Instant Quality FISH. The name says it all.

HER2 IQFISH pharmDx™
IQ: Instant Quality every time.

Dako’s new IQFISH hybridization buffer is revolutionizing cancer diagnostics

The cutting-edge IQFISH* hybridization buffer, introduced by Dako, reduces diagnostic test turnaround time from ~18 hours to less than 4 hours.

Pathology labs can now perform DNA-based hybridization assays in much less time, with higher fluorescent signal intensity for better results compared to traditional FISH assays (1). This represents a major advance for pathologists and oncologists, and ultimately for patients.

IQFISH hybridization buffer is free from formamide, making it a safer choice for your staff and the laboratory environment.

HER2 IQFISH pharmDx™ is the first FDA-approved product that uses the revolutionary, non-toxic IQFISH hybridization buffer. Top-quality stains, combined with diagnostic certainty, speed and safety. That’s real progress.

* Patent pending
“In summary, the 1-day HER2 IQFISH approach is a potent method for the determination of HER2 status offering some relevant advances further to the short incubation time, including enhanced tissue integrity and preserved fluorescent signal intensity when compared with the conventional HER2 FISH kit (2).”


Timeline for IQFISH procedure vs. traditional FISH
IQFISH: Setting new standards for quality and speed.

In cancer diagnostics, providing the right diagnosis to the right patient on time is everything

**Top quality:** Enhanced visualization of morphology and bright signals help pathologists identify cancer cells more easily. Crisp, clear signals make counting accurate, easy and fast.

**Fast:** Hybridization takes only 1 to 2 hours with IQFISH hybridization buffer. Enhanced staining quality and a total turnaround time of less than 4 hours from dewax to counting. The ultimate combination of quality and speed.

**Accurate:** The robust assay delivers accurate results with high concordance to other FDA-approved FISH assays (3, 4).

**Non-toxic:** Protect the health and safety of your lab personnel by eliminating their exposure to formamide, which can cause harm to the fetus.
“IQFISH provided excellent quality signals without any background staining.”

“As a rule, DAPI stain and red and green signals were brighter with IQFISH than with FISH.”

“The highly concordant data support IQFISH as a useful alternative to FISH, allowing reliable assessment of HER2 status. Use of this method could lead to reporting of HER2 status to the oncologist within a day (5).”


HER2 IQFISH pharmDx™

- Quantitatively determines HER2 gene amplification
- Identifies patients with breast or gastric cancer likely to benefit from Herceptin® (trastuzumab) treatment

Outstanding concordance to traditional FISH

Concordance to HER2 FISH pharmDx™ of 98.6% for gastric cancer and 99.2% for breast cancer (3). Concordance to PathVysion® of 100% for breast cancer (4).

Brighter signals within 1 hour (1)

Time-chase comparison of HER2 DNA FISH signal intensities using IQFISH hybridization buffer and formamide buffer on FFPE breast carcinoma tissue sections. The black bars represent the 95% confidence interval (n=45 signals).
IQFISH: Save time, reduce costs and increase quality.

A study was conducted to compare two FDA-approved HER2 kits on almost 1500 patient samples tested over an eight-month period by ProPath Services. The results showed that HER2 IQFISH pharmDx™:

**Saves time**
- Less hands-on time and reduced risk of errors
- Shorter turnaround time
- Reduced scoring time

**Reduces costs**
- Less repeat testing
- Reduced hands-on time
- Shorter interpretation time

**Increases quality**
- Brighter signals
- Improved signal/background ratio
- More accurate analysis

Download the white paper at [www.dako.com/iqfish-study](http://www.dako.com/iqfish-study)

HER2 IQFISH pharmDx™ stains of HER2 amplified (current page) and HER2 non-amplified breast tumors (opposite page). See acknowledgement.
HER2 IQFISH pharmDx™ kit includes:

- Dual-target probe mix (HER2/CEN-17)
- Pre-treatment solution
- Pepsin, ready-to-use
- Pepsin diluent
- Stringent wash buffer
- Wash buffer
- Fluorescence mounting medium, with DAPI
- Coverslip sealant

“In our opinion, the improved signal to background ratio generated by the HER2 IQFISH pharmDx™ assay allowed for a more accurate determination of copy numbers for both HER2 and the control probe. The HER2 IQFISH pharmDx™ assay also required significantly less time to score (6).”

Cohen and Alsobrook, 2014.

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Relentless in our commitment to fighting cancer. Together.

Acknowledgement

Special thanks to ProPath Services for supplying the stains presented in this brochure. The presented FISH images have not been edited or manipulated and are published in their original format as provided by ProPath Services, not in any way affiliated with Dako, an Agilent Technologies Company.

References


3. Internal validation studies as referenced in the package insert for the HER2 IQFISH pharmDx™ kit.


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