

D-100™ Hemoglobin Testing System

Specifications

HbA1c Testing for Diabetes

General Specifications

Dimensions

W x D x H.....660 mm x 650 mm x 725 mm
(26 in x 26 in x 29 in)

Weight103 kg (227 lb)

Operating Environment

Temperature.....15 – 35 °C

Humidity.....20 – 80%, non-condensing

Altitude.....3048 m (10,000 ft) max

Heat Generation4092 BTU/h

Power Consumption1200 VA max

Power Input Requirements.....100 – 240 V ~, 50 – 60 Hz

User Interface Integrated LCD touchscreen

Adapter/Ports

- Ethernet on RJ45 port
- RS232 on DB9 port
- External DVI-I connectors (with VGA)
- 6 External USB ports

Liquid Waste Handling

- 2 external waste bottles (5 L each)
- Can be connected to a laboratory drain

Printing Options

- On-screen result review
- Electronic printing to PDF
- External printer (available)

Required Maintenance

- Empty waste bottles (as needed)
- Clean surfaces, touchscreen, and racks (as needed)
- Perform the Clean System procedure (2 minute automated process, every 30,000 tests)

LIS Specifications

- Bi-directional capability with broadcast download of test orders
- Option to add patient demographics to printed results
- LIS result output with option to include comment record
- Chromatogram PDF can be sent automatically to a network folder

Consumable Specifications

D-100™ HbA_{1c} Elution Buffer A

Volume.....2600 mL

Number of Tests > 1100 tests per bottle

Storage Requirements.....15 – 35°C

Onboard Capacity.....2 bottles

D-100™ HbA_{1c} Elution Buffer B

Volume.....1400 mL

Number of Tests > 3000 tests per bottle

Storage Requirements.....15 – 35°C

Onboard Capacity.....2 bottles

D-100™ Wash Solution

Volume.....3300 mL

Number of Tests > 1100 tests per bottle

Storage Requirements.....15 – 35°C

Onboard Capacity.....2 bottles

D-100™ HbA_{1c} Analytical Cartridge

Number of Tests 10,000

Storage Requirements.....2 – 8°C

Onboard Capacity.....1 cartridge

D-100™ HbA_{1c} Calibrator Pack

Calibration Frequency.....once per cartridge

Storage Requirements.....2 – 8°C

D-100™ Prefilters

Number of Tests2,000

Storage Requirements.....2 – 8°C, 120 days at 15 – 35°C

Onboard Capacity.....1 prefilter



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Sample Handling Specifications

Sample Throughput.....	80 tests/hour
Time to First Result.....	2 minutes, 15 seconds
Sample Analysis Time.....	45 seconds
Sample Preparation.....	None required
Sample Capacity.....	100 samples, continuous loading
Stat Area Sample Capacity.....	3 samples (primary tube or microvial)
Minimum Sample Volume.....	1 mL (13 x 75 mm primary tube)
Specimen Type.....	Whole blood, capillary**
Whole Blood Sample Aspiration Volume.....	9 µL
Prediluted Sample Aspiration Volume.....	495 µL

Acceptable Sample Tube Types

- K2-EDTA
- K3-EDTA
- Potassium Oxalate/Sodium Fluoride
- Sodium Citrate
- Sodium Heparin
- Lithium Heparin

Supported Barcode Symbologies

- Code 39
- Code 128
- Codabar
- Interleaved 2 of 5
- EAN
- UPC

Performance Specifications

Total Precision*.....	≤1.7% CV (NGSP units)
Accuracy.....	Total Error <6%
Linear Range.....	3.5% – 20% HbA _{1c}
Minimum QC Frequency.....	Once per day
Sample Concentration Range.....	50,000 – 350,000 mAU
HbA _{1c} Units Reported.....	IFCC and NGSP

Hemoglobin Interferences

- No interference from hemoglobins S, C, D, or E
- No interference from fetal hemoglobin up to 30%
- No interference from labile HbA_{1c}
- No interference from carbamylated hemoglobin

* Total precision is based on a 3-instrument, 60-day precision study using 3 lots of reagents to generate a total of 720 data points per sample. It includes the following sources of variation: within-run (repeatability), between-run, between-day, between-instrument, and between-lot.

** Not available in US for the capillary collection kit.



**Bio-Rad
Laboratories, Inc.**

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