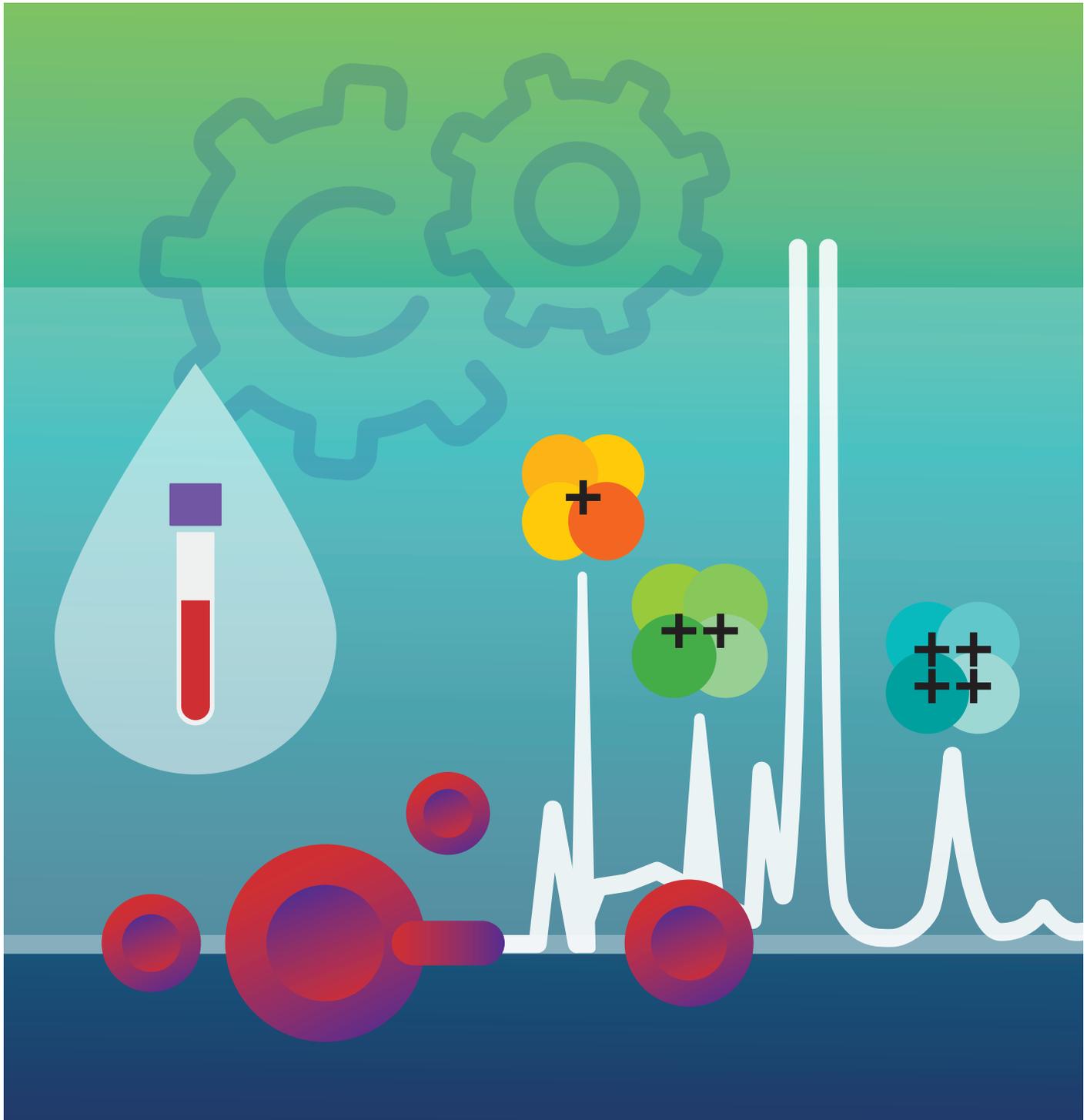


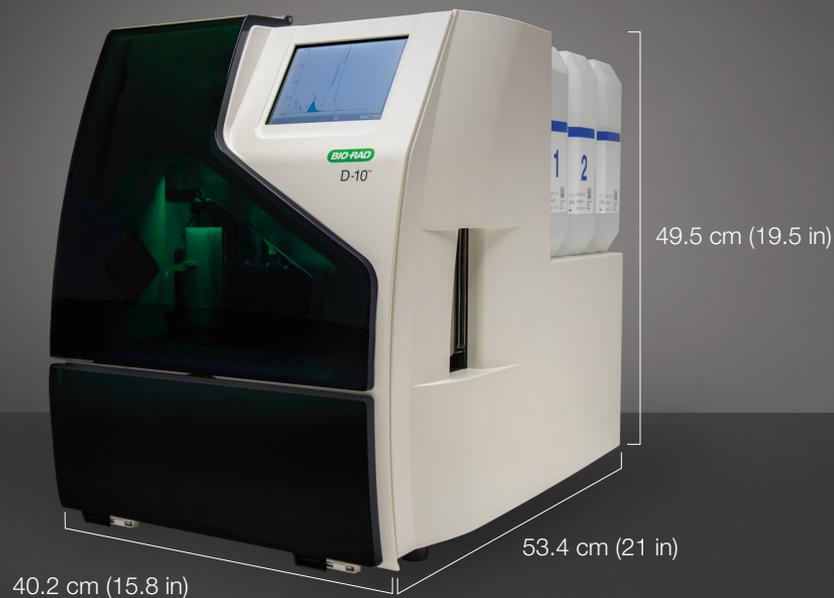
D-10 Hemoglobin Testing System

HPLC simplified in a compact, easy-to-use, automated HbA1c 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, and R. Jayashri, Sr. Laboratory Manager
Dr. Mohan's Diabetes Specialities Centre, 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 countries worldwide. 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 System requires minimal maintenance beyond checking buffers 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.



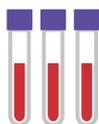
Easy Start Up*

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



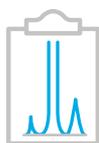
Minimal Calibration and Quality Control†

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



Sample Processing

Load samples and press Start. No sample preparation, barcode alignment, or de-capping required.



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 Program to the D-10 Extended Program.

A Case for Bio-Rad 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 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.

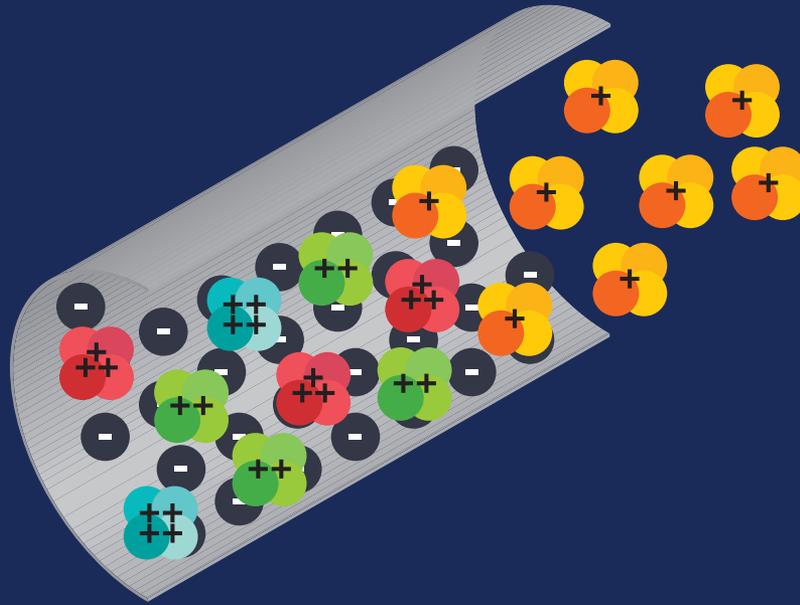
Be the difference for clinicians and patients who count on you

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.

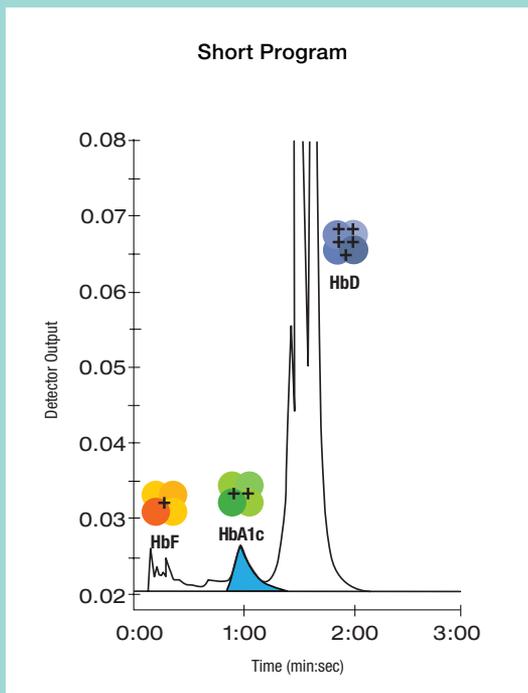
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2. Nathan, DM et al. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *The New England Journal of Medicine* 329(14), 977–986. doi.org/10.1056/NEJM199309303291401.
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. doi.org/10.2337/dc20-S009.

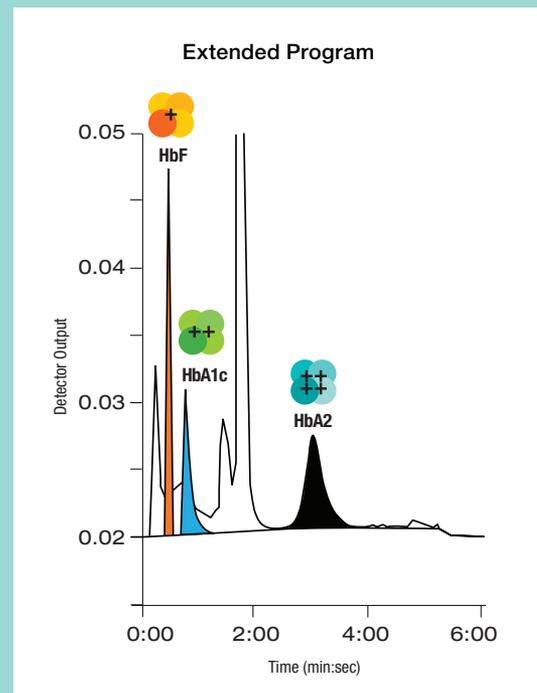
Take Control of Your Diabetes and β -thalassemia with HPLC Separation



Clinicians are Turning to HPLC for Accurate HbA1c, HbA2, and HbF Results



AD sample: Only HbA1c is measured.
HbD and its glycated fraction are excluded.



β -thalassemia trait sample: HbA1c is measured with HbF and HbA2

Report Clinically Accurate A1c Results with the D-10 System

Not All A1c Methods Are Equal

Bio-Rad HPLC separates A1c and other hemoglobins based on their differing charges. In non-charge-based methods, such as immunoassay, enzymatic, and boronate affinity, the risk of reporting clinically inaccurate A1c results is high in the presence of lipemia, elevated HbF, and homozygous and double heterozygous variants.

If A1c assays cannot reveal hemoglobin variants or minimize interference from other common physiological conditions, A1c values may be erroneously elevated or depressed. This may lead to misinterpretation of A1c results, false diagnoses, or misdiagnoses, and unnecessary or delayed patient treatment – all of which contribute to increased healthcare costs. This is why the right A1c method matters.

With the D-10 System, you can be confident that you are reporting the best quality results available.



Customer Testimonial

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

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

Conditions Affecting A1c Measurement

Comparing different methods and potential for reporting clinically inaccurate results

	Lipemia	Elevated HbF (up to 10%)	Homozygous & Double Heterozygous Variants
D-10 Cation-Exchange HPLC System	Clinically accurate results* produced	Clinically accurate results produced	Hemoglobin variants revealed in chromatogram
Immunoassay	Results† released with potential unknown interferents	Results released with potential unknown interferents	Clinically inaccurate results‡ released
Enzymatic			
Boronate Affinity			

For informational purposes only and not intended to provide medical advice or diagnosis.

* Up to 6,000 mg/dL

† Variable claims between 500 mg/dL and 3,000 mg/dL^{1,2}

‡ A1c is not an appropriate analyte to determine glycemic status. For homozygous and double heterozygous cases, HbA is not present so there is no A1c to measure. Another analyte must be used to evaluate glycemic status, per the ADA guidelines.³

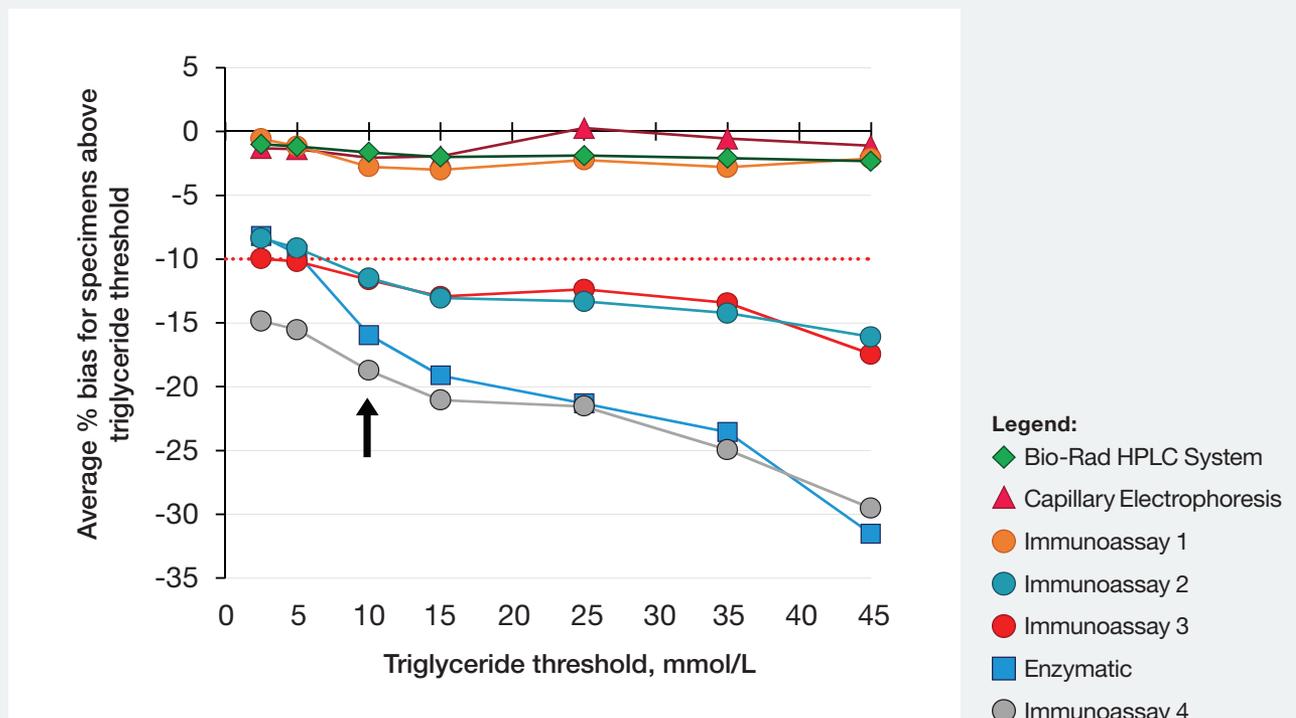
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1. Parker ML et al. (2018). HbA1c platforms are variably affected by increasing lipemia. Abstract A-288. 70th AACC Annual Scientific Meeting Abstracts.
2. Mainali S et al. (2017). Frequency and causes of lipemia interference of clinical chemistry laboratory tests. Practical Laboratory Medicine 8, 1–9. <https://doi.org/10.1016/j.plabm.2017.02.001>.
3. ADA (2022). Standards of medical care in diabetes—2022. Diabetes Care, 45 (Supplement 1), S17-S38.

Report Clinically Accurate A1c Results without Lipemic Interference

Many people living with diabetes also present with lipemia, defined by elevated triglycerides. Certain A1c testing methods release falsely lowered A1c results due to lipid interference. In a study presented at the American Association for Clinical Chemistry in 2018 titled "HbA1c Platforms are Variably Affected by Increasing Lipemia,"¹ the performance of nine A1c platforms was evaluated using clinically lipemic samples. This study demonstrated that both immunoassay and enzymatic methods were susceptible to lipemic interference from elevated triglycerides, while HPLC and CE methods were not. A second head-to-head study by Wu et al. also concluded that the immunoassay method showed negative bias in the presence of lipemia.²

Assay Performance in the Presence of Clinical Lipemia



The graph shows that most immunoassays and the enzymatic method show negative bias in the presence of triglycerides, with some even showing increased bias in proportion to the level of lipemia. The Bio-Rad HPLC System, a lipemia-resistant platform, reported A1c values without significant change from baseline in the presence of triglycerides.

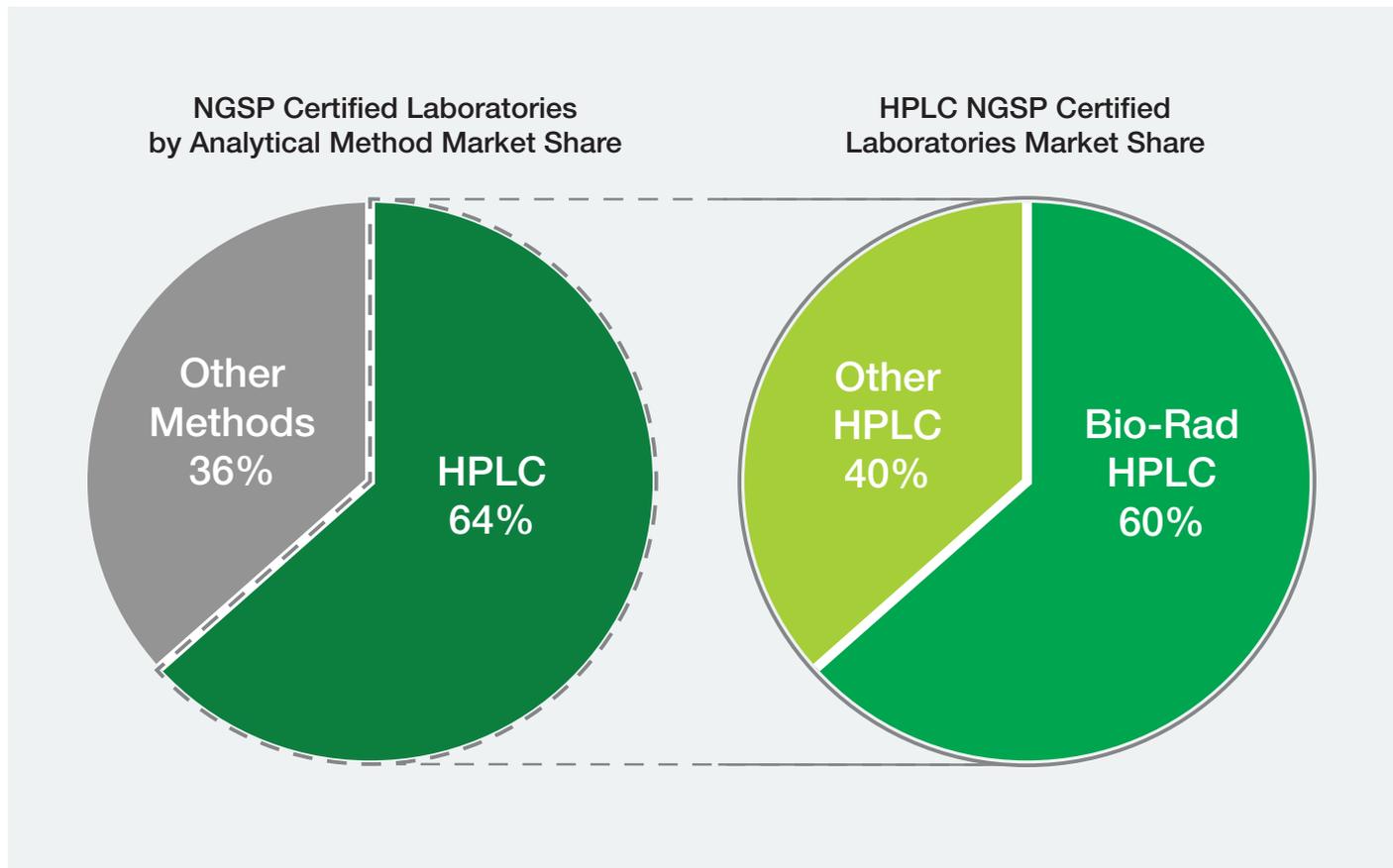
The authors concluded that a serum triglyceride threshold of approximately 10 mmol/L (indicated by a black arrow in the graph above) may warrant a cautionary note when reporting HbA1c or reflexive testing on a lipemia-resistant platform.

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1. Parker ML and Yip PM (2018). HbA1c platforms are variably affected by increasing lipemia. Department of Laboratory Medicine and Pathobiology, University of Toronto, Department of Clinical Biochemistry, University Health Network, Toronto, Canada. https://www.bio-rad.com/sites/default/files/2021-08/doc_HbA1c-Lipemia-Poster_AACC_2018-06-29_FINAL.pdf. Accessed July 21, 2022.
2. Wu X et al. (2016). A comparative evaluation of the analytical performances of Capillarys 2 Flex Piercing, Tosoh HLC-723 G8, Premier Triglycerides Hb9210, and Roche Cobas c501 Tina-quant Gen 2 analyzers for HbA1c determination. *Biochimica Medica*. 26, 353-64.

Compare How Bio-Rad Ranks Among NGSP Certified Labs

Our ion-exchange HPLC is the gold standard for A1c testing because of our technology's role 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 A1c testing guidelines established by the results of these landmark trials, to aid in the diagnosis and monitoring of patients living with diabetes.



The CE marked and FDA cleared D-10 HbA1c Assay is:

- NGSP (National Glycohemoglobin Standardization Program) certified
- Standardized to DCCT (Diabetes Control and Complications Trial) per American Diabetes Association (ADA) recommendations⁴
- IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) traceable

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. ADA (2022). Standards of medical care in diabetes – 2022. *Diabetes Care*, 45 (Supplement 1), S17-S38.

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 common hemoglobin variants: HbS, HbC, HbD, and HbE. 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, which can be installed in a single service visit, and improve your lab's HbA1c efficiency and overall productivity.



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 Software

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 Liquichek 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 those of 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.

Access Remote Service and Support with BRiCare

Rounding out our tools to control and manage your D-10 System are BRiCare Remote Service and Support and Bio-Rad's Product Cybersecurity Program to provide services that help you maintain the integrity of your instruments and stay on top of the latest cybersecurity threats.

BRiCare Remote Service and Support

BRiCare is a cloud application that securely connects Bio-Rad instruments to fast and efficient remote Bio-Rad support.

When connected to Bio-Rad instruments
BRiCare offers remote:

- system management
- D-10 Application updates
- cybersecurity monitoring
- training and technical support



Through continuous monitoring and remote sessions of the instrument's computer, the BRiCare cloud server monitors, collects, and saves instrument information such as instrument logs, assay information, etc. Bio-Rad's technical teams can access the information to quickly identify issues to improve instrument uptime.



HIPAA, GDPR, and CLSI Standards Met for Remote Internet Access

BRiCare meets remote internet access standards including HIPAA guidelines for encrypted internet access, GDPR directives regarding cookies and tracking technologies, and CLSI standards.

Defend Against Digital Threats with CylancePROTECT®

Bio-Rad is making advances in defending against online threats with a novel approach to antivirus programs. CylancePROTECT® uses sophisticated artificial intelligence to identify and neutralize viruses before they infect or immobilize critical healthcare systems.

Unlike traditional antivirus programs, CylancePROTECT® uses AI, not signatures, to block known and unknown malware from running. This means it delivers premium protection without the need for constant updates and connectivity. CylancePROTECT® offers unparalleled protection from potentially crippling cyberattacks for Bio-Rad's range of diagnostic systems.

AI-Driven Malware Prevention

Lightning-fast artificial intelligence software inspects any application attempting to run on the system before it can execute.

"Zero-Day" Threat Prevention

Utilizing unique mathematics models, CylancePROTECT® can identify and neutralize cyber threats without ever having "seen" them before.

Lightweight

CylancePROTECT® is a lightweight program that uses only a fraction of system memory and resources compared with traditional antivirus software, meaning no impact on your daily testing environment.

Device Management

The program has built-in components that control and regulate the use of external devices, helping to eliminate threats from infected USB drives that are possible vectors of attack.

Labs with Limited Connectivity

Using a self-contained AI mathematical model, CylancePROTECT® has minimal needs for updates or a cloud connection.

Validated by Bio-Rad Laboratories

CylancePROTECT® is the antivirus software of choice, validated for compatibility with your critical Bio-Rad diagnostic systems.



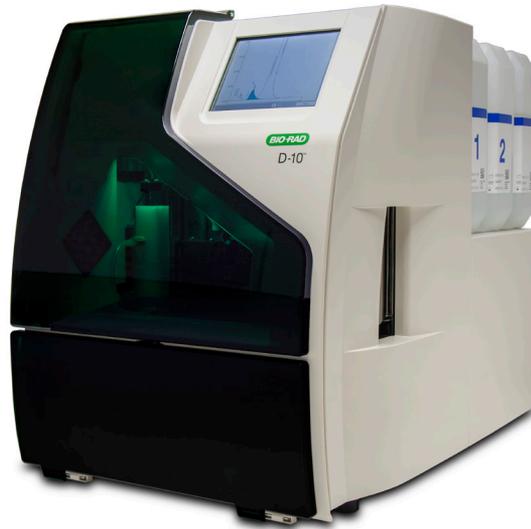
Microsoft AppLocker

Protection against malicious software

AppLocker is validated and deployed on the D-10 Hemoglobin Testing System. This helps control which programs and executable services can be run, preventing unwanted applications.

The Microsoft Windows 10 built-in "whitelist" protection feature specifies exactly which applications are allowed to run in order to protect the D-10 System and your laboratory network from cybersecurity threats. For instance, predefined Bio-Rad D-10 Executable Files and Windows executable files are allowed to run, while all other non-system executable files, including malware, cannot run.





Our Commitment of Support

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. Their experience combined with our remote diagnostic software keep your system running smoothly. Less downtime for your laboratory means more uptime for generating high-quality results.



"Test Your Knowledge" Education Program

As the world becomes smaller and people move around, it's inevitable that your lab will start seeing more hemoglobin variants in your A1c samples. To help you evaluate unknown peaks from potential hemoglobin variants on your chromatograms, we've developed educational resources and case studies for your lab.



Library of Variants

The Library of Variants is an educational tool and reference database of over 200 hemoglobinopathy cases. Reviewing challenging chromatograms against the cases in the database can offer valuable insights and guidance.

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 HbA1c tests or 200 HbA2/F/A1c tests
553	Lyphochek Hemoglobin A ₂ Control, Bilevel (2 each of 2 levels)	4 x 0.5 mL
740	Lyphochek Diabetes Control, Bilevel (3 each of 2 levels)	6 x 0.5 mL
12011343	Liquichek Diabetes Control Level 1	6 x 1 mL
12011344	Liquichek Diabetes Control Level 2	6 x 1 mL
12011345	Liquichek Diabetes Control Level 3	6 x 1 mL
12000070	Lyphochek 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 Software	Annual subscription
11000759	CylancePROTECT	1 each

*If your lab runs less than 200 tests per month or fewer than four 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

Visit bio-rad.com/diabetes for more information.

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**Bio-Rad
Laboratories, Inc.**

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 **Mexico** +52 (55) 5488 7670
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Republic of Korea +82 080 007 7373 **Russia** +7 (495) 721-14-04 **Singapore** +65 6415 3170 **South Africa** +27 11 442 8508 **Spain** +34 91 49 06 580
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