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GenASIs Platform for Genetics

GenASIs system platforms are designed to meet requirements of any cytogenetics laboratory, large or small.

ASI’s scalable and modular platform can grow to meet your future laboratory needs. As your caseload demands grow, so can your lab, upgrading your single slide workstations 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.

The table below provides a guideline for GenASIs modular platforms:
Multi Application Imaging Database

GenASIs Case Data Manager (CDM) is the central portal and database for the entire GenASIs cytogenetic suite and is designed to support the modern paperless laboratory environment. CDM’s integrated database with advanced search and report generating capabilities also offers statistical analysis and cross-case comparisons of all data.

Many valuable features are incorporated in the robust GenASIs CDM. You can easily manage data, compare chromosomes and produce comprehensive reports to ensure optimal chromosome analysis. The built-in database can be used to store patient details or connecting to hospital information systems.

Efficient Data Management

CDM can be adapted to all languages with multi-language support and editable labels. It offers cross-application management of all samples for manual and scanning applications, including metaphase and interphase karyotyping, FISH, HiSKY and CGH.

As a powerful search tool, CDM filters specific cases and cells by any field and/or subtext. A flexible image gallery accommodates viewing of all case images.

Security Maintenance

Laboratory administrators can set a separate security level for each user, to allow system access according to protocol.

Archiving and Backup

Archiving and backup to any storage media minimizes the need for system administration. All textual data and representative images are saved in the database even after archiving. Import and export utilities facilitate easy access to archived material and storage of external sample data.
Flexible Report Generator

Multiple reports are available in multi-languages and support customization according to user choice of fields, images and format.

- Physician reports are automatically generated with data from key fields.
- Statistics reports are easily created, including physician’s name, referral details and test results, with a choice of multiple images.
- Multi-application summary reports review all sample types in a case.
- A freehand report using a choice of annotation styles can include any information or available images across multiple cases.

Chromosome Comparisons

A flexible comparison tool compares chromosomes within or across cases of multi-clinical applications.

Paperless Laboratory Design

Various management workstations can be set up to review, compare and summarize results and organize statistics. Data is accessible from any workstation in the network, with no requirement for tedious paperwork.
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 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.
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.

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

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.

Cost Savings
using
GenASIs Scan & Analysis Platform

Studies show
work hour savings of 50–67%

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

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<table>
<thead>
<tr>
<th>Automation</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescan</td>
<td>1</td>
</tr>
<tr>
<td>Scan</td>
<td>2</td>
</tr>
<tr>
<td>Accept Best Cells</td>
<td>3</td>
</tr>
<tr>
<td>Auto Oil Dispense &amp; Smear</td>
<td>4</td>
</tr>
<tr>
<td>Automatic High mag (100x)</td>
<td>5</td>
</tr>
</tbody>
</table>

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

- **8 am**
  - Blood
  - Karyotyping
  - Auto Scan 10x
  - Auto Detection
  - Auto Capture 100x
- **10 am**
  - Blood
  - Karyotyping
  - Auto Scan 10x
- **12 pm**
  - Blood
  - Karyotyping
- **2 pm**
  - Blood
  - Karyotyping
- **4 pm**
  - Blood
  - Karyotyping
  - Auto Scan 10x & 100x
- **Night Scan**
  - Blood
  - Karyotyping
  - Auto Scan 10x & 100x

*Images of system usage and diagrams are shown.*
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

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, CGHView for high-resolution CGH 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.
FISH technology is at the forefront of biomedical clinical and research development, demonstrating high accuracy in diagnosing disorders such as hematological malignancies, breast tumors and bladder cancer with genetic markers such as BCR/ABL, HER2/neu and UroVysion. The necessity for easing the workload, expediting the process of slide visualization and signal counting of various FISH probes, is becoming more and more important.

GenASiS FISHView®, running under the GenASiS Capture and Analysis platform, is a convenient, flexible FISH capture and analysis system designed to meet the demands of medical research and the rigors of the clinical lab.

**Powerful Automated Multi-layer Imaging**

Automatic image exposure and enhancement, together with the auto-conversion of image sequences at various focal planes (3D Z-stacking), makes image acquisition highly efficient. Original image data is always preserved and various color display modes offer the possibility of exact illustration of the required information.

**Timesaving Image Enhancement and Reports**

Automatic background correction, as well as manual or automatic contrast, brightness and sharpness adjustments, enable optimal display of the faintest signals in a few seconds. Multiple report templates are available with the ability to customize with annotation tools.

**Integrated Karyotyping Module**

FISHView includes full karyotyping support with unique band enhancement and signal sharpening.

**Quantitative Imaging**

Researchers benefit from the quantitative signal and object analysis module incorporated in FISHView. Cell or object segmentation, followed by morphology and intensity analysis, provides full freedom to extract the exact data required.

**mCounter**

Counting by intuitive use of the mouse and keyboard replaces existing lab counters and enables you to easily spot count for numerical changes, or classify cells according to their signal pattern, instantly providing statistics for customized reports.
HR-Comparative Genomic Hybridization (CGH)

GenASIs CGHView, running under the GenASIs Capture and Analysis platform, is an extension to ASI’s FISHView. CGHView, is a high resolution application with superb imaging capabilities and full karyotyping support. CGHView incorporates a simple training scheme to automatically extract error probability. You can define gains and losses based either on fixed or variable limits (confidence intervals) and display profiles and gain/loss bars for all case chromosomes. Automatic DAPI inversion and superb band enhancement make classification simple and fast. A choice of multiple display options allows you to view the metaphase in original color or in pseudo colors to highlight gains and loses. Easily generate statistics and compare cells and cases and print customized reports.

Reagents—Whole Chromosome Paints (WCP)

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.
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 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.

### Automatic Cell Signal Detection & Classification

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

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.

High Throughput

Similar to MetScan, the GenASIs Scan and Analysis platform 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.
Detection of HER2/neu Gene Amplification in Breast Cancer Biopsy

Whether performed as a single test or as part of a breast panel, SpotScan analysis is a valuable aid to the pathologist in the clinical laboratory. Included in SpotScan is an advanced module to scan and analyze HER2/neu tissue samples with either manual or automatic microscopes.

Because of the complexity of the sample, automated tissue analysis is typically inefficient due to poor performance in segmentation and signal detection. ASI’s unique flow and algorithms have overcome this barrier with superior cell segmentation and signal counting of the most complex tumor samples. Exact spot count is calculated per cell even with signal clusters (HSRs). Interactive free-hand definition of tumor regions offers recursive region-in-region inclusion for complex tissue sections. The end result is a gallery of identified cells displayed with corresponding classification and statistics.

Automated UroVysion

ASI’s unique solution for UroVysion dramatically improves quality in throughput, giving a clear advantage in cost savings and manpower efficiency over manual counting.

A preliminary low magnification density scan ensures the fastest throughput. Full color control and advanced display options are available to enable the fastest and most accurate review. You can approve, reject or modify system-assigned cell classifications and produce summary reports.
PTEN Prostate Four Color FISH

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.
Spectral Karyotyping / Multicolor FISH

GenASIs HiSKY®, running on the GenASIs Spectral 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 HiSKY, you can easily and efficiently identify the most subtle abnormalities.

For SKY 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.

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.

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

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

Spectral FISH
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.
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.
GenASIs Cloud—Analysis Anywhere

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 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.
The Company

Applied Spectral Imaging (ASI) is a privately held company founded in 1993. ASI is a leading developer and manufacturer of comprehensive solutions for imaging and data management in the cytogenetics and pathology fields. ASI's superior image capture (acquisition) and analysis utilities are the basis for its state of the art diagnostic aids. All solutions are integrated into the Laboratory Information System (LIS), which incorporates the Picture Archive Communication System (PACS).

Applied Spectral Imaging is committed to excellence and accuracy, striving to remain a leader in cutting edge technology for cytogenetic and pathology diagnosis. It is dedicated to maintaining a supportive environment for all laboratory staff including physicians, technologists and technicians.

ASI's GenASIs platforms with multiple application modules are geared towards diagnosing pre- and post-natal disorders and diseases such as cancer, and are suitable for clinical and research use world-wide.

Full product coverage, from basic manual operations with existing laboratory microscopes, all the way to fully automatic operations including slide manipulation, scanned acquisition and fully automatic analysis diagnostic tools, are all interconnected through a laboratory communication network to allow team work, supervision, peer review and a paperless environment, at a single or multi-site laboratory.

Quality and Regulatory Compliance


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.

• 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 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.

GenASIs SpotScan is to be used as an adjunctive automated enumeration tool. 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.