AUTOMATED FISH

A comparative study conducted at an independent clinical laboratory to evaluate the performance of ASI's automated FISH scanning and analysis solution, GenASIs™ SpotScan, compared to unassisted manual analysis.

The purpose of the study was to determine whether GenASIs SpotScan yields time saving benefits, while still maintaining concordance with manual analysis.

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CLINICAL STUDY

Principal Researcher
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The principal researcher in this study holds board certification in cytogenetics from the American Board of Medical Genetics, and in cytogenetics and oncology molecular detection from the New York State Department of Health. He earned a PhD in genetics and developmental biology from West Virginia University with thesis research at Duke University. He received his post-doctoral training in cytogenetics at the University of North Carolina at Chapel Hill.
The principal researcher's responsibilities at the clinical lab include chromosome/ FISH diagnosis and interpretation of prenatal, postnatal, and oncology samples; development and expansion of FISH and single-nucleotide polymorphism (SNP) microarray techniques and analysis; and literature review for related cytogenetic cases. He is a fellow of the American College of Medical Genetics and a member of the American Society of Human Genetics.

Background

Abstract

Applied Spectral Imaging ("ASI") conducted a comparative study at an independent clinical laboratory to evaluate the performance of its automated FISH scanning and analysis solution, GenASIs SpotScan, compared to the "gold standard" manual analysis.

The purpose of the study was to determine whether GenASIs SpotScan yields time saving benefits, while still maintaining concordance with manual analysis.

GenASIs integrates with the lab's existing hardware and workflow, automating key aspects of the lab's workflow.

Conclusion

GenASIs SpotScan successfully reduced Full Employee Time (FET) by an average of 55%, while maintaining an average clinical concordance of 98.5% in auto-detection of abnormal cell

GenASIs

The GenASIs Platform system is an image capture and analysis platform for brightfield and fluorescent microscopy. GenASIs SpotScan is an application that integrates with an automatic microscope outfitted with a 9 slide stage (and optional 81 slide robotic tray loader), which automates image capture and analysis by scanning and classifying the FISH samples.

Scanning begins at a low magnification to determine cell density throughout the scanning region. Scanning continues at high magnification, returning to the best regions for scanning and image capture.

ASI's algorithms automatically segment, classify cells and enumerate signals while coping with faint signals, background noise non-specific staining and signal-like debris. The cells are then presented in a review gallery together with valuable information such as probe signal count and cell classification for each individual cell scored.

The FISH technologist or director then reviews the results and has the ability to reassign cell classification as needed. Once analysis is completed, a report can be generated with case imagery and statistics.

Method

The study compared the analysis time and the concordance of the clinical analysis of 130 FISH slides, consisting of 10 unique samples for 13 different FISH probes.

FISH Probes:

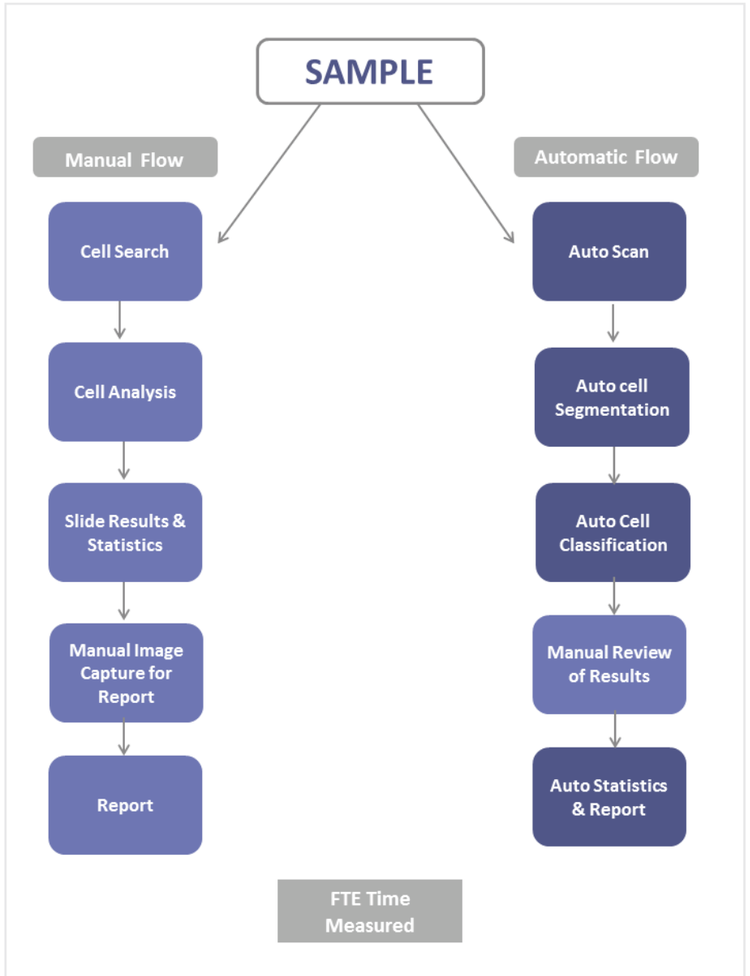
BCR/ABL + ASS, ATM, 4;14, 1P1Q, ETO/AML1, INV16, 5Q, 7Q, MLL, PML/RARA, 11;14, 13Q, 14;16

The results of the GenASIs SpotScan were compared to the "gold standard" manual analysis.

Each sample was analyzed using the lab's manual scoring procedure. Separately, each sample was subsequently scanned using the GenASIs SpotScan and reviewed manually by the lab technologist.

The clinical results and technologist's analysis/review time required for each test were then compared.The clinical comparison was applied to both abnormal and normal case results, as well as overall abnormal cell count per probe.

GenASIs SpotScan enables scanning of 300-600 cells in 4-10 minutes, which allows scanning of large quantity of slides.
Overnight scanning ability provides an optimized workflow solution for large slide capacity, by ensuring that the FISH cells are ready for review upon arrival of the FISH technologists.



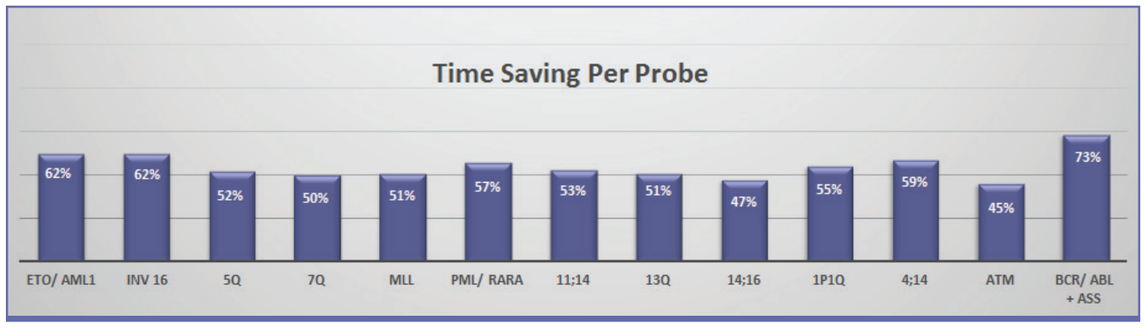
Results

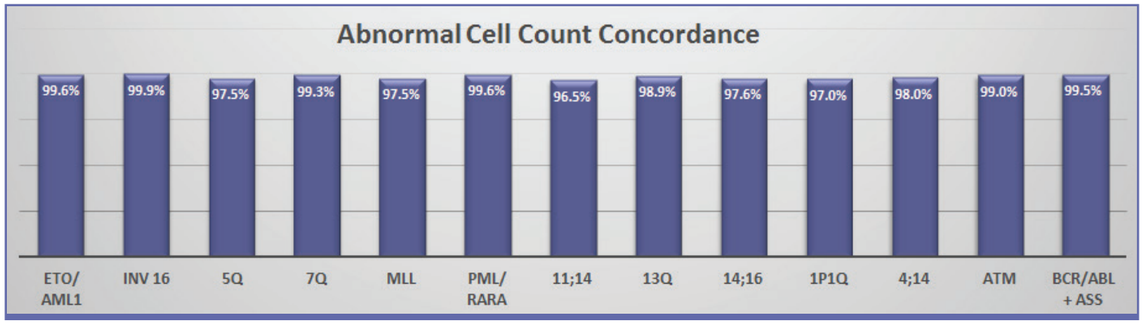
As each probe requires a different amount of cells to be reviewed, and different patterns and signals counted, the GenASIs SpotScan's time savings ranged from 73% with probe BCR/ABL to 45% for probe ATM. On average, 55% FTE savings were achieved when using the GenASIs SpotScan.

Abnormal patient concordance examined clinical results, with "normal" or "abnormal" being the two possible outcomes. When using the GenASIs SpotScan, a 100% concordance was achieved in 7 out of 13 probes, and 90% in 5 out of 13 probes, resulting in an overall concordance for all probes of 95%.

To determine abnormal cell count concordance, the study examined the overall percentage of normal and abnormal cells per probe (i.e., all 10 unique samples per FISH probe were aggregated to give an overall percentage of abnormal and normal cells, thereby standardizing the statistics between the higher cell count of automated FISH compared to manual FISH.

When using GenASIs SpotScan, concordance ranged from 96.5% to 99.9%, with 6 out of 13 probes obtaining concordance of 99%, which resulted in an average concordance for all probes of 98.4%.





55% average time saving, and 98.5% average clinical concordance in auto-detection of abnormal cells between GenASIs SpotScan and manual diagnosis.

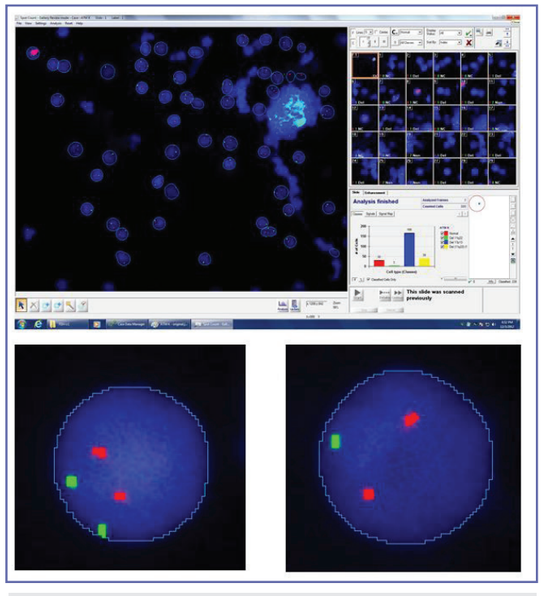
Conclusion

The saving in FTE and high concordance of clinical results positions GenASIs SpotScan as an effective solution for significantly reducing FTE related costs and increasing lab efficacy by automating key aspects of the lab's workflow.

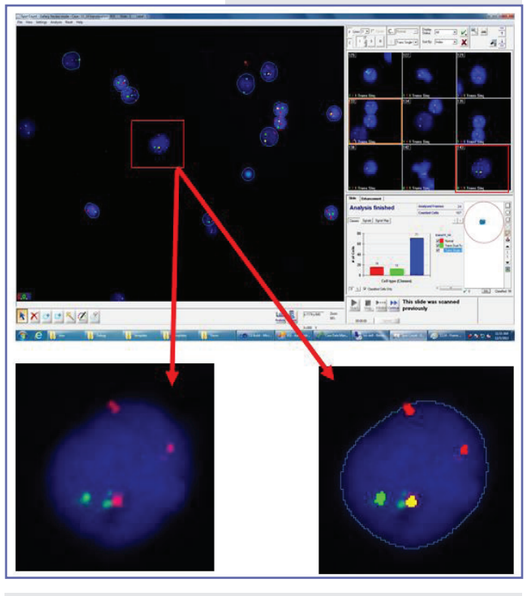
Additional key benefits identified in the study, include faster turnaround times, increased employee confidence in the results and greater workplace comfort.

The lab valued additional time saving aspects which were not part of this study, such as automatic statistics calculation and generating customized reports complete with images and statistics.

100% Concordance	90% Concordance	80% Concordance
INV16	ETO/AML	5Q
MLL	7Q	
11;14	PML/RARA	
1P1Q	13Q	
4;14	14;16	
ATM		
BCR/ABL		



Screen shot of probe ATM with enlarged view of normal cell (bottom left) and cell with deletion (bottom right)



Probe 11;14 with fusion (bottom left) and with superimposed computer analysis (bottom right)

Key Benefits

Speed

Automatic scanning does not require employee attendance.

Consistency

Automated cell classification ensures consistent high quality and accurate results by a common laboratory standard.

All cells used for the analysis can be saved and reviewed at a later time

Confidence

All relevant cells within each frame are analyzed, including complex cell clusters, to achieve better statistics

Cells are segmented and classified accurately with signal and cell detection algorithms

Training

Pre-analyzed sample clinical results can be used as a training and teaching tool

Computerized case archive used to retain laboratory knowledge base

Comfort

FISH samples are scanned in a dark room, while the review can be performed anywhere in the lab

Reports are available for multiple cases and analysis

Compliments of Applied Spectral Imaging

FDA cleared for the following GenASIs applications:
ALK, BandView, FISHView, UroVysion, CEP XY & HER2/neu FISH

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