

Company Profile

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

The **GenASIs** automated imaging platforms for genetic and pathological analysis provide state of the art diagnostic aids for cytogeneticists and pathologists. **GenASIs** platforms enable automated tissue analysis for primary diagnostics, with reproducible and reliable results. **GenASIs** Hyperspectral with HiSKY® Probes provide superb biomedical analyses surpassing the abilities of normal human vision.

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

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



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Quality and Regulatory Compliance

ASI conforms to ISO 9001 and ISO 13485 quality standards for medical devices and is compliant with HIPAA.

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 gene scanner used for lung cancer therapy selection
- GenASIs BandView used for karyotyping with real time microscope images from stained metaphases, for cytogenetics.
- GenASIs FISHView used for karyotyping with real time microscope images from cultured and stained cell specimens in their metaphase. In addition, 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

GenASIs Scan & Analysis has been cleared to be used as an adjunctive automated enumeration tool for HER2/neu, UroVysion and ALK only.

All other applications are intended for research use only:

- **GenASIs HiPath** – a computer aided evaluation for IHC and CISH assays that assists pathologists in reaching accurate, repeatable and standardized results.
- **GenASIs HiSKY** – a high resolution spectral karyotyping analysis system.
- **GenASIs SpectraView** – an image acquisition and analysis tool combining spectroscopy, multi-dimensional imaging and computing for hyperspectral image analysis.

ASI's scalable and modular platforms are designed to meet current and future laboratory needs. As your caseload increases, so can your lab's capacity, enabling growth from a single slide stations to 9-slide or 81-slide scanning stations, additional workstations, dedicated servers, and modular LIS/LIMS connection to automate your workflow.



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