# tech. guide

### Anatomic and Digital Pathology Instruments and Tools

| | **Applied Spectral Imaging**<br>Carlsbad, CA<br>760-929-2840<br>https://spectral-imaging.com | **BioGenex**<br>Fremont, CA<br>510-824-1400<br>www.biogenex.com | **BioView**<br>Billerica, MA<br>www.bioview.com |
|---|---|---|---|
| 1. What is the brand name of your company's product for anatomic or digital pathology? | PathFusion, HiPath Pro | NanoVIP | Duet system |
| 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 v8.3.2 in 2023 | FDA IVD Class I, 2019 | First release on 2003, last version 3.8 released in 2023 |
| 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. | FISH, ISH, immunohistochemistry, single and multiplex slide-based staining including fluorescence, metal-conjugated, peptide-conjugate, etc. | Automated microscopy imaging, analysis and report for clinical and research use |
| 4. What types of specimen/ sample does the product employ? | FFPE, cell suspension, and smear slides. | FFPE  blocks, cyto-preparations, cytospins, smear slides, fresh-frozen fixed tissue, fixed cultured cells, etc. | FFPE, cell suspension, smear, liquid biopsy (using any cell enrichment technology) |
| 5. What types of diseases, conditions, or analytes does the product detect? | Cancer and genetic aberrations | Mapping genetic abnormalities in tissue and cells, spatialtemporal patterns of protein-biomarkers, multi-omics with spatial proteomics & genomics | Cancer,  genetic aberration, protein expression |
| 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) | N/A | From x2 to x100 optical magnification (resolution down to 0.054µ/pixel) |
| 7. Under ideal conditions, what is the time to first result; how are the test results made available? | Scan may last one to a few minutes. Results are typically available in realtime, parallel to scan. | Execution of protocol in 2.5 hours to 24 hours with  display device. Support for printing or LIMS. | Automated scan duration as short as 2 minutes per sample. Results are available in real time. Automated interpretation is performed during sample scan. |
| 8. What are the product's maximum capacity and throughput under ideal conditions? | ASI's trayloader high throughput system capacity is 99 slides with special design that allows to add and replace trays while system is scanning, making it a continuous scanner. | Maximum 10 slides with STAT or Continuous protocols. | BioView's high throughput ENCORE system equipped with 120 samples trayloader. Allowing add/replace of trays for continuous scan. |
| 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. | Fully automated slide staining including hybridization and stringency wash. | Automated FISH/protein imaging and analysis for FFPE and cytological samples, with tissue matching between consecutive cuts and consecutive stains on same sample. HIPPA compliant application for review, analysis and reports from any computer using standard browser. |
| 10. What is the typical training time for the product? | Typical installation and training is one week. ASI collaborates with the lab pre and post installation to verify smooth integration with lab workflow. | 1-3 days. | Typical installation and training is one week. Unlimited remote training and optimization provided post installation to ensure smooth workflow integration. |
| 11. What types of technical support are available? | Remote and onsite technical support is available | User manual,onsite, phone and email support, product demo, training, and protocol optimization. | Onsite support as well as remote support |
| 12. What capabilities, features, or accessories distinguish this product from others on the market? | End-to-end workflow for digital pathology, including scanning and scanner-agnostic analysis, bridging the gap between brightfield pathology and FISH, combining Whole Slide Imaging, digital FISH analysis, digital tissue matching of FISH with H&E/IHC samples. Accurate results under real conditions and slide variabilities for clinical and research app. | Fully automated only benchtop system for slide-based staining. Accurate temperature control over individual slides. Runs spatial proteomics and genomics inclusive of OPAL protocol, RNA scope, and other spatial biology platforms. | FDA- and IVDR-cleared automated bright field and fluorescent imaging, analysis and report system for FFPE, liquid biopsy and cytological samples. Provides scalable, easy-to-deploy web-based application, allowing remote consultation and analysis, seamless communication, and workflow control from case status and assignment to final report. |

| Mikroscan | Motic Instruments, Inc | Nikon Instruments Inc. | Primera Technology |
|---|---|---|---|
| Vista, CA. (760) 893-8095 www.mikroscan.com | Schertz, TX 877-977-4717 https://moticscientific.com/ sales@motic-america.com | Melville, NY 800-52-NIKON www.microscope.healthcare. nikon.com nikoninstruments.us@nikon.com | Plymouth, MN 763-475-6676 www.primera.com |
| Mikroscan L5 | PA53 BIO Digital Slide Scanning System | ECLIPSE Ci-E Motorized Upright Microscope | Signature EVO |
| Mikroscan L5 live-only remote robotic microscope, March 2017. | 2023 | ECLIPSE Ci-E Motorized Remote Controlled Clinical Microscope introduced in 2019 | Signature EVO Slide Printer 2023 Signature Slide Printer first released in 2011 |
| Supports routine surgical pathology and cytology. | Whether it is traditional paraffin sectioned pathology slides; frozen section slides; or liquid biopsy cell suspension slides or microbiology smears, system can scan and stitch the image with standard mode, high definition mode, with extended focus or a z-stack scan. | View live images from a remote site and have full control of the microscope for consultation and collaboration | Prints barcodes and patient identification information directly onto slides. |
| Biopsy specimens, including fine needle aspiration biopsies, frozen sections, hematoxylin and eosin stained tissues, immunohistochemistry specimens, needle core biopsies, smears, and touch-preps. | Whole slide images, paraffin sectioned pathology slides, frozen section slides, liquid biopsy cell suspension slides, microbiology smear, botany sample, zoology sample, human tissue sample | Any specimen prepared on a glass slide for viewing under a microscope including biopsy specimens, H&E stained tissues, IHC specimens, smears | N/A |
| Broad-based use, not disease specific. | Cancer diagnosis, diagnosis of genetic disease, pre-natal screening, and leukemia diagnosis | N/A | N/A |
| 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. | 2x, 10x, 20x, 40x, 100x. With built-in 1.2 Mpixel camera for focusing and a 5 Mpixel high resolution sCMOS camera for imaging. | Range from 2x, 4x, 10x, 20x, 40x, to 60x (50x, 60x, 100x oil objectives available). Typical digital image capture resolution is 6 megapixels. | N/A |
| Real-time assessment by a pathologist. | Dependent upon the pathologist diagnosis/ findings | Whole slide scanning varies depending on the objective magnification and sample size. Scans under 1 minute are achieved with a 4x objective. | N/A |
| 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 | Single slide live viewing available both on-site or from a remote location | Slides can be printed at up to 10 per minute. |
| 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. | Full controls of the microscope include the motorized stage, controller box, specimen holder, motorized quintuple nosepiece. | 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. | N/A |
| Training and product setup are typically completed in less than 4 hours. | 1 to 2 hours | 1 to 2 hours | 30 minutes. Phone and email support available |
| Annual warranty and support contracts, with the first year included. Support hotline, onboard system diagnostics, and depot service. | User manual, onsite, phone, email support, product demo, training and protocol optimization. | Remote & onsite support | Phone and email support, Monday through Friday, 8 am to 5 pm CST. |
| 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. | Better quality with full Kohler illumination setting; high precision stage and rescan with high resolution; No limitation on use of objective, super-high resolution scan with oil immersion objective becoming possible; no limitation on contrasting methods, phase contrast, polarizing contrast, etc. can be used. | A fully motorized, compact microscope stand combined with full remote control and 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. | A patented air-puff system for perfectly fed slides, every time. Integrated PTLab software can significantly increase a lab's efficiency, helping to reduce the risk of specimen misidentification. Due its small size, many labs place a printer at each workstation, helping to reduce or eliminate errors. |

| Proscia<br>Philadelphia, PA<br>215-608-5411<br>http://proscia.com | StatLab Medical Products<br>McKinney, TX<br>800-442-3573<br>statlab.com | TECHNIDATA Medical Software<br>General Headquarter:<br>Montbonnot (France)<br>Americas Regional Headquarters:<br>Montreal (Canada)<br>855-550-5705<br>americas@technidata-web.com<br>www.technidata-web.com/en-ca | XIFIN<br>San Diego, CA<br>858-436-9596<br>www.xifin.com |
|---|---|---|---|
| Concentriq Dx | PiSmart Printers | TDHistoCyto (LIS) | XIFIN LIS 9.0 |
| Version 4.3 | PiSmart Cassette Printers, 2022; PiSmart Slide Printer, 2023; PathSmart Tracking Software, 2023 | TDHistoCyto V13.71 - Released in October 2023 | Version 9 (2023) |
| Primary diagnosis. Concentriq Dx has regulatory clearance in the European Union, UK, Switzerland, and Canada. It is available in the US under the COVID-19 enforcement policy. | Automated printing for accurate labeling and tracking patient samples | A scalable LIS, digital pathology ready, TDHistoCyto is focused on patient safety and contributes to improving laboratory efficiency by optimizing business processes and by making the most of technological advances. | Lab information system (anatomic pathology, clinical pathology, molecular) |
| Whole slide images of formalin-fixed, paraffin-embedded specimen | Paraffin embedded tissue, Slide tissue | All specimen types can be recorded in the LIS based on a customized dictionary. | All specimen types including biopsy specimen; cultured cell lines; formalin-fixed, paraffin-embedded tissue; smear, blood, urine, etc. |
| Not disease-specific | N/A | Not applicable to LIS | N/A |
| 2x, 5x, 10x, 20x, 40x, 60x, 100x | 300 dpi | Not applicable to LIS | XIFIN LIS integrates digital pathology solutions (scanners, image management software, and AI solutions) within the LIS workflow. |
| N/A | 3-5 second print time per cassette or slide | Not applicable to LIS | Configurable based on test type. Test results are made available by portal, EMR integration, fax, etc. |
| N/A | 6 hopper cassette printer: 240 cassettes, 1 hopper cassette printer: 40 cassettes, dual hopper slide printer: 144 slides | Not applicable to LIS | There is no practical limit on the LIS capacity. |
| Automated image ingestion and scanner integration; automated case assembly; bi-directional laboratory information system integration; bi-directional image analysis integration | The PiSmart printers are compatible with LIS using WHQL certified Windows Driver. Printing is easy and automatic using bitmap or delimited file formats. Print via USB through use of a customer-supplied PC or print server and ethernet connection. | Automated reports for cervical cancer screening (HPV), scheduled tasks for result print out, sample labeling and downloading on HIS workstations, track all actions related to individual requests and non-conformities, communication with Digital Pathology Systems | Ordering and resulting portal, digital pathology and histology automation platform integration, client EMR integration, configurable workflow engine, TCPC workflows, robust reporting w/ case summary reports. |
| 90 minutes | A high-resolution touch screen display with an intuitive menu structure makes the printer easy to learn. Has flexible connectivity options and simple LIS integration to fit into existing workflow to reduce training time. | 1 to 2 weeks | Onsite and online training are available as needed. |
| Standard support includes 24x7 self-service knowledge base and 5x9 support in EMEA and North America; premium support levels available upon request | StatLab Technical Support: tech@statlab.com, 1-800-442-3573 X5 | Customer support is available by phone, email and customer portal. | Emergency support is available 24-7. Routine support is available during standard office hours. |
| Scalability and performance to support laboratories and networks of all sizes; world-class interoperability; high-throughput primary diagnostic workflows; pathologist-centric user experience; seamless collaboration; enterprise-grade administration; designed with AI in mind | Not only has the highest character capacity and quickest print time, all printers now come with the PathSmart tracking solution. Connect your processes with PathSmart, transforming your lab to be more connected and efficient. Links all PiSmart printers to one computer in the lab, syncing user management, templates, software updates and more. | Can easily connect with digital pathology systems, generate real-time dashboards for precise workload monitoring, can be interfaced with TDGenet (genetics LIS), can trace all the technical preparation and record non-conformities if any. | True SaaS offering includes software and hardware upgrades at no additional cost. Research and clinical trials project support. Multi-entity architecture that supports multiple labs in a single LIS build. API for client driven integrations. Seamless integration with XiFin RPM billing solution. |