



Applied Spectral Imaging
Bringing Details to Light



GenASIs Cytogenetics Suite
Manual and Automatic Karyotyping and FISH Applications



www.spectral-imaging.com



Table of Contents

GenASIs Platform for Genetics.....	3
GenASIs Capture & Analysis - Karyotyping	4
GenASIs Scan & Analysis - MetScan	5
GenASIs Capture & Analysis - FISHView	8
Reagents - Whole Chromosome Paints - WCP	9
GenASIs Scan & Analysis - SpotScan	10
GenASIs HER2/neu Gene Amplification Detection.....	12
GenASIs Automated UroVysis	12
GenASIs Scan & Analysis, SpotScan - PTEN	13
GenASIs HyperSpectral	14
Reagents—SKYPaint® Probes	15
GenASIs Case Data Management - CDM.....	16
GenASIs Cloud	17
Server Networks	17
GenASIs mCounter	18
The Company	19

GenASIs Platform for Genetics

Designed to Meet the Requirements of Any Cytogenetic Laboratory - Large or Small

ASI's scalable and modular platform can grow to meet your future laboratory needs. As your caseload increases, so can your lab by upgrading your single slide stations to 9-slide or 81-slide scanning stations, additional workstations, dedicated servers, and modular LIS /LIMS connection to automate your workflow. GenASIs platforms enable you to process more cases, quicker, with better clinical results.

GenASIs Capture & Analysis platform is a high-end computer aided diagnostic system with multiple assay support. This versatile solution may be adapted to a plurality of pathology and cytogenetic applications. The system is designed to work with a manual or automated microscope and includes a dedicated, high powered microscope camera combined with state-of-the-art image analysis software for clinical and research oriented image analysis.



GenASIs Scan & Analysis platform is a top-of-the-line, automated computer aided slide scanning diagnostic platform. This modular platform enables automation of a wide range of laboratory selected assays in pathology and cytogenetic applications. This flexible solution may be adapted to the advanced automation and workflow needs of any laboratory or research institution. The system includes a fully automated, computer-controlled microscope, motorized 9-slide stage and high powered microscope-camera. This platform also comes with a variety of additional components, such as an oil dispenser, automated fluorescent illumination control and state-of-the-art image analysis software for clinical and research oriented image analysis and automation.



High Throughput Scanning platform is a robotic slide loading system, enabling high-throughput automated slide analysis for a wide range of cytogenetic applications. This platform, combined with the GenASIs Scan & Analysis platform, provides a true "walk-away" functionality, scanning up to 81 slides consecutively, without human intervention. These scanning capabilities, presented with the GenASIs High Throughput platform, offer the most efficient and cost-effective way to optimally use the scanning and analysis system for uninterrupted scanning.



GenASIs Analysis & Review platform is an advanced analysis platform with full case review capability. This versatile platform supports the analysis and review of a wide range of pathology and cytogenetic applications. The platform allows users to review, analyze, sign-off and generate reports for case data captured using the GenASIs Scan & Analysis and Capture & Analysis platforms. Case data may be accessed from any network location.



GenASIs HyperSpectral platform is a cutting-edge, dual-mode optical device, which allows both interferometer image capture for hyperspectral imaging and direct view mode for high-resolution CCD image capturing. In interferometer mode, the GenASIs HyperSpectral reveals the spectrum of every pixel in the image, creating a spectral-signature for each point in the image. In Direct View mode, the system records image details under extremely low intensities. The result is a finely detailed high-resolution and high-definition image.



GenASIs Capture & Analysis - Karyotyping

Intuitive Workflow with Optimization Tools

GenASIs BandView®, ASI's karyotyping application running under the GenASIs Capture and Analysis platform, is designed to save time without compromising results for a true paperless environment.

Superb High Resolution Image

High resolution images are captured by a 12-bit digital camera with a wide field of view for capturing highly spread metaphases in one image acquisition. Fully automated contrast, exposure and coordinate listing facilitate easy capture with one click.

Seamless Advanced Automation

Advanced automation is what makes GenASIs BandView unique, offering background uniformity correction, automatic segmentation of touching chromosomes, optimized image enhancement, contrast and band sharpness. 'Smart' tools, like the unique single "Magic Tool", streamline the karyotyping process. The Magic Tool is an all-in-one multi-function tool that eliminates the need for switching between other functions.

Review Utility

A fast and flexible workflow process can be created with the 'Detailed Review' feature, enabling comparison of chromosomes and full editing of the karyotype, the cell and case results.

Database and Reports

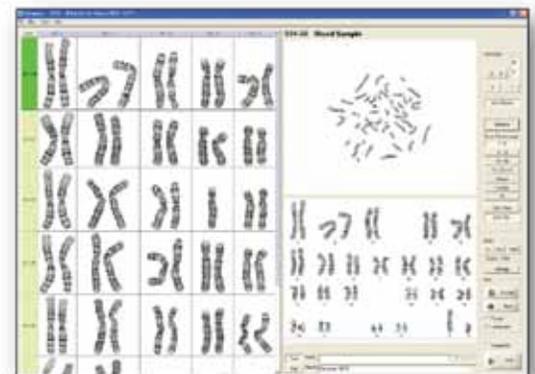
The integrated database, Case Data Manager (CDM) helps your lab move towards a paperless environment by providing review and marking tools for supervisors. The multi-case gallery or multi-chromosome panel allows for quick case-review. Cell and Case summary reports can be customized, annotated, viewed and exported to a LIS/LIMS.

Multi-Species Support

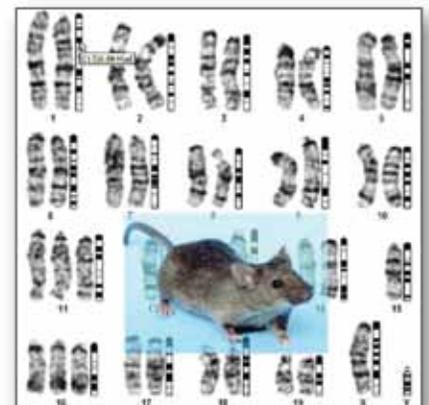
A dynamic karyotype table fits any species type. A predefined Ideogram library has been specially prepared for multiple species, and includes capabilities to add custom ideograms of animal or plant species.



Excellent image quality for extracting the subtlest detail



Chromosome comparison within and between cases

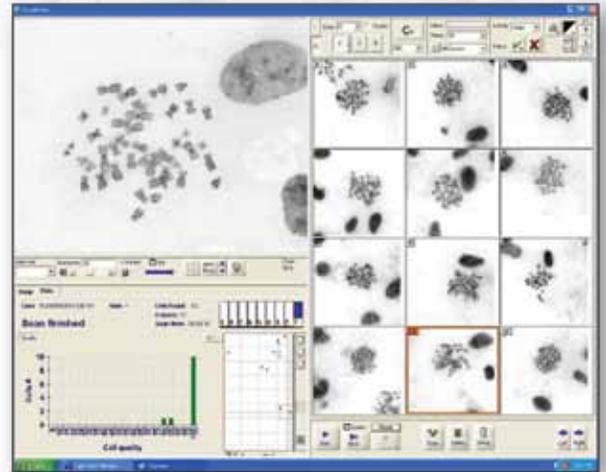


Rat karyotyping

GenASIs Scan & Analysis - MetScan

Providing Quality Results

Many cytogenetic labs are searching for more effective ways to reduce the tedious, yet critical processes of metaphase search and image analysis. By introducing GenASIs MetScan, ASI's automated metaphase finder running under the GenASIs Scan and Analysis platform, to your cytogenetics laboratory, you can simplify day-to-day manual processes and maintain and increase quality standards.



Metaphase Scan in brightfield

Cost Savings

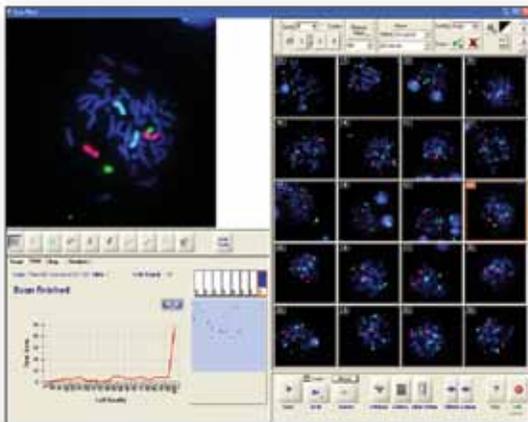
using
GenASIs Scan & Analysis Platform

Studies show
work hour savings of 50–67%

Using a motorized 9-slide scanning stage, GenASIs MetScan carries out semi-automatic or fully unattended scans on brightfield and multi-colored fluorescent slides.

GenASIs MetScan reliably detects metaphases of any source based on user-trainable classifiers. Results are displayed in a user friendly gallery and each metaphase can be relocated with a single mouse click for review.

Smart automation enables the detection of cover slip regions and colonies during prescan to identify any type of metaphase, sparse to condensed.



Fastest extraction of metaphases in full color using a dual scan process

Automation

Up to five successive fully automated scan steps:

- 1 Prescan
- 2 Scan
- 3 Accept Best Cells
- 4 Auto Oil Dispense & Smear
- 5 Automatic High mag (100x)



GenASIs Scanning Process

Unattended Continuous Scanning

GenASIs MetScan is upgradeable to a fully automated, walk-away operation that allows maximum scanning throughput and efficiency for various sample preparations, types and staining, using a 9-slide stage or ASI's GenASIs High Throughput Loader. Either option, automatically identifies the sample type and performs scanning accordingly.

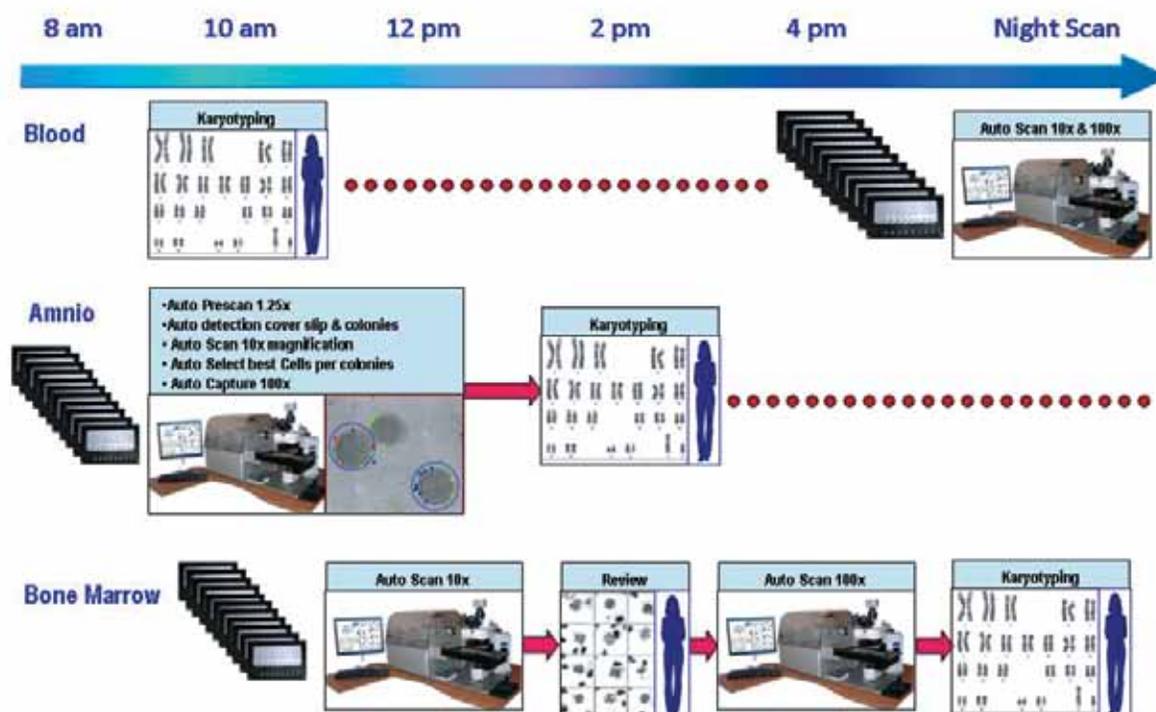
ASI's innovative Tray Loader is an extension of ASI's GenASIs Scan and Analysis platform that meets the most demanding requirements for multi-slide scanning. Unattended continuous scanning of 81 diverse slides is possible even for a combination of fluorescent and brightfield slides.

Functionality

The Tray Loader's convenient desktop design features a front-loading transparent cover for viewing tray status and for replacing trays even while the Tray Loader is running, allowing non-stop scanning well over the original capacity of 81 slides. Nine trays conveniently hold nine slides each, allowing three cases of triple-slide probes to be included on one tray. Swift, automatic barcode reading during loading simplifies case and sample identification with no added time requirement.

Additional trays can be added or reloaded with fresh slides while the system is scanning, to enable a more convenient and continuous workflow.

Suggested Use of System During the Day





Distributed Relocation

High magnification capture can be done in multiple system configurations on the scanning system, as part of the automated process. Alternatively, slides or full 9-slide trays can be placed on other microscopes for high magnification relocation and capture.

Modular Capability

GenASIs MetScan grows with demand. ASI's software and hardware are modular, and the level of automation can be increased to suit higher workloads. Optional features such as the Tray Loader, the automated Barcode Reader and the automated Immersion Oil Dispenser are easily provided upon demand.

Networking with other ASI software and systems is enabled, including BandView for karyotyping, FISHView for analyzing FISH imaging and HiSKY for multicolor karyotyping.

Reliability

The Tray Loader is manufactured with industry proven, high-end components. Slides are firmly attached in the trays so each scan is efficient, and repeated tray replacement is simple and accurate to enable high accuracy when relocating to pre-identified cells.

Compatibility

The tray loader is compatible with automatic microscopes and is able to take advantage of a full set of six objectives.

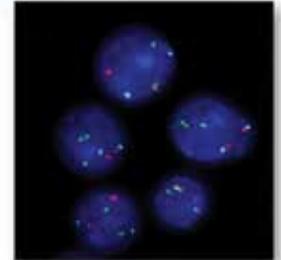


GenASIs High Throughput Scanning Tray Loader for 81 slides per batch using an integrated barcode reader for tracking, and an oil dispenser for high-power scans.

GenASIs Capture & Analysis – FISHView

Targeting the Right Treatment for the Right Patient

FISH technology is at the forefront of biomedical clinical research applications demonstrating high accuracy in diagnosing disorders such as hematological malignancies, breast tumors and bladder cancer with genetic markers such as BCR/ABL, HER2/neu, ALK, PTEN and UroVysion. Computer aided diagnostics, documentation and reporting have proven a valuable tool in obtaining quality, reliable pathology FISH analysis, quicker.

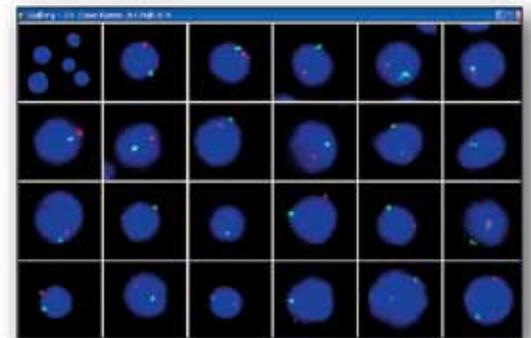


3-Color translocation probe

GenASIs FISHView®, running on the GenASIs Capture & Analysis platform, is a convenient, flexible FISH capture and analysis system designed to meet the demands of the clinical and research lab.

Powerful Automated 3D Imaging

State-of-the-art image enhancement and analysis capabilities combined with 3D capabilities (multiple focal planes) ensure clinicians and researchers have both enhanced images revealing information not readily available when using a simple microscope system while always preserving the original captured images for reference and documentation.



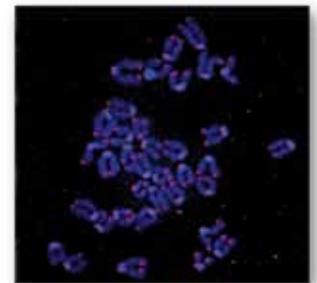
Easily capture images and make reports that summarize all sample types.

Timesaving Image Enhancement and Reports

Features such as automatic background correction, manual and automatic contrast, brightness and sharpness adjustments, enable optimal display of even the faintest signals in seconds. Customized reports make sure analysis information (such as annotations, notes and clinical observations) are preserved and documented along with the corresponding images.

Integrated Karyotyping Tools

GenASIs Capture & Analysis, FISHView includes full karyotyping support with unique band enhancement, signal sharpening and other karyotyping support tools.



Telomeric probes on mouse metaphase

Quantitative Imaging and Research Capabilities

GenASIs Capture & Analysis, FISHView takes imaging beyond quality and enhancement with the added ability to quantify signals and objects. The FISHView instrument may be calibrated and trained to detect specific objects and signals and create a detailed report based on user-defined parameters.

Reagents - Whole Chromosome Paints - WCP

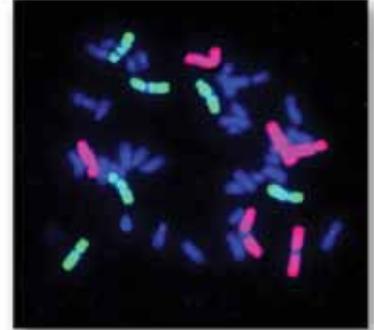
Simultaneous Visualization

ASI offers a comprehensive range of whole chromosome painting probes for human, mouse and rat chromosomes. These probes are designed for use in fluorescence in situ hybridization analysis.

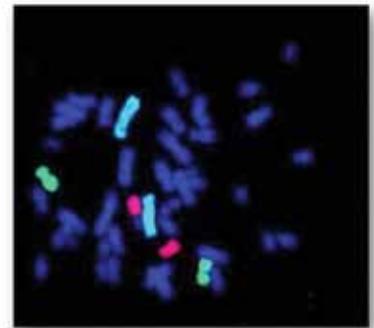
ASI's Whole Chromosome Paint (WCP) probes are labeled with FITC, Rhodamine and Aqua. A combination of two or three colors can be visualized simultaneously. They are ready to use in hybridization solution and supplied in an economical 5 or 10 test format, or as a complete paintbox set.

The painting probes are visible using single band pass filters or a standard triple DAPI/FITC/Texas Red filter. They have a guaranteed shelf life of 24 months. Due to their excellent stability, they are shipped at room temperature and should be stored at -20°C/-4°F upon arrival.

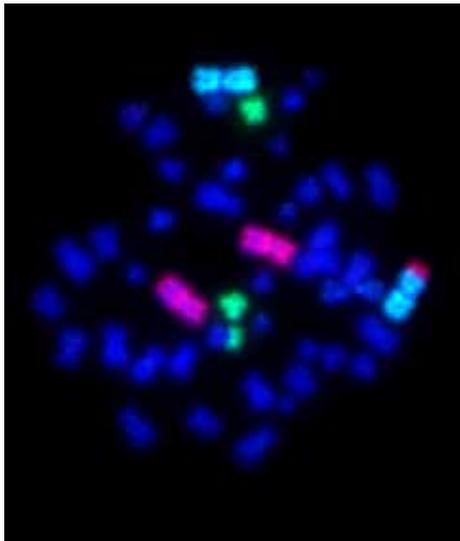
All ASI probes are manufactured in compliance with ISO 9000:2003 under rigorous quality control and strict GMP standards.



Two paint chromosome metaphase



Three paint chromosome metaphase



*Three paints for chromosomes
1(aqua); 2(red) and 16 (green) .*

GenASIs Scan & Analysis - SpotScan

Automated FISH Signal Detection, Classification and Enumeration

GenASIs SpotScan, running under the GenASIs Scan and Analysis platform, is adaptable to various magnifications, preparations and staining procedures. The software handles automatic counting of enumeration, amplification and translocation probes, providing dedicated algorithms for multi-fusion probes and intensity ratios for DMs and HSRs. Cells are sorted based on size and shape parameters and displayed in a gallery with the exact corresponding signal count. Powerful ASI designed algorithms cope with non-uniformities of illumination, cell clusters and cells with dominant heterochromatin regions.

Due to the unique nature of FISH slides, there are times when results from fully-automated processes are not cost effective. To address these concerns, ASI has designed GenASIs SpotScan that offers a multi-level user interaction concept. Depending on the specific sample and staining protocol, you may define the level of automation in the scanning process, which ranges from a walk-away operation to a highly user-controlled process for defining regions and cells suitable for analysis.

Challenges in FISH Analysis	ASI Solution
Exhaustive score of hundreds of cells in dark room	Slide scanning is fully automatic for high number of cells. No dark room is needed.
Sparse samples – long scan time	Pre-density scan to identify cell location – minimize scanning time
Cell cluster and touching cells	Unique algorithms to separate touching cells
Tedious repetition of switching filters while focusing to see all signals	Automatic scan of all colors and focal planes provides an all-in-focus image for user review
Very faint signals, barely seen	Sensitive camera detects even unseen signals
Problematic supervised review	All scored cells are kept in gallery for review
After manual scoring, cells can be captured as examples for reporting	Automatic report with as many cells as required
Exhaustive and tedious scans	Ergonomically user friendly – the system is completely automatic.

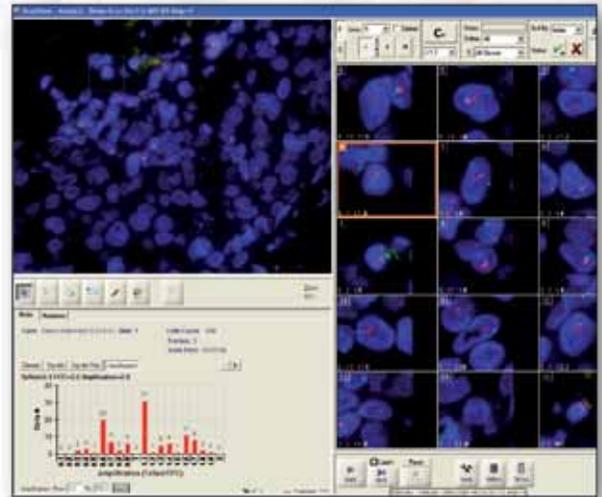


Semi-Automatic Signal Detection

GenASIs SpotScan, running under the GenASIs Scan and Analysis platform, allows you to address tissue samples or slides with high density of cells. The modularity of this system allows selective manual image capture of tumor regions, followed by automatic analysis. The advantage of this option is the use of a manual microscope, making the product a viable and affordable alternative to a fully-automated scanning option.

Automatic Cell Signal Detection

GenASIs SpotScan provides fully automated spot counting for a variety of applications in genetics, hematology, pathology and more. Dual phase scanning schemes allow fast cell localization followed by accurate multi-color imaging. Multiple focal planes can be acquired to extract focused 3D Z-stack images which are kept for optimal quality during review.



Images are displayed in a gallery for review with corresponding classification and statistics.

High Throughput

Similar to MetScan, the GenASIs SpotScan can be upgradeable to the GenASIs High Throughput scanning Platform using ASI's Tray Loader. Using the Tray Loader enables unattended scanning, location and capture of fluorescence slides, minimizing fading problems and sending images to remote stations for onscreen analysis.

Flexibility

Fluorescent spot counting slides can be combined with giemsa stained slides in the same batch. Empty slides and trays are automatically skipped.

Adaptability

Results are stored together with nucleus images and can be displayed in the image gallery or in convenient histograms and scatter plots. Data can be summarized in customizable reports for printing or exporting.



GenASIs High Throughput Scanning Tray Loader for 81 slides per batch using an integrated barcode reader for tracking, and an oil dispenser for high-power scans.

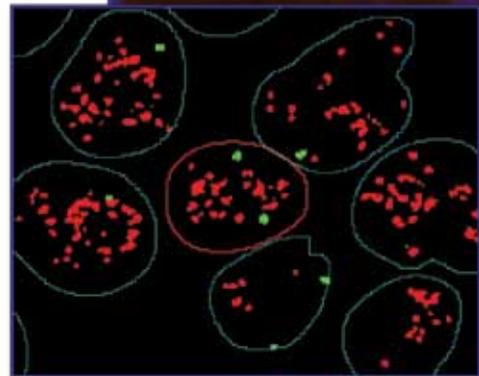
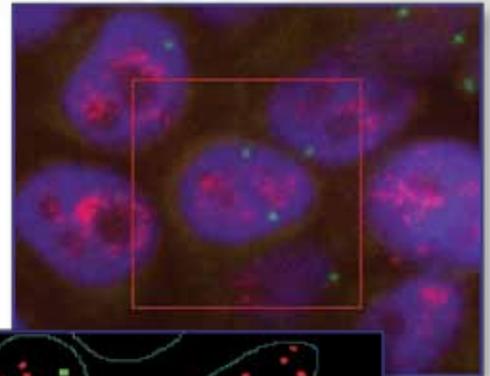
GenASIs HER2/neu Gene Amplification Detection

Detection of HER2/neu Gene Amplification in Breast Cancer Biopsy

ASI's GenASIs Suite is FDA cleared for intended use in HER2/neu gene amplification analysis of breast cancer tissue samples. ASI's advanced computer aided analysis tools combine superior accuracy with high throughput and seamless integration into existing laboratory workflows.

Whether performed as a single test or as part of a breast cancer panel, ASI's GenASIs Scan & Analysis, SpotScan - HER2/neu is a valuable aid to cytogeneticists in clinical laboratories. GenASIs enables both manual and automated HER2/neu tissue samples analysis.

ASI's GenASIs Scan & Analysis, SpotScan - HER2/neu incorporates unique workflows and advanced algorithms leveraging superior cell segmentation and signal counting of the most complex tumor samples. GenASIs is the tool of choice for laboratories seeking either automated or manual tissue analysis for HER2/neu Gene Amplification.



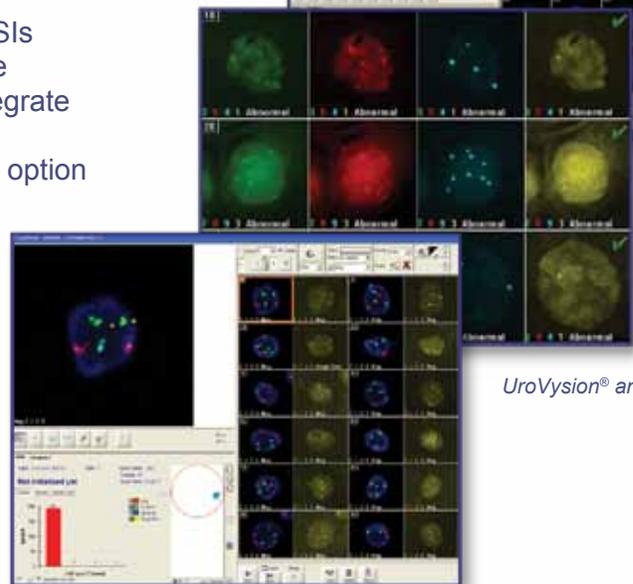
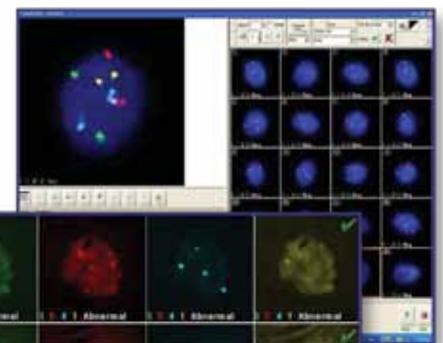
HER2/neu segmentation

GenASIs Automated UroVysion

GenASIs Scan & Analysis, SpotScan - UroVysion® is FDA approved and designed for the microscopic imaging and analysis of chromosomal aberrations using fluorescence in situ hybridization (FISH) in urine specimens from individuals suspected of having bladder cancer.

Slide imaging and analysis is performed using the GenASIs Scan & Analysis, SpotScan - UroVysion with ASI's unique clinical analysis software. The solution is designed to integrate seamlessly into the laboratory workflow providing a true automated walk-away option for UroVysion analysis. The option to review the results and conduct computer-aided analysis further provides persistent and accurate analysis documentation. Results are managed and archived in ASI's CDM (Case Data Manager) database which includes a reporting tool and interfaces with LIS.

GenASIs Scan & Analysis, SpotScan - UroVysion is intended for in-vitro diagnostic use as a diagnostic aid to the cytogeneticist in the automatic detection, counting and classification of bladder cancer cells based on color, size and their signal patterns.



UroVysion® analysis

GenASIs Scan & Analysis, SpotScan - PTEN

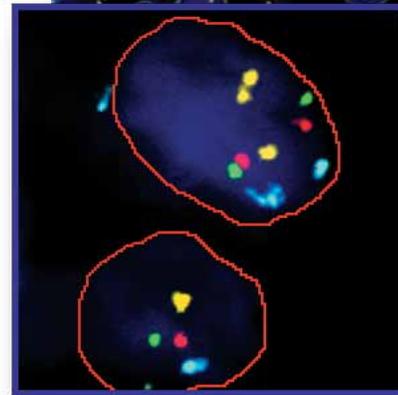
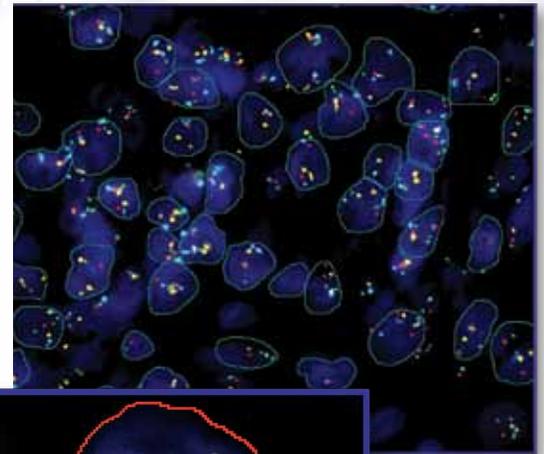
PTEN Four Color FISH for Prostate Cancer

The new patent pending platform technology for FISH Deletion Detection (del-TECT™) from CymoGen Dx has been designed primarily for FISH analysis of formalin fixed paraffin embedded (FFPE) tissue sections in solid human tumors to detect deletions of the PTEN gene.

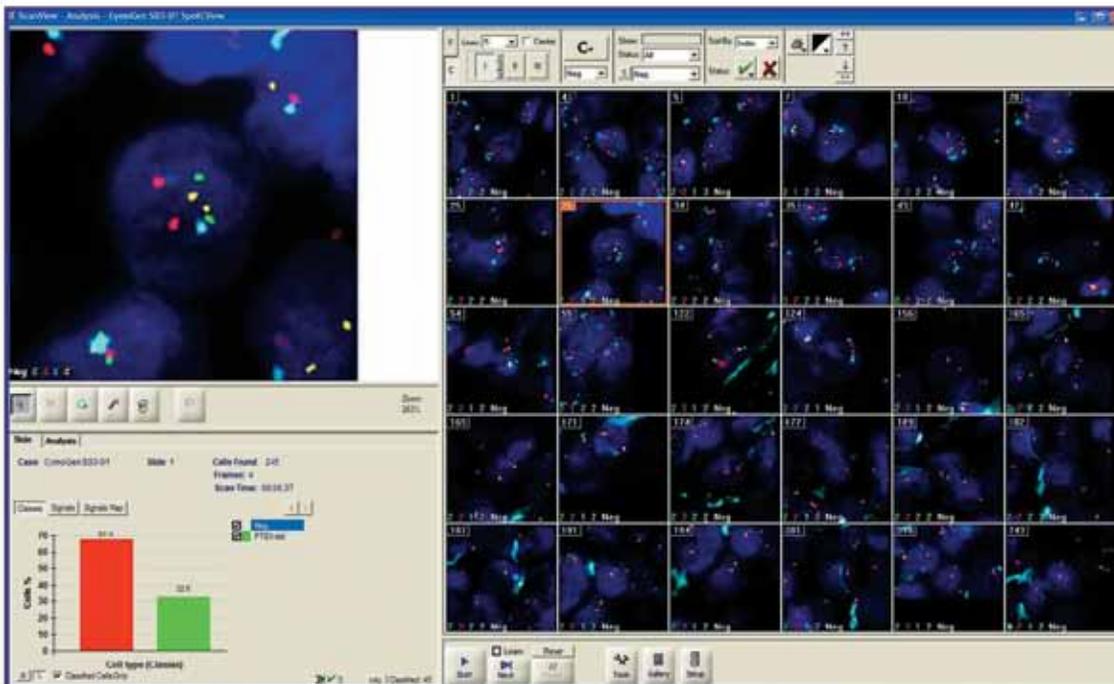
PTEN is one of the most commonly lost tumor suppressor genes in human cancer. For example, up to 70 percent of prostate cancer patients lost one copy of the PTEN gene by the time of diagnosis.

While the FISH prostate kit enables the detection of PTEN deletion, its manual review under the microscope is exhausting and requires a high degree of effort and experience. Four filters need to be switched while the focus is changed to reveal all signals in 3D.

ASI has addressed these issues by developing a computerized 3D capture, image enhancement and analysis solution that has a clear advantage over manual counting in cost saving and manpower efficiency.



Cell zoom view



PTEN using GenASIs SpotScan

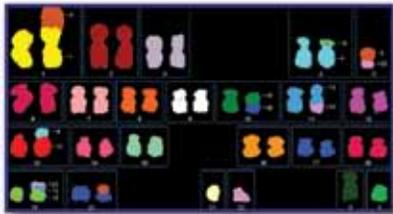
GenASIs HyperSpectral

Spectral Karyotyping

GenASIs HiSKY®, running on the GenASIs HyperSpectral Platform, is designed to be user friendly, simplifying the process of identifying small translocations, insertions, markers and other aberrations. This makes it the Gold Standard Multicolor FISH application.

Traditional karyotyping allows scientists to view the full set of human chromosomes in black and white. Interpreting a karyotype requires an expert who might need hours to examine a single karyotype. Using GenASIs HiSKY, you can easily and efficiently identify the most subtle abnormalities.

For spectral karyotyping of human metaphase chromosomes, 24 chromosome-specific painting probes are used in just one FISH experiment. Each probe is combinatorially labeled with a different subset of the five dyes, resulting in a unique spectral signature for each chromosome. The colorful metaphases are captured by ASI's patented technology for spectral imaging to extract the most detailed information on each point of the chromosome. Together with chromosome banding information from an inverted DAPI staining, a comprehensive overview of chromosomal aberrations is obtained.



Detection of a translocation $t(11; 22)$ using HiSKY in a patient that was diagnosed as having neuroblastoma. This translocation is specific to Ewing sarcoma. Based on the SKY results the diagnosis and the treatment of this patient were changed.

Powerful Flow and Display

Metaphases and chromosomes are represented in eight color options in the karyotype table: enhanced color, band-enhanced DAPI, classified color and any of the five pure cross-talk-free staining colors.



Single Dye concentration



Human Inverted DAPI image

Human Classified image

Human Spectral image

Detection of partial trisomy 21 by HiSKY in a baby with dysmorphic features and cytogenetically normal karyotype :46, XY

Editing Tools

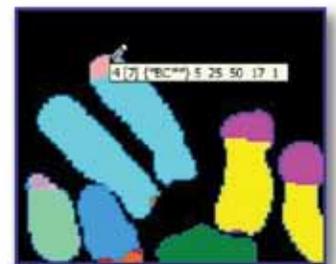
GenASIs HiSKY features intuitive easy-to-use tools to analyze subtle rearrangements and complex translocations.

Foolproof Accuracy

GenASIs HiSKY is known for its precise and robust accuracy. Multiple advanced verification capabilities are included to guarantee perfect results

Spectral FISH

GenASIs HiSKY also introduces Spectral FISH, a module that integrates HiSKY and FISH so that you may easily see and resolve a significant number of spectrally overlapping probes in nuclei imaging.



Tool tip displaying classification results on specific pixels

Reagents—SKYPaint® Probes

Spectral Karyotyping

SKYPaint® Probes are 24-color combinatorially labeled FISH probes specifically designed for GenASIS Spectral Karyotyping (HiSKY®). Kits are available for human, mouse and rat clinical applications. Hybridization procedures with SKYPaint are as simple as standard FISH protocols.

Accurate and Cost Effective

A single hybridization saves time and money in comparison to high-cost multiple hybridizations necessary with other FISH probes. Many high quality HiSKY images can be obtained from just one kit.

Linked to Classical Cytogenetics

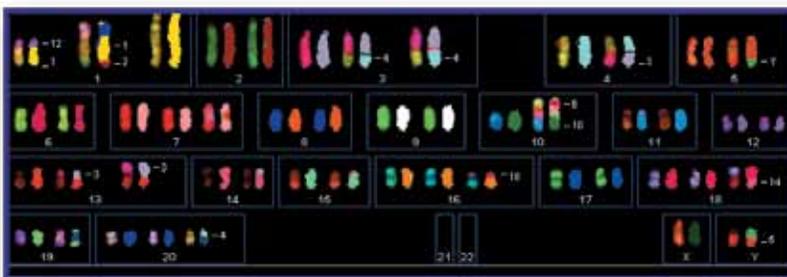
SKYPaint hybridization is identical to familiar FISH protocols, ensuring ease of use. Painting is uniform along the entire length of the chromosome, with superb band enhancement of the DAPI inverted chromosomes.

Effective for a Gamut of Sample Types

Applicable sample types include cancer cell lines, bone marrows, leukemias and lymphomas, lymphocyte preparations, oocytes, amniotic fluid and other species.



SKY paint probes



Rat karyotype



Classified image of mouse cell line. Courtesy of A. Venkitarman, Cambridge University, UK.



Amniocentesis with HiSKY. Unidentified material on chromosome 11 was classified as belonging to chromosome Y

GenASIS Case Data Management - CDM

Unified Patient Data Management and Reporting for All GenASIS Applications

GenASIS Case Data Manager (CDM) is the central portal and database for the entire GenASIS suite. CDM is designed to support the modern paperless laboratory. An integrated multi-application microscopy imaging database with advanced search and reporting capabilities offers statistical analysis and cross-case comparison.

CDM features simple, multi-site data management with real-time case summary and the ability to produce comprehensive reports ensuring comprehensive case analysis.

Security Maintenance

Laboratory administrators can set access rights for each user and lab, to accommodate data access policies based on the laboratory and the organization's protocol.

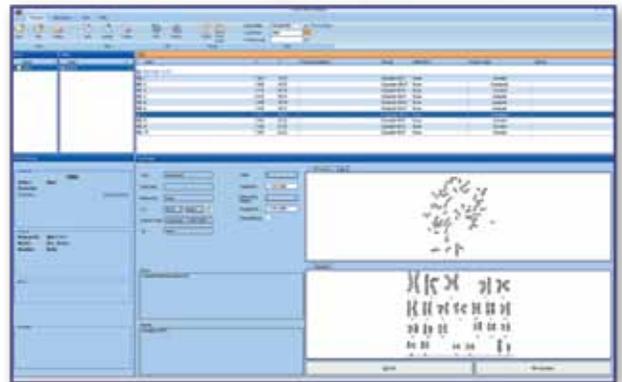
Data Integrity – Archiving and Backup

Data integrity is strictly preserved by allowing archiving and backup of all clinical data to any storage media. The flexibility CDM allows in the selection of archiving and backup media ensures a simple and quick solution for maintaining data integrity. Import and export utilities facilitate easy access to archived material and storage of external data.

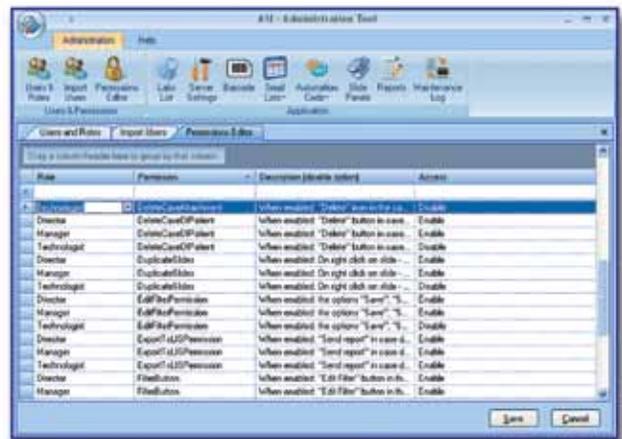
Robust and Flexible Reporting

Multiple reports may be defined in CDM and are available in multiple languages. CDM's advanced reporting tools support customization according to the user's needs with the ability to select which fields, images and format are used in each report.

- Physician reports are automatically generated with data from key fields
- Statistics reports may be easily created, including multi-application summary reports reviewing all sample types in a case
- A freehand report using a choice of annotation styles may include any information or image across multiple cases



CDM Interface



Highlights:

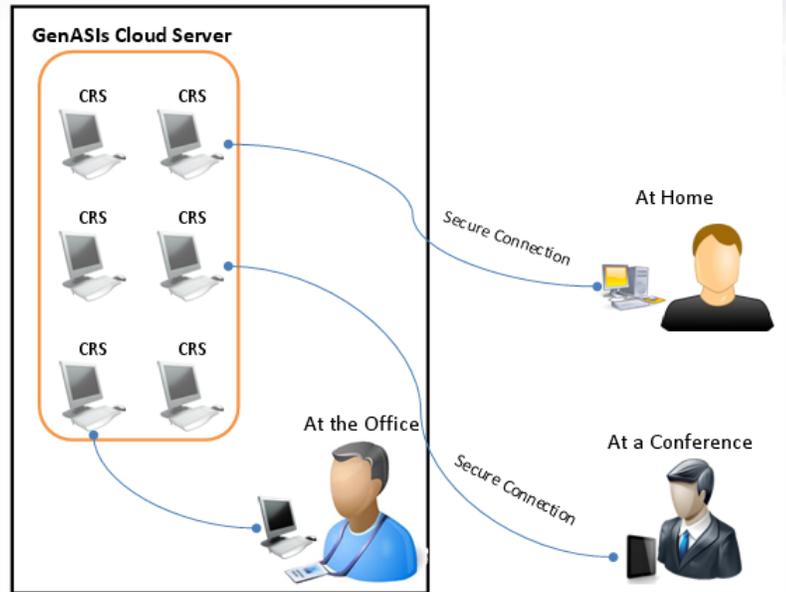
- Integrated, clinical utilities for multi-application support for pathology and cytogenetic
- Flexible data management and storage options may be adapted to the needs of any size laboratory or multiple laboratories.
- Multi-site laboratory support with seamless connectivity for remote clients
- Advanced multiple-user access and user permission management mechanism
- Real time connectivity to LIS systems
- Advanced design supporting the “paperless laboratory” including automated count-sheet update

GenASIs Cloud—Analysis Anywhere

Dedicated Analysis and Review Station

GenASIs Cloud allows GenASIs users to view, analyze and review cases anywhere, with the same tools and functionality as at their laboratory workstations. GenASIs Cloud is installation-free, requiring no software installation on the user's remote computer.

Dramatically reduce costs and increase efficiency by setting up GenASIs Cloud for your laboratory team. Assign each GenASIs user a Cloud Review Station (CRS), a dedicated analysis and review station located on a laboratory server that can be accessed from anywhere, without the need for extra software. Set up multiple CRSs on a single laboratory server empowering each user with remote access to GenASIs systems anywhere, from their PC tablet, mobile device, home computer or even in the laboratory itself.



A CRS is a software-only solution with the functions of an actual 'physical' station but involving no hardware components whatsoever. This means a GenASIs Cloud Review Station far surpasses an actual workstation in mobility, flexibility and cost effectiveness...anywhere.

Server Networking

ASI's servers are optimized and validated to work with all GenASIs products and are integrated with the software in accordance with our ISO certified quality management system which helps comply with HIPAA standards. The size of your lab determines the type of server required, and ASI offers a variety of options.

Distributed Workflows

All GenASIs platforms are designed to enable a smooth lab workflow. As an example, the flow of data entering or importing from a LIS/LIMS, slide scanning, remote relocation, cell analysis, case review and case authorization can be done sequentially on multiple stations in the network.

Flexible Architecture

GenASIs platforms can be configured on single standalone systems or with remote systems that establish additional workspaces.

GenASIs mCounter

A New Age in FISH Sample Manual Counting and Classification

GenASIs mCounter makes manual analysis of FISH samples simpler, quicker and more reliable. The GenASIs mCounter provides FISH technologists with a powerful tool for the manual counting and classification of cells based on a signal pattern. GenASIs mCounter offers laboratory managers simplified and improved technologist training and better laboratory QC and QA, whilst validating results and signing-off cases.

GenASIs mCounter's unique, unified and integrated approach to probe and signal counting allows clinical accuracy in a streamlined workflow. With the GenASIs mCounter software and integrated wireless counting-pad users achieve improved, more efficient and more reliable manual counting and classification of FISH samples.



Integrated Wireless Counting Pad

GenASIs mCounter brings unparalleled performance and efficiency in cases when fluorescent FISH sample cells are classified on signal pattern determining the clinical result.

Multiple probes are supported to match any staining kit. A set of cell classes can be defined for each probe to correlate with the clinical definitions of normal and abnormal cells. Users can map classes to specific keys on the counting-pad. This mapping allows users to quickly and easily count cells without having to look away from the microscope. The mCounter is optionally assisted by an audible indication ensuring an accurate, reliable and comprehensive count. The gathered statistics are displayed both graphically and in an easy-to-read table. Results are recorded in the GenASIs Case Data Manager (CDM) and are integrated into and used by GenASIs' advanced reporting system.

Highlights:

- Saves time and increases accuracy and efficiency
- Easy to use and simple to learn
- Reliable, accurate and comprehensive cell counting and classification
- Quality results leveraging double blind multiple technologists scoring
- Efficient and effective training and QA/QC validation
- Supports any microscope, cell type and signal pattern
- Allows continuous counting focusing on clinical rather than technical aspects of cell classification and counting
- Integrated patient case result management and reporting



Viewing the Summary

The Company

Applied Spectral Imaging (ASI) makes patient care better through advanced biomedical imaging.

The GenASIs Automated Imaging Platforms for Genetic and Pathological Analysis are the foundation of ASI's offering. With superior imaging and analysis capabilities, ASI provides state-of-the-art diagnostic aids, offering cytogeneticists and pathologists accurate analysis. GenASIs enables automated tissue analysis for primary diagnostics, with reproducible and reliable results. GenASIs Hyperspectral with HiSKY® Probes adds a new dimension to biomedical image analysis.

GenASIs is FDA cleared for FISH clinical applications such as UroVysion, HER2/neu, CEP XY and Karyotyping. ASI complies with major regulatory requirements and international quality standards.

ASI is the industry's leading microscopy imaging solution provider since 1993, with over 30 registered patents in the US, Europe and Japan and over 2,500 systems deployed worldwide. With worldwide offices in the US, Europe and Asia, ASI has a global network of over 50 distributors.

Quality and Regulatory Compliance

ASI conforms to ISO 9001:2008 and ISO 13485:2003 quality standards for medical devices and is fully conversant with HIPAA, Health Insurance Portability and Accountability Act requirements for patient privacy and security.

ASI is FDA cleared for in-vitro diagnostic procedures of detection of the following:

- GenASIs BandView to be used for karyotyping with real time microscope images from stained metaphases, for Cytogenetics.
- GenASIs FISHView to be used for karyotyping with real time microscope images from cultured and stained cell specimens in their metaphase. In addition, FISHView is intended as an aiding tool for digitally visualizing, processing, counting and classifying stained cells and storing FISH multi-dye images.
- GenASIs UroVysion designed 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 to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.
- GenASIs HER2/neu FISH for in-vitro diagnosis as an aid to the cytogeneticist/pathologist in the deletion, classification, and counting of cells of interest in tissue specimens from breast cancer patients.

GenASIs SpotScan was cleared to be used as an adjunctive automated enumeration tool for all the above products.

All other applications are intended For Research Use Only.



**ASI is proud to have a worldwide network
of business and service partners.**

For enquiries, please contact your local ASI partner or one of our offices below.
To find your local partner, visit www.spectral-imaging.com
or contact sales@spectral-imaging.com.

Copyright © 2012 Applied Spectral Imaging (ASI) - All rights reserved. Information described in this document is subject to change without notice.
The software described in this document is furnished under licensed agreement. The software may be used or copied only in accordance with the terms of this agreement. No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means electronic or mechanical, including photocopying and recording for any purpose other than personal use of the purchaser, without the written permission of Applied Spectral Imaging Ltd.

North America

Applied Spectral Imaging Inc.
Tel: + 1 760 929 2840

E-mail: sales-inc@spectral-imaging.com

Headquarters

Applied Spectral Imaging Ltd.
Tel: +1 817 886 6031

E-mail: sales@spectral-imaging.com

Europe

Applied Spectral Imaging GmbH
Tel: + 49 6203 923800

E-mail: sales@spectral-imaging.com

www.spectral-imaging.com

DOC000091 Rev. C