt Diagnostics Spokane, WA (509) 492-4912 www.gestaltdiagnostics.com	**Mikroscan** Carlsbad, CA. (760) 893-8095 www.mikroscan.com	**Nikon Instruments Inc.** Melville, NY (800) 52-NIKON www.microscope.healthcare.nikon.com nikoninstruments.us@nikon.com
1. What is the brand name of your company's product for anatomic or digital pathology?	PathFlow	Mikroscan L5	ECLIPSE Ci-E Motorized Upright Microscope
2. What is the latest version; what year was this version first released to market?	Version 4.0 released in 2021	Mikroscan L5 live-only remote robotic microscope, March 2017.	ECLIPSE Ci-E Motorized Remote Controlled Clinical Microscope introduced in 2019
3. What is the intended use or primary function of the product?	Primary diagnosis*, remote consultations, tumor boards, research, and education	Supports routine surgical pathology and cytology.	View live images from a remote site and have full control of the microscope for consultation and collaboration
4. What types of specimen/ sample does the product employ?	Whole slide images	Biopsy specimens, including fine needle aspiration biopsies, frozen sections, hematoxylin and eosin stained tissues, immunohistochemistry specimens, needle core biopsies, smears, and touch-preps.	Any specimen prepared on a glass slide for viewing under a microscope including biopsy specimens, H&E stained tissues, IHC specimens, smears
5. What types of diseases, conditions, or analytes does the product detect?	N/A	Broad-based use, not disease specific.	N/A
6. What level of magnification can be achieved; what level of image resolution is captured?	Any level of magnification can be supported, as defined by scanner.	Device includes a suite of 5 Olympus objectives of 2x, 4x, 10x, 20x, 40x, with an optional 60x upgrade replacement. Equivalent optical magnification up to 120x.	Optical objective magnifications range from 2x, 4x, 10x, 20x, 40x, to 60x (50x, 60x, 100x oil objectives available). Typical digital image capture resolution is 6 megapixels.
7. Under ideal conditions, what is the time to first result; how are the test results made available?	Dependent upon the pathologist; diagnosis*/findings are reported through a final report and distributed via PathFlow or back to the LIS.	Real-time assessment by a pathologist.	Whole slide scanning varies depending on the objective magnification and sample size. Scans under 1 minute are achieved with a 4x objective.
8. What are the product's maximum capacity (eg, number of slides) and throughput under ideal conditions (limit 150 characters, with spaces)?	Unlimited scalability in number of cases, pathologists, users, studies, trials and courses, depending upon module.	Low throughput (2 to 4 slide capacity) and medium throughput option (20-slide autoloader); intended for specific high-value applications where bench space is limited.	Single slide live viewing available both on-site or from a remote location
9. Briefly describe any automation or connectivity features or options that pertain to the product.	The universal viewer, workflow and image management functions allow for tight integration with scanners, LIS, LIMS, EMR, EHR, Artificial Intelligence, etc.	Autocalibration, auto sample detection, automated focusing and scanning. Accurate color representation software ensures the integrity of the sample is preserved. Can be remotely and securely accessed worldwide.	The controls of the fully motorized microscope include the stage, nosepiece and condenser, with an automated slide scanning capability to capture whole or partial slide samples from remote locations.
10. What is the typical training time for the product?	3-3.5 days	Training and product setup are typically completed in less than 4 hours.	1-2 hours
11. What types of technical support are available?	5x9, 5x12, 24x7 support levels	Annual warranty and support contracts, with the first year included. Mikroscan has a support hotline, onboard system diagnostics, and depot service.	Remote & onsite support
12. What capabilities, features, or accessories distinguish this product from others on the market?	An intelligent, configurable, and vendor-agnostic digital pathology workflow with fully-integrated custom Artificial Intelligence solutions, AI image analysis, and machine learning. **Research Use Only (RUO) unless following CAP guidelines for LDT in primary diagnosis. Fully integrated modules for education and research with full anonymization and real-time collaboration.*	Full illumination control, wide range of samples, use of non-coverslipped objectives for cytology, small footprint suited for histology vehicles and mobile transport carts between biopsy suites, real-time response for live robotic microscopy, rapid automated scanning for archival and retrieval.	A fully motorized, compact microscope stand combined with full remote control and Nikon's superior objectives. Couple this upright clinical microscope with a high-resolution camera for accurate color capture and control the complete system with Nikon's NIS-Elements software to provide real time measurements, image stitching, annotation and much more.

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	NovoPath Bridgewater, NJ www.novopath.com	**Primera Technology** Plymouth, MN (763) 475-6676 www.primera.com	**Primera Technology** Plymouth, MN (763) 475-6676 www.primera.com
1. What is the brand name of your company's product for anatomic or digital pathology?	NovoPath 360	Signature	Signature
2. What is the latest version of your named product; what year was this version first released to market?	N360	Signature EVO Cassette Printer 2022 Signature Cassette Printer first released 2015	Signature EVO Slide Printer 2022 Signature Slide Printer first released 2011
3. What is the intended use or primary function of the product?	Anatomic pathology and molecular Laboratory Information System	Prints barcodes and patient identification information directly onto cassettes.	Prints barcodes and patient identification information directly onto slides.
4. What types of specimen/ sample does the product employ?	Configurable to support anatomic pathology sample types such as surgical, cytology, autopsy and molecular samples.	N/A	N/A
5. What types of diseases, conditions, or analytes does the product detect?	N/A	N/A	N/A
6. What level of magnification can be achieved; what level of image resolution is captured?	Able to integrate into any digital pathology hardware and software.	N/A	N/A
7. Under ideal conditions, what is the time to first result; how are the test results made available?	Configurable based on workflow	N/A	N/A
8. What are the product's maximum capacity (eg, number of slides) and throughput under ideal conditions (limit 150 characters, with spaces)?	Available to track and release reports as fast as the lab is able to go. Each workflow has configurations that allow the lab to work at the pace they need to achieve their overall outcomes.	Cassettes can be printed at up to 8 per minute	Slides can be printed at up to 10 per minute
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Test ordering portal; specimen tracking; real-time analytics; automated work assignment; pre-populated fields based on pathologist, workstation, etc.; ancillary testing combined into one case and report; seamless interoperability; discrepancies tracking; on-demand scalability; hands free grossing; voice dictation	N/A	N/A
10. What is the typical training time for the product?	One week onsite and virtual training	30 minutes	30 minutes
11. What types of technical support are available?	24/7 - round the clock support	Phone and email support, Monday through Friday, 8 am to 5 pm CST.	Phone and email support, Monday through Friday, 8 am to 5 pm CST.
12. What capabilities, features, or accessories distinguish this product from others on the market?	Intuitive UI-not only easy to use but easy to train employees; SaaS-Based-we manage everything; perform ancillary tests in a single case and create a single report; accessioning to storage specimen tracking; real-time analytics; in-house interoperability-no 3rd party needed; self-servicing admin customizations on almost everything.	New Signature EVO Cassette Printer with integrated PTLab software allows labs to print black or color ink directly onto cassettes, eliminating handwriting and the need for different colored cassettes. The printers can significantly increase your lab's efficiency while helping to reduce the risk of specimen misidentification.	New Signature EVO Slide Printer with integrated PTLab software can significantly increase your lab's efficiency while helping to reduce the risk of specimen misidentification. Because the units are small, many labs place a printer at each microtome workstation, helping to reduce or even eliminate mishandling and subsequent error rates.

	Proscia Philadelphia, PA (215) 608-5411 proscia.com	Tribun Health Paris, France www.tribun.health contact@tribun.health +33 1 89 20 00 07	Visiopharm Hoersholm, Denmark 0045 88 20 20 88 www.visiopharm.com
1. What is the brand name of your company's product for anatomic or digital pathology?	Concentriq Dx	CaloPix	Qualitopix
2. What is the latest version of your named product; what year was this version first released to market?	Version 4.2 was released in July 2022.	CaloPix 5.0.0.1, march 2022	2022
3. What is the intended use or primary function of the product?	Concentriq Dx is CE-marked under IVDR for primary diagnosis and available for remote use in clinical practice in the United States during the COVID-19 public health emergency.	An image management system at the heart of the digital pathology workflow, addressing a significant and fast-growing need for expert end-to-end digitization in pathology departments.	Monitoring IHC stain consistency
4. What types of specimen/sample does the product employ?	Whole slide images of formalin-fixed, paraffin-embedded specimen.	Primary diagnostic slide examination; frozen section microscopy; formalin-fixed, paraffin-embedded tissue; biopsies.	Whole slide images of formalin-fixed, paraffin-embedded tissue
5. What types of diseases, conditions, or analytes does the product detect?	Not disease specific.	Various pathologies and more particularly cancer diseases.	N/A
6. What level of magnification can be achieved; what level of image resolution is captured?	2x, 5x, 10x, 20x, 40x, 60x, 100x	4x, 20x, and 40x objectives.	N/A
7. Under ideal conditions, what is the time to first result; how are the test results made available?	N/A	N/A	Analysis is typically within a day. Results can be viewed in the web-browser
8. What are the product's maximum capacity (eg, number of slides) and throughput under ideal conditions (limit 150 characters, with spaces)?	N/A	N/A	There is no throughput limit.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Automated image upload and scanner integration; automated case assembly; bi-directional laboratory information system integration; automated image analysis integration; Proscia, third-party, and customer-built AI application integration.	N/A	The system is web based and needs no integration and no local computing hardware. No patient data is uploaded.
10. What is the typical training time for the product?	1 hour	2 to 3 hours to learn the basic features	A typical training time is less than an hour.
11. What types of technical support are available?	Phone and email 5x9 standard; additional support levels available upon request.	A helpdesk team is on hand to answer all queries by email or phone. You can also access video tutorials available on our e-learning platform.	Technical support team available
12. What capabilities, features, or accessories distinguish this product from others on the market?	Enterprise scalability supporting large pathology networks & remote teams; pathologist-centric user experience; seamless AI integration for Proscia, third-party, and customer-built applications; intuitive consults and collaboration; best-of-breed interoperability with scanners, image analysis & LIS.	Our 360° digital pathology suite is fully integrated to the pathologists' workflow around CaloPix IMS. It covers the management, AI analysis, and remote sharing of pathology cases, as well as cost-effective storage. Its uniqueness rests in the presence of many integrated modules that support every stage of the pathologist's workflow.	Allows you to monitor and document staining consistency on standardized, validated test materials over time, complementing EQA-led proficiency testing. The simple, rapid and cost-effective cloud-based deployment does not require integration or local computing hardware.