# Agilent Dako Omnis

Automated IHC and ISH solution
for fast and reliable answers to patients





Agilent
Trusted Answers
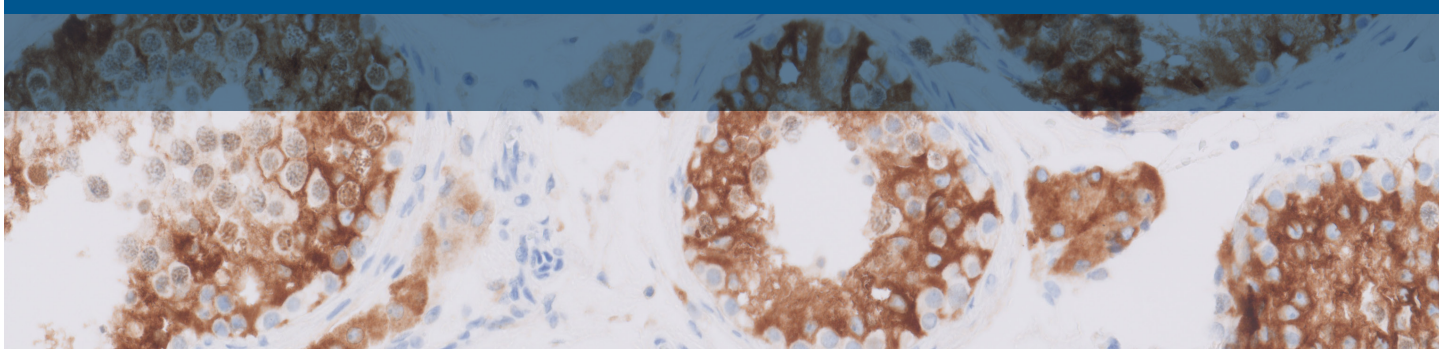
# Looking for Opportunities to Further Boost Your Lab's Performance?

**Patient case management with Dako Omnis increases the number of patient cases completed per day considerably, while also reducing hands-on time.**

Pathology labs are putting a lot of effort into optimizing their workflow and improving turnaround times to provide fast results to patients. Dako Omnis helps you do this with continuous processing and by managing patient cases holistically. Slides belonging to the same case are kept together on the same instrument throughout the staining workflow, thus eliminating the hassle and wasted time of splitting and reassembling cases. This accelerates time to patient case completion, and enables you to provide pathologists with a continuous delivery of patient cases ready for diagnosis.

Data from real-world workflow studies show that switching from batching mode to patient case mode with Dako Omnis can support labs in reducing their daily hands-on time, in addition to reducing the time to patient case completion.

Optimization of the pathology workflow with Dako Omnis resulted in:

**86%** ▲
more cases
completed within 24 hours

**37%** ▼
reduction
in hands-on time

**68%** ▼
less sorting
between instruments

# Enable faster results to benefit the lab, the pathologist, and ultimately the patient

Speed is critical in the race against cancer, but fast results for individual slides are inadequate. The pathologists need all slides—the complete case—to make an assessment. A holistic staining approach using an optimized case management workflow enables faster results for the complete patient case.

Below are examples of the impact that a case management approach had on modern pathology labs. Would you like to see the same in your lab?

## Pathology Lab 1
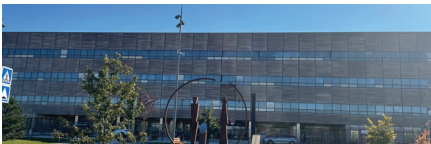


- 29,000 IHC slides per year
- 124 antibodies, three CISH and one FISH probe
- Operating hours: 7:00 a.m. to 3:30 p.m. (Monday to Friday)

*Switched from competitor platforms to two Dako Omnis instruments*

**Impact**
- **86% more cases completed within 24 hours**
- **28% reduction in total hands-on time**
- **23% reduction in workflow steps**

*Read the paper*

## Pathology Lab 2



- 60,000 IHC slides per year
- > 200 antibodies
- Operating hours: 6:00 a.m. to 4:00 p.m. (Monday to Friday)

*Switched from batch loading practice to continuous loading on Dako Omnis*

**Impact**
- **20% faster patient case delivery time**
- **Up to 68% less sorting on instruments**
- **Up to 51% less sorting on racks**

*Read the paper*

## Pathology Lab 3



- 48,000 IHC slides per year
- 145 antibodies
- Operating hours: 7:30 a.m. to 5:00 p.m. (Monday to Friday)

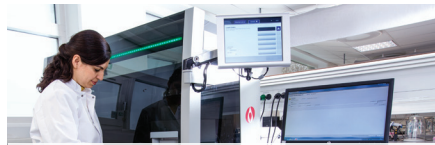*Switched from four competitor platforms to two Dako Omnis instruments*

**Impact**
- **12% faster patient case delivery time**
- **30% reduction in total hands-on time**
- **50% fewer instruments**

*Read the paper*

## Pathology Lab 4



- 22,000 IHC slides per year
- Approximately 140 antibodies
- Operating hours: 7:00 a.m. to 17:00 p.m. (Monday to Friday)

*Switched from five competitor platforms to two Dako Omnis instruments*

**Impact**
- **74% increase in patient cases finalized the same day as requested**
- **37% reduction in total hands-on time**
- **60% fewer instruments**

*Read the paper*

# How Does Dako Omnis Do It?

## Dako Omnis is designed to handle patient cases

Dako Omnis is designed to process entire patient cases, both IHC and ISH, the same day they are requested. A large reagent compartment with 60 temperature-controlled reagent positions leaves up to 50 positions for specific antibodies in addition to the visualization system reagents. This high capacity enables many test panels to be ready onboard the instrument so entire patient cases can be started quickly, without having to shuffle antibodies or split cases between instruments.

**Patient case management**

A patient case is being loaded in a slide rack. Simple and easy.

- Dako Omnis has independent staining units and an unequalled capacity of patient cases, which can be continuously loaded and unloaded. Sixty slide positions enable your lab to process 12 racks of five slides simultaneously.

- Having 60 reagent positions reduces the need to split patient cases based on the required antibodies.

- Without case splitting, the time-consuming reassembly process is eliminated.

- Access to reagent and bulk solutions during operation removes delays and reduces time to patient case completion.

# Slides Per Patient Case

The Dako Omnis slide racks are designed to fit the majority of patient cases.

Data obtained by Agilent Workflow Team demonstrated that the majority of patient case requests need five or fewer slides to complete the request[1].
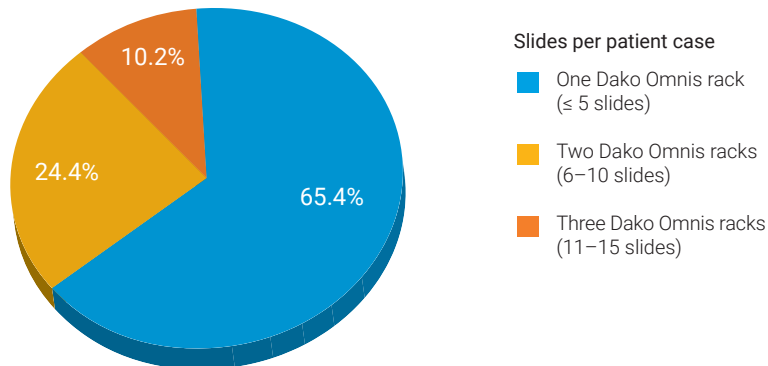


**Slides per patient case**

- One Dako Omnis rack (≤ 5 slides)
- Two Dako Omnis racks (6–10 slides)
- Three Dako Omnis racks (11–15 slides)

10.2%

24.4%

65.4%

**Figure 1.** Distribution of slides per request for 49 cases, 225 slides. Of the 49 cases, 32 cases could be analyzed using five or fewer slides, 12 cases needed between six and 10 slides, while five cases were analyzed using 11 to 15 slides.

A similar observation was made at University of Rochester Medical Center, Rochester, NY, where 90% of all patient cases (N=301) were completed with five or fewer slides[2].



**Patient case management**

Parallel processing enables you to load and unload patient cases while the instrument continues staining other cases onboard the instrument.

# Working in Patient Case Management Mode

The major difference between working in slide-batching mode and patient case mode is that in batching mode the slides are sorted by which instrument holds the antibody, whereas in patient case mode with Dako Omnis, the slides for a patient case are kept together in the same slide rack in a single instrument. This shortens time to case completion and reduces hands-on time, which supports a LEAN and efficient workflow.

# Integrate Fast, High-Quality FISH and CISH Into Your IHC Workflow*

## Load your patient cases as they arrive to the lab, regardless of required technique

Dako Omnis enables fully automated FISH and CISH for high efficiency and flexibility.

Unlike other systems, Dako Omnis is designed to enable simultaneous FISH, CISH, and IHC runs. FISH and CISH slides can be run with modest impact on the IHC throughput, as shown in the graph below.
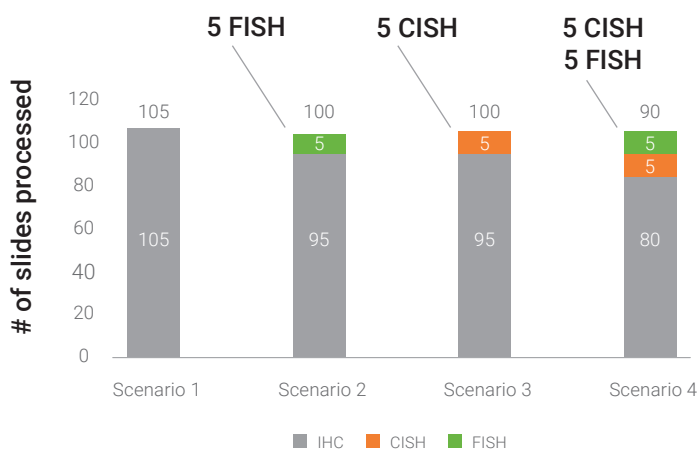


**Figure 2.** Number of slides processed in an 8-hour workday.

## Define your FISH and CISH assays on Dako Omnis

Dako Omnis performs automated FISH and CISH staining on FFPE tissue sections. The solution supports FISH and CISH assays with IQFISH Fast Hybridization Buffer, as well as the creation of user-defined protocols, which enables fast, automated FISH and CISH on Dako Omnis.
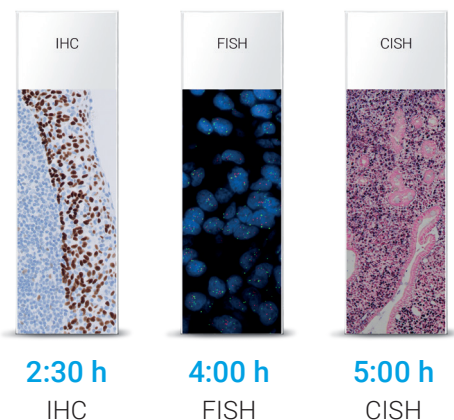
## Add 52 more FISH and CISH days per year

The high throughput of Dako Omnis, combined with the IQFISH Fast Hybridization Buffer, enables an IHC-like turnaround time for FISH and CISH. IQFISH Fast Hybridization Buffer reduces hybridization to just 1-2 hours, which enables a 4-hour turnaround time for FISH and a 5-hour TAT for CISH.

This enables your lab to:

– Start and complete FISH and CISH tests every day - also on Fridays

– Run FISH and CISH whenever it is needed, with little impact on workflow

*\* Please note that Dako Omnis FISH and CISH probes are not available in all countries. Contact us to hear about availability in your country.*

### Run FISH and CISH with IHC-like turnaround times



| 2:30 h | 4:00 h | 5:00 h |
|--------|--------|--------|
| IHC | FISH | CISH |

# Quality Control Features
# Ensure Staining Results You Can Trust

Dako Omnis helps your lab provide diagnostic certainty for better patient care. Its host of integrated quality control features support your lab in delivering results you can trust:

**The Quality Control features on Dako Omnis include:**

A **double check of reagent vials** help avoid dispensing problems and ensures that the necessary volumes are dispensed on every single slide, and that negative staining is avoided.

The **Dynamic Gap Staining** process ensures full and even reagent coverage of the slide to deliver consistent high-quality staining slide after slide.
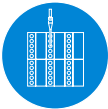
The **temperature of reagents is controlled** and monitored at two levels: At 18 ºC in the reagent compartment, protecting reagents on board from any temperature fluctuation caused by protocols. At 32 ºC in the staining chamber, to ensure reproducibility of staining conditions.

Full workflow **transparency** and **full traceability** of patient cases.

Hardware designed to **eliminate human errors** and **smart alerts** that draw your attention to any errors should they occur.

# Ready-to-Use Primary Antibodies for Accurate and Reliable Results



We offer a series of high-quality ready-to-use (RTU) primary antibodies for Dako Omnis that are based on the renowned Dako heritage for quality of IHC primary antibodies. They come in a FLEX RTU format that encompasses all relevant aspects of the staining process for a simple effective approach to staining:

– Robust IHC tests based on carefully selected clones calibrated and validated for reliable diagnostic use, ensuring that the antigen is correctly demonstrated at both high and low expression levels in tissue

– The RTU antibodies are accompanied by appropriate plug-and-play protocols to provide reliable and reproducible diagnostic results

– The EnVision FLEX visualization system enables robust and clear signal amplification

– The FLEX RTU Atlas of Controls provides precise recommendations for appropriate tissue controls to verify staining results

## Delivering accurate staining results and improving time to diagnosis

The FLEX RTU Solution was developed in close collaboration with leading pathologists and lab managers.

The expert panel specified the required criteria and staining performance for each individual antibody.

Based on these guidelines, we developed a standard procedure and individual, but aligned, protocols for all FLEX RTU primary anitibodies that increase productivity without compromising the staining performance defined by the panel.
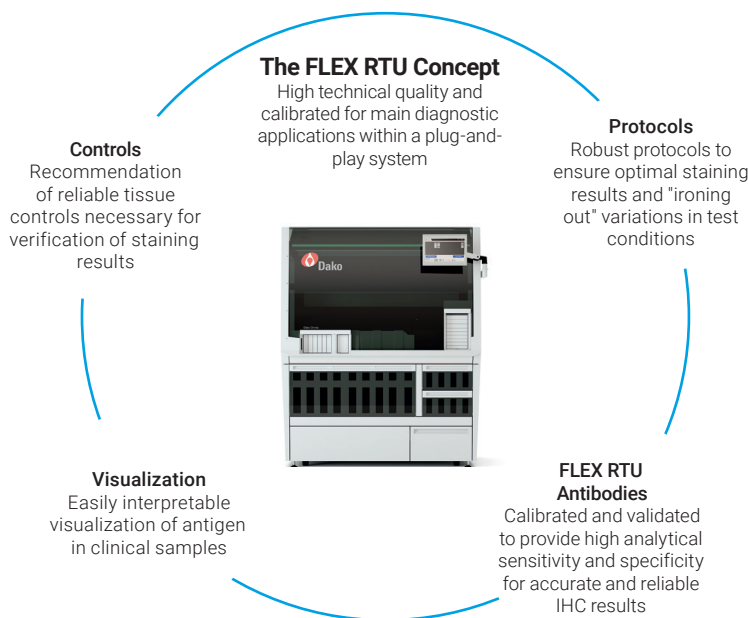
**The FLEX RTU Concept**
High technical quality and calibrated for main diagnostic applications within a plug-and-play system

**Protocols**
Robust protocols to ensure optimal staining results and "ironing out" variations in test conditions

**Controls**
Recommendation of reliable tissue controls necessary for verification of staining results

**Visualization**
Easily interpretable visualization of antigen in clinical samples

**FLEX RTU Antibodies**
Calibrated and validated to provide high analytical sensitivity and specificity for accurate and reliable IHC results



**Figure 3.** Diagnostically important RTU IHC tests. Calibrated and validated for reliable diagnostic use. Provided as total plug-and-play solutions facilitating implementation for clinical use.

## Atlas of Controls
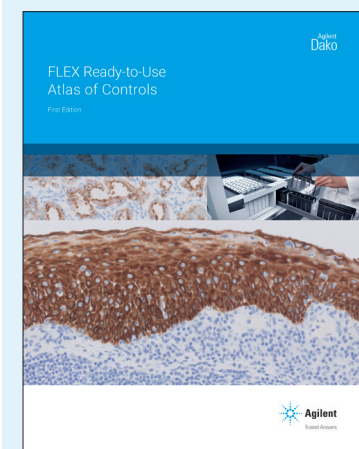


Atlas of Controls provides recommendations for selection of tissue controls and examples of accurate reaction patterns required to confirm that a correct level of analytical sensitivity is obtained in each test.

# One Detection System with Two Color Options*

## Easily run both 'red' and brown visualization with Dako Omnis

HRP Magenta is a chromogen available in the EnVision FLEX portfolio that complements the brown color obtained with DAB chromogen.

HRP Magenta simplifies your IHC visualization:

- Two visualization systems in one workflow
- Load 'red' cases as an integral part of your routine IHC
- Only adds one new vial to the plug-and-play EnVision FLEX system
- Gives your lab a LEAN workflow and fast turnaround times

## HRP Magenta enables confident patient diagnosis

HRP Magenta is both sensitive and specific. A clear presentation of the tissue is maintained, allowing you to recognize tissue and cellular structures. With its crisp clear contrast, the intense staining and color nuance make HRP Magenta an excellent complementary color for your staining on Dako Omnis.



**Figure 4.** Adenocarcinoma of the lung. Stained with Anti-Cytokeratin 7.
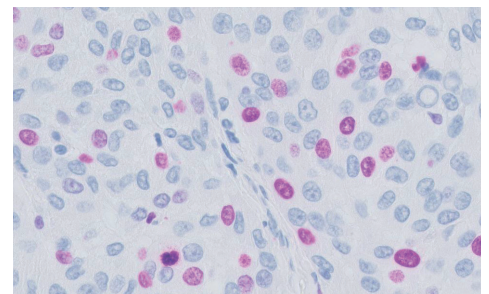


**Figure 5.** Melanoma. Stained with Anti-Ki-67.

# Double staining with HRP Magenta

## Fully automated, sequential double staining enables clear visualization of two targets in the same tissue section with excellent contrast and transparency

Sequential double staining on Dako Omnis addresses several daily workflow challenges in pathology labs.

- Make informed diagnostic decisions by running fewer slides from a limited sample
- Confident diagnosis with localization of different antigens in relation to each other
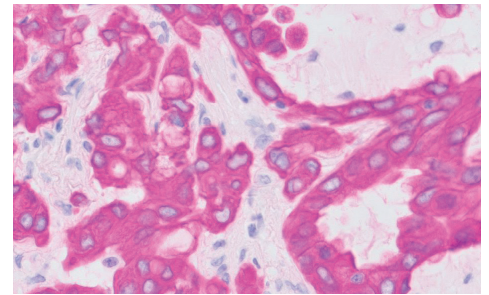- Full automation on Dako Omnis reduces hands-on time
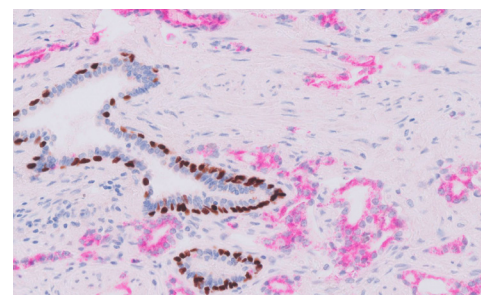


**Figure 6. Prostate adenocarcinoma. p63** (DAB, nuclei): Expressed in the nuclei of the basal epithelial cells of nonneoplastic prostatic glands which are surrounded by adenocarcinoma. Not detected in malignant cells. **AMACR** (Magenta, cytoplasm): Expressed in the cytoplasm of invasive adenocarcinoma cells and prostatic intraepithelial neoplasia (PIN). Not detected in normal cells.



Please scan the code for more details on HRP Magenta and double staining

*  Please note that HRP Magenta is not available in all countries. Contact us to hear about availability in your country.

# Expand Your Breast Cancer Offering with HercepTest™ mAb pharmDx on Dako Omnis*
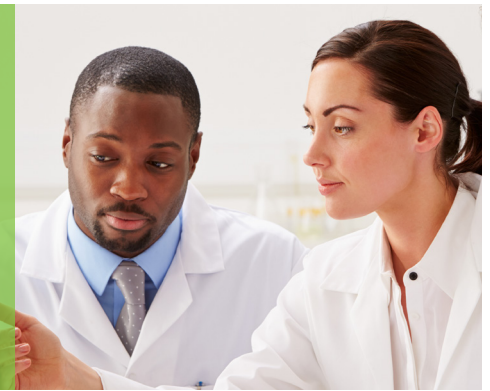
**With a rabbit monoclonal antibody, HercepTest™ mAb pharmDx for Dako Omnis provides your lab with robust and reproducible HER2 staining of breast cancer tissue when considering Herceptin® treatment for breast cancer patients**
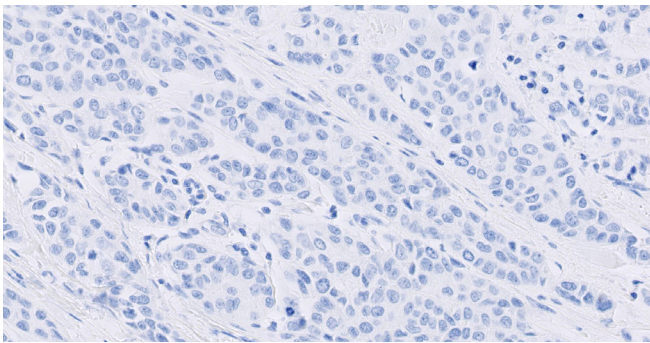


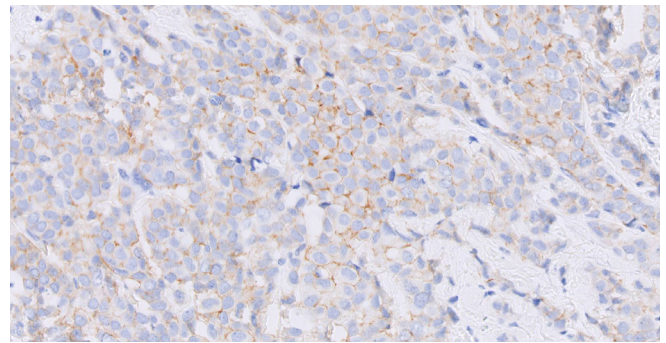Figure 7. Breast carcinoma (FFPE) stained with HercepTest™ mAb pharmDx on Dako Omnis. Score 0.



Figure 8. Breast carcinoma (FFPE) stained with HercepTest™ mAb pharmDx on Dako Omnis. Score 1+.
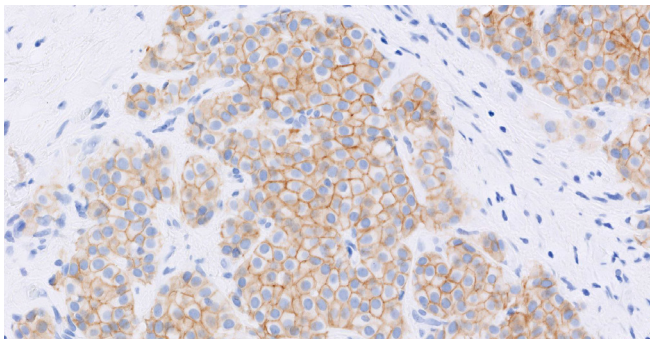


Figure 9. Breast carcinoma (FFPE) stained with HercepTest™ mAb pharmDx on Dako Omnis. Score 2+.
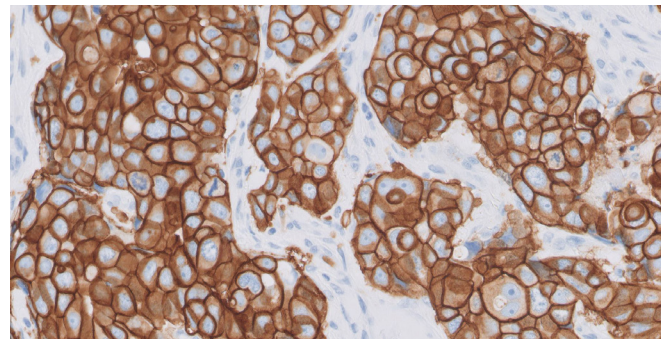


Figure 10. Breast carcinoma (FFPE) stained with HercepTest™ mAb pharmDx on Dako Omnis. Score 3+.

## What does HercepTest™ mAb pharmDx for Dako Omnis provide?

– A rabbit monoclonal antibody that gives clear and specific staining

– Four control cell lines for improved reagent control, introducing a new cell line for medium staining intensity

– Excellent agreement with existing HER2 IHC and FISH assays

– Optimized design for Dako Omnis

*\* Please note that HercepTest™ mAb pharmDx on Dako Omnis is not available in all countries. Contact us to hear about availability in your country.*

Please scan the code to read about the strong NordiQC performance achieved by HercepTest™ mAb pharmDx

Please scan the code to read about the HercepTest™ mAb pharmDx comparison study with Ventana PATHWAY anti-HER-2/neu (4B5) in breast cancer

# Bring Faster Answers to Patients*

## Fast, accurate PD-L1 results

Dako Omnis workflow enables labs to complete more cases and hence more CDx tests every day. Run PD-L1 IHC 22C3 pharmDx, Code GE006, to ensure fast diagnostic answers that are unlocking patients' potential treatment future.

Identify non-small cell lung cancer (NSCLC) patients eligible for treatment with KEYTRUDA® monotherapy** using PD-L1 IHC 22C3 pharmDx, Code GE006, a fully validated CE-marked PD-L1 assay that has been reconfigured for use on the Dako Omnis staining platform[3].
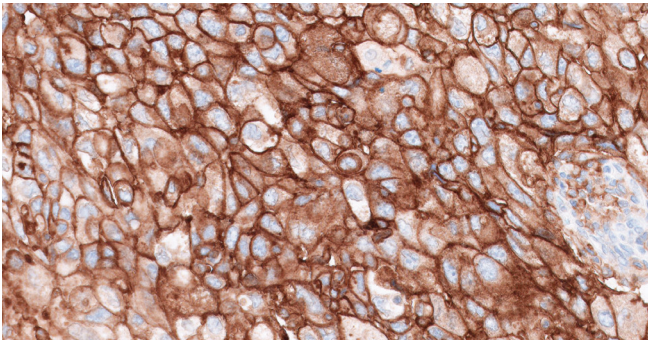


**Figure 11.** Non-small cell lung cancer. Partial or complete cell membrane staining, at any intensity, in ≥ 50% of viable tumor cells. Stained with GE006 on Dako Omnis.



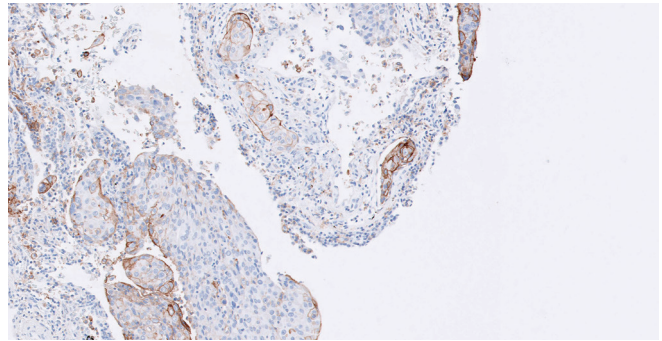**Figure 12.** Non-small cell lung cancer. Partial or complete cell membrane staining, at any intensity, in ≥ 1% - ≤ 49% of viable tumor cells. Stained with GE006 on Dako Omnis.

PD-L1 IHC 22C3 pharmDx, Code GE006:

– Enables PD-L1 slides to be delivered on the same platform as your routine IHC and lung IHC panel for an efficient and LEAN workflow

– Provides controlled onboard environment with a fully optimized, standardized, and validated assay protocol for consistent results every time

Dako Omnis provides your lab clinically proven, high-quality PD-L1 diagnostic results.



*   PD-L1 IHC 22C3 pharmDx, code GE006 is not available in all countries. Contact us to hear about availability in your country.
**  See the KEYTRUDA® product label for PD-L1 expression cutoff values and specific clinical circumstances guiding therapy.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

## References

1. 29295 Case Study on Dako Omnis - Dutch experience.

2. Routine clinical data, University of Rochester Medical Center, USA.

3. PD-L1 IHC 22C3 pharmDx, code GE006, Instructions for Use. Carpinteria, CA: Dako, Agilent Pathology Solutions.

4. Nielsen S External quality assessment for immunohistochemistry: experiences from NordiQC. Biotech Histochem **2015**;90:331-40.

5. Mogens V, Nielsen S. Proficiency testing in immunohistochemistry—experiences from Nordic Immunohistochemical Quality Control (NordiQC). Virchows Arch **2016** 468:19–29.

**Agilent**

Trusted Answers