

# tech guide

Anatomic and Digital Pathology Instruments and Tools

## Aiforia Technologies

Helsinki, Finland  
(617) 315-8741  
www.alere.com

## Applied Spectral Imaging

Carlsbad, Calif  
(760) 929-2840  
spectral-imaging.com

## BioGenex

Fremont, Calif  
(510) 824-1400  
www.biogenex.com

1. What is the brand name of your company's product for anatomic or digital pathology?	Aiforia	HiPath Pro and PathFusion	NanoVIP
2. What is the latest version of your named product for anatomic and digital pathology; what year was this version first released to market (US, OUS)?	Released 2018	Latest version is 8.2 and year to market 2015	FDA IVD Class I, 2019
3. What is the intended use or primary function of the product (eg, diagnosis, patient monitoring, point-of-care applications, therapeutic drug monitoring, viral load monitoring)?	Primary diagnosis.	Diagnosis.	Fluorescence in situ hybridization, in situ hybridization, and immunohistochemistry.
4. What types of specimen/sample does the product employ (eg, biopsy specimen; cultured cell lines; formalin-fixed, paraffin-embedded tissue; smears)?	Any digitized 2D image for digital pathology.	Tissue and cell-suspension.	Formalin-fixed, paraffin-embedded and frozen tissues, cell preparations, smears, and fine needle aspirations.
5. What types of diseases, conditions, or analytes does the product detect?	Any disease (Aiforia supports the analysis of any 2D image from any field).	Genetic diseases and cancers or oncological malignancies.	To determine spatial-temporal patterns of gene expression within tissues or cells.
6. What level of magnification can be achieved; what level of image resolution is captured?	All levels of magnification and resolution (depending on the user's device) can be achieved with Aiforia's software.	80x digital zoom in high resolution.	N/A
7. Under ideal conditions, what is the time to first result; how are the test results made available?	Aiforia automates time-consuming image analysis tasks such as neuron counting from 45 minutes per section with traditional methods to 5 seconds.	Scan to review takes a few minutes depending on the sample. A defined workflow moves the user from imaging to analysis to reporting.	2.5 hours to 24 hours. Execution of the test parameters can be displayed on a computer, printed, or transmitted to a laboratory information system.
8. What are the product's maximum capacity (eg, number of slides) and throughput under ideal conditions?	There is no maximum capacity. An unlimited number of slides or images can be stored in our image management software and analyzed.	Unlimited capability due to a continuous high-throughput tray loader which digitizes, manages, and stores slides automatically.	Maximum capacity is 10 slides
9. Briefly describe any automation or connectivity features or options (eg, autocalibration, autodetection of specimens, onboard real-time quality control, troubleshooting) that pertain to the product.	The Aiforia platform is an image-agnostic image management, sharing, and analysis software that with the help of deep learning artificial intelligence automates time-consuming and manual applications such as neuron body counting, tumor grading, and more.	Scanning automation, tissue detection, automated cell segmentation, real-time quantitative analysis.	Performs fully automated staining of slides including the hybridization and stringency wash. All protocol steps of immunohistochemistry from baking to final coverslip are fully automated.
10. What is the typical training time for the product?	Varies among customers on the complexity of their analyses but onboarding typically takes a few weeks. All of the training is done remotely and at the customer's convenience.	Up to 1 week installation and training on-site.	3 days.
11. What types of technical support are available?	Aiforia is Cloud-based, so support is all done remotely.	24-hour all year-round, from trained biomedical engineers.	Phone support, email support, technical documents, user manual, onsite support.
12. What capabilities, features, or accessories distinguish this product from others on the market?	Aiforia is a Cloud-based platform that increases the speed, accuracy, and consistency of analyzing large and complex medical images across a variety of fields. The technology, based on deep-learning AI, is intuitive and requires only an Internet connection and the user's own domain knowledge to begin training AI models.	Calibration tool facilitates accurate digital analysis, algorithms support higher turnaround time of results, comprehensive workflow enables scanning to reporting.	Nano VIP is the only benchtop system available for fully automated FISH application. It provides precise temperature control for each slide.



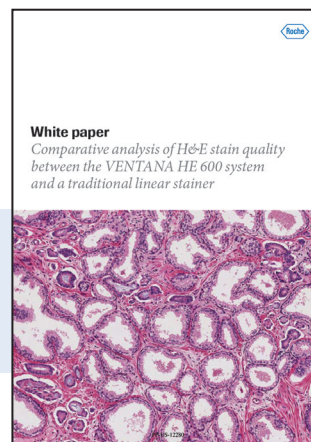
## See the difference.

### *Individual slide staining with the VENTANA HE 600 system*

Unlike a traditional dip-and-dunk stainer, the **VENTANA HE 600 system** is the only all-in-one H&E system that treats each patient's tissue individually and with fresh reagent.

As a result, it delivers consistent, high-quality stains to provide confidence in patient diagnosis.

In a comparative study, the VENTANA HE 600 system produced 3x more "excellent" stain quality ratings than a traditional dip-and-dunk H&E system. **Download the white paper at [go.roche.com/ventana-he-600](https://go.roche.com/ventana-he-600).**



[diagnostics.roche.com](https://diagnostics.roche.com)

VENTANA and VENTANA HE are trademarks of Roche.  
© 2020 Roche. MC-US-06863-0720

General Data Healthcare	Gestalt Diagnostics	Mikrosan	Milestone Medical Technologies
Cincinnati, Ohio (844) 643-1129 www.general-data.com	Spokane, Wash (508) 868-6827 www.gestaltiagnostics.com	Carlsbad, Calif (760) 893-8095 www.mikrosan.com	Kalamazoo, Mich; Bergamo, Italy (866) 995-5300 www.milestonemed.com
LaserTrack Cassette Printers	PathFlow	Mikrosan L5	MacroPath
LaserTrack PH1, PH6, PH8, JBY1, PH1 released in 2017	V3, released in 2020	Mikrosan L5 live-only remote robotic microscope, March 2017.	MacroPath QX, 2019
Diagnostics.	Primary diagnosis, remote consultations, tumor boards, research, and education.	Supports routine surgical pathology and cytology.	Documentation of gross images.
Tissue and biopsy specimen.	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.	Gross specimens.
Cancer	NA	Broad-based use, not disease specific.	Does not detect; used only for documentation.
Positive patient identification.	Any level of magnification can be supported, as defined by the 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.	30x optical zoom digital camera with autoiris and autofocus; resolution up to 20 megapixels.
Prints cassettes every 3 to 12 seconds.	Dependent upon the pathologist; diagnosis/findings are reported through final report and distributed via PathFlow or back to the laboratory information system.	Real-time assessment by a pathologist.	Instantaneous picture, audio, and video capturing.
PH1: up to 320 cassettes; PH6: up to 480 cassettes; PH8: up to 480 cassettes; JBY1: up to 70 each magazine, 1 to 5 magazines.	Unlimited scalability in number of cases, pathologist worklists, and whole slide images associated with cases.	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.	N/A
LaserTrack cassette printers use laser printing technology that consistently produces permanent, crisp text and 2D barcodes and delivers nearly perfect scan rates.	PathFlow's universal viewer and image management system allows for tight integration with any scanner vendor, laboratory information system, electronic medical record, 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 via any network worldwide.	Touchscreen monitor, autoiris, autofocus, connectivity via team-viewer, laboratory information system integration, network capabilities, onscreen annotations, audio/video capabilities, foot-pedal controlled, onscreen keyboard, various levels of licensing.
1 to 2 hours	3 to 3 1/2 days	Training and product setup are typically completed in less than 4 hours.	1 day
Software and technical support, depot and on-site service, nationwide repair, and customized service plans.	5x9, 5x12, 24/7	Annual warranty and support contracts, with the first year included. Mikrosan has a support hotline, onboard system diagnostics, and depot service.	Milestone offers 24/7 technical support with the ability to remotely connect and troubleshoot.
PH1 is capable of printing as fast as one cassette every 3 seconds; PH6 meets high-volume needs without manual changing of magazines; PH6 Sorter has built-in cassette management system; PH8 can print on 1, 2, or 3 sides of a cassette, PH8 Duo chute cassette management system moves cassettes to right or left for workflow efficiency.	PathFlow is a full digital pathology platform providing a single, unified workflow for the pathologist for both glass and digital cases. It integrates with any scanner vendor, and multiple simultaneously, and can integrate seamlessly with any, and multiple, ordering applications.	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 user-friendly system that provides high-resolution images, video, and audio files; can be mounted to fit any grossing station or used as a standalone system; remotely connects to outside facilities for telepathology consultations.

Assisting the global **COVID-19** response

# WE'LL SOLVE IT. TOGETHER.

Diagnosis | Confirmation | Surveillance | R&D



**No matter what angle you're attacking COVID-19 from, Bio-Rad has best-in-class solutions to strengthen your fight.**

If you have a vital role in solving this global health crisis, you can trust Bio-Rad's precise, reliable tools. Our solutions for diagnostic screening, confirmation of test results, surveillance, and therapy/vaccine research and development have the sensitivity and accuracy to help you find the right answers.

**How can Bio-Rad support your mission?**  
Find out more at [bio-rad.com/COVID-19](https://bio-rad.com/COVID-19)

**BIO-RAD**

<b>Motic Digital Pathology</b>	<b>Primer Technology</b>	<b>Proscia</b>	<b>Spot Imaging/Diagnostic Instruments</b>
San Francisco (800) 275-3716 moticeasyscan.com	Plymouth, Minn (763) 475-6676 www.primer.com	Philadelphia, Pa (877) 255-1341 proscia.com	Sterling Heights, Mich (866) 604-SPOT www.spotimaging.com
FS-Live	Signature Cassette Printer	Concentriq Dx	Spot/PathSuite
FS-Live software; January 2019.	2015	2019	PathSuite 2.077 released 2020; PathCast 1.0.1 released 2020
Remote-controllable live microscopy for routine surgical pathology, frozen section, and cytology adequacy support.	Prints barcodes and patient identification information directly onto cassettes.	Concentriq Dx is CE-marked for primary diagnosis and available for remote use in clinical practice in the United States during the covid-19 public health emergency.	Pathology image acquisition and management with secure telepathology software suite.
Biopsy specimens including fine needle aspirations, frozen sections, and other rapid on-site evaluation samples. Supports non-coverslipped slides.	N/A	Whole slide images of formalin-fixed, paraffin-embedded specimens.	Primary and frozen section biopsy specimens, frozen section microscopy, cytology fine needle aspiration smears, primary diagnostic slide examination.
Applicable for frozen section review as well as adequacy assessment in fine needle aspiration and other telecytology uses.	N/A	Diseases such as cancer that can be diagnosed in an anatomic pathology laboratory.	Used to investigate and document neoplasms.
4x, 20x, and 40x objectives. Additional objectives can be customized.	N/A	2x, 5x, 10x, 20x, 40x, 60x, 100x	Instrument dependent.
Real-time slide review in under a minute; 100 seconds for a 40x-resolution scanned image.	N/A	N/A	Images are captured, autoprocessed, and autoarchived in 3 to 7 seconds.
Add-on for MoticEasyScan One and MoticEasyScan Pro supports up to 6 slides during live review.	Cassettes can be printed at up to 8 per minute.	N/A	Central image archive is limited only by server storage capacity; image save times are typically between 3 and 12 seconds.
Autocalibration, tissue autodetection, laboratory information system integration, z-stack scanning, z-stack snapshot, built-in barcode reader and metadata tagging, direct connectivity to the MotiCloud platform and Digital Slide Server programs.	N/A	Automated image upload and scanner integration, automated case assembly, automated case assignment, automated laboratory information system integration, automated image analysis integration, automated tissue microarray de-array.	Autoannotation, autosave/archive, direct laboratory information system connectivity, autocalibrated images, and telepathology interface.
Less than 3 hours	Approximately 1 hour	1 to 2 days	Less than 20 minutes
24/7 live support, with remote-connected troubleshooting available.	Phone and email support, Monday through Friday 8 am to 5 pm CST.	5x9 standard. Additional support levels available upon request.	Online/phone help desk 9 to 6 EST.
The continuous autofocus feature means users never have to readjust the focus when viewing a live specimen and can focus on moving the sample and making a diagnosis.	Offers color printing to help reduce inventory and purchasing activity for multiple color cassettes by printing colors directly onto white cassettes. Can print on 35- to 45-degree angles with lid on or off, no adjustments needed.	Configurable workflows, user permissions, and roles; multisite workflow support; performance analytics dashboard for productivity and quality tracking.	Central shared image archive, autoimage copy, autosave by case number, direct laboratory information system connection, secure telepathology module, streamlined workflow, common interface across each solution.



## Visiopharm A/S

Hoersholm, Denmark  
(877) 843-5268  
www.visiopharm.com

## Xifin

San Diego  
(919) 605-5245  
www.xifin.com

Advanced image analysis and tissue mining tools software packaged into on-premise subscriptions.	Xifin LIS
Our latest platform version is 2020.06. The first version was released in 2002.	Xifin LIS 6 (v6.9) (2020-06-21)
In Europe Visiopharm offers slide scanners and CE-IVD APPs for primary diagnostics. In the United States and in Europe, Visiopharm offers research tools that allow data mining for clinically relevant patterns.	Web-based digital pathology-enabled commercial laboratory information systems. Xifin LIS integrates digital pathology into the laboratory's workflow and allows the lab techs and pathologists to open images associated with a case while they review the case data.
Digital images of formalin-fixed, paraffin-embedded normal and neoplastic breast or colorectal tissue. For research, any digitalized image of tissue or cell-lines can be analyzed without limitations.	All pathology specimen/sample types images and data.
The CE-IVD APPs are intended for use with Ki-67, ER, PR or HER2 stained breast cancer slides and for H&E stained lymph node slides for breast and colorectal cancers.	A multispecialty lab information system that offers a complete workflow solution for digital pathology including technical and professional splits and secondary consultations.
Dependent on the resolution at which the slide was scanned.	Scanning device independent and integrates with all major scanning solutions. Slide images and regions of interest are integrated with the laboratory information system.
Within seconds for small field of view images. High magnification, whole slide analysis requires more time.	1 to 3 minutes, depending on the scanning device capabilities.
No limit	Dependent on the digital pathology scanning and image management solution that has been integrated with Xifin LIS.
Vendor neutral. Can connect to all major scanners and image formats and integrate to the majority of lab information management/picture archiving and communications systems.	Image uploading can be automated. Xifin LIS is also fully integrated into the Xifin ProNet consultation platform.
2 days for an introduction. Advanced courses are also available.	4 to 6 hours
Remote support via screen sharing tools.	8 to 8 CT standard support. 24/7 emergency support.
Visiopharm has the most comprehensive tissue experience in the industry. Two decades of partnering with thought leaders to discover, understand, and mitigate sources of error from biopsy to data, leading to breakthroughs in tissue data mining tools, precision, workflow, and automation.	Xifin LIS is a highly configurable SaaS solution that includes monthly enhancements that require no major technology upgrades. It offers multispecialty (ie, NGS) and clinical trial workflows, TC/PC split management and comprehensive reports. Platform offers revenue cycle, analytics, precision medicine informatics, and digital pathology consults.

# NEUROLOGICAL AUTOIMMUNITY

For over 30 years, KRONUS has been a leading provider of highly-specialized immunoassay test kits to the world's most respected laboratory facilities.

In the area of autoimmune neurology testing, KRONUS is pleased to offer immunoassay test kits for the detection and measurement of the following autoantibodies:

- **Aquaporin-4 Autoantibody (AQP4Ab)**
- **Acetylcholine Receptor Antibody (AChRAb)**
- **Voltage-Gated Calcium Channel Antibody (VGCCAb)**
- **Voltage-Gated Potassium Channel Antibody (VGKCAb)<sup>†</sup>**
- **Titin Antibody (TitinAb)<sup>†</sup>**

<sup>†</sup> For Research Use Only. Not For Use in Diagnostic Procedures.

To obtain additional information regarding these kits and KRONUS' complete offering of immunoassay test kits, please call us toll-free at **800 4 KRONUS** or email us at [kronus@kronus.com](mailto:kronus@kronus.com).

 **KRONUS**<sup>®</sup>

Your Source for Sensitive Autoimmune Diagnostics

ISO 13485 : 2016 QMS Certified

**800 4 KRONUS | WWW.KRONUS.COM**