



CytoVision*

Bring cellular and tissue FISH out of the dark

Tissue FISH

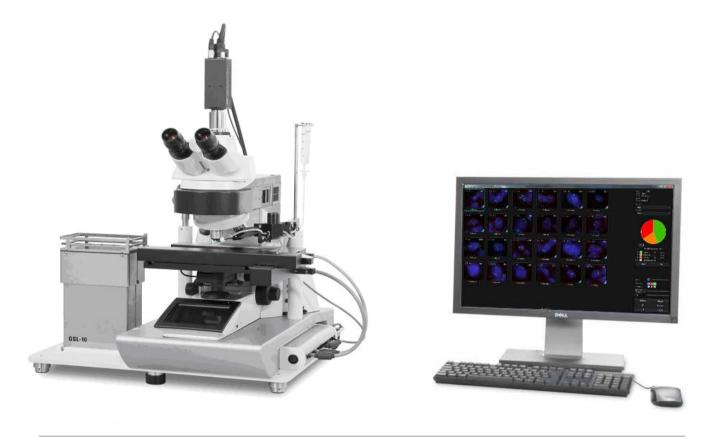


Figure 1: GSL-10 performing cellular FISH scanning and analysis

CytoVision* version 7.3.1 Tissue FISH module is flexible, supporting fully automated workflows to manually directed capture and analysis.

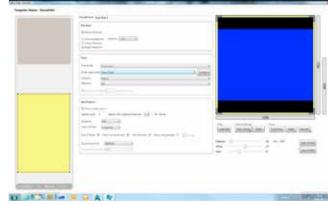


Figure 2: Tissue FISH scan template in full auto mode, set to pre-scan and detect etched areas of the slide, auto capture and auto camera setup.



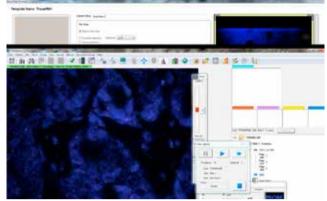


Figure 3: Assay setup in the CytoVision* Tissue FISH module is simple and fast, ideal for diagnostic applications where consistent results are of most importance. Templates can be quickly reused for multiple assays further reducing set up time.

Figure 4: Automatic capture of tissue FISH

Low power scanning (10X) locates interphase cells. Frames are then captured at high power with DAPI masking of probe signals to eliminate extraneous fluorescence outside of cells. Proprietary Adaptive Image Processing algorithms are then used to classify cells based on user defined morphology. Cells that meet the classification are captured and displayed as frames ready for manual or automatic scoring.

The fully automated Tissue FISH workflow finds areas of slides marked up by etching the slide, for FISH hybridization.

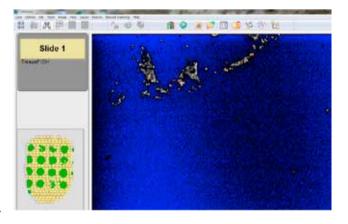


Figure 5: CytoVision* 7.3.1 scanning a tissue FISH slide. The areas where probe signal has been detected are coloured green. The capture frames have been assigned automatically in an optimised layout within the etched area of the slide.

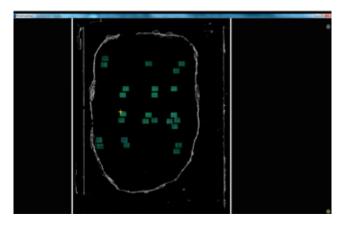


Figure 6: Overview screen showing etched area of slide and 5 x 5 grids of capture frames. From here the user can directly select and view capture frames and scores at high magnification.

Cellular FISH

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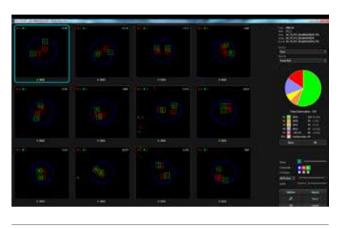


Figure 9: Cellular FISH case, each frame displays signal score and classification. The interactive pie chart shows the percentage of each class allowing rapid review, sorting, re-classification and reporting.

CytoVision* version 7.2 introduced new levels of accuracy and easy of use to cellular FISH scanning and analysis. Now version 7.3.1 introduces further refinements of automated FISH scoring for break-apart, enumeration, and fusion assays. Display scored cells in a grid for easy viewing and sorting of cells assigned to each class. Interactive pie charts and keyboard controls allow rapid review of automated scoring and statistical assessment.

<u>Leica</u>	1111 Nowhere Road Where Ever, CA 0000 Client Services: 888.888.888 Fax: 888.888.888	A.N. Other, M.D Laboratory Director CLIA I.D. # XXXXXX CAP #: XXXXX	
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Reports

Reports produced by Cytogenetics laboratories are the most valuable part of the work performed, but they can also be time consuming. CytoVision* version 7.3.1 introduces a new report tool dedicated to reporting cellular and tissue FISH cases. Laboratories simply need to create a template for their reports in Microsoft Word. Most objects in the FISH analysi modules can then be added to the report with a single click. CytoVision* reports not only look great, they also save time and add value to your lab's work.

Multisession scoring

Traditional multisession scoring (also know as blind scoring) is a manual process performed post hoc on cases. CytoVision* version 7.3.1 introduces the ability to perform 2 scoring sessions on the same case, independently. At the end of both sessions the users are presented with a summary

result of their individual and average scores to allow the reporting of a concurred interpretation of the result.



Figure 10: Multiple scoring sessions of the same case. Two users have the option to score the case independantly and then review the average scores from the two sessions.

Find out more

CytoVision* version 7.3.1 is available with new systems and as an upgrade to existing systems. To find out more and discuss how CytoVision* can help your laboratory please contact your Leica representative.



CYTOVISION* VERSION 7.3.1 – INTENDED USE

The CytoVision* Image Analysis and Capture System is a rapid metaphase finder, image acquisition and computer aided chromosome analysis system which assists the operator in viewing the chromosome display and looking for cellular anomalies. CytoVision* enables a qualified Cytogeneticist to rapidly and accurately analyze the chromosome banding pattern.

All diagnostic decisions are made by the qualified clinician.

Regions where CytoVision* is available for clinical/diagnostic use

	Karyotyping	CEP XY	CGH	R X FISH	M FISH
USA	Approved	Approved	Re	search only	
EU	Approved	Research only	Re	search only	
Australia	Approved	Research only	Re	search only	
Brazil	Approved	Research only	Re	search only	
Canada	Approved	Research only	Re	search only	
India	Approved	Research only	Re	search only	
Japan	Approved	Research only	Re	search only	
Jordan	Approved	Research only	Re	search only	
Malaysia	Approved	Research only	Re	search only	
Mexico	Approved	Research only	Re	search only	
Republic of South Africa (RSA)	Approved	Research only	Re	search only	
Russia	Approved	Research only	Re	search only	
South Korea	Approved	Research only	Re	search only	
Thailand	Approved	Research only	Re	search only	
Turkey	Approved	Research only	Re	search only	

United States of America

In the US, CytoVision* is approved for In-Vitro Diagnostic Use for CEP XY and Karyotyping.

CytoVision* CEPXY_ENG is an accessory to the CEP® X Spectrum Orange™/CEP® Y Spectrum GreenTM DNA Probe kit (Abbott Laboratories. Abbott Park, Illinois, U.S.A) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants. **Rx Only**

Rest of World

CytoVision* Karyotyping is approved for In-Vitro Diagnostic Use in the following regions: Europe, Australia, Canada, India, Japan, Russia, South Korea and Thailand

All diagnostic decisions are made by the qualified clinician.

CytoVision* systems can also assist the operator in the following Research Applications: Flexible Karyotyping (plants and animals), Fluorescence In-Situ Hybridization (FISH), FISH Spot Counting, Comparative Genomic Hybridization (CGH), RxFISH Color Chromosome and M-FISH Color Chromosome Image Acquisition and Analysis. A **Research Application** is an application which is not intended for in-vitro diagnostic or clinical use, but is intended solely for use in the research setting, for example university or pharmaceutical development. These applications are described as Research Applications or **Research Use Only.**

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