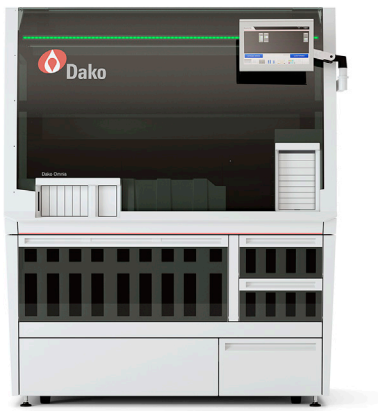


Dako Omnis - A Full IHC and ISH Solution Designed for True Patient Case Management



Continuous case-based, and lean workflow

Independent staining units, and a high reagent capacity enable you to run IHC, IF, FISH, CISH and double staining IHC simultaneously on the same instrument, each with a unique combination of reagents. Combined with an onboard capacity of 60 slides and 60 temperature-controlled reagent positions, this gives you a flexible and lean workflow that supports fast patient case turnaround times.

Access to antibodies, visualization and bulk solutions while running removes lead time delay and process interruption to load/unload reagents.

Diagnostic certainty is vital with a life-threatening disease like cancer. That is why Dako Omnis is designed with a host of built-in safety features to control its performance and protect the lab against errors in the staining process that could negatively influence results.

An example of these built-in safety features is the double check for reagents to ensure that the necessary volumes are both available and dispensed correctly on slides every single time.

The Dako Omnis Solution includes:

- FLEX ready-to-use antibodies - calibrated and validated to provide high analytical sensitivity and specificity for accurate and reliable IHC results
- Optimized validated protocols developed in collaboration with leading pathology experts
- EnVision FLEX detection system with two colors: DAB and HRP Magenta
- Proven consistent high-quality staining
- DakoLink Omnis Software with LIS and LAN/WAN connectivity enables full lab integration
- Dedicated Service & Support provides fast, professional support when hands-on assistance is needed

Dako Omnis Solution Specifications

Table 1. Instrument specifications.

| Specification | Description |
|---|--|
| Intended use | Dako Omnis is an in vitro diagnostic device intended for automated slide-based immunohistochemistry (IHC) and in situ hybridization (ISH) on formalin-fixed paraffin-embedded tissue sections and immunocytochemistry (ICC) on formalin-fixed cytology specimens. It is intended to be operated by qualified professionals, trained in the use of Dako Omnis, in a pathology laboratory environment. |
| Operation | Continuous workflow (or batches). 5-slide racks to optimize capacity utilization and patient case management. Reagents and slides can be loaded and unloaded as needed, also during runs. Easy-to-use software interface. Designed with built-in safety measures to minimize potential human errors. |
| Labeling | CE, IVD and CSA marked. |
| Quality system | ISO 13485, ISO 13485 MDSAP. |
| Starter pack content (All delivered with starter pack; can also be ordered separately) | At delivery, the Dako Omnis instrument contains: <ul style="list-style-type: none"> – Dako Omnis Water Container, 7 L, 5 pcs., Code GC11030 – Dako Omnis Bulk Bottle, Waste Container, 7 L, 5 pcs., Code GC11930 – Dako Omnis Buffer/Solvent Container, 3.5 L, 8 pcs., Code GC10930 <p>Additional products provided with delivery of a new instrument:</p> <ul style="list-style-type: none"> – Dako Omnis Slide Rack, 6 pcs, GC10130 – Dako Omnis Slide Rack Color Clips (4 colors, 25 pcs), Code GC10330 (Red), GC10430 (Blue), GC10530 (Green), GC10630 (Grey) – Dako Omnis Mixing Strips, 25 pcs, Code GC10730 – Dako Omnis Solid Waste Bag, 25 pcs, Code GC10830 – Dako Omnis Buffer/Solvent Container Label sets, Code GC11130 – Dako Omnis Water/Waste Container Label sets, Code GC11230 – Dako Omnis Small Vial, 2 mL, box of 25 pcs., Code GC20130-6 – Dako Omnis Large Vial, 30 mL, box of 25 pcs., Code GC20230-6 – Large Flap Slide Label Kit, Code S341730 – Dako Omnis ISH Lid, 5 pcs, Code GC10230 – Dako Omnis Quick Reference Guide, Code GI10330 – Dako Omnis User Guides CD, international translations, Code GI10430 |
| Alarms | Sound and visual alarms (green, yellow, red) indicating instrument run status. |

Table 2. Reagents.

| Specification | Description |
|------------------------------------|--|
| Ready-to-Use reagents (antibodies) | Quality-controlled FLEX Ready-to-Use reagents and protocols for optimal staining results. Reagents kept under temperature-controlled conditions (18 °C) to protect reagents from temperature fluctuations. Please refer to the Agilent website for a complete list of reagents: https://www.agilent.com/en/product/dako-omnis-solution-for-ihc-ish |
| Reagent capacity | 60 reagent vials. |
| Visualization kits | EnVision FLEX family offers two color options: DAB and HRP Magenta. Please refer to the Agilent website for a complete list of visualization kits. |
| Bulk fluid capacity | 8 x 3.5 L bottles, for dewax, retrieval buffers, and wash buffers. In addition 4 x 7 L bottles for DI Water. |

Table 3. Staining Module.

| Specification | Description |
|-----------------------------------|---|
| Loading of slide racks | Dako Omnis is designed for continuous loading and unloading. The instrument holds 12 racks of 5 slides (60 slides). Dynamic Gap staining technology. Temperature and humidity-controlled processing environment. |
| Process time (turnaround time) | Average IHC staining time: 2 hours 30 minutes. Average FISH staining time: 4 hours. Average CISH staining time: 5 hours. |
| Loading capacity | 165 IHC slides can be loaded in a typical working day (8 hours including preparation for overnight run). 105 IHC stained during working hours and 60 to be stained overnight. (Based on the average TAT of 2 hours 30 minutes for IHC and continuous loading). 30 FISH/CISH slides can be loaded in a typical working day (8 hours including preparation overnight). 15 FISH/CISH slides stained during working hours and 15 slides overnight (Based on an average TAT of 4 h for FISH and 5h for CISH and a continuous loading setting) |
| Overnight run | 12 racks (60 slides), three of which can be ISH (same combination of racks as stated before). Two overnight run modalities: <ul style="list-style-type: none"> - Continuous run (as standard daily runs) - Delayed run (based on requested finishing time) |
| Type of slides | The following slides are validated for Dako Omnis: <ul style="list-style-type: none"> - FLEX IHC Microscope Slides (K8020) - SuperFrost Plus slides |

Table 4. Dimensions and requirements.

| Specification | Description | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|--|---------------|----------------|----------------------------|--------|--------------|-------------------|----------------|---------------|----------------|----------------------------|---------------|--|--|--|------------------------|-----------------|--|--|--|------------------------|
| Instrument dimensions | H x W x D: 177 cm x 150 cm x 80 cm (69.7" x 59.1" x 31.5"). Height with front cover open: 220 cm (86.6"). Packaging dimensions and weights: <table border="1" data-bbox="544 1228 1377 1365"> <thead> <tr> <th>Instrument</th> <th>Length</th> <th>Width</th> <th>Height</th> <th>Gross Weight</th> </tr> </thead> <tbody> <tr> <td>Dako Omnis packed</td> <td>156 cm (61.4")</td> <td>92 cm (36.2")</td> <td>205 cm (80.7")</td> <td>Approx. 580 kg (1,278 lbs)</td> </tr> <tr> <td>Wooden pallet</td> <td></td> <td></td> <td></td> <td>Approx. 30 kg (66 lbs)</td> </tr> <tr> <td>Outer packaging</td> <td></td> <td></td> <td></td> <td>Approx. 20 kg (44 lbs)</td> </tr> </tbody> </table> | Instrument | Length | Width | Height | Gross Weight | Dako Omnis packed | 156 cm (61.4") | 92 cm (36.2") | 205 cm (80.7") | Approx. 580 kg (1,278 lbs) | Wooden pallet | | | | Approx. 30 kg (66 lbs) | Outer packaging | | | | Approx. 20 kg (44 lbs) |
| Instrument | Length | Width | Height | Gross Weight | | | | | | | | | | | | | | | | | |
| Dako Omnis packed | 156 cm (61.4") | 92 cm (36.2") | 205 cm (80.7") | Approx. 580 kg (1,278 lbs) | | | | | | | | | | | | | | | | | |
| Wooden pallet | | | | Approx. 30 kg (66 lbs) | | | | | | | | | | | | | | | | | |
| Outer packaging | | | | Approx. 20 kg (44 lbs) | | | | | | | | | | | | | | | | | |
| Electrical requirements/power | The instrument supports both 115 V, 220 V and 230 V. Power consumption: 1200 W per hour. | | | | | | | | | | | | | | | | | | | | |
| External ventilation | Not necessary. | | | | | | | | | | | | | | | | | | | | |
| Water supply | 4 bottles of 7 L each. DIW specifications: <ul style="list-style-type: none"> - Conductivity 0.5–10 uS/cm (free of particles and air bubbles.) | | | | | | | | | | | | | | | | | | | | |
| Waste/drain | Waste separation between hazardous and nonhazardous waste. | | | | | | | | | | | | | | | | | | | | |
| Waste capacity | Nonhazardous: 4 x 7 L bottles. Hazardous: 1 x 7 L bottle. Average waste produced per slide: <ul style="list-style-type: none"> - 29 mL hazardous waste - 293 mL nonhazardous waste - 0.49 g plastic waste | | | | | | | | | | | | | | | | | | | | |
| Environmental conditions | The Dako Omnis solution is intended for indoor use only. Dako Omnis requires an environment with an ambient temperature between 18–28 °C (64–82 °F), not facing direct sunlight, and normal operating humidity between 25-85% RH; noncondensing. Altitude: Up to 1000 m (3280 feet). Pollution degree 2. During transport, the instrument should be kept dry, at a temperature between 5–40 °C (41–104°F) and at a humidity between 10–90% RH; noncondensing. | | | | | | | | | | | | | | | | | | | | |

Table 5. Requirements.

| Specification | Description |
|-----------------|---|
| Noise level | Noise level measurement per EN 61010-1 (safety requirements for electrical equipment for measurement, control, and laboratory use): 63.7 dBA, which is below recommendations for the permissible level. These can be different from country to country and are often in the range of 85–90 dBA. |
| Heat generation | Max theoretical heat generation is 4100 BTU. Normal running conditions (full load) is 1500–3000 BTU. |

Table 6. Protocols

| Specification | Description |
|---------------------|--|
| Validated protocols | All Dako Omnis FLEX RTU validated protocols are pre-loaded in the system, as well as the <i>HER2</i> IQFISH, PD-L1, HercepTest mAb pharmDx (EU + CA), IQFISH IVD panels, EBER RNA CISH and Kappa, Lambda mRNA CISH protocols. |
| Protocol templates | IHC-HRP including chromogens DAB and Magenta. IHC-AP templates (Avidin-Biotin based or polymer based visualization). Immunofluorescence template (direct and indirect). Sequential double staining template. FISH and single-signal CISH templates. |

Table 7. Dako Link Omnis Software

| Specification | Description |
|------------------------|--|
| Network/LIS connection | Connectivity to the Laboratory Information System using ULISA software can be ordered as an additional option. Data transfer using either HL7, XML or CSV formats is supported. Bi-directional connectivity allowing a “staining complete” message to be returned to your LIS on successful completion of a slide is available where supported by the LIS. The following barcode types are supported; 2D (Datamatrix, QR) and 1D (Code128, I2of5, Code 93, Code 39, Codabar, PDF417). Requirements: <ul style="list-style-type: none"> – Network connection from the Dako Omnis Server to the customer network. – Dako ULISA Software installed by a trained Agilent representative. – LIS System generating HL7, XML or CSV files. – LIS Administrator or LIS vendor to configure customer interface. |

Table 8. Service & support

| Specification | Description |
|--------------------------|---|
| Installation and service | Deployment services ensure that your Dako Omnis solution is correctly installed and integrated into your lab's workflow. This includes: <ul style="list-style-type: none"> – Pre-site inspection – Installation – Connectivity and operational qualification – Instrument service including planned maintenance, corrective maintenance and software upgrades Application and technical support including protocol design, optimization, product training and demonstrations for optimal staining performance. Instrument service agreement extends the benefits from the standard instrument warranty to avoid unplanned expenses. |

D52080_03

This information is subject to change without notice.