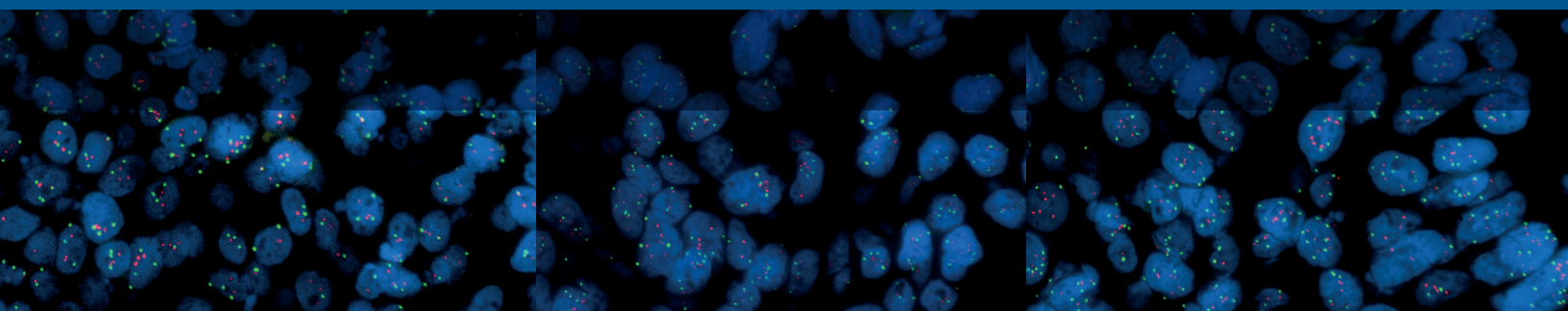


# HER2 IQFISH pharmDx on Dako Omnis

Integrate fast, high-quality FISH into your IHC workflow

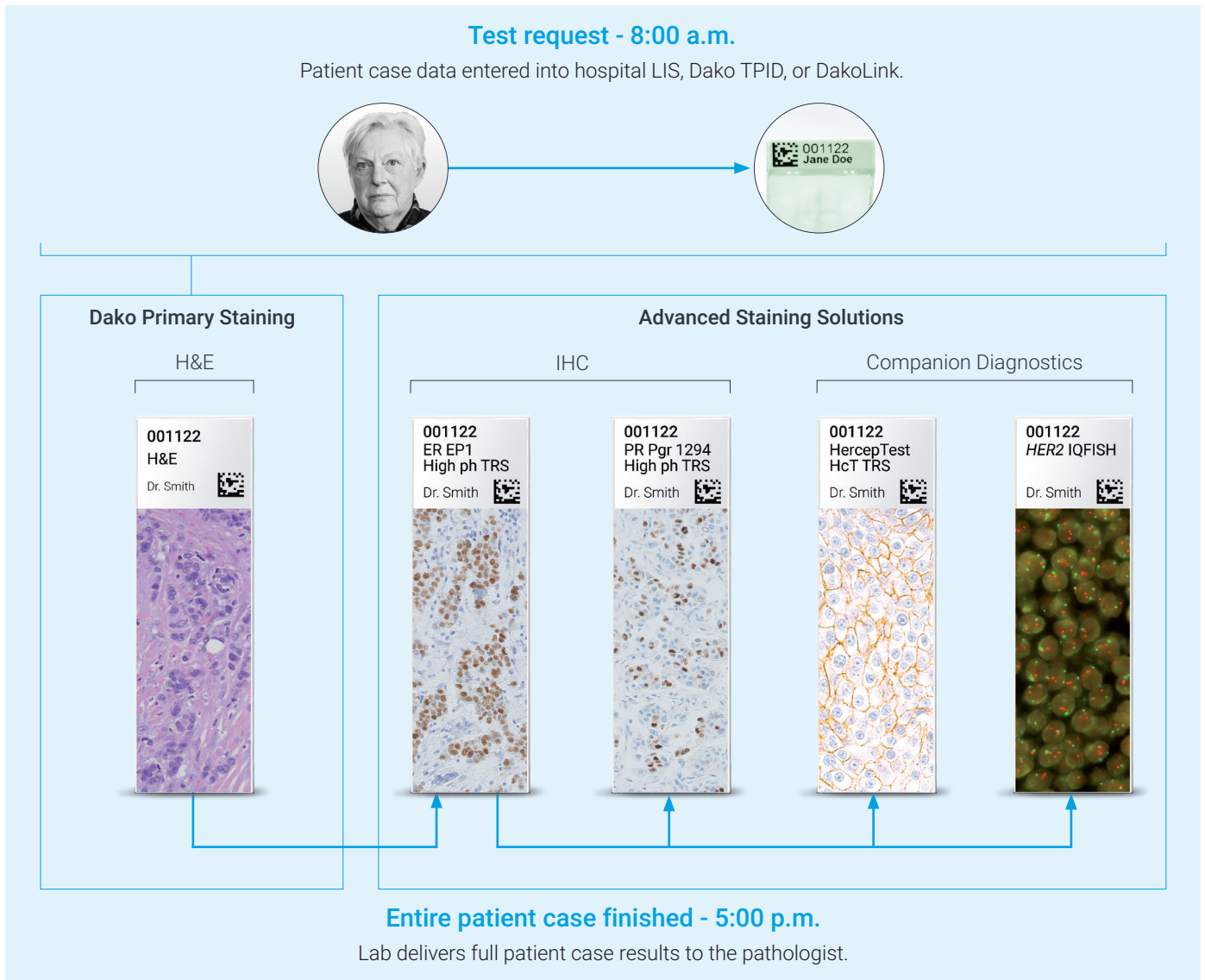




# Workflow efficiency and better patient care

Our flexible pathology solutions are designed to meet the individual needs of your lab. They work together to increase quality, enhance your lab's productivity and efficiency and help you minimize errors to provide answers you can trust.

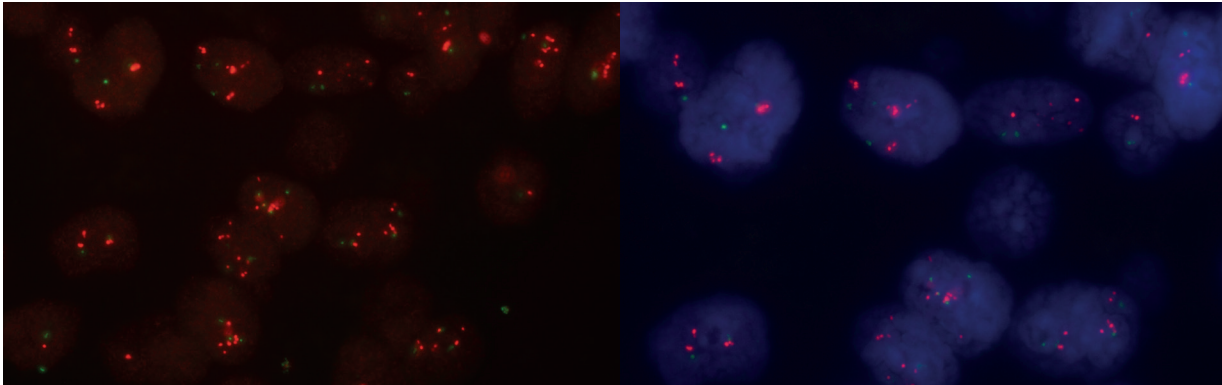
## Same-day patient case management with Dako staining solutions



**Figure 1.** Agilent automated solutions for the anatomic pathology laboratory enable a complete patient case workflow in a single work day. The workflow includes: primary staining with the Dako CoverStainer and advanced staining with the Dako Omnis/Autostainer Link 48. Integrating Agilent's automated platforms into the hospital's LIS, Dako TPID or DakoLink enables tracking of the patient's case.

# HER2 IQFISH pharmDx is part of our expanding ISH portfolio for Dako Omnis

IQFISH sets new standards in anatomic pathology. IQFISH Fast Hybridization Buffer enables processing of FISH slides in four hours with remarkable quality.<sup>1</sup>



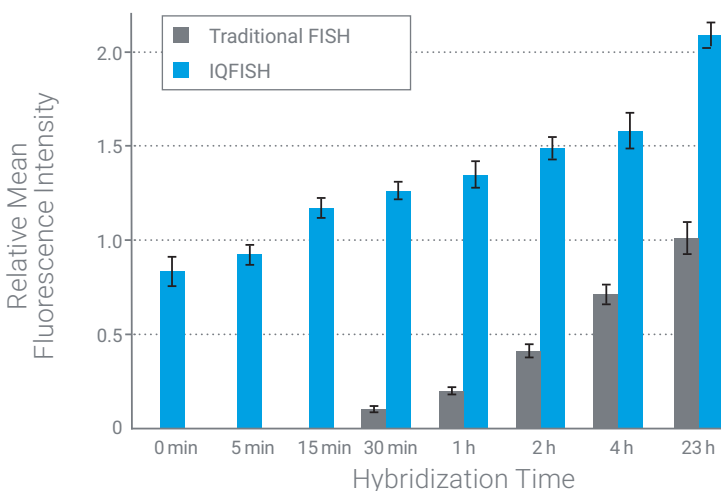
**Figure 2.** Breast carcinoma stained with *HER2* IQFISH pharmDx. Left: Staining visualized with a double filter (Red/Green). Right: Image color merged with DAPI (Red/Green/DAPI). Tumor cells show *HER2* gene amplification.

## IQFISH outperforms traditional FISH

Get brighter signals with IQFISH and dramatically reduce diagnosis turnaround time.

- Less repeat testing than with traditional probes saves time and reduces cost<sup>1</sup>
- Dramatically reduces diagnostic turnaround time from 18 hours to four hours
- IQFISH fast hybridization buffer is non-toxic, which prevents exposure of lab personnel to toxic formamide

### IQFISH Fast Hybridization Buffer



**Produces brighter signals and improves signal to background ratio<sup>2</sup>**

Time-chase comparison of *HER2* DNA FISH signal intensities using IQFISH Hybridization Buffer and formamide buffer on FFPE breast carcinoma tissue sections. Identical probe concentration was used in the two buffers. The black bars represent the 95% confidence interval (n = 45 signals).

Maximal signal intensity is achieved much faster with IQFISH than traditional FISH buffer.

**Figure 3.** Time-chase comparison of *HER2* DNA FISH signal intensities.

# Automated FISH on Dako Omnis



### Get IHC-like turnaround time for IQFISH with Dako Omnis

Run FISH simultaneously with IHC, with minimal impact on IHC throughput, and achieve fast IHC and FISH turnaround time.

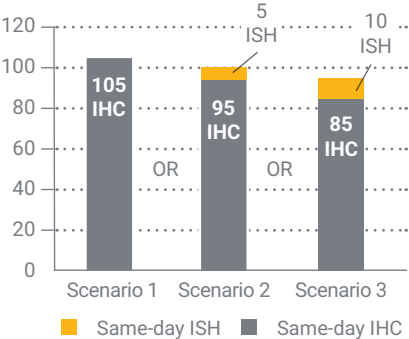


Figure 4. Number of slides processed in a 8-hour workday

### Automated FISH on Dako Omnis

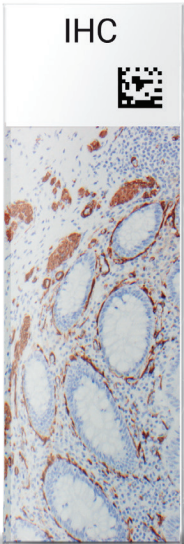
Dako Omnis provides a fully automated FISH solution with high efficiency and flexibility. With the short FISH protocol and high slide and reagent capacity, Dako Omnis processes FISH slides in an IHC-like turnaround time - fast and with high quality.

### Exceptional processing flexibility

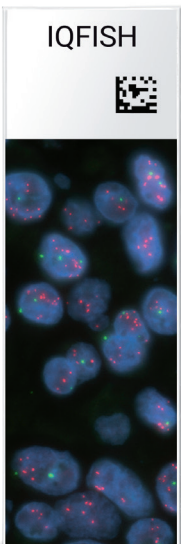
- Enable simultaneous FISH and IHC protocols with minimal impact on IHC throughput
- Run during working hours or overnight

### Eliminate need for batch processing

- Five effective FISH testing days every week
- Run FISH whenever needed, any day of the week, with little impact on workflow



2:30 h  
IHC



4:00 h  
FISH

# Outstanding quality on Dako Omnis<sup>2, 3</sup>

## Outstanding accuracy of *HER2* IQFISH pharmDx on Dako Omnis

- 100% concordance for *HER2* status in breast cancer compared with manual PathVysion<sup>2</sup>
- 100% concordance for *HER2* status in breast cancer compared with manual *HER2* IQFISH pharmDx<sup>2</sup>
- 99,3% concordance for *HER2* status in gastric cancer compared with manual *HER2* IQFISH pharmDx<sup>3</sup>

## Implementation of *HER2* IQFISH pharmDx on Dako Omnis

### The validated protocol provides outstanding results.

The automated FISH staining procedure on Dako Omnis includes deparaffinization of tissue sections, pretreatment, pepsin digestion, hybridization and stringent wash. All protocol steps are pre-programmed into the Dako Omnis software.

Three validated *HER2* IQFISH protocols that only differ in pepsin digestion time: Short (10 min.), Medium (15 min.) and Long (20 min.) are pre-programmed into the Dako Omnis software and can be selected for each of the five slides in the slide rack. This allows optimization of the tissue digestion which may depend on pre-analytical conditions. The different staining protocols can be viewed on the Dako Link Omnis Workstation.

In addition, the user can choose to use a template IQFISH protocol to adjust for variation in specimen type and preparation method. It is the responsibility of the user to validate such protocols. The items in blue text below can be modified by the user.

### Comparison of *HER2* IQFISH pharmDx Protocol with the new Template IQFISH Protocol

| Step           | <i>HER2</i> IQFISH pharmDx Protocol | Template IQFISH Protocol |
|----------------|-------------------------------------|--------------------------|
| Dewax          | 10 minutes<br>38 °C                 | On/Off                   |
| Pretreatment   | 15 minutes<br>97 °C                 | 3-60 minutes<br>60-97 °C |
| Wash           | 6 minutes<br>32 °C                  | 6 min<br>32 °C           |
| Digestion      | 10, 15 or 20 minutes<br>32 °C       | 3-60 minutes<br>32 °C    |
| Drying         | 15 minutes<br>45 °C                 | 15 minutes<br>45 °C      |
| Denaturation   | 10 minutes<br>66 °C                 | 5-20 minutes<br>66 °C    |
| Hybridization  | 75 minutes<br>45 °C                 | 30-120 minutes<br>45 °C  |
| Stringent Wash | 10 minutes<br>61 °C                 | 3-20 minutes<br>50-97 °C |
| Extra Wash     |                                     | RT<br>2 x brief rinse    |



## The flexibility to optimize your IQFISH assay on Dako Omnis

Dako Omnis performs automated FISH staining on FFPE tissue sections. The solution supports FISH assays with IQFISH Fast Hybridization Buffer as well as creation of user-defined FISH protocols thereby facilitating fast, automated FISH staining on Dako Omnis.

### Enhance your laboratory workflow

- Save time by using the same LIS created barcode for slide identification throughout the entire staining workflow.
- Connect your Dako instruments to your laboratory network and Laboratory Information System to share information from anywhere on the network, or even between multiple sites. Up to four Dako Omnis instruments can be connected for easy monitoring and management from the same workstation.
- Experience real time monitoring of staining processes, reagent usage, waste levels, and progress of patient cases to know where to optimize your staining operation.
- Easily generate customized reports and receive a full electronic audit trail to support quality and regulatory needs.

### Improve patient safety

- Receive and enter test requests directly in LIS eliminating the need for manual data entry and reducing the risk of transcription errors or case mix-ups. Every slide is uniquely identified throughout the staining process.
- Add tracking capabilities and extend the detailed case log to include data recorded in the workflow steps before and after staining, to enhance the audit trail and further increase patient safety.

## Ordering information

|   | Product Name                                  | Code      | Vol. and tests per unit           |
|---|---|-----------|-----------------------------------|
| ☹ | HER2 IQFISH pharmDx (Dako Omnis)              | GM33311-2 | 1.6 mL, RTU, 20 tests             |
| ☹ | ISH Ethanol Solution, 96 (Dako Omnis)         | GM30011-2 | 14 mL, RTU, 20 tests              |
| ☹ | ISH Pre-Treatment Solution (20x) (Dako Omnis) | GM30111-2 | 175 mL for 3.5 L bulk, 5-25 tests |
| ☹ | ISH Pepsin (Dako Omnis)                       | GM30211-2 | 7 mL, RTU, 20 tests               |
| ☹ | ISH Stringent Wash Buffer (20x) (Dako Omnis)  | GM30311-2 | 175 mL for 3.5 L bulk, 5-25 tests |
| ☹ | Fluorescence Mounting Medium (Dako Omnis)     | GM30411-2 | 0.8 mL, 20 tests                  |
| ☹ | ISH Cleaning Solution (Dako Omnis)            | GC20730-2 | 10 mL, 100 tests                  |
| ☹ | Dako Omnis ISH Lid                            | GC10230   | Box of 5, 25 tests                |
| ☹ | Dako Omnis Mixing Device                      | GC11630   | 1 pcs                             |

## Companion devices



Dako Omnis Mixing Device



Dako Omnis ISH Lids



Texas Red/FITC double filter  
(not sold by Agilent)

Learn more:

[www.agilent.com](http://www.agilent.com)

### References

- (1) Cohen DS, Alsobrook S. ProPath Services, Dallas, TX. Improved quality and efficiency in manual preparation and analysis of formalin fixed paraffin embedded fluorescence in situ hybridization (FISH) specimens: A comparison of two FDA approved *HER2* kits. White paper, 2014, document no. 29087.
- (2) Viale G, Paterson J, Bloch M, Csathy G, Allen D, Dell'Orto P, Kjærsgaard G, Levy YY, Jørgensen JT. Assessment of *HER2* amplification status in breast cancer using a new automated *HER2* IQFISH pharmDx (Dako Omnis) assay. *Pathology – Research and Practice* 212 (2016) 735–742.
- (3) Viale G, Paterson J, Bloch M, Csathy G, Allen D, Dell'Orto P, Kjærsgaard G, Levy YY, Jørgensen JT. Analysis of *HER2* status in gastroesophageal tumor specimens using a new automated *HER2* IQFISH pharmDx (Dako Omnis) assay. *Histol Histopathol* (2016) 31: 1327-1335.

If you receive lot 2005092 and want to use the template IQFISH protocol, you can download the updated instructions for use at [Agilent.com](http://Agilent.com).

For In Vitro Diagnostic Use.

This information is subject to change without notice.