oncoFISH® her2

FULLY AUTOMATED MICROSCOPY APPLICATION FOR THE DETERMINATION OF HER-2 STATUS* BY FISH ANALYSIS

*FDA cleared for the assessment of patient HER-2 status utilizing Abbott Molecular's PathVysion® HER-2 reagents.

ikonisys

FINDING THE CELLS THAT MATTER

oncoFISH® her2

Now you can focus on what's important—getting valuable results back to your clinicians

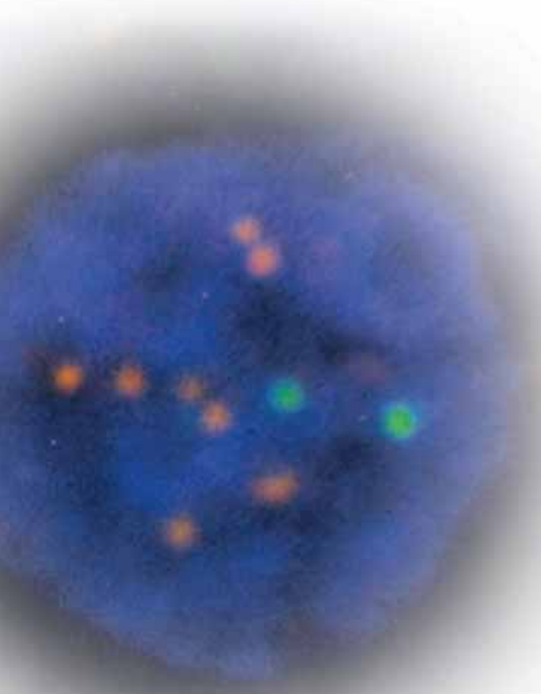
oncoFISH® her2 is an FDA-cleared automated application for the determination of HER-2 status in human breast cancer specimens processed with Abbott's PathVysion® HER-2 DNA Probe Kit*.

Automate the laborious steps associated with HER-2 FISH analysis. The *oncoFISH* her2 application provides walk-away functionality by automating critical process steps:

- Colocalization of areas of interest on H&E slides with the corresponding FISH slides
- FISH slide scanning
- Preliminary classification of cells

Automated slide imaging and analysis is performed on the revolutionary Ikoniscope® Digital Microscopy System with integrated brightfield slide scanner and application-specific Ikonisoft® Image Analysis Software.

The Ikoniscope images and scores PathVysion® HER-2 slides by enumerating the probe signals, analyzing the HER-2/CEP17 ratios, and presenting a digital gallery of classified cells for review. It provides a highly efficient means of generating valuable, accurate laboratory results. And it runs right in your lab—no darkroom required!

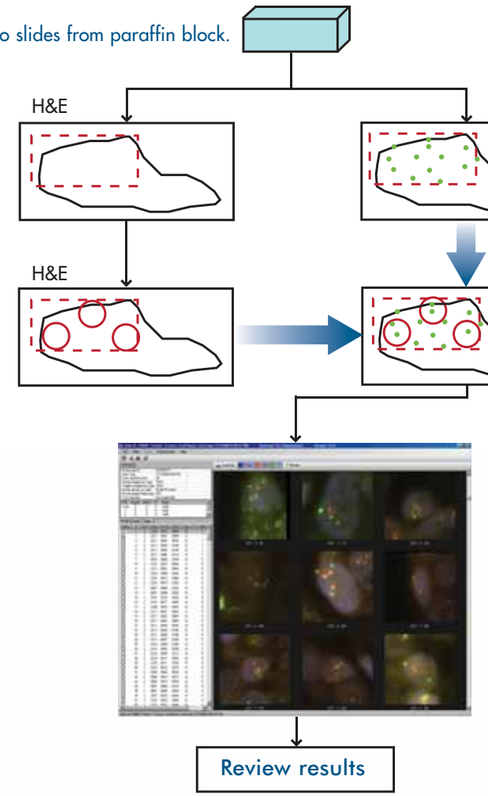


Orange and green fluorescence represent copies of HER-2 and CEP17, respectively. HER-2/CEP17 ratios are automatically calculated from selected cells.

Benefits of *oncoFISH* her2

- **Detects, enumerates and classifies cells** for review with fully automated intelligent microscopy.
- **Reduces subjectivity and risk of human error** associated with fatigue.
- **Documents** that the **areas of interest** highlighted on an H&E slide have been analyzed on the corresponding FISH slide.
- **Speeds turnaround time**, delivering PathVysion® HER-2 results in as little as 20 minutes.
- Increases overall **workflow efficiency** by reducing operator attended time.
- **Enables high throughput**, with the option of unattended overnight FISH slide processing.
- **Eliminates work in the darkroom**.
- **Focuses on critical interpretation and reporting**, rather than reading slides.
- Delivers the **outstanding sensitivity** of FISH analysis.
- **Maintains a record** of the scoring process.

oncoFISH her2 simplifies your work by automating critical process steps



2. Prepare H&E slide.
3. Use the high resolution slide scanner to enter the tissue into the system.
4. From the H&E slide, determine the area to apply FISH probes (dashed rectangle).
5. Digitally mark the cellular areas of interest (circles).
6. Apply fluorescent probes to FISH slide.
7. Place FISH slide in Ikoniscope—and **Press Start** (the remainder of the process is automated).
8. The areas of interest on the H&E slide are mapped to the FISH slide.
9. Cellular areas of interest are analyzed by the Ikoniscope.
10. Fluorescent signals and classification are presented for review.

*The PathVysion® HER-2 DNA Probe Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.

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FINDING THE CELLS THAT MATTER

Automated microscopy imaging and analysis meets laboratory needs—today and tomorrow

The Ikoniscope is a robotic walk-away microscopy system for whole slide digitization and analysis. It performs fluorescent digital imaging and preliminary analysis of whole slides processed for *in vitro* diagnostic applications, automating a complicated and time consuming manual procedure.

The Ikoniscope goes far beyond other systems to improve workflow, speed turn-around time, and provide capacity for a larger menu of diagnostic tests. And, by eliminating tedious manual tasks, it provides a real solution to the shortage of laboratory professionals, allowing them to focus on interpreting results.

The Ikoniscope is the most efficient method of generating valuable, reliable information from FISH-processed slides.

True walk-away functionality—just load the slides and the Ikoniscope does the rest, completely unattended.

Easy fit into any laboratory setting—no darkroom required.

Easy to maintain—uses dry lens optics (no oil required). Remote diagnostic capabilities facilitate troubleshooting.

Comprehensive scanning, with exceptional sensitivity and speed—dramatically increases the amount and quality of data generated, making the Ikoniscope particularly well-suited for early detection of abnormal and rare cells.

Ultra-high resolution imagery—maximizes signal intensity and signal-to-noise ratio, for exceptional image quality.

Large 175-slide load capacity—increases lab throughput and sample capacity.

Integrated Ikonisoft Analysis Software—provides application-specific whole slide or area of interest scanning and algorithmic analysis, eliminating subjectivity and increasing repeatability. Secure digital data can be accessed in real time or on demand.

Integrated IkoniLAN® server—networks with other Ikoniscopes or virtually any laboratory information system, facilitating data sharing and reporting, on site or remotely.

Automate the PathVysion® HER-2 DNA Probe Test

Focus on valuable her2 gene analysis—not the process

Eliminate the tedium of processing and evaluating Abbott PathVysion® HER-2 slides with *onco*FISH her2 and the Ikoniscope. Focus on delivering timely, high value results to your clinicians. To learn more, visit us at **www.ikonisys.com/her2** or call us at **203.776.0791**.

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43-0006-06 Rev A Printed in USA