Data Sheet

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Dako

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

Continuous case-based and lean workflow

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

Access to antibodies, visualization, and bulk solutions during operation eliminates lead time delays and prevents interruptions caused by loading or unloading reagents.

Improved diagnostic certainty is critical when dealing with life-threatening diseases like cancer. That's why Dako Omnis is equipped with a range of built-in safety features designed to monitor performance and safeguard the lab against staining errors that could compromise results.

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

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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. The processed slides are intended to be evaluated by qualified pathologists.
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, MDSAP
Starter Pack Content (All items can also be ordered individually)	At delivery, the Dako Omnis instrument contains: – 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 Additional products provided with delivery of a new instrument: – 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
Reagent List	Please refer to the Agilent website for a complete list of reagents.
Reagent Compartment	Temperature-controlled conditions (18 °C), protecting reagents from temperature fluctuations. 60 reagent vials
Visualization Kits	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 five slides (60 slides). Dynamic Gap staining technology. Temperature and humidity-controlled processing environment.
Staining Compartment and Technology	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 hours for FISH and 5 hours for CISH and a continuous loading setting).
Overnight Run	Two overnight run modalities: – Continuous run (as standard daily runs) – Delayed run (based on requested finishing time) 12 racks (60 slides), three of which can be ISH (same combination of racks as stated before).
Type of Slides	The following slides are validated for Dako Omnis: – FLEX IHC Microscope Slides, Code 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:

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: 115 V, 220 V, and 230 V Power consumption: 1,200 W per hour
External Ventilation	Not necessary
Water Supply	Four bottles of 7 L each. DIW specifications: – Conductivity 0.5–10 uS/cm (free of particles and air bubbles)
Waste Separation	Waste separation between hazardous and nonhazardous waste
Waste Capacity	Nonhazardous: 4 x 7 L bottles Hazardous: 1 x 7 L bottle
Waste Production	Average waste produced per slide: – 29 mL hazardous waste – 293 mL nonhazardous waste – 0.49 g plastic waste
Environmental Conditions	For indoor use only. Requires an environment with: – Ambient temperature between 18–28 °C (64–82 °F) – Not facing direct sunlight – Normal operating humidity between 25–85% RH; noncondensing – Pollution degree 2 – Depending on the altitude, it may be necessary to make protocol adjustments to ensure the pretreatment temperature is kept below the boiling point.

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): < 65 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: 4,100 BTU – Normal running conditions (full load): 1,500–3,000 BTU

Table 6. Protocols

Specification	Description
Validated Protocols	Validated protocols are preloaded in the system.
Protocol Templates	– IHC-HRP templates including DAB and Magenta chromogens – IHC-AP templates (avidin-biotin-based or polymer-based visualization) – Immunofluorescence templates (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. Bidirectional connectivity allows a 'staining complete' message to be returned to your LIS upon successful slide completion, where supported by the LIS. Supported barcodes are: 2D (Datamatrix, QR) and 1D (Code128, I2of5, Code 93, Code 39, Codabar, PDF417). Requirements: – Network connection from the DakoLink 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 system is correctly installed and integrated into your lab's work-flow. This can be ordered as an additional option and includes: – 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 A supplemental instrument service agreement extends the benefits of the standard instrument warranty, providing additional coverage to prevent unplanned expenses.

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