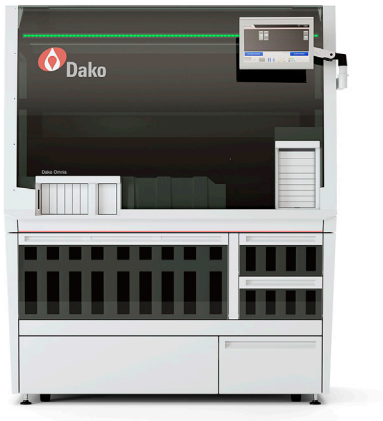
Data Sheet

Agilent Dako

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



Continuous patient-based, and lean workflow

Independent staining units, and a high reagent capacity enable you to run IHC, IF, FISH, CISH and double IHC staining 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 – confirmed by various EQA schemes
- Optimized validated protocols developed in collaboration with leading pathology experts
- EnVision FLEX detection system with two colours: 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
Processes	Fully automated staining, from deparaffinization to counterstaining. IHC and ISH validated protocols and reagents.
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, please see more details in the DakoLink Omnis software section. Designed with built-in safety measures to minimize potential human errors.
Labeling	CE and IVD-marked.
Quality system (All delivered with starter pack; can also be ordered separately).	ISO 13485, ISO 13485 CMDCAS (Canada). At delivery, the Dako Omnis instrument contains: – Dako Omnis Water Container, 7 L, 5 pcs. GC11030 – Dako Omnis Bulk Bottle, Waste Container, 7 L, 5 pcs. GC11830 – Dako Omnis Buffer/Solvent Container, 3½ L, 8 pcs, 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), GC10330 (Red), GC10430 (Blue), GC10530 (Green), GC10630 (Grey) – Dako Omnis Mixing Device, 1 unit, GC116 – Dako Omnis Mixing Strips, 25 pcs, GC10730 – Dako Omnis Solid Waste Bag, 25 pcs, GC10830 – Dako Omnis Buffer/Solvent Container Label sets, GC11130 – Dako Omnis Water/Waste Container Label sets, GC11230 – Dako Omnis Small Vial, 2 mL set, GC20130-6 – Dako Omnis Large Vial, 30 mL set, GC20230-6 – Large Flap Slide Label Kit, S341730 – Dako Omnis ISH Lid, 5 pcs, GC10230 – Dako Omnis Quick Reference Guide, GI10330 – Dako Omnis User Guides CD, international translations, 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 ensure their integrity. Please refer to the Agilent website for a complete list of reagents: http://www.agilent.com/en/products/dako-omnis-solution-for-ihc-ish
Reagent capacity	60 reagent vials.
Visualization kits	The EnVision FLEX family offers two color options: DAB and HRP Magenta. Please refer to the Agilent website for a complete list of visualization kits: http://www.agilent.com/en/products/dako-omnis-solution-for-ihc-ish
Bulk fluid capacity	8 x 3½ L bottle, for dewax, retrieval buffers and wash buffers and 4 x 7 L bottle for DI Water.
Other Dako reagents	All Dako concentrated antibodies are preloaded in the Dako Omnis database.

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 workday (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: – Continuous run (as standard daily runs) – Delayed run (based on requested finishing time)
Type of slides	The following slides are validated for Dako Omnis: – Dako FLEX IHC microscope slides (K8020) – SuperFrost 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 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: – Conductivity 0.5-10 uS/cm (Free of particles and air bubbles.)
Waste/drain	Waste separation between hazardous and non-hazardous waste.
Waste capacity	Non-hazardous: 4 x 7 L bottles. Hazardous, all below limit values: 1 x 7 L bottle. Average waste produced per slide: – 29 mL hazardous waste – 293 mL non-hazardous waste – 0.49 g of 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; non-condensing. Altitude: Up to 1000 m (3280,84 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; non-condensing.

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 *HER2* IQFISH and the EBER RNA CISH and Kappa, Lambda mRNA CISH protocols.
Protocol templates	IHC-DAB (polymer based with/without amplification). 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 Dako's 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: – 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 work-flow. This 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. Instrument service agreement extends the benefits from the standard instrument warranty to avoid unplanned expenses.

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