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MEDICAL

ASI's Digital Pathology Suite

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Applied Spectral Imaging
Bringing Details to Light

ASI's Digital Pathology Suite

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

Enhance Your Microscope's Capabilities

ASI's 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.

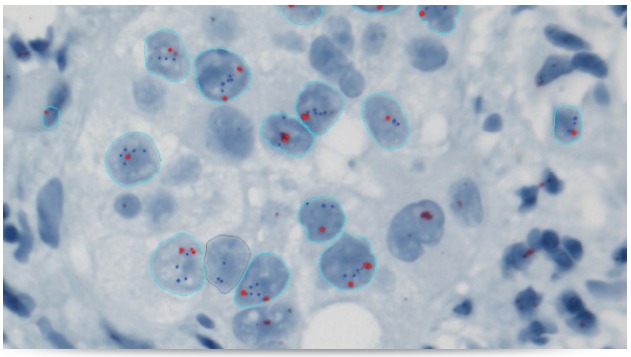
Combining the benefits of computer-aided scoring with the advantages of traditional microscopy, ASI's Pathology Suite is the ideal solution for every lab.

Save Time with Powerful Algorithms

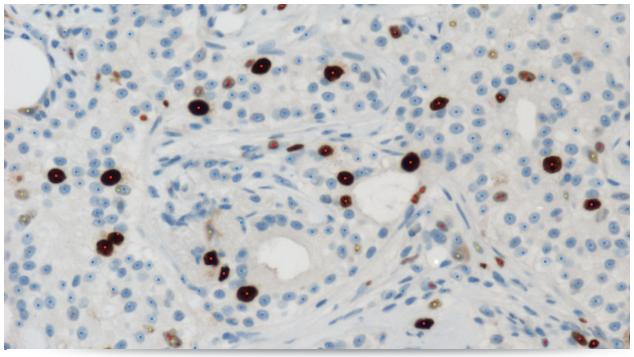
The GenASIs platform's strong algorithms make ASI's Pathology Suite more dependable, with clinical results that users can rely upon with confidence. These powerful algorithms accurately identify, capture and classify samples. Capable of analyzing quantitative IHC, FISH or CISH samples, ASI's Pathology Suite helps you obtain a standardized and repeatable analysis while saving time and improving efficiency.

Applications

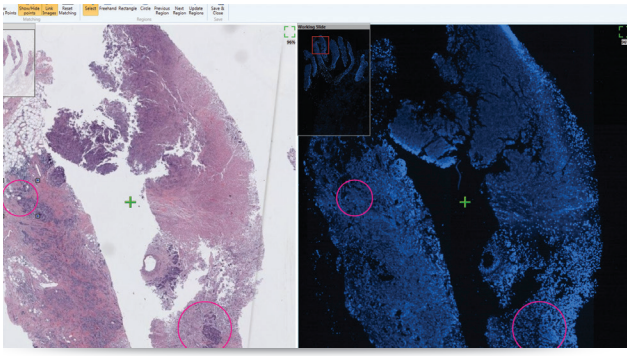
Membrane IHC (HER2)



CISH



Nuclear IHC (Ki67)



H&E / FISH Tissue Matching

Made For Your Lab

ASI's 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, an interactive Case Data Manager (CDM) and responsive global customer support.

- Integration with existing LIS & microscopes
- Multiple work stations
- Off-site review & collaboration
- Immediate analysis
- Small data footprint
- Roles & permissions
- Audit tool
- HIPAA compliant

Automated Scanning & Manual Acquisition Platforms

Pathology Quantitative Diagnostic Aid

9-Slide Scanner for FISH

Cloud Based Review & Data Management

ASI's Pathology Suite 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 Pathology Suite also allows you to benefit from a convenient Professional/Technical division of workflow and billing purposes.

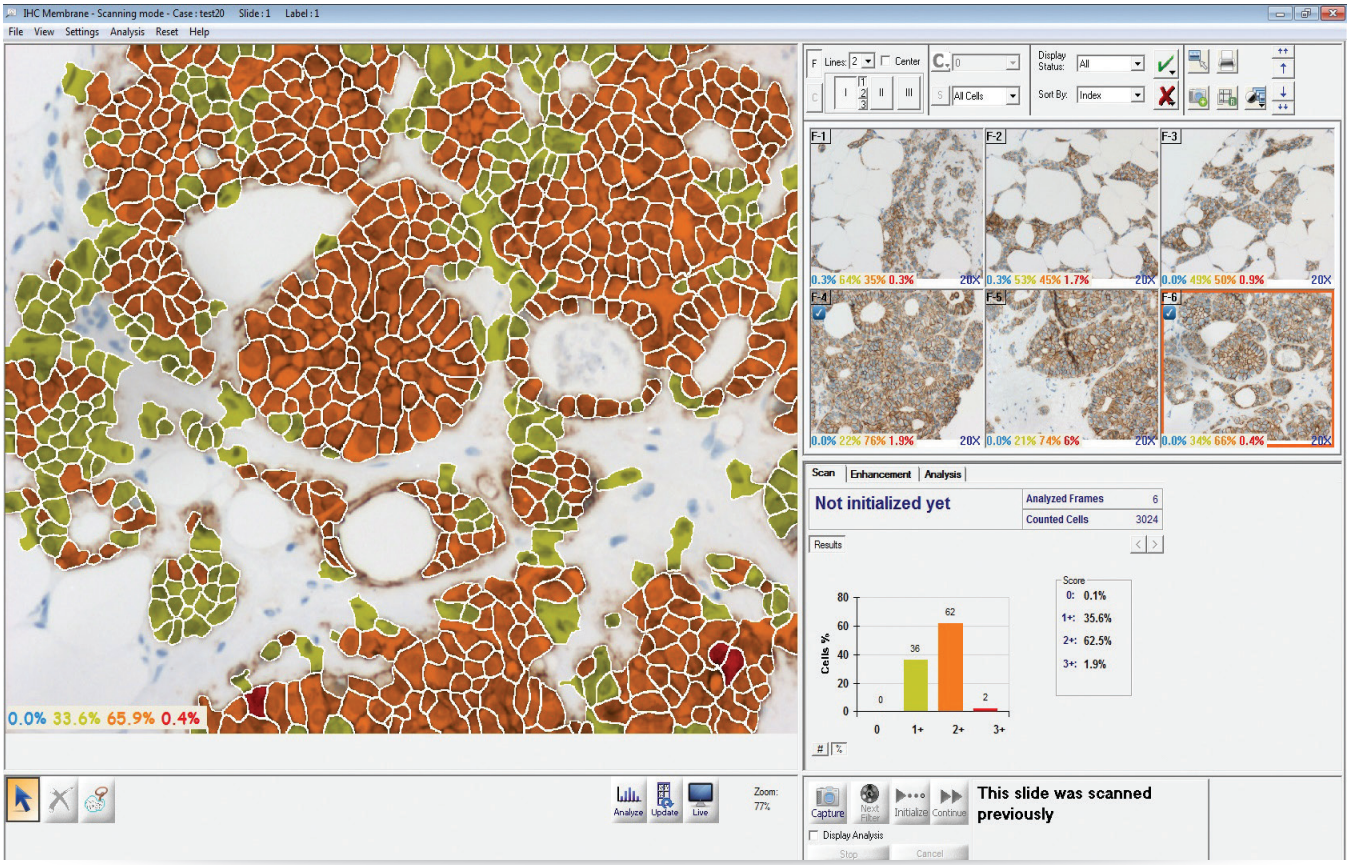
Performance • Security • Data Integrity

ASI's HiPath

HiPath on the GenASIs platform provides computer-aided scoring and reporting for quantitative IHC and CISH samples. Pathologists can now capture images with their own 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

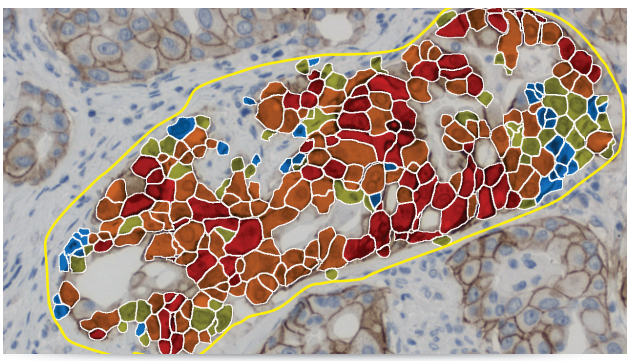
HiPath



Real Time Scoring and Statistics

Region of Interest

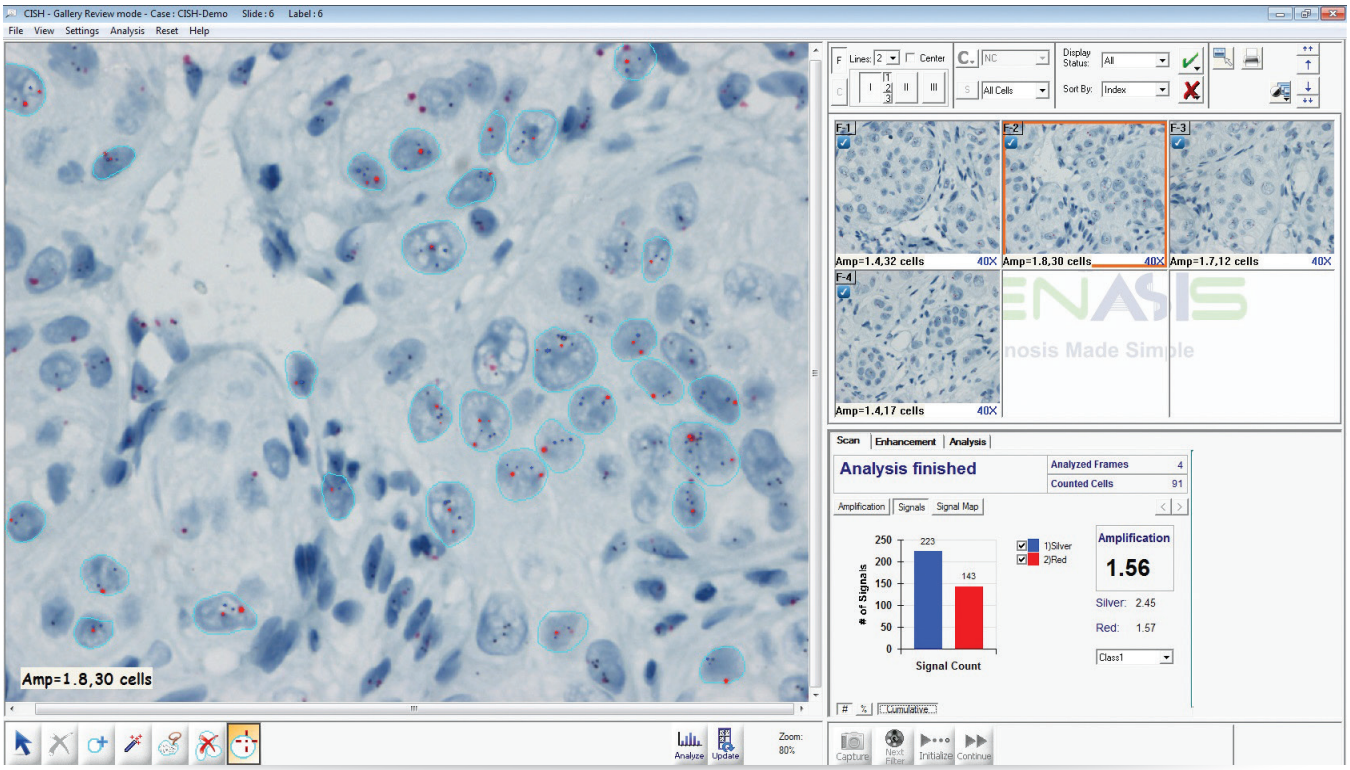
HiPath analysis is based on Regions of Interest (ROI). The user selects areas to be analyzed through the microscope and then presses a button to capture the image seen through the microscope. Selection of relevant regions within the frame allows analysis to be isolated to specific tumor areas, providing more reliable results while requiring modest data storage needs.



HiPath capturing Region of Interest (ROI)

HiPath for IHC & CISH

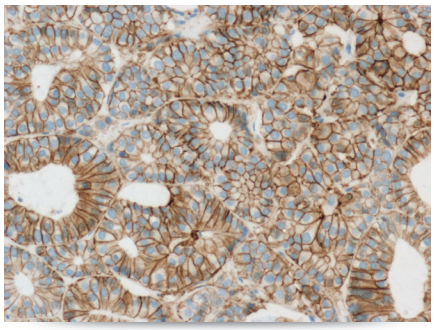
HiPath CISH automatically segments cells and enumerates signals. Each cell is classified into normal or abnormal categories according to customary practices within the lab.



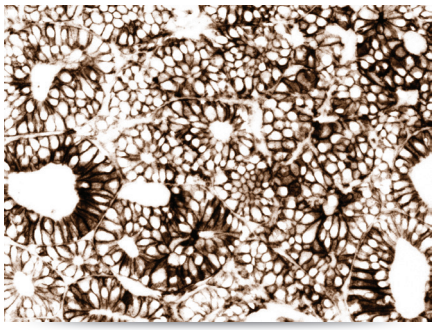
HiPath for CISH

Image Analysis

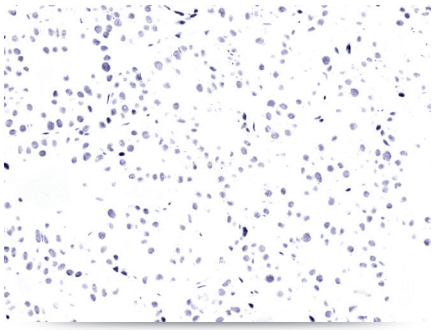
In addition to providing labs standardized and objective data, the powerful image enhancement tools allow pathologists to glean more clinical data from each picture. HiPath allows images to be separated by multiple parameters, as well as the ability to mark off and analyze distinct regions on each image. Using HiPath, the process of analysis and diagnosis becomes more efficient, accurate and effective.



HER2 - Original



DAB - Membranes



Hematoxylin - Nuclei

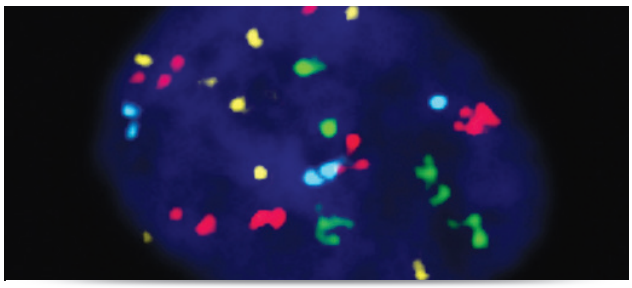
ASI's Solution for FISH

ASI's FISH solution allows labs to obtain computer aided results of fluorescent *in situ* hybridization samples quicker, more efficiently and with greater clinical relevance. By offering the strongest imaging algorithms, ASI's FISH solution offers unsurpassed accurracy in capture, segmentation and cell classification; translating to faster reviews and more effficient workflow.

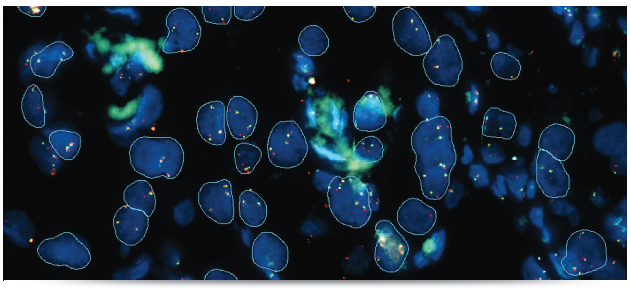
Automated filter switching and Z-stacking • Open platform supports most FISH probes • Automated classification of cells

FISH Probe Support

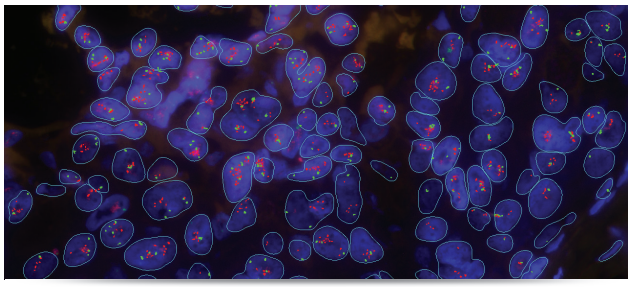
Benefit from a FISH platform that gives you the freedom to analyze almost any FISH probe. ASI's FISH solution provides quantitative signal and object analysis, cell or object segmentation and morphology and intensity analysis for most test types and probe manufacturers. The user friendly interface makes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



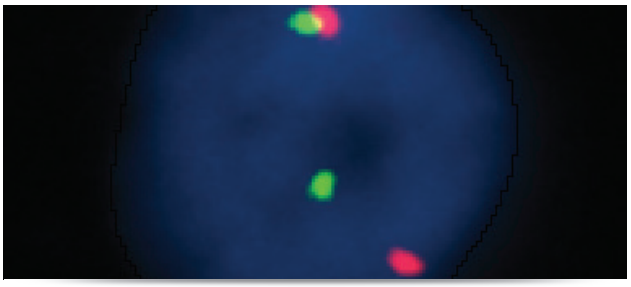
UroVysion®



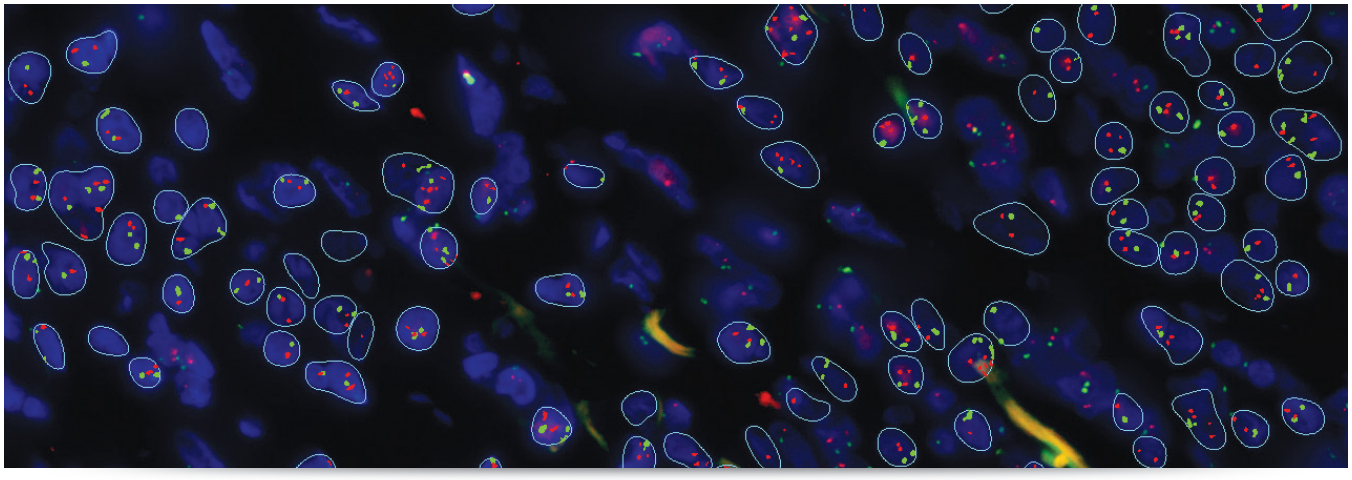
PTEN



HER2



ALK



Accurate Cell Segmentation

ASI's FISH solution 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 & Analysis

Automatic background correction, as well as manual or automatic contrast, brightness and sharpness adjustments enable instantaneous and optimal display of the faintest signals.

ASI's FISH solution provides all the information you need on a single screen, including a cell gallery, statistics & complete region view.

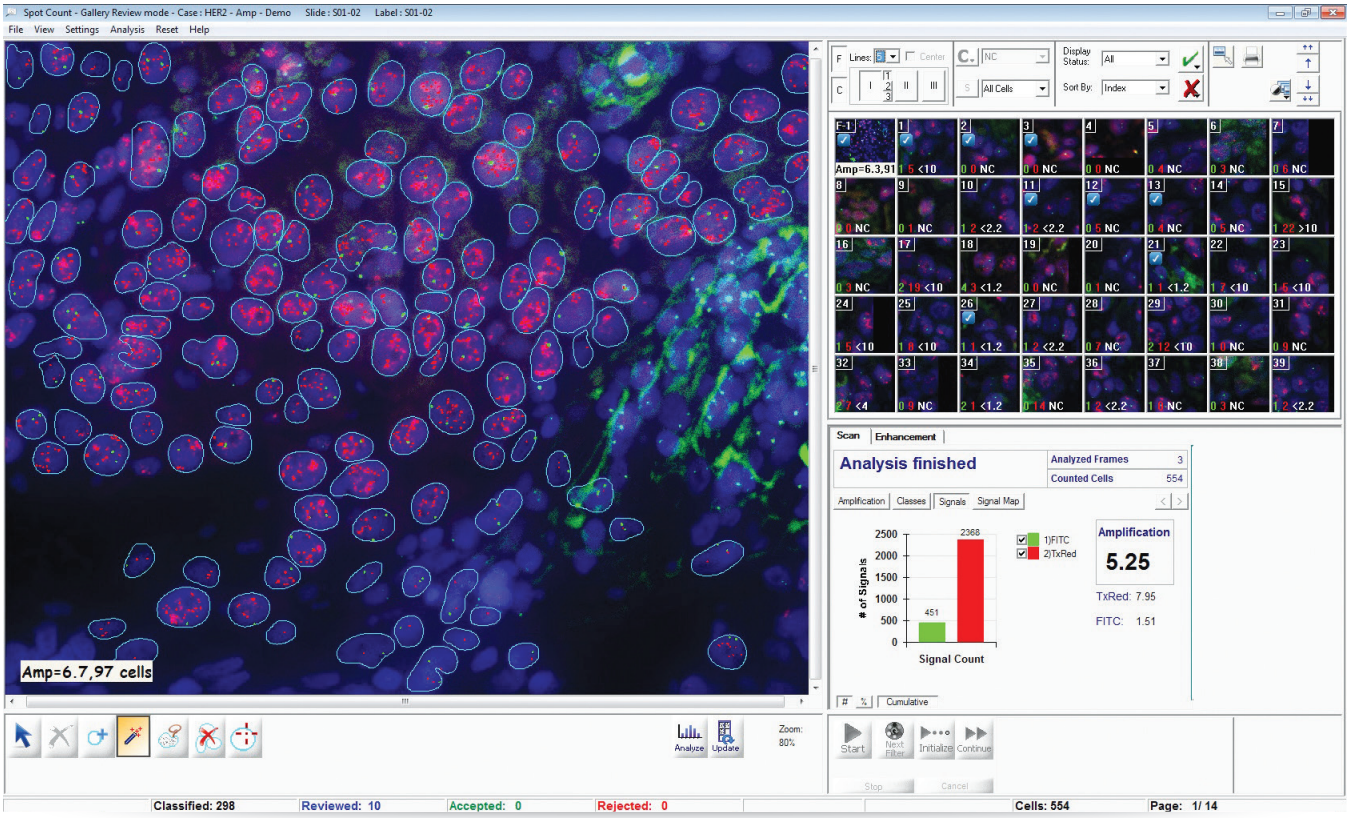
ASI's FISH solution also allows users to deliver image rich reports with statistical analysis and annotations; using images that were captured during the diagnostic process.

FISH Automation

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

The automated FISH solution saves significant technical time by performing 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.

Another key benefit of fully automated FISH is that review, analysis and reporting may be performed outside of the dark room using ASI's FISH Review and Analysis stations.

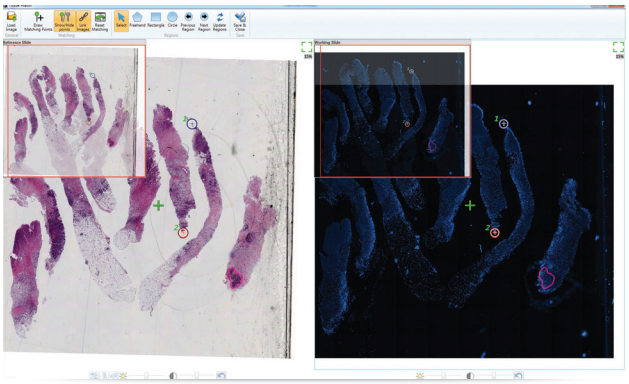


FISH

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.



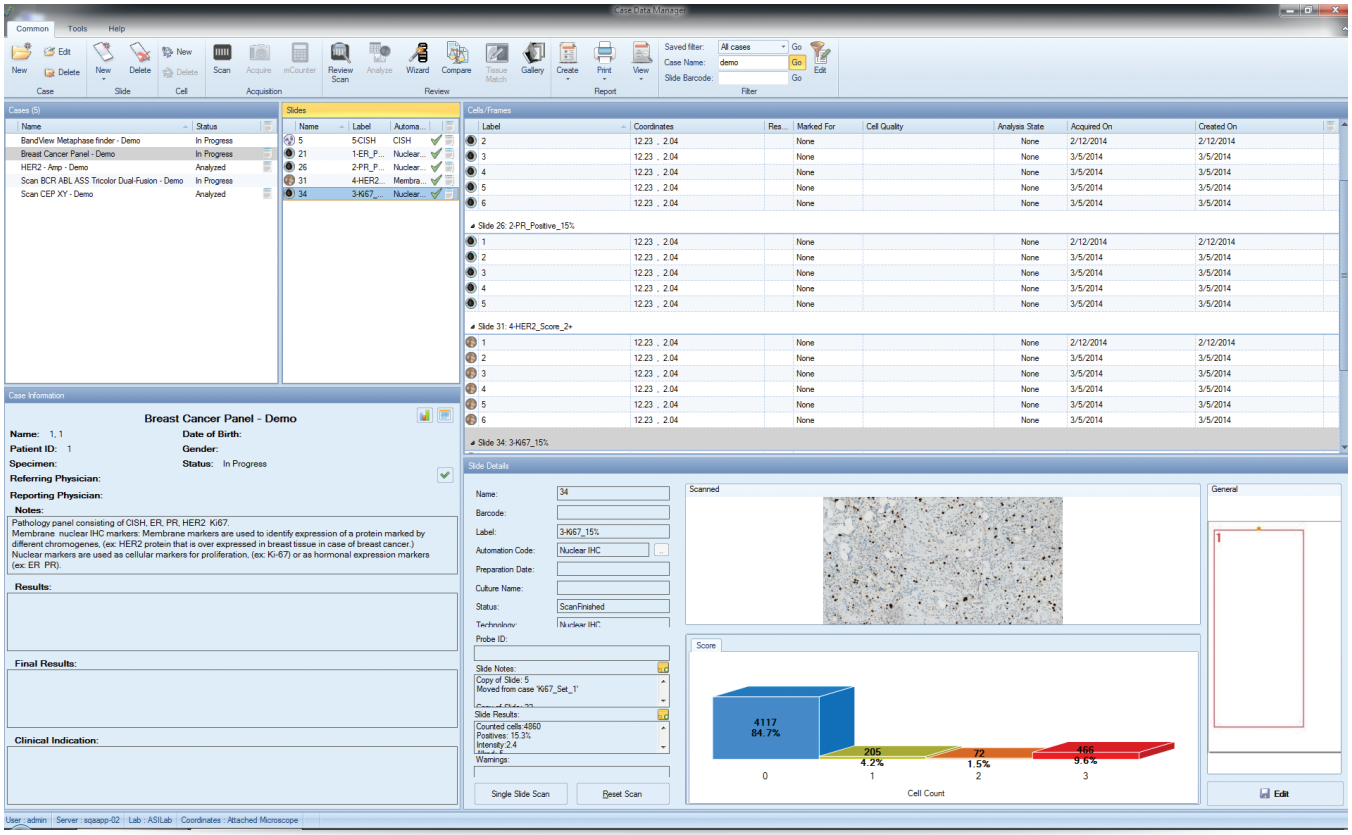
Tissue Matching

Case Management and Reporting

Case Data Manager – Information at Your Fingertips

With ASI's Pathology Suite, labs benefit from an interface - designed specifically for their workflow. Data integrity is preserved by archiving all clinical workflow processes and providing an audit trail of all work performed. Lab administrators can set access rights for each user and reporting becomes efficient and extremely easy.

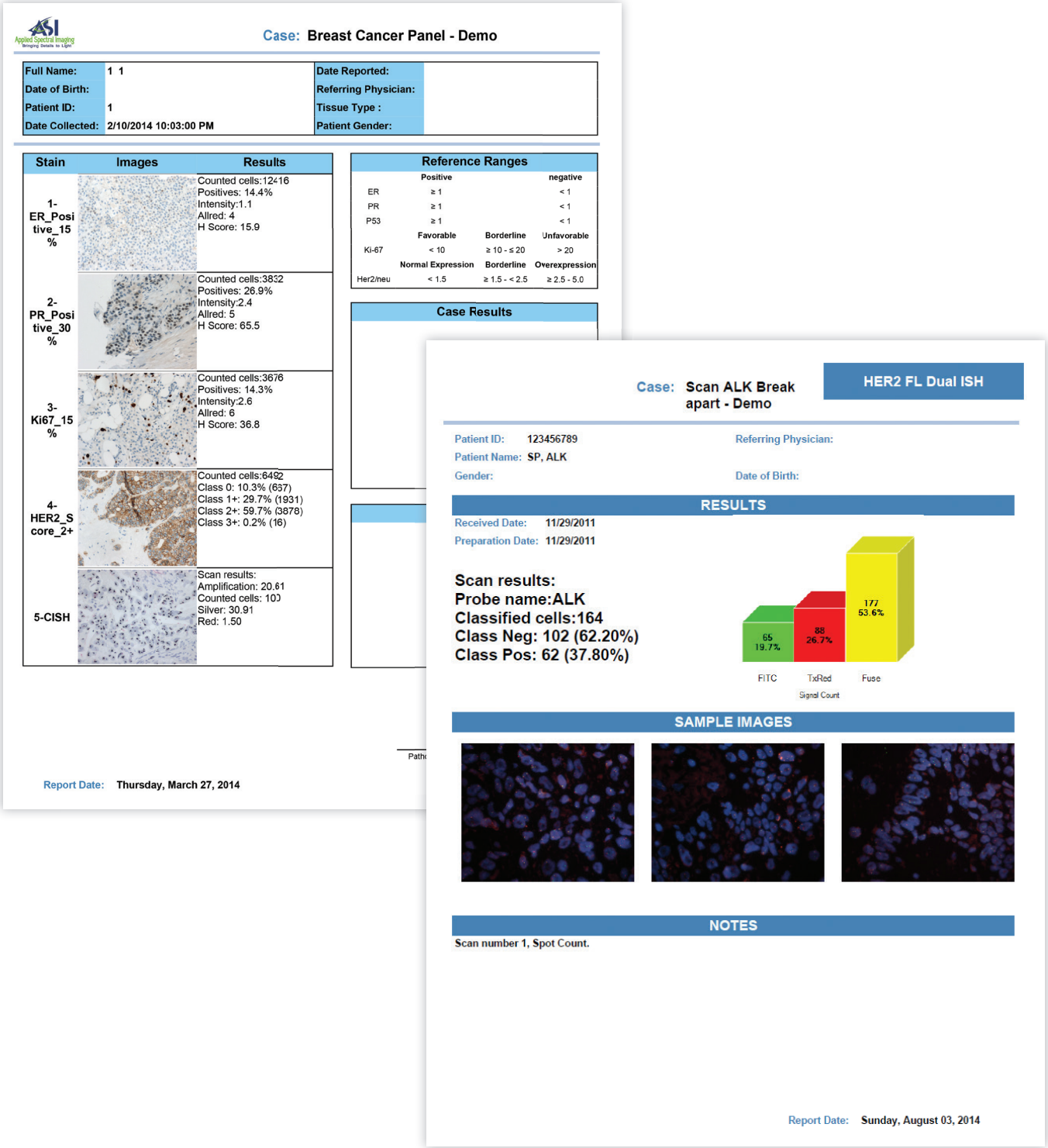
The Case Data Manager (CDM) allows coordination between all of ASI's analysis applications such as HiPath for nuclear and membrane stains and CISH; and FISHView™ and SpotCounting™ for manual and automated FISH. The CDM integrates with the lab's Laboratory Information Systems (LIS) and provides case information at a glance, including: patient information, captured images and charts and analysis. The CDM unifies all Pathology, FISH and Image Analysis in one location, which may be accessed from any review station.



Reporting

Multiple report types and templates are available within CDM, along with the ability to fully customize any report or set up templates for different reference sites and users. Reports with full statistical analysis and graphs can be generated with the click of a button.

In addition to the powerful reports generated by the CDM directly, the CDM can also integrate with the lab's LIS and export the relevant statistics and images for use in existing reports.



Case: Breast Cancer Panel - Demo

Full Name:	1 1	Date Reported:	
Date of Birth:		Referring Physician:	
Patient ID:	1	Tissue Type :	
Date Collected:	2/10/2014 10:03:00 PM	Patient Gender:	

Stain	Images	Results
1-ER_Positive_15 %		Counted cells:12416 Positives: 14.4% Intensity:1.1 Allred: 4 H Score: 15.9
2-PR_Positive_30 %		Counted cells:3832 Positives: 26.9% Intensity:2.4 Allred: 5 H Score: 65.5
3-Ki67_15 %		Counted cells:3676 Positives: 14.3% Intensity:2.6 Allred: 6 H Score: 36.8
4-HER2_Score_2+		Counted cells:6492 Class 0: 10.3% (637) Class 1+: 29.7% (1931) Class 2+: 59.7% (3878) Class 3+: 0.2% (16)
5-CISH		Scan results: Amplification: 20.61 Counted cells: 103 Silver: 30.91 Red: 1.50

Reference Ranges

	Positive		negative
ER	≥ 1		< 1
PR	≥ 1		< 1
P53	≥ 1		< 1
	Favorable	Borderline	Unfavorable
Ki-67	< 10	≥ 10 - ≤ 20	> 20
	Normal Expression	Borderline	Overexpression
Her2/neu	< 1.5	≥ 1.5 - < 2.5	≥ 2.5 - 5.0

Case Results

Report Date: Thursday, March 27, 2014

Case: Scan ALK Break apart - Demo

HER2 FL Dual ISH

Patient ID: 123456789
Patient Name: SP, ALK
Gender:
Referring Physician:
Date of Birth:

RESULTS

Received Date: 11/29/2011
Preparation Date: 11/29/2011

Scan results:
Probe name:ALK
Classified cells:164
Class Neg: 102 (62.20%)
Class Pos: 62 (37.80%)

SAMPLE IMAGES

NOTES

Scan number 1, Spot Count.

Report Date: Sunday, August 03, 2014

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 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.

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