GenASIs™ Pathology Suite

FDA 510(k) cleared for the following GenASIs applications: ALK, BandView, FISHView, UroVysion, CEP XY & HER2/neu FISH per the description found on the back page of this booklet. All other products and applications are intended for research use.
GenASIs Pathology Suite

GenASIs™ Pathology Suite is a digital pathology platform for imaging, scoring and reporting of quantitative brightfield & fluorescent samples. A robust and user-friendly solution, the system fits the workflow of any sized lab, improves efficiency and encourages cost savings – allowing your lab to spend more time on what you do best.

Solutions for the Modern Lab

GenASIs Pathology Suite combines image capture, analysis, case management, data collaboration and report generation for quantitative pathology samples.

The GenASIs Pathology Suite consists of two application based solutions:

• GenASIs HiPath for quantitative IHC and CISH
• GenASIs FISH for fluorescent in situ hybridization

Automatic Cell Count & Stain Analysis

With a focus on the “Region of Interest”, GenASIs algorithms automatically count cells and analyze stains.

The computerized automation of the GenASIs platform simplifies and improves case throughput by quickly performing time-consuming tasks.
Enhance Your Current Microscope’s Capabilities
The GenASIs Pathology Suite integrates within the traditional workflow of microscope and pathologist and provides labs with a cost-effective and easy-to-use solution for digital pathology applications. These include cloud based review and analysis, automatic location of FISH signals and immediate quantitative analysis.

Combining the benefits of computer aided scoring with the advantages of traditional microscopy, the GenASIs Pathology Suite is the ideal solution for every lab.

Applications

CISH

IHC-HER2

IHC-Ki67

FISH

IHC-ER

Tissue Matching

Cloud Based Review & Data Sharing
GenASIs offers labs and reference labs a solution for cloud-based viewing, analysis and case sign-out. An unlimited number of labs can gain secured access to the central database, and perform analysis and report generation from any location.

You can now work from any location, expand your reference lab activities or send out samples to other labs with greater confidence. The GenASIs Pathology Suite allows you to benefit from a convenient Professional/Technical split for workflow and billing purposes.

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GenASIs HiPath provides computer aided scoring and reporting for quantitative IHC and CISH samples. Pathologists can now capture images with their microscope and receive immediate statistical analysis and scoring of the chosen region of interest.

- Tissue images captured straight from the microscope
- Cells counted and classified according to predefined and customizable classes
- Automatic picture-rich and statistical reporting

**Region of Interest**

GenASIs HiPath analysis is based on Regions of Interest concept. The user selects areas to be analyzed through the microscope, and then presses a button to capture the image seen through the microscope.

The Lab’s Benefit: As images weigh only a few Mbs, the GenASIs platform provides digital pathology solutions with modest data storage needs, allowing you to operate the lab without affecting your current IT setup.
GenASIs HiPath for CISH

GenASIs HiPath CISH solutions automatically segment cells and enumerate the CISH signals. Each cell is classified into normal or abnormal categories according to customary practices within the lab.

Image Analysis

GenASIs HiPath provides image enhancement tools including separation into different staining layers so that the clinical significance of each layer can be viewed separately. These tools may also help overcome quality issues of variability in the staining process. Using GenASIs HiPath, the process of analysis and diagnosis becomes more efficient, accurate and effective.
GenASIs FISH allows labs to obtain computer aided results of fluorescent in situ hybridization samples quicker, more efficiently and with greater clinical relevance. GenASIs FISH automatically switches filters, captures Z-stacks, counts all signals, segments cells, calculates statistical analysis, and provides advanced editing tools.

- Automated filter switching and Z-stacking
- Open platform supports most FISH probes
- Automated classification of cells

**FISH Probe Support**

Start to benefit from a FISH platform which gives you the freedom to analyze almost any FISH probe. GenASIs FISH provides quantitative signal and object analysis, cell or object segmentation and morphology & intensity analysis for most test types and probe manufacturers. The user friendly interface makes setting up new FISH tests easy, while our library of existing FISH probes covers most major manufacturers and probe types.

GenASIs FISH improves automated tissue analysis with auto cell segmentation and signal detection. The precise algorithms ensure the highest rate of accurate cell segmentation, making review fast and efficient with little need for classification correction.
Display & Reporting
Automatic background correction, as well as manual or automatic contrast, brightness and sharpness adjustments enable instantaneous and optimal display of the faintest signals.

GenASIs FISH provides all the information you need on a single screen, including a cell gallery, statistics and a complete view of the region.

GenASIs FISH also allows users to deliver image rich reports with statistical analysis and annotations, using images that were captured during the diagnostic process.

FISH Automation
For labs with a large caseload of FISH samples, FISH automation is the ideal tool for increasing throughput while decreasing costs.

Automated GenASIs FISH performs a pre-scan of the entire sample at a low magnification, and then returns to the areas with the highest cell population for imaging with a higher magnification.

A key benefit of automated GenASIs FISH is that the review, analysis and reporting may be performed outside of the dark room using GenASIs review and analysis stations.

Tissue Match
The Tissue Match application supports an end to end flow between the pathologist and the FISH technologist, starting from the H&E or IHC slide through FISH review and analysis. The application provides a way to replicate the region of interest defined by the pathologist on the brightfield H&E or IHC sample to the corresponding sequential FISH slide.

Tissue Match ensures that the FISH technologist will be analyzing the precise location defined by the pathologist. This improves confidence and accuracy in the FISH results and reduces costs associated with staining the sequential FISH sample.
The Complete Digital Workflow
Case Data Manager and Reports

With the GenASIs Pathology Suite, labs benefit from an interface designed specifically for their workflow. It provides an efficient throughput of casework and easy reporting.

Information at Your Fingertips
A central Case Data Manager (CDM) integrates with the lab’s Laboratory Information Systems (LIS). The CDM supports the paperless lab by providing a patient case database which can be accessed by all review stations with advanced search and cross-case comparison functionality.

Reliable Data
Data integrity is preserved by archiving all clinical and workflow processes, and providing an audit trail of all work performed.

Lab administrators can set access rights for each user and lab.

Reports
Multiple report types and templates are available within CDM. Labs can easily customize their reports or set up multiple templates for different reference sites and users.

For reports generated by the LIS, the CDM exports the relevant statistics and images to the LIS.

- Automatic report generation
- Full statistical analysis
- Easy annotation and freehand reporting

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The GenASIs Pathology Suite gives pathologists a digital scoring aid that can help diagnose challenging cases. Introduce the GenASIs solution into your lab, and benefit from accuracy, reproducibility and standardization.

By analyzing all cells only in regions of interest, the GenASIs Pathology Suite provides accurate, standardized and objective data.

A study at a U.S. cancer center compared manual analysis to GenASIs HiPath for quantitative IHC breast cancer panel slides. An overall high concordance rate was achieved, with manual analysis being revised in several instances to match the score that GenASIs HiPath provided.

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Quantitative Image Analysis of Ki-67 Immunohistochemistry Compared with Manual Pathologist Analysis in Breast Cancer Author Block: Rosanna L. Lapham, MD Keith J. Kaplan, MD. Department of Pathology, Gibbs Cancer Center, Spartanburg, SC.
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Made For Your Lab

GenASIs Pathology Suite offers you everything you need to make your work easier and more effective. Automated and manual microscope platforms for brightfield and fluorescent applications, LIS integration, a robust CDM, and responsive global customer support

Automated Scanning & Acquisition Platforms

- 81-Slide Robotic Scanner
- 9-Slide Scanner
- Pathology Quantitative Diagnostic Aid

Review & Analysis Platform

- Integration with existing LIS & microscopes
- Multiple work stations
- Off-site review & collaboration
- Immediate analysis

Central Storage & Data Management

- Small data footprint
- Roles & permissions
- Audit tool
- HIPAA compliant
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GenASIs Platform

ASI develops computer aided image analysis & diagnostic tools for clinical and research applications. The GenASIs Pathology Suite integrates within the existing workflow of the microscope, pathologist and LIS framework, improving upon the lab’s capabilities by providing a turn-key solution for slide capture, image analysis, case reporting and sign-out. With the GenASIs Pathology Suite, labs achieve higher throughput and enhanced clinical results based on accurate, reproducible and standardized analysis.

A Board Certified Pathologist
“For labs seeking a digital pathology solution which is both economic and fits the workflow, ASI is the solution.”

Director of Pathology Lab at U.S. Cancer Center
“I have found GenASIs HiPath to be an invaluable tool in my office, especially when dealing with equivocal samples.”

FISH Lab Manager
“ASI’s FISH technology was a great fit for our lab. We enjoy the easy to navigate design and editing tools, and have been completely wowed by its accurate segmentation and its ability to pick up faint signals.”
ASI is FDA cleared as an aid for In-Vitro Diagnostic procedures of detection with the following:

- **GenASIs ALK**, the world’s first FDA cleared ALK automated analysis used for lung cancer therapy selection.
- **GenASIs BandView** used for karyotyping with real time microscope images from stained metaphases, for cytogenetics.
- **GenASIs FISHView** used for karyotyping with real time microscope images from cultured and stained cell specimens in their metaphase. In addition, GenASIs FISHView is intended as an aid tool for digitally visualizing, processing, counting and classifying stained cells and storing FISH multi-dye images.
- **GenASIs UroVysion** used for the microscopic imaging and analysis of chromosomal aberrations using fluorescence in situ hybridization (FISH) in urine specimens from persons suspected of having bladder cancer.
- **GenASIs CEP XY** used to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.
- **HER2/neu FISH** used for in-vitro diagnosis as an aid to the cytogeneticist/pathologist in the detection, classification, and counting of cells of interest in tissue specimens from breast cancer.

All other applications are intended for research use only.