

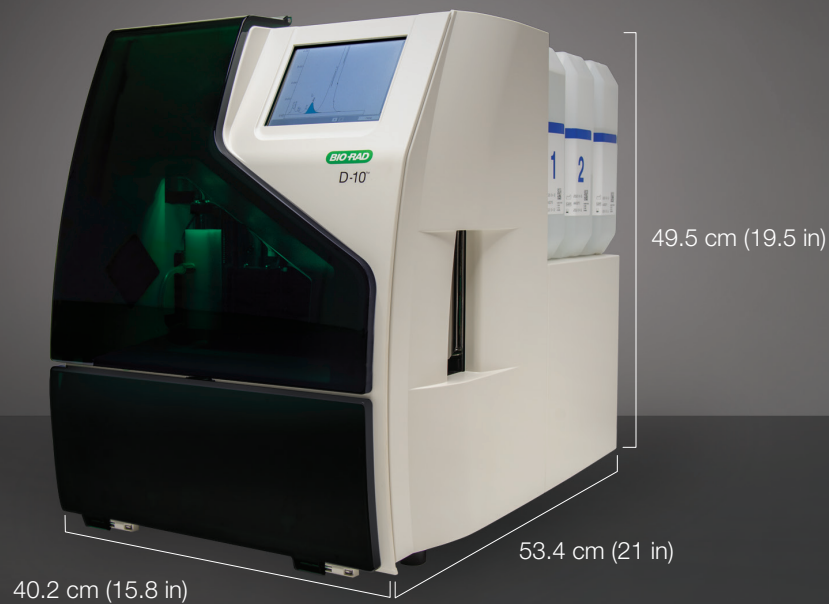
D-10 Hemoglobin Testing System

HPLC simplified in a compact, easy-to-use,
automated HbA_{1c} and HbA₂/F system



Small System with a Big Impact

The D-10 System provides comprehensive, fully automated HbA1c and HbA₂/F testing with a compact footprint. Designed for clinics, physician offices, and clinical laboratories with small to medium sample volumes, the D-10 System, with an integrated computer, fits in almost any lab and saves valuable bench space.



Customer Testimonial

“We rate the glycated hemoglobin [HbA1c test] by Bio-Rad as simply the best. Twenty years of our clinical and research experience convinces us of this fact. The D-10 HbA1c analyzer is compact, user-friendly, and gives quick results. It provides accurate and precise HbA1c results to help the physician to monitor the risk assessment for diabetes complications. The reliable results are traceable to the IFCC reference method. Chromatograms help to see the abnormal variants of hemoglobinopathies. Need we say more?”

Dr. V. Mohan, Chairman, Dr. Mohan's Diabetes Specialities Center, Chennai, India

R. Jayashri, Sr. Laboratory Manager, Dr. Mohan's Diabetes Specialities Center, Chennai, India

Over 9,000 labs worldwide have chosen the D-10 System

Bio-Rad ion-exchange HPLC is simple to use. This is one of the reasons why the D-10 System is in more than 55% of the world's countries. The D-10 System offers high performance, user-friendly steps, and no sample preparation. Most importantly, the D-10 System delivers results clinicians can trust.



Low Maintenance, Fewer Service Visits

The D-10 requires minimal maintenance beyond checking buffer and column life to run your daily samples. Minimal maintenance means less hands-on technician time and higher productivity. With the D-10 System your maintenance calendar could look like this:

DAILY
5 minutes



MONTHLY
15 minutes



BIANNUALLY
30 minutes



With an average intervention rate of less than one visit per year, you won't be caught by surprise with unexpected downtime.

Easy to Use, Easy to Train

From easy reagent preparation to results review, the D-10 System is designed to simplify HPLC so you can easily train your staff. With automated features and a multilingual user interface, it's easy to integrate into your lab workflow.



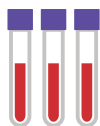
Easy Start Up*

The kit CD automatically updates lot information and settings. Then simply reconstitute reagents and install the cartridge.



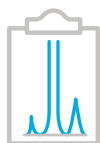
Minimal Calibration and Quality Control†

Calibrate just once for the HbA1c kit and run quality control every 24 hours.



Sample Processing

Load samples—no sample preparation, no de-capping—and press Start.



Results Review

Easy-to-read colored, calibrated peaks simplify results review. Common hemoglobin variants appear in dedicated windows.

Personalized report headers are available. Add your logo or laboratory name to all of your results.

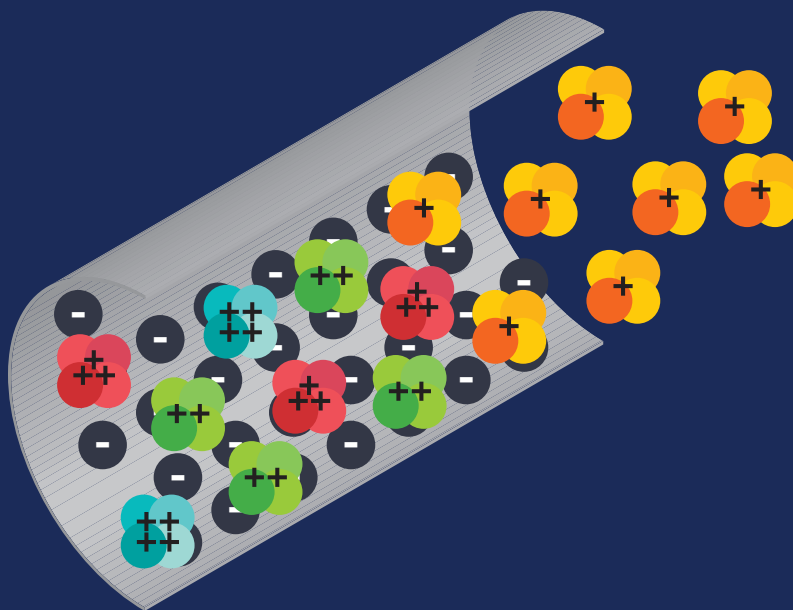
Send results to a file, a USB drive, a network folder, or the LIS. Or, print your results with the optional D-10 Printer Installation Kit.

Export chromatograms to link with results on the LIS.

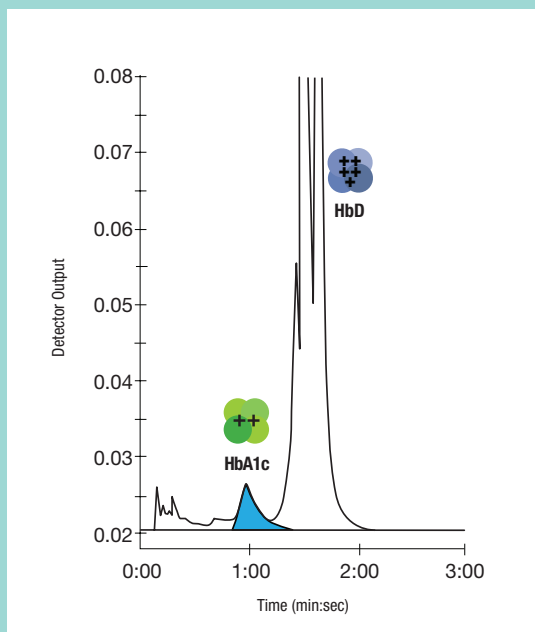
*Automatic start up is available so the D-10 System is ready when you are.

†Calibrate every 24 hours when switching from the D-10 Short to the D-10 Extended Program.

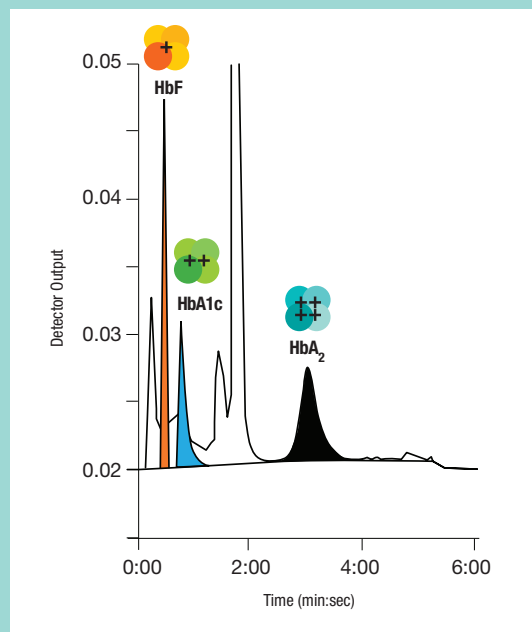
Take Control of Your Diabetes and β -thalassemia with Ion-Exchange HPLC Separation



Clinicians are Turning to Ion-Exchange HPLC for Accurate HbA1c and HbA₂/F Results



A1c sample in the presence of HbD:
HbA1c program



Sample from a β -thalassemia trait:
HbA₂/F/A1c program

Why Clinicians Value HPLC for Accurate A1c Results

Not all HbA1c assays are created equally

Given our history and experience in HbA1c and β -thalassemia testing, it's no wonder that over 9,000 of your peers around the world have chosen the D-10 System over other methods.

Bio-Rad ion-exchange HPLC provides a complete picture

Our HPLC technology provides both a numerical result and a visual picture of the separated hemoglobins, distinguishing hemoglobin fractions based on charge differences. Other methods cannot provide this clinical information. A chromatogram helps clinicians see potential interferences that may affect their patients' HbA1c results and help explain discordant results in the presence of interferences so they can choose the appropriate treatment.



Customer Testimonial

"The D-10 System helps healthcare providers manage patients with military precision."

*William Maranto, MD,
Bossier Family Medicine,
Bossier, Louisiana, USA*

Uncovering the Ion-Exchange HPLC Advantage

HbA1c accuracy in the presence of:

	Elevated HbF (up to 10%)	Elevated HbF (> 10%)	Common Hemoglobin Variants	HbA ₂ /F	Homozygous & Double Heterozygous Variants
Bio-Rad Ion-Exchange HPLC	RR	RNR	RR	RR (Dual Kit Extended Program)	RNR
Immunoassay	RR	RR	RR	RR	RR
Enzymatic					
Boronate Affinity					

RR = Results released
RNR = Results not released

- Clinically accurate
- Clinical accuracy unproven (potential interference is unknown) and no patient chromatogram is provided
- Clinically accurate: HbA1c can't be released when HbF > 10%
- Clinically accurate: HbA1c is not present so it can't be measured and is not reported
- Clinically inaccurate: HbA1c is not present so it can't be measured and should not be released

For informational purposes only and not intended to provide medical advice or diagnosis. Data comes from the respective Instructions For Use of each methodology.



Every patient deserves quality results. You can rely on the D-10 System to provide accurate, repeatable, gold-standard results without interference from lipemia up to 6,000 mg/dl (60g/L) and from elevated HbF up to 10%, as well as the most common heterozygous hemoglobin variants: HbS, HbC, HbD, and HbE.

One System, Two Tests

The D-10 System offers easy switching between HbA1c and HbA₂/F/A1c testing on a single platform without changing the cartridge or reagent. Report results in NGSP and/or IFCC units. Spend less time preparing sample runs, get testing done faster, and increase overall lab productivity.



D-10 Hemoglobin A1c Program

400 HbA1c tests



Screen for prediabetes, diagnose, and monitor patients living with diabetes

Directly measure HbA1c with ion-exchange HPLC which meets the most stringent guidelines for diagnosing diabetes. Report high quality, clinically-relevant HbA1c results without interference from HbS, HbC, HbD, and HbE heterozygotes. HbF is detectable and there's no interference with the results at normal levels and up to 10%.



D-10 Dual Program

400 HbA1c tests or 200 HbA₂/F/A1c tests



Test for diabetes and β -thalassemia in one kit

The D-10 Dual Program can be used for β -thalassemia screening by quantitation of HbA₂ and HbF, and for the detection of abnormal hemoglobins. Select the Short Program to report HbA1c without interference from HbS and/or HbC. Choose the Extended Program to report HbA1c without interference from HbS, HbC, HbD, and HbE. The Extended Program is also the method of choice for β -thalassemia testing. HbA1c, HbF, and HbA₂ are calibrated to provide accurate results including clear resolution of HbS from HbA₂.



Customer Testimonial

"We have used the D-10 System since 2007 and it is very user-friendly. Thanks to the D-10 Dual application [Extended Program], we report accurate HbA1c results even in the presence of hemoglobins S, C, D, and E! We totally trust our D-10 for reporting HbA1c, HbA₂, and HbF results. For us, the D-10 stands for reliability and confidence to take care of our patients."

Mrs. Ledortz, Biologist and Mrs. Poisson, Technician, Saint Camille Hospital, Bry-Sur-Marne, Paris, France

As Your HbA1c Testing Volumes Grow Add a D-10 Rack Loader

The incidence of diabetes is increasing worldwide. At some point, you might need to expand your HbA1c testing capacity. Because the D-10 System grows with the testing needs of your lab, you won't have to buy a new system or perform a validation study. Expand your walkaway capacity with a D-10 Rack Loader, that can be installed in a single service visit, and improve your lab's HbA1c efficiency and overall laboratory productivity.



A Case for Bio-Rad Ion-Exchange HPLC

Bio-Rad Laboratories has played a leading role in the advancement of scientific discovery by providing tools and services to the life science research and clinical diagnostics markets. Founded in 1952, Bio-Rad serves more than 85,000 research, industry, and clinical laboratories across the globe and is the world's leading specialty diagnostics company. Bio-Rad products are recognized as the gold standard for diabetes testing, hemoglobinopathy screening, and quality control (QC) systems.

Bio-Rad ion-exchange HPLC is the gold standard in HbA1c testing

The reason Bio-Rad ion-exchange high performance liquid chromatography (HPLC) is the gold standard for HbA1c testing is our distinct technology/method used in the Diabetes Control and Complications Trial (DCCT)^{1,2} and the UK Prospective Diabetes Study (UKPDS).³ To this day, healthcare providers around the world still follow the HbA1c testing guidelines, established by these landmark trials, to aid in the diagnosis and monitoring of patients living with diabetes. No other commercial method or HPLC system can make this claim.

Certifications for quality HbA1c results clinicians can trust

Backed by 40 years of research in diabetes, hemoglobinopathies, and β -thalassemia, the D-10 System is NGSP certified, standardized to DCCT as recommended by the American Diabetes Association (ADA),⁴ and IFCC traceable. In addition, our assays are CE marked and FDA cleared. Calibration uncertainty is certified.

Be the difference for clinicians and patients who count on you

Your clinicians depend on HbA1c results to help provide accurate treatments and diagnoses. We're dedicated to helping you be the difference for your clinicians and their patients. That's why we're committed to quality products and reliable results to help improve patient outcomes. Like you and your clinicians, we believe that missing one diagnosis is one too many.

REFERENCES

1. DCCT Research Group (1996). The absence of a glycemic threshold for the development of long-term complications: the perspective of the Diabetes Control and Complications Trial. *Diabetes* 45(10), 1289–1298.
2. Nathan, DM et al. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *The New England Journal of Medicine* 329(14), 977–986. doi.org/10.1056/NEJM199309303291401
3. U.K. Prospective Diabetes Study (UKPDS) Group (1998). Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *UK Prospective Diabetes Study (UKPDS) Group. Lancet* 352:837-53.
4. American Diabetes Association (2020). Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2020. *Diabetes Care* 43(Supplement 1): S98-S110. Retrieved from doi.org/10.2337/dc20-S009

Commitment to Quality Control

With over 50 years of experience, Bio-Rad Laboratories offers a vision and a commitment to quality control that is unsurpassed in the clinical laboratory industry. The D-10 System's onboard QC module easily integrates into your laboratory's quality management program and can help to improve the reliability of your laboratory's results.



Onboard QC Module

Fixed ranges

Use if you are using a QC reagent lot for the first time or have set decision limits for several systems or laboratories.

Levey-Jennings reports

Visualize QC trends at a glance. The system plots QC data over time and calculates mean, standard deviation, and CV.

Export QC results to Unity Real Time

Reduce hands-on time and fully automate your laboratory's QC management program.

Option to stop sample processing when QC is flagged

Prevent erroneous patient results from being released to the LIS and preserve patient samples to rerun after the QC failure is resolved.

Optional Westgard rules

Implement the rules after obtaining a minimum of 20 QC data points to fine tune your quality control.

- 2-2s rule flags when 2 points are more than 2 standard deviations from the mean
- 1-3s rule flags when 1 point is more than 3 standard deviations from the mean

Supplemental QC Products



Quality Control Products

Bio-Rad multilevel Liquechek and Lyphochek Diabetes Controls can assist your laboratory in delivering quality HbA1c results. Choose the quality control product that suits your program the best.



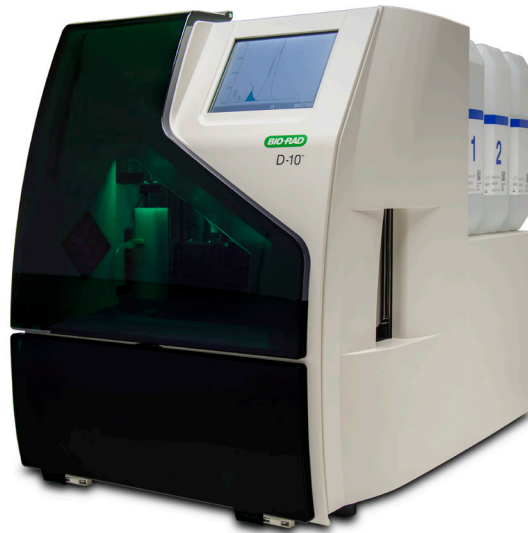
EQAS Hemoglobin Program

External quality assessment programs are invaluable tools used by laboratories to periodically monitor the performance of their test systems. Results are objectively compared to other laboratories using the same methodologies, instruments, and reagents. When used in conjunction with daily quality controls, these external programs can give laboratories added confidence in reporting their patient test results.



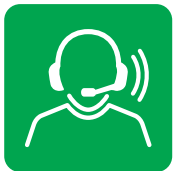
QC Data Management Solutions

The ability to successfully manage and interpret your quality control results is essential to producing solid, dependable laboratory outcomes. Connect your laboratory to the Unity Interlaboratory Program, the world's largest community of quality control users, to improve patient results and cost effectiveness.



Our Commitment

Quality patient care is at the heart of what you do and the reason why we're constantly working to ensure that our products, services, cybersecurity applications, and educational tools meet your needs. No matter the continent, country, or city, Bio-Rad offers direct support that you can depend on.



Unparalleled Support

Bio-Rad's world class technical support and service engineers are backed by over 40 years of expertise in HbA1c testing and quality controls. Should you need immediate assistance, our hemoglobin testing systems can be connected to BRiCare, Bio-Rad's 24/7 remote application support to keep your system running smoothly. Less downtime for your laboratory means more uptime for generating high-quality results.



Cybersecurity

Rest assured, your laboratory and the D-10 System are protected. The AppLocker whitelisting utility locks down the D-10 software configuration so only known and approved programs can be executed. Microsoft Windows 10 OS guarantees support for security updates and our optional AI-driven CylancePROTECT antivirus software defends against online threats.



Library of Variants

The Library of Variants is an educational tool and reference database of over 200 hemoglobinopathy cases. Should you encounter a challenging case, Bio-Rad is committed to ensuring you have the resources you need. No other company provides this service and at no cost. Visit the Library of Variants portal at hemoglobins.bio-rad.com.

Ordering Information

Catalog No.	Description	
12010405	D-10 Hemoglobin Testing System (110/220V) with Accessories	1 unit
220-0600	D-10 Rack Loader	1 unit
12011384	D-10 Printer Installation Kit	1 unit
220-0468	D-10 Printer Paper	10 rolls
12000949	D-10 Hemoglobin A1c Program	400 tests
220-0109	D-10 Hemoglobin A1c Supplemental Reagent Pack*	1 each
220-0201	D-10 Dual Program Reorder Pack	400 HbA _{1c} tests or 200 HbA ₂ /F/A1c tests
553	Lyphocheck Hemoglobin A ₂ Control, Bilevel (2 each of 2 levels)	4 x 0.5 mL
740	Lyphocheck Diabetes Control, Bilevel (3 each of 2 levels)	6 x 0.5 mL
171	Liquichek Diabetes Control Level 1	6 x 1 mL
172	Liquichek Diabetes Control Level 2	6 x 1 mL
173	Liquichek Diabetes Control Level 3	6 x 1 mL
12000070	Lyphocheck Hemoglobin A1c Linearity Set (1 each of 6 levels)	6 x 0.5 mL
BC80	EQAS™ Hemoglobin Program (3 analytes)	12 x 0.5 mL
804	Unity Real Time Installation Package	Single use
804-1	Unity Real Time	Annual subscription
11000759	CylancePROTECT® 5 yr Subscription	1 each

*If your lab runs less than 200 tests per month or fewer than 4 samples per run, a Supplemental Reagent Pack ensures that your lab will fully utilize the 400 test cartridge.

D-10 Replacement Accessories

Catalog No.	Description	
220-0302	D-10 Sample Rack	1 each
220-0314	D-10 Buffer Tubing Set	1 set
220-0380	D-10 Sample Bar Code Labels	2 sheets of 45 labels
220-0634	D-10 Rack Loader Rack ID Bar Code Labels	1 set
220-0149	D-10 Microvial Tubes	1 each
220-0297	D-10 Microvial Tube Adapters	1 set
220-0303	D-10 Rack Adapter, 12 mm	1 set
220-0304	D-10 Rack Adapter, 13 mm	1 set
220-0305	D-10 Rack Adapter, 14 mm	1 set

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**Clinical
Diagnostics Group**

Website www.bio-rad.com/diagnostics **U.S.** 1 800 224 6723 **Australia** +61 (2) 9914 2800 **Austria** +43 (0) 1 877 89 01 9 **Belgium** +32 (0) 3 710 53 00 **Brazil** +55 11 3065 7550
Canada +1 514 334 4372 **China** +86 21 6169 8500 **Czech Republic** +420 241 431 660 **Denmark** +45 44 52 10 00 **Finland** +358 9 804 22 00 **France** +33 (0)1 47 95 60 00
Germany +49 (0) 89 31884 393 **Greece** +30 210 7774396 **Hong Kong** +85 2 2789 3300 **Hungary** +36 1 459 6190 **India** +91 124 4029300 **Israel** +972 03 963 6025
Italy +39 024 94 86 600 **Japan** +81 3 6361 7070 **Korea** +82 080 007 7373 **Mexico** +52 (55) 5488 7670 **The Netherlands** +31 (0)318 540 666 **New Zealand** +64 (9)415 2280
Norway +47 23 38 41 30 **Poland** +48 22 331 99 99 **Portugal** +351 21 47 27 700 **Russia** +7 495 721 1404 **Singapore** +65 6415 3170 **South Africa** +27 11 442 8508
Spain +34 91 490 6580 **Sweden** +46 844 98053 **Switzerland** +41 (0) 61 717 9555 **Taiwan** +886 (2) 2578-7189 **Thailand** (662) 651 8311 **United Kingdom** +44(0)1923 471301