

Dako Omnis

Automated IHC and ISH solution
for fast and complete patient case results



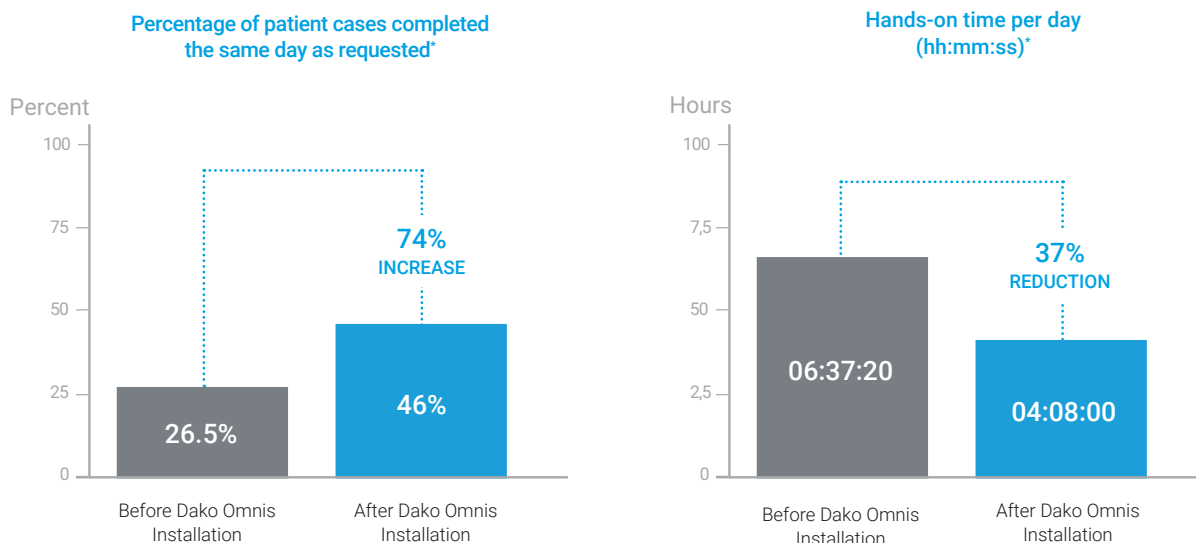


It's Patient Cases That Matter, Not Individual Slides

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 by managing patient cases efficiently. 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 and accelerating time to patient case completion. This enables you to provide pathologists with a continuous delivery of patient cases ready for diagnosis.

Data from 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.



* Data from Dako Omnis workflow study: The Dutch Case.

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.
- An unmatched 60 reagent positions mean that there is rarely a need to split up a patient case according to which instrument has the needed antibody onboard. When a patient case is not split, there is no need to reassemble the case after staining.
- 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 our workflow team demonstrated that the majority of patient case requests need five or fewer slides to complete the request¹.

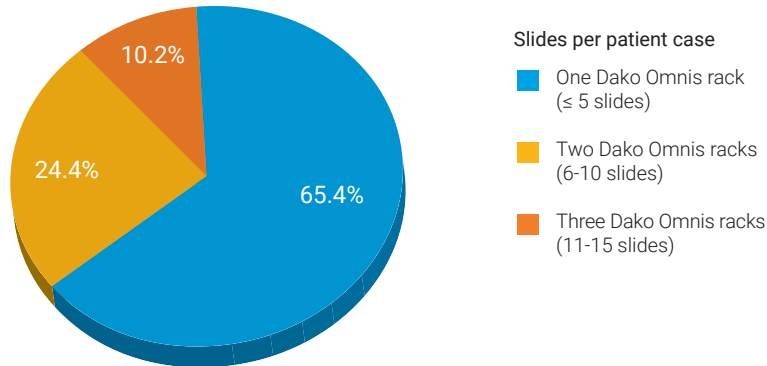


Figure 1. Distribution of slides per request for 49 cases, 225 slides. Of the 49 cases, 32 cases could be analyzed using five or fewer slides, 12 cases needed between six and 10 slides, while five cases were analyzed using 11 to 15 slides.

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 slides².



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 on the same instrument. This shortens time to case completion and reduces hands-on time, which supports a LEAN and efficient workflow.

Integrate PD-L1 Testing Into Your Fully Automated IHC Workflow*

PD-L
1
ONE

Delivering PD-L1 on Dako Omnis

Combine the clinical relevance of PD-L1 22C3 pharmDx with the flexibility and choice of Dako Omnis to provide a fully automated PD-L1 diagnostic service integrated into the core of your laboratory workflow.

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 re-configured for use on the Dako Omnis staining platform².

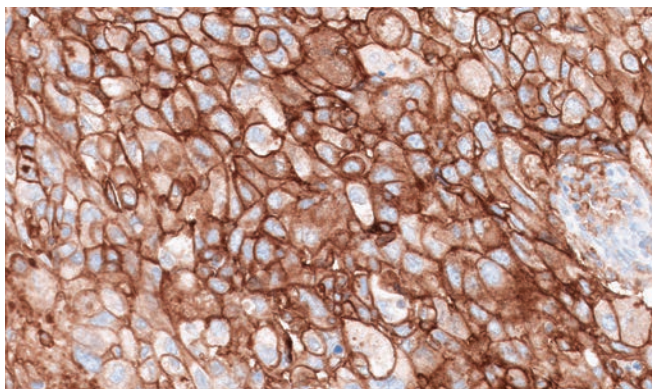


Figure 3. Non-small cell lung cancer. Partial or complete cell membrane staining, at any intensity, in $\geq 50\%$ of viable tumor cells. Stained with GE006 on Dako Omnis.

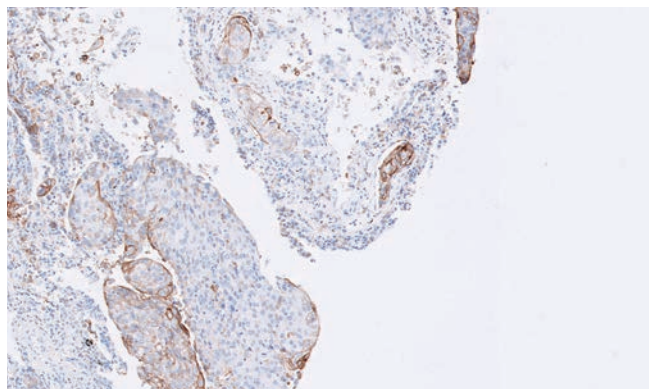


Figure 4. Non-small cell lung cancer. Partial or complete cell membrane staining, at any intensity, in $\geq 1\% - \leq 49\%$ of viable tumor cells. Stained with GE006 on Dako Omnis.

Dako Omnis offers full 'walk away' automation of 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
- Controlled onboard environment with a fully optimized, standardized and validated assay protocol ensures consistent results every time

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

For technical product details, performance data and intended use, please see the instructions for use or visit www.agilent.com.

* Please note that PD-L1 IHC 22C3 pharmDx for Dako Omnis is not available in all countries. Contact us to hear about availability in your country

** See KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing. The intended use for PD-L1 IHC 22C3 pharmDx may not be approved, certified or listed in all countries. Please consult the local product label for approved indications and expression cutoff values to guide therapy².

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

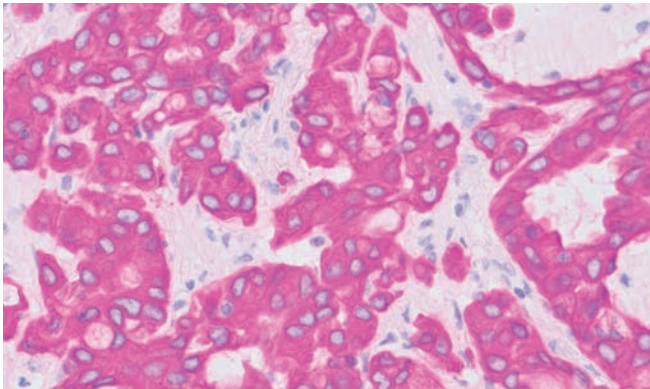


Figure 5. Adenocarcinoma of the lung. Stained with Anti-Cytokeratin 7.

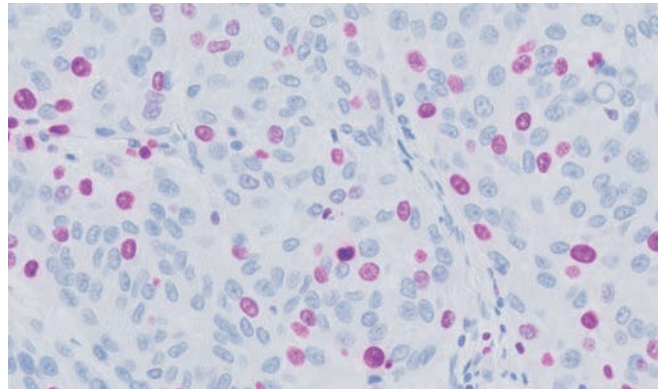


Figure 6. Melanoma. Stained with Anti-Ki-67.

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.



Please scan the code
for more details on
HRP Magenta

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

Accurate and Reliable Staining Results Made Easy, Slide After Slide



The FLEX RTU Solution provides your lab a simple and effective approach to the most difficult choices in the IHC staining process:

- 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 antibodies that increase productivity without compromising the staining performance defined by the panel.

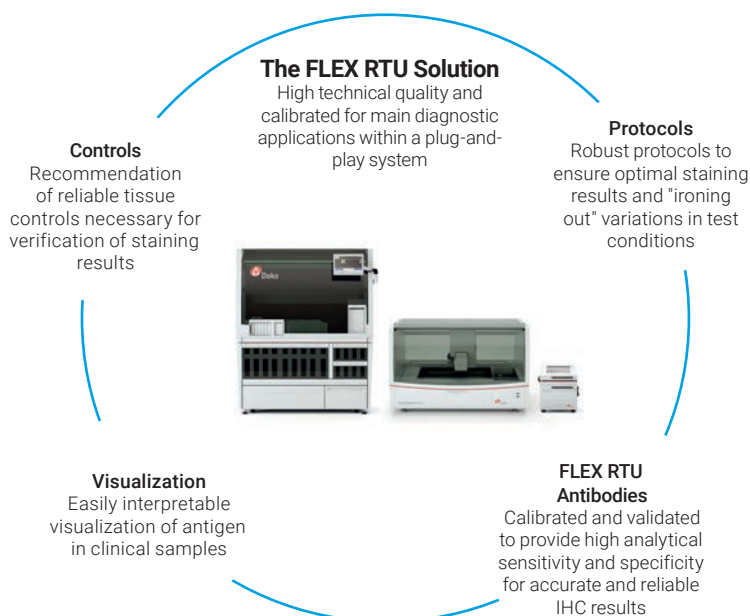


Figure 7. Diagnostically important RTU IHC tests. Calibrated and validated for reliable diagnostic use. Provided as total plug-and-play solutions facilitating implementation for clinical use.

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.

Integrated 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:

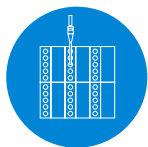
The Quality Control features on Dako Omnis include:



A **double check of reagent** vial helps 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.



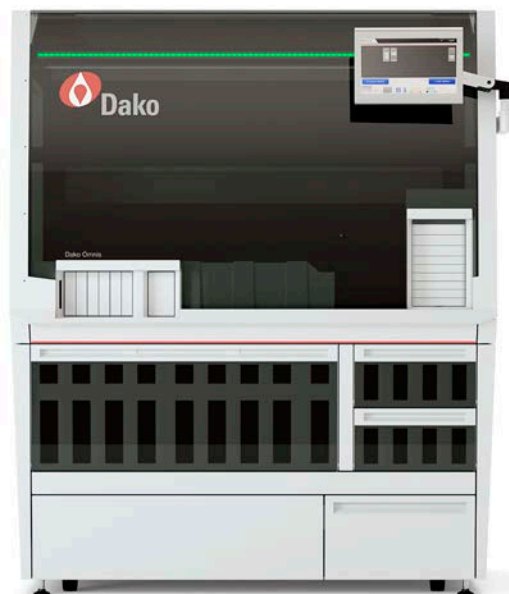
The **temperature of reagents is controlled** and monitored at two levels: At 18 °C in the reagent compartment, protecting reagents on board from any temperature fluctuation caused by protocols. At 32 °C in the staining chamber, to ensure reproducibility of staining conditions.



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.



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

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

Dako Omnis includes a fully automated FISH solution with high efficiency and flexibility. Unlike other systems, Dako Omnis is designed to enable simultaneous FISH and IHC runs. FISH slides can be run with modest impact on the IHC throughput, as shown in the graph below.

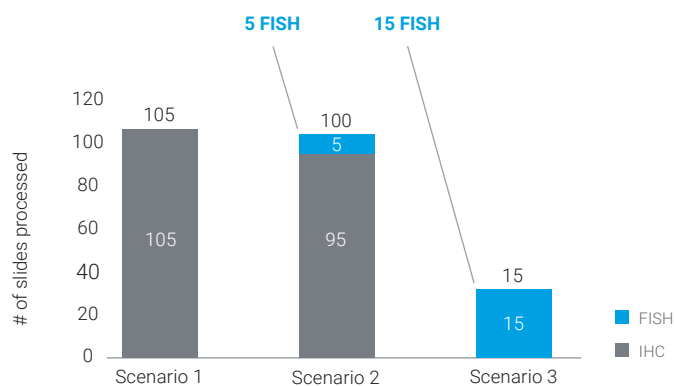


Figure 8. Number of slides processed in an 8-hour workday.

Define your FISH assays 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 the creation of user-defined protocols, which enables fast, automated FISH on Dako Omnis.

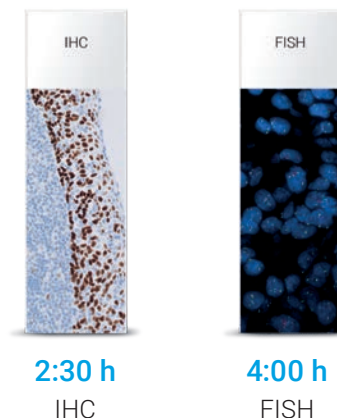
Add 52 more FISH days per year

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

This enables your lab to:

- Start and complete FISH tests every day - also on Fridays
- Run FISH whenever it is needed, with little impact on workflow

Run FISH and with IHC-like turnaround times



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

Unprecedented Flexibility for the Unpredictable Lab Environment

Developed for pathology labs, with pathology labs

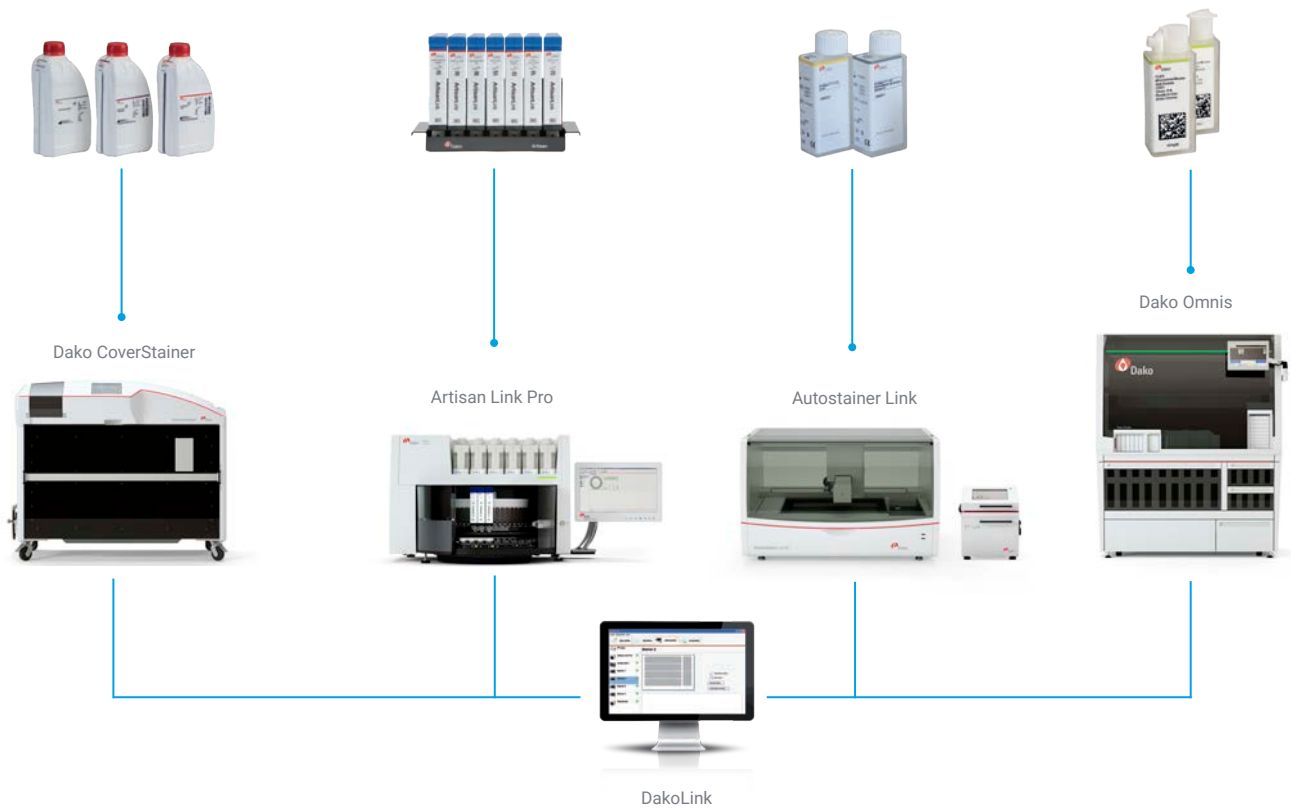
Dako Omnis was developed in close collaboration with pathologists, lab managers and lab technicians from around the world, and was designed to help meet the ever-increasing challenges faced by the modern pathology lab. Today, Dako Omnis is used worldwide to process tens of millions of slides and provide labs with:

- **More time:** Process more complete patient cases per working day, fast and with little hands-on time needed
- **Greater choice:** Have the flexibility to manage your workload as you need, via continuous loading and overnight staining
- **Better patient care:** Supports your lab in providing patients fast, accurate results, when they need them the most



Dako Staining Solutions for H&E, Special Stains, IHC and ISH

Integrated, innovative and automated pathology solutions for complete diagnostic confidence



References

1. Routine clinical data, University of Rochester Medical Center, USA.
2. PD-L1 IHC 22C3 pharmDx [package insert]. Carpinteria, CA: Dako, Agilent Pathology Solutions; 2020.
3. Nielsen S External quality assessment for immunohistochemistry: experiences from NordiQC. *Biotech Histochem* 2015;90:331-40.
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