



**DIGITAL  
PATHOLOGY**

**EVERY  
DIAGNOSIS  
COUNTS**

## Company Overview

### Applied Spectral Imaging (ASI) is a Global Leader in Digital Pathology and Cytogenetics

Founded in 1993, ASI has established a global presence across more than 80 countries. With over **5000 systems installed worldwide**, the Company provides a comprehensive product portfolio in the field of biomedical imaging.

ASI's technology, powered by GenASIs, offers a broad range of solutions for brightfield, fluorescence and spectral imaging. Its multiple applications address diagnostic needs across several domains, including **karyotyping, FISH, digital pathology** and a combined **"All in One"** solution.

The Company's extensive portfolio of **FDA-cleared products** include BandView, FISHView, SpotScan for CEP XY, UroVysion, ALK, and HER2/neu FISH, as well as the HiPath immunohistochemistry (IHC) Family for HER2, ER, PR, and Ki67 in manual configuration. The ASI product family is **IVDR compliant**.

With offices in the USA and Asia, as well as a vast network of global distribution partners, ASI is dedicated to advancing diagnostic capabilities worldwide, because **every diagnosis counts**.



## Product Portfolio



HiPath Pro	PathFusion



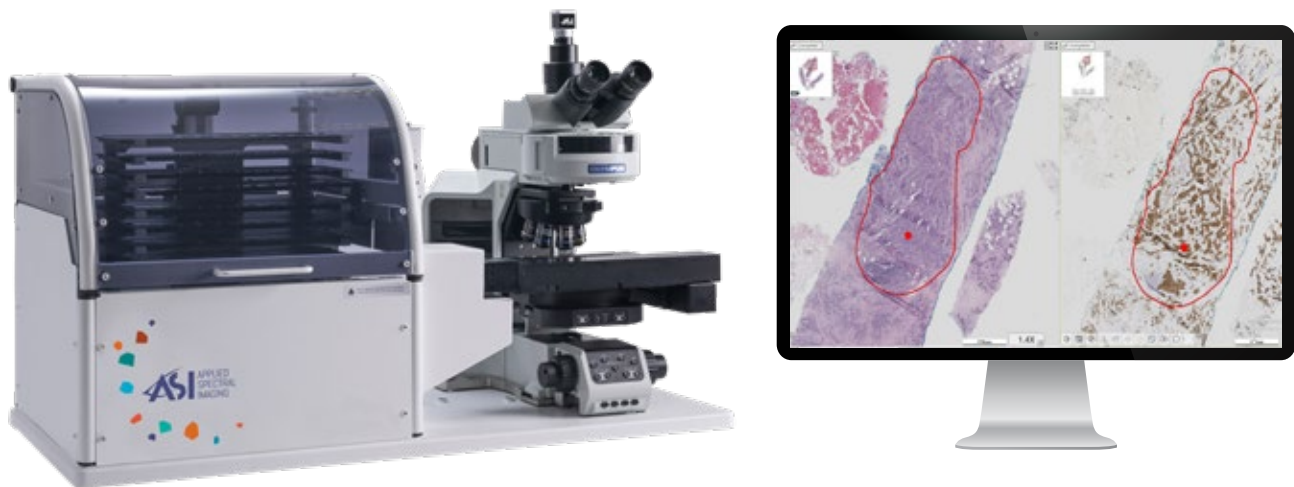
HiBand	HiFISH	CytoPower

## Comprehensive Digital Pathology Solution

### Scanning and Quantitative Analysis of Brightfield and Fluorescent Slides

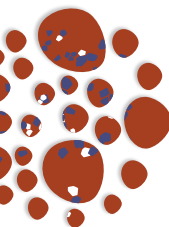
ASI's digital pathology platform is a comprehensive solution for the scanning, visualization and analysis of **H&E**, **IHC** and **FISH** slides. The software combines advanced navigation and image management tools with an intuitive and user-friendly interface. Exceptional image quality, combined with the ability to zoom up to 80X digitally, allows for in-depth examination of tissue samples, making it easy for pathologists to measure, annotate and mark areas of interest in whole slide images **acquired on ASI or other scanning systems**. The platform features advanced computer-aided cell

segmentation and classification tools for both nuclear and membranous IHC staining (**HiPath Pro**), as well as quantitative analysis of FISH images (**PathFusion**). Tissue matching between brightfield images acquired on ASI or third-party scanners with FISH specimens imaged on the ASI platform helps selecting relevant tissue areas for FISH analysis. Automated tissue detection and quantitative analysis across multiple sample types and FISH probes support pathologists in providing their diagnosis more efficiently.



### Image Acquisition Platforms

From 1-slide manual capture to 9 or 99-slide scanners, ASI offers diverse platforms to accommodate **all image acquisition needs**. Equipped with automatic tissue detection algorithms for both **brightfield and fluorescent** specimens, ASI's digital pathology scanning technology automatically identifies and locates tissue on the slide, reducing the potential for human error and improving overall scanning efficiency. This **unattended continuous scanning** helps technologists focus on other important tasks while handling **large volumes** of slides and maintaining **high productivity**.



# HiPath Pro

**HiPath Pro** is a state-of-the-art digital pathology software that provides accurate and standardized analysis of **brightfield images acquired on ASI or third-party scanners**. With its streamlined workflow, HiPath Pro offers a user-friendly interface featuring advanced marking and annotation tools, **tissue matching** across multiple images, and automatic transfer of regions of interest between registered slides. Quantitative IHC analysis of both **nuclear** and **membranous** staining can be performed on images acquired on ASI or other scanning systems.

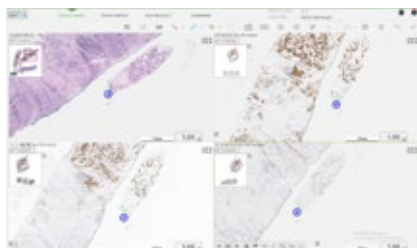


## Benefits to your lab

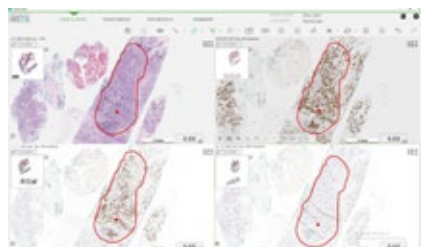
- **Wide range of tissue samples** (e.g. breast, lung, colon, bladder, brain)
- **Intuitive** whole slide image navigation and review **up to 80X digital zoom**
- Open system with **unique classifiers** adjustable to any digital pathology practice
- **Vendor neutral IHC** analysis for ER, PR, HER2, Ki67, P53, PD-L1 and more
- Applicable to images acquired on **ASI or third-party scanners**
- Analysis and scoring of **chromogenic in situ hybridization (CISH)** stain



Automatic tissue detection



Co-registration of up to 4 slides



Tissue matching and automatic transfer of region of interest



Automatic scoring and quantification of ER, PR, HER2, Ki67, P53 and PDL1

"As an early adopter of the PD-L1 immunostaining methodology, our group quickly recognized the inter- and intra-observer variability in scoring and interpretation of the stain, especially when there is non-uniform staining among tumor regions. We have been very pleased with the added confidence that HiPath Pro provides us in improving accuracy and precision of interpretation"

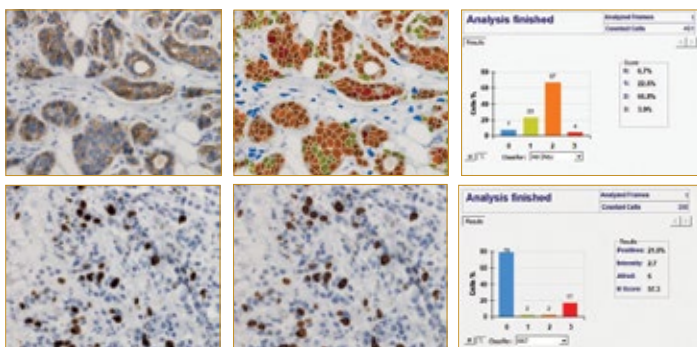
*Dr. Lija Joseph, Lowell General Hospital*



## Quantitative IHC Analysis

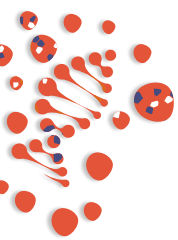
Powered by advanced algorithms, the IHC analysis of whole slide images enables quantitative, computer-aided analysis of images acquired on ASI or other scanners. Featuring morphology and intensity-based **scoring** and **quantification** for both nuclear and membranous stains, the IHC analysis aids pathologists to enhance their diagnostic confidence with the assistance of computer-aided second opinion.

IHC analysis on a broad range of tissue samples (e.g. breast, lung, colon, bladder, brain)



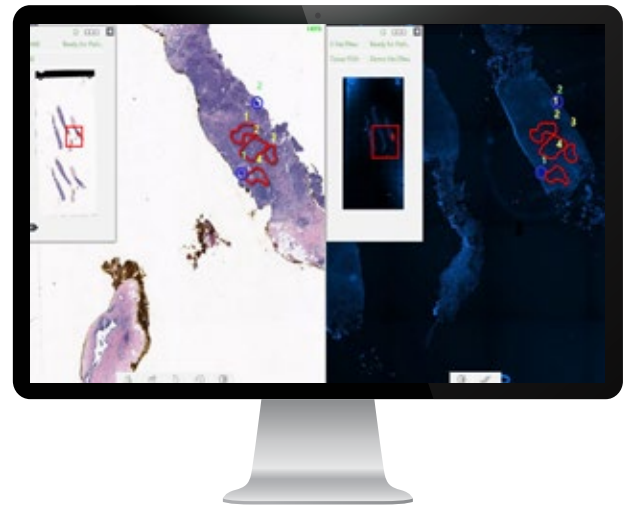
"The comparison on the inter- and intra-observer variability showed that there is minimal or no influence of the person performing the review or time on the image analysis, and image analysis can provide very reproducible results, minimizing the human error, which is the major strength of digital image analysis over manual morphometric analysis"

*Chong Y, Kim TE, Cho U, Jin MS, Yim K, Thakur N, Cho J, Park G, Diagnostics*

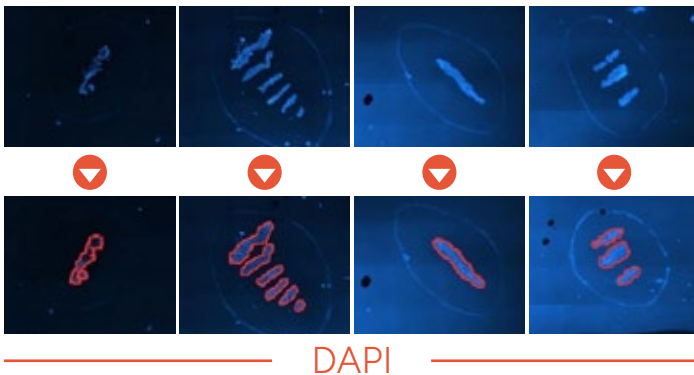


# PathFusion

**PathFusion** offers a comprehensive digital pathology workflow, **bridging the gap between brightfield and FISH imaging** across multiple probe vendors and sample types. The application features state-of-the-art functionalities including **computer-aided FISH tissue detection** and proprietary algorithms for automatic cell identification, signal detection, cell classification and quantification. With its **tissue matching** capabilities and its automatic transfer of regions of interest from H&E or IHC images acquired on ASI or third-party scanners to FISH slides scanned on the ASI platform, PathFusion combines both **versatility** and **reliability**.



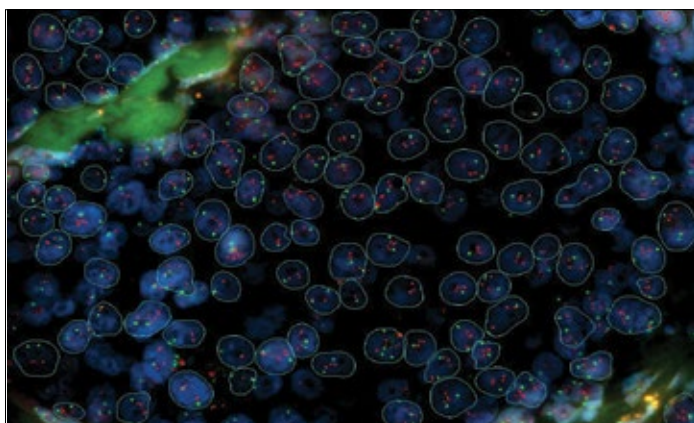
## — Automated Tissue FISH Detection —



"Annotated whole slide images of H&E and FISH sections can be digitally aligned, so that areas of tumor within a section can be matched and evaluated with a greater degree of accuracy. Images can be archived permanently, providing a means for examining the results retrospectively"



*Liew M, Rowe L, Clement PW, Miles RR, Salama ME., J Pathol Inform*



## Quantitative FISH Analysis

ASI's proprietary algorithms provide robust and **consistent image quality**, enabling accurate signal detection and cell classification in tissue FISH. This, in turn, enables to generate standardized and reliable quantitative results, even for **complex probes and samples**.

## High Image Quality

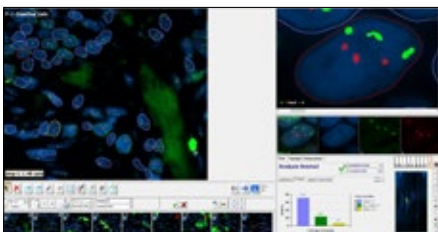
ASI's unique scanning capabilities feature image acquisition with **unlimited layers of automatic Z-stack**, as well as proprietary algorithms for **automatic detection of faint signals**. These cutting-edge Z-Stacking and 3D Focus functionalities lead to impeccable analysis and higher accuracy. Furthermore, the **automated optimization of acquisition parameters**, together with robust signal detection, **debris reduction** and automatic image enhancement, contribute to provide high image quality.



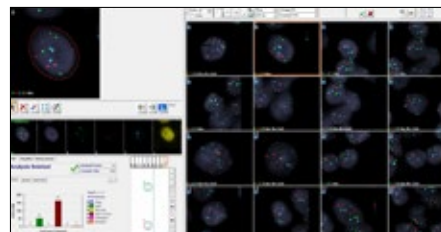
"Digital FISH analysis provides more efficient and accurate results and better patient care in comparison to traditional FISH methods"



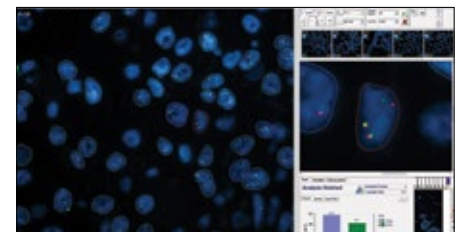
*Liew M, Rowe L, Clement PW, Miles RR, Salama ME., J Pathol Inform*



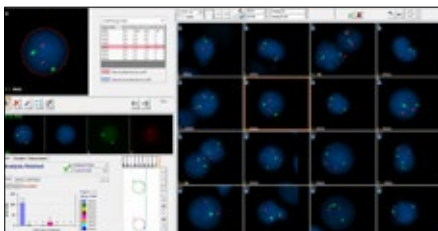
HER2/neu (Breast)



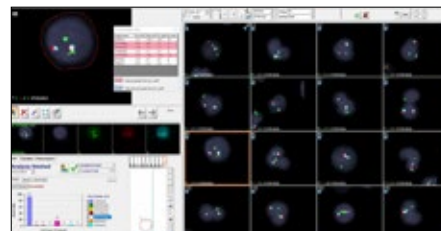
UroVysion



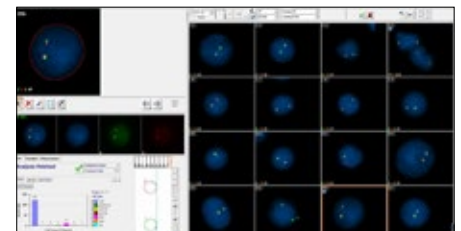
ALK (Lung)



Hematology Enumeration



Hematology Fusion



Hematology Breakapart

## Multiple Sample Types

- ◆ Breast
- ◆ Lung
- ◆ Prostate
- ◆ Gastrointestinal
- ◆ Skin
- ◆ Bladder
- ◆ Brain
- ◆ Cervix
- ◆ Bone Marrow
- ◆ Blood
- ◆ Lymph nodes

## Benefits to your lab

- ◆ Whole Slide Imaging with **intuitive viewing** and advanced tools
- ◆ **High Image Quality** with automated optimization and enhancement
- ◆ **User Independent Scanning** for increased productivity
- ◆ **Z-Stacking & 3D Focus** for impeccable analysis and higher accuracy

# ● Bridging the Gap between Brightfield Pathology and FISH Analysis

# 1

## Scan, View & Mark

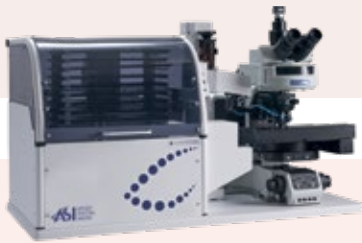
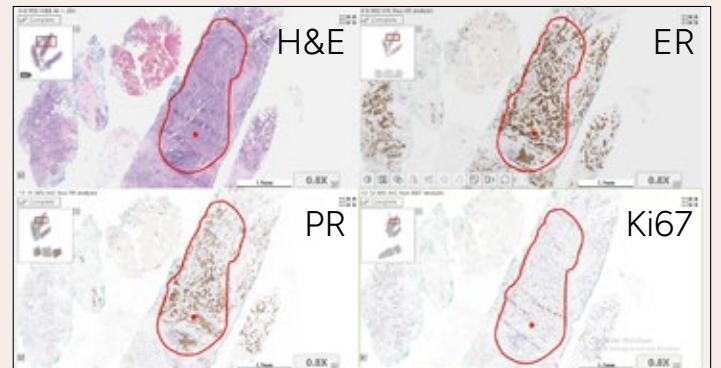
Digitize your brightfield pathology slides on ASI or other image acquisition system

# 2

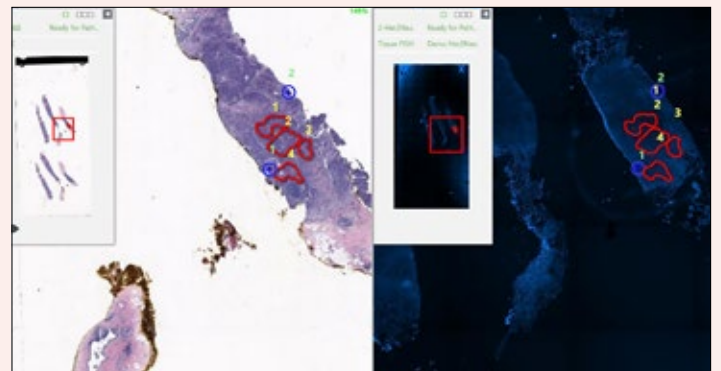
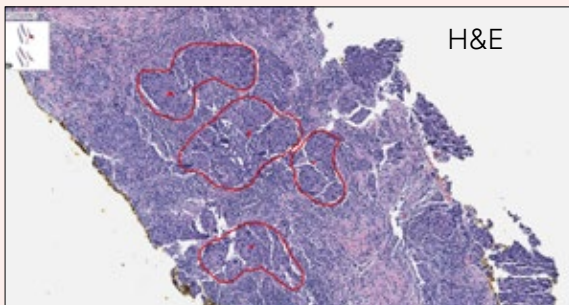
## Match & Align

Simultaneously review up to 4 registered slides and automatically transfer regions of interest

HiPath Pro



PathFusion





# 3

## Analyze

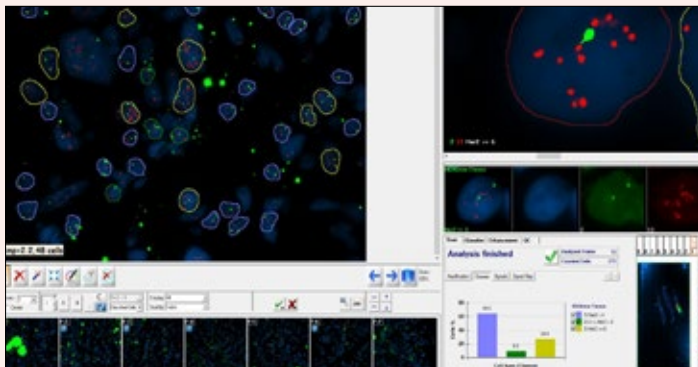
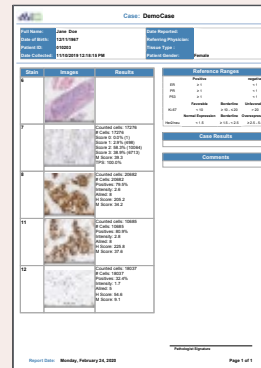
Perform quantitative analysis for standardized results



# 4

## Report

Prepare customized reports including screenshots, images and quantitative results



Stain	Images	Results
H&E		
Her2Neu		Counted cells: 8449 Class 0: 27.9% (2356) Class 1: 4.4% (372) Class 2: 43.6% (3687) Class 3: 24.1% (2034)
Her2Neu		Scan results: AMPLIFIED Probe: Her2Neu Amplification: 2.89 Counted cells: 252 Red: 6.66 Green: 2.24

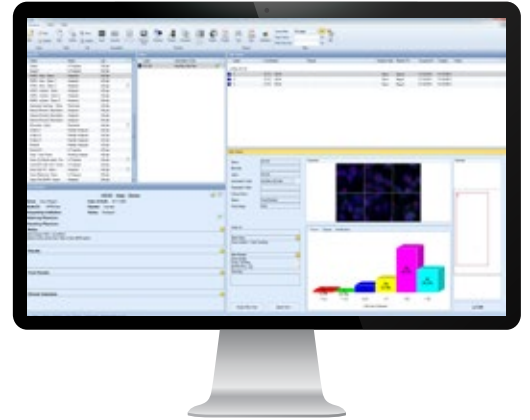
Reference Ranges			
	Positive	Negative	
ER	≥ 1	< 1	
PR	≥ 1	< 1	
PSS	≥ 1	< 1	
Ki67	Favorable < 10	Borderline ≥ 10 - 20	Unfavorable ≥ 20
Her2Neu	Normal Expression < 1.5	Borderline ≥ 1.5 - 2.5	Overexpression ≥ 2.5 - 6.0
Case Results			
Comments			

## Case Data Manager and LIS Connectivity

With its **Case Data Manager (CDM)** application, ASI offers a unique and comprehensive solution that can help streamline the data management process and provide a more **efficient and secure system** for the pathology laboratory. By integrating with the **Lab Information System (LIS)**, the ASI platform can help manage data more effectively, saving time and resources.

### Benefits to your lab

- ◆ **Paperless** workflow
- ◆ **Secure** data management
- ◆ Central portal and **database**
- ◆ Secure integration with **LIS**
- ◆ Supports **HL7/FHIR, XML, ShireText** and more
- ◆ Data integrity & **HIPAA compliance**



## GenASIs AnyWhere

ASI's **advanced virtual access** solution enables HIPAA-compliant access to your lab's GenASIs platform from any location. This secure and trouble-free solution makes remote data management easy, ensuring that you can **access your lab's data anytime, anywhere**.

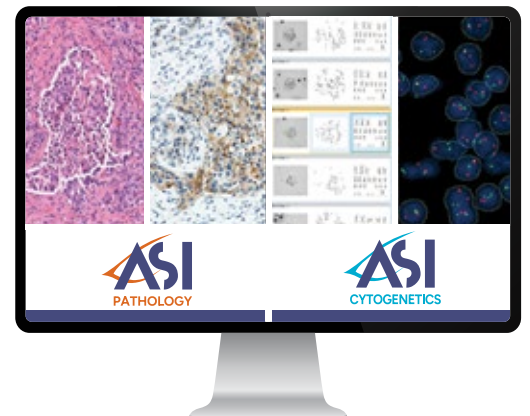
### Benefits to your lab

- ◆ Optimal for **remote consultation**, educational and training needs
- ◆ Uncompromised **data security**
- ◆ Efficient management and maintenance of **multiple systems, and users**
- ◆ Compatible with Microsoft Remote Desktop Services (RDS), **Citrix, VMware Horizon**



## All-in-One Solution

Combining digital pathology, karyotyping and FISH, ASI's **All-in-One** solution offers a **comprehensive workflow** from scanning to image viewing, quantitative analysis and reporting of both brightfield and fluorescent images. All-in-One provides a modular and versatile solution addressing the needs of both **cytogenetics** and **pathology** laboratories in one single platform.

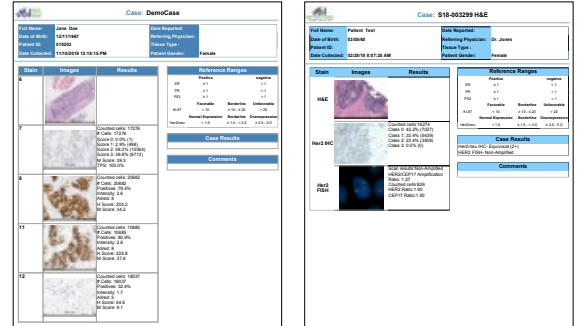


## Advanced Reporting

ASI's reporting tool provides a user-friendly interface to create laboratory-branded **customizable reports** according to the user's needs.

### Benefits to your lab

- **Dedicated report** for each application
- **Quantitative** and **graphical** results
- User-selected **screenshots** and **images**
- **Freehand report** using multiple annotation styles



## LabLife Statistics



### Benchmarks

**Calculate performance** and track KPIs to help meet certification and regulatory requirements



### Optimization

**Identify best practices** to increase return of investment and focus improvement efforts



### Growth

**Justify investment** in additional capital equipment to improve lab efficiency



### Annual Review

**Compare performance** year on year and make decisions based on data driven analyses

## Diverse Image Acquisition Platforms



1-Slide Capture System



9-Slide Scanning System



99+ Slide Tray Loader



Review & Analysis Station



AnyWhere Remote Connectivity

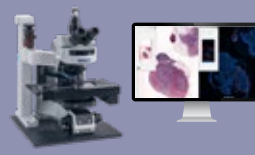
## Adapted Service Offering

The ASI team is committed to supporting your laboratory by providing expert and superior service throughout the year. Different **Service Packages** are available to provide the highest level of service according to your specific needs.

# System Specifications



Manual 1 Slide



9 Slide Motorized Stage



99+ Slide Tray Loader

		HiPath Pro	PathFusion	HiPath Pro	PathFusion	HiPath Pro	PathFusion
Microscope Support	OLYMPUS	BF upright microscopes	BF+FL upright microscope	BX63* BF	BX63* BF   FL	BX63* BF	BX63* BF   FL
	ZEISS			Axiolmager Z2 BF	Axiolmager Z2 BF   FL	Axiolmager Z2 BF	Axiolmager Z2 BF   FL
Objectives	OLYMPUS	4x/0.16NA 20x/0.5NA 40x**/0.75NA	4x/0.16NA 20x/0.5NA 40x**/0.75NA 60x/1.25NA	4x/0.16NA 10x/0.3NA 20x/0.5NA	4x/0.16NA 10x/0.3NA 20x/0.5NA 40x**/1.3NA 60x/1.42NA	4x/0.16NA 10x/0.3NA 20x/0.5NA	4x/0.16NA 10x/0.3NA 20x/0.5NA 40x**/1.3NA 60x/1.42NA
	ZEISS	5x/0.16NA 20x/0.5NA 40x**/0.75NA	5x/0.16NA 20x/0.5NA 40x**/0.75NA 63x/1.44NA	5x/0.16NA 10x/0.3NA 20x/0.5NA	5x/0.16NA 10x/0.3NA 20x/0.5NA 40x**/1.3NA 63x/1.44NA	5x/0.16NA 10x/0.3NA 20x/0.5NA	5x/0.16NA 10x/0.3NA 20x/0.5NA 40x**/1.3NA 63x/1.44NA
Camera	5MP CMOS Color		5MP CMOS Color		5MP CMOS Color		
Slide Capacity	1 Slide		9 Slides		99 Slides		
Barcode Reader	Handheld 1D/2D		Handheld 1D/2D		Integrated 1D/2D		
Automated Oil Dispenser	N/A		Optional		Integrated		
Dimensions (WxDxH)	According to installed microscope		61cm x 69cm x 85cm (24"x27.2"x33.5")		100cm x 90cm x 90cm (39.4"x35.5"x35.5")		
Weight	According to installed microscope		45kg   99.2lb		80kg   176.4lb		

\* Although, the Olympus BX61 is no longer available to purchase and is obsolete, ASI will still support this model.

\*\* Optional

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