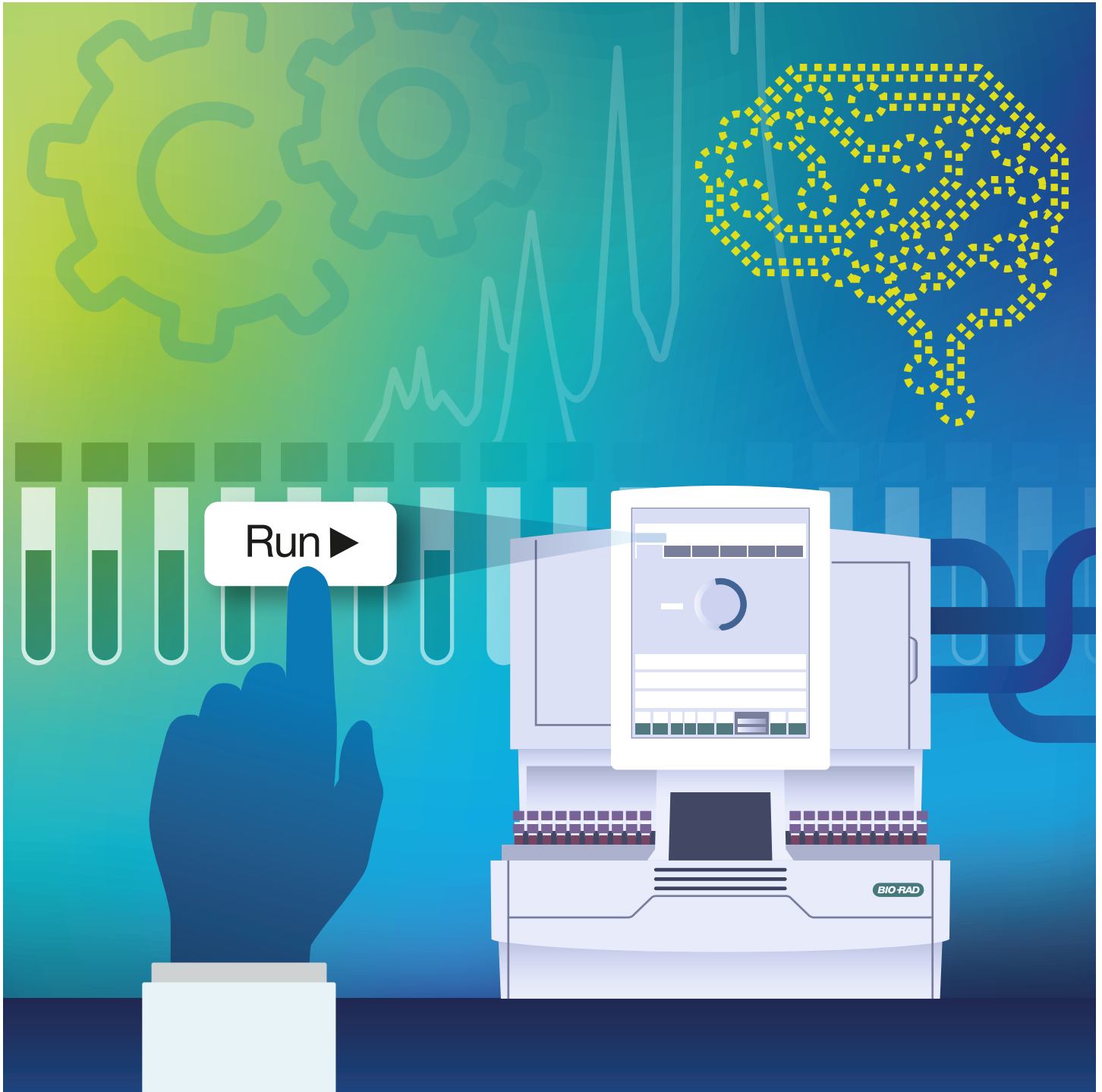


D-100 Hemoglobin Testing System

Get More Done. Work Smarter. Be Confident.



Pinnacle of A1c Efficiency and Productivity



The D-100 is the pinnacle of A1c testing because it offers large volume laboratories a complete A1c solution from high throughput performance with gold standard quality to streamlined operation, reduced costs, and improved productivity.

Get More Done

The D-100's automated features eliminate redundant, low-value tasks such as daily maintenance to optimize A1c efficiency, reduce costs, and improve turnaround time.

Work Smarter

The D-100 is the only A1c system to bring you SMART HPLC and a user-friendly Onboard Advisor Software to automate results review.*

Be Confident

Bio-Rad HPLC technology powers more NGSP certified labs than any other A1c system in the world.

A1c Support

We are the partner of choice in delivering a complete A1c solution of support: 24/7 technical support, BRiCare remote support, CylancePROTECT® cybersecurity, quality controls, and online educational resources.

*Please consult your local regulations regarding autoverification.



Get More Done

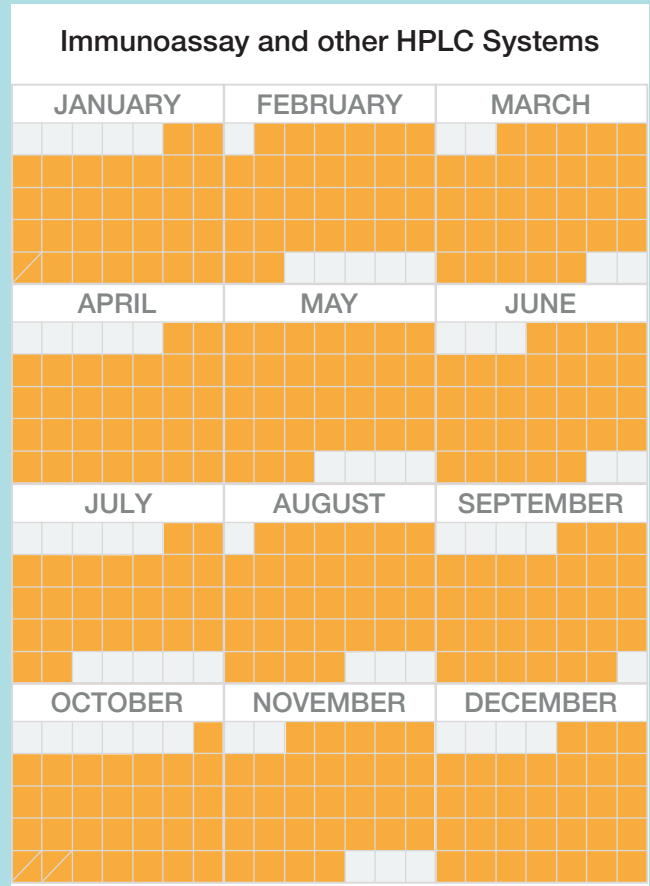
The D-100 System is the most advanced A1c testing solution. It was designed to simplify your workflow by marrying decades of R&D innovation with lean six sigma principles. The D-100 simplifies high throughput A1c testing without sacrificing high-quality results. The D-100 streamlines workflow through automation unlike other systems on the market. The D-100 allows you to simply load your samples and walk away. The D-100's automated features do the work and save you time.

In the real-world case studies that follow, the D-100 demonstrates how it achieves lean six sigma objectives by eliminating redundant, low value tasks, instrument interactions, daily maintenance, and unnecessary operator movement to help your lab optimize A1c productivity and reduce costs.

Eliminate Daily Maintenance

Based on an annual throughput of 60,000 A1c tests, lab operators would need to perform system cleaning on the D-100 once every 30,000 tests, or twice a year. The D-100 cleaning procedure takes only 15 minutes and is fully automated – no operator hands-on time. Other HPLC and immunoassay methods require routine daily maintenance.

Which maintenance routine would you prefer?



■ Scheduled Hands-on Maintenance



Click to
view video >

See how the D-100 eliminates operator tasks and hands-on time like daily maintenance.

bio-rad.com/d100/reduce-time

Simplify Operator Movement

The D-100 System does not require daily maintenance. And what's more, startup and sample running processes are automated. Just load and go!

In contrast, immunoassay systems require extensive daily maintenance and instrument preparation activities before starting the run. This wastes valuable time and labor every day.

Which system workflow would you prefer?

D-100 Workflow

- Load QC and patient samples all at once
- **Start**

Immunoassay Workflow

- Daily maintenance
- Load reagents
- Program startup operations
- Load & perform QC run
- Analyze QC results
- Place samples in rack
- Orient barcode
- Mix samples
- Load
- **Start**



Click to
view video >

See how the D-100
simplifies your lab operator
movement compared to
immunoassay.

bio-rad.com/d100/reduce-time

Release A1c Results Faster

Does your A1c system require pre-analytical activities and low-value tasks that increase the time to first result? The D-100 System is the solution for reducing redundant, time-consuming operator tasks.

What if you could reduce time to first result?

D-100 System



7.5 minutes

■ Perform & analyze QC ■ Rack samples ■ Sample analysis

Immunoassay



91 minutes

■ Daily maintenance ■ Program startup ■ Load reagents ■ Perform & analyze QC
■ Rack samples ■ Orient barcodes ■ Mix samples ■ Sample analysis

In this real-world case study, the D-100 eliminated pre-analytical activities through an automated system that starts running samples within eight minutes. The immunoassay, however, required multiple pre-analytical activities before samples were processed in 91 minutes.

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

Customer Testimonial

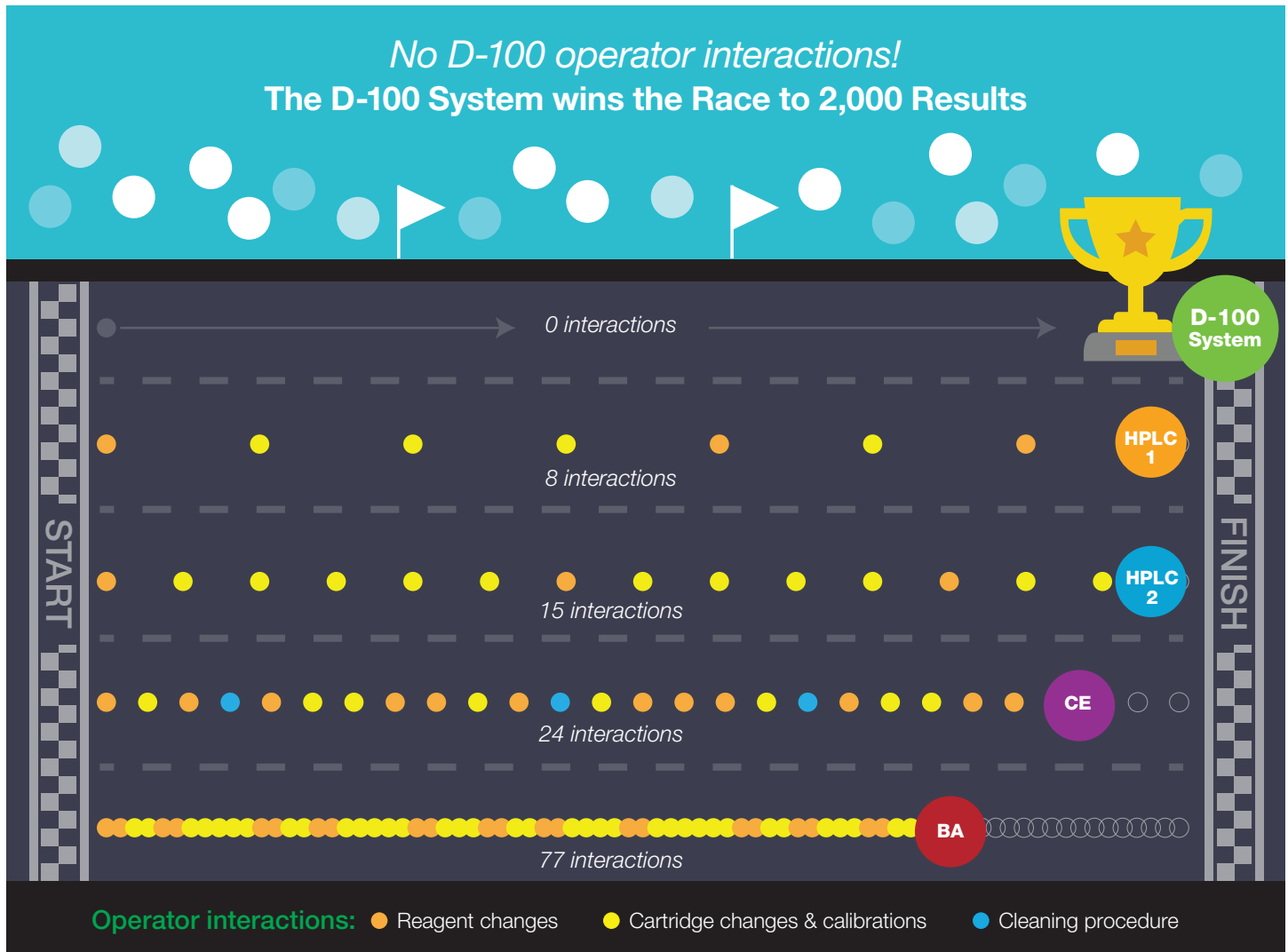
“D-100 provides a number of advantages in daily operation including the instrument's computer and software, that is controlled by an easy-to-use touchscreen.”



Reduce Instrument Interactions and Improve Turnaround Time

The workflow performance of five A1c systems was evaluated by reviewing their IFUs and operation manuals for sample throughput and operator interventions.

The D-100 System, with an onboard reagent capacity of 2,000 samples, runs continuously without operator intervention. When reagents need to be changed, they can be loaded “on-the-fly” without stopping the run.



Data on file. Interactions were evaluated by reviewing each of the assays' respective Instructions for Use and product documentation. For informational purposes only and not intended to provide medical advice or diagnosis.



Click to view video >

See how fast the D-100 is compared to its competitors.

bio-rad.com/d100/raceto2000



Work Smarter

Operators are your most valuable asset. Our technology was developed to complement their skills and maximize efficiency, so your lab becomes more productive. D-100 incorporates intelligent features that deliver best-in-class quality results, streamlined workflow, leading edge security, and remote service capabilities that unleash the full potential of your lab staff. Give them back time and empower them to work smarter with D-100 A1c.

Automate Security and Traceability

The D-100 reduces the potential for human error by automating redundant, low value tasks like manual documentation of reagents, QC results, and sample IDs along with reagent consumption monitoring for full traceability. The D-100 System includes advanced security features to protect against unauthorized access and malware.



Role-based User Access

When a user logs in, the D-100 System allows for three different user profiles and system privileges including those for the lead tech, secondary tech, and supervisor. Robust security includes complex user passwords and customization of password reset intervals set up by the supervisor or administrator.



RFID Tagged Reagents

Lab operators can load RFID tagged reagents which avoids manual entry of test parameters, resets the test counter, monitors reagent consumption, and tracks reagent lots and expiration to provide traceability and automation while eliminating mistakes.



Comprehensive System Logging

Built-in event logging allows you to trace every result. The D-100 System's onboard storage of 100,000 results provides security and traceability to give you the confidence and trust in passing your laboratory's audits smoothly and easily.



Cybersecurity

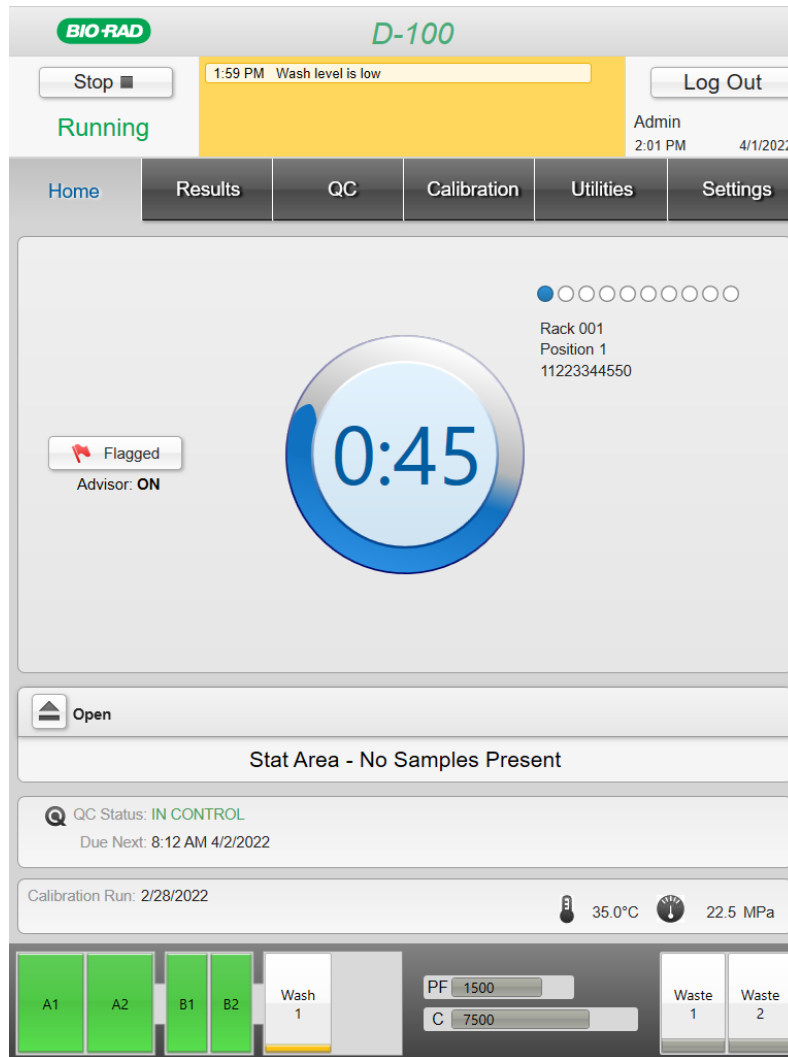
Bio-Rad is committed to working with hospitals and laboratories to protect your systems and mitigate potential security risks to patients and operators. We utilize an interconnected approach to maximize the protection of your diagnostic systems through system firewalls, Microsoft AppLocker, CylancePROTECT®, BRiCare, and Windows security updates.

Experience SMART HPLC

The D-100 System offers the best user experience on the market. SMART HPLC automates uninterrupted sample analysis to simplify the release of patient results and notifies operators about key information to run the D-100 nonstop. The D-100's large touchscreen display is an intuitive interface that gives your lab operators real-time system status at a glance.

Banner

Color-coded notifications highlight the status



Menu and Navigation

Interface gives quick access to system functions and workflow status

Consumables Panel

Provides reagent status

Customer Testimonial

“Through the screen the operator has access to all system controls and configurations, maintenance procedures, change of reagents, performance of analyses, data collection, and inspection of chromatograms. The change of reagents, column and pre-filter is very simple.”



Click to view video >

Experience the user interface and see for yourself why laboratories love the D-100.

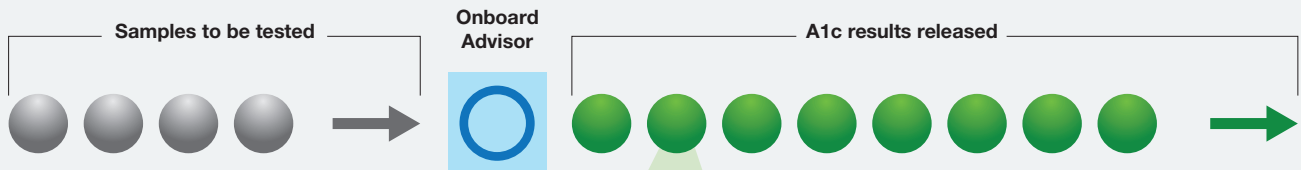
bio-rad.com/d100/user-experience

D-100 Onboard Advisor – Automate Result Review

The D-100 auto-verification software simplifies result review.* Unlike any other A1c system, the Onboard Advisor analyzes each chromatogram and automatically releases results from samples with no interference from HbS, HbC, HbD, HbE, and HbF. No operator intervention is required.

Automatic Release of Typical Results

For a **typical chromatogram**, the software confirms that peaks are within their reference ranges and **automatically releases the A1c result**.



Rack: **U74** Position: **5** HbA1c: **4.5%**
Run Date/Time: **12/13/2018 5:03:05 AM**

Note: Comment:

Peak Name	RT (sec)	Area	Area %	Concentration (% NGSP)
A1a	5.76	842.38	0.67	---
A1b	7.44	872.85	0.69	---
F	8.79	828.45	0.66	---
LA1c	11.74	2256.83	1.80	---
HbA1c	14.12	4021.69	---	4.5
P3	19.41	6526.92	5.19	---
A0	24.24	110350.34	87.79	---

Total Area : 125699

Status: **Released**

All 4567 of 13497

Automatically Released



Customer Testimonial

“More than 90% of our HbA1c samples are now run, reported, and auto-verified without tech intervention.”



Click to view video >

See how typical results are automatically released with the D-100 Advisor.

bio-rad.com/d100/typical-a1c

*Please consult your local regulations regarding autoverification.

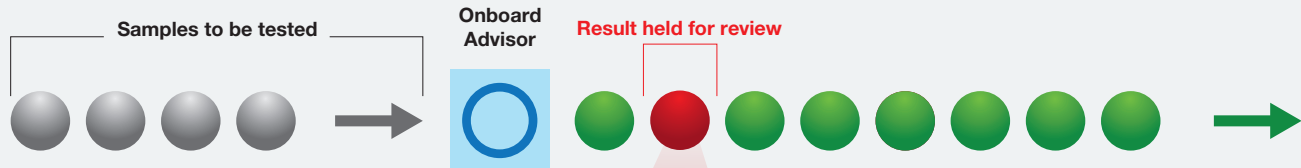
Hemoglobin Expertise at Work for You

The D-100 Onboard Advisor reveals hemoglobin variants* that may affect A1c. For example, samples from patients with sickle cell disease do not contain hemoglobin A. Without hemoglobin A, A1c does not exist.

Unlike immunoassay, enzymatic, and boronate affinity methods which falsely produce an A1c result when no HbA is present, the D-100 holds false A1c results and reveals clinically-relevant information about the patient.

Sickle Cell Disease Sample Triggers Advisor Flag

For a **sickle cell disease chromatogram**, the software **alerts you that A1c does not exist**. An alternative analyte should be used to monitor glycemic status, per the ADA guidelines.¹



Rack: Position: 0 HbA1c:
Run Date/Time: 3/1/2022 11:59:35 AM

Note: No HbA1c result Comment: No HbA1c peak

Held for Review

Peak Name	RT (sec)	Area	Area %	Concentration (% NGSP)
Unknown	6.00	6703.85	---	---
Unknown	7.27	619.23	---	---
Unknown	8.42	3348.90	---	---
P3	18.86	881.39	---	---
Unknown	23.28	2202.15	---	---
A0	24.17	6731.41	---	---
S-Window	28.66	112076.74	---	---

Total Area : 162664

Status: **Held**

More Details
Print

Reject Release Custom Filter 1 of 1

No Hemoglobin A is present, therefore A1c does not exist

Customer Testimonial

“Using the Onboard Advisor and customizing the review criteria for holds, we were able to cut down our manual chromatogram technician review time by approximately 80%. We now only need to review samples that are held in the instrument.”



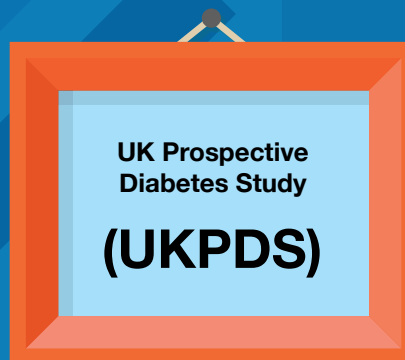
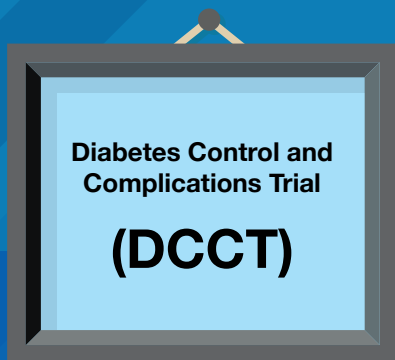
Click to view video >

See how the D-100 Advisor handles atypical samples.

bio-rad.com/d100/atypical-a1c

1. ADA (2022). Standards of Medical Care in Diabetes – 2022. Diabetes Care, 45 (Supplement 1), S17-S38.

* Interferences from common heterozygous hemoglobin variants: HbS, HbC, HbD, and HbE were tested. Based on net performance criteria the results were acceptable.



Be Confident

The analytical and clinical quality of A1c results provided by Bio-Rad HPLC directly translates to better patient care. Our HPLC technology powered the landmark studies, DCCT and UKPDS, and became the gold standard for an A1c result you can trust. The reason is the science.

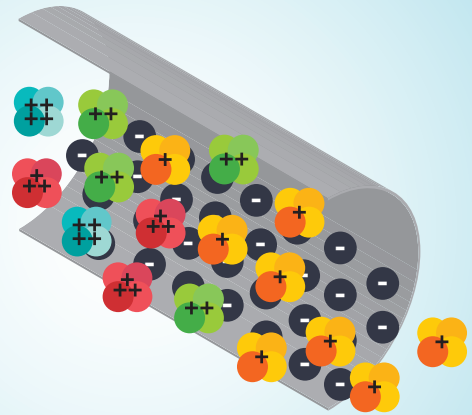
Report Clinically Accurate A1c Results with the D-100 System

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-100 System you can be confident that you are reporting the best quality results available.



Conditions Affecting A1c Measurement

Comparing different methods and potential for reporting clinically inaccurate results

	Lipemia	Elevated HbF (up to 30%)	Homozygous & Double Heterozygous Variants
D-100 Cation-Exchange HPLC	Clinically accurate results* released	Clinically accurate results released	Clinically inaccurate results† flagged
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/dL²

‡ 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

REFERENCES

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.



Click to view video >

See how Bio-Rad HPLC works.

bio-rad.com/d100/Why-BR-HPLC

The Impact of Fetal Hemoglobin on A1c Results

A Patient Case Study*

Introduction

A patient sample is run on two A1c methods: Bio-Rad HPLC and immunoassay.

Results

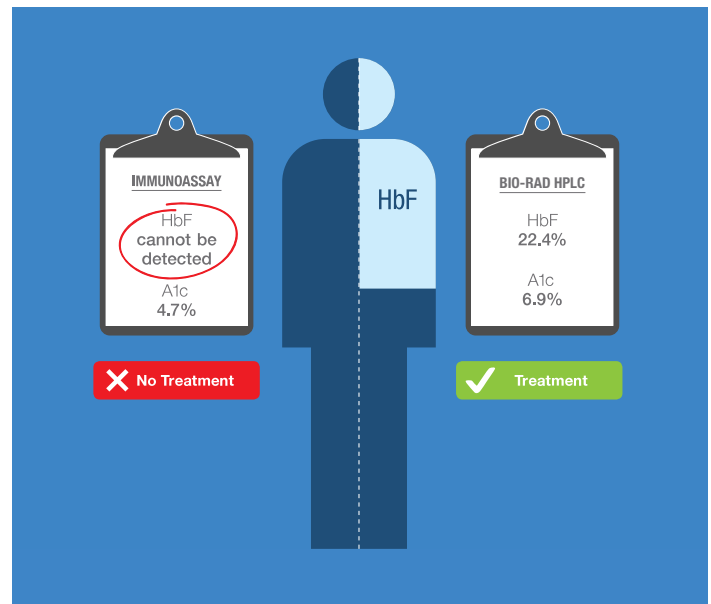
The Bio-Rad HPLC method reveals the presence of HbF (22.4%) and reports an A1c result of 6.9%, leading to a diagnosis of diabetes and patient treatment per ADA guidelines.†

The immunoassay method cannot reveal the presence of HbF and reports an A1c result of 4.7%, leading to no diagnosis of diabetes and no treatment per ADA guidelines.†

The same patient sample run on two different A1c methods produces different patient outcomes. How is this possible?

Discussion

Different technologies led to the observed difference between the two methods.



Immunoassay

A1c results are invalid on immunoassay methods in the presence of HbF as low as 7% due to interference. Specimens containing >7% of HbF may result in lower-than-expected mmol/mol A1c values (IFCC) and %A1c values (NGSP).

In this case, the glycation of HbF interferes with the glycation of HbA leading to an inaccurate A1c value. But the laboratory and clinician are not made aware of the interference. Glycated HbF is not detected by the assay because the immunoassay antibodies only recognize the β -chain that characterizes A1c.

Bio-Rad HPLC

A1c results are clinically accurate on the D-100 System in the presence of HbF up to 30%. In this case, the D-100 reveals the presence of HbF (22.4%) and its chromatogram provides a complete patient profile to clinicians along with an accurate A1c result.

Per the immunoassay FDA black box warning, the 4.7% A1c immunoassay result is invalid and should not be reported due to significant negative interference from HbF. In this scenario, the critical question is, “How would you know that the A1c immunoassay result is invalid if immunoassay methods do not reveal HbF?”

Conclusion

HbA1c testing methods that do not detect elevated levels of HbF might lead to a missed diagnosis and delayed patient treatment or under treatment. In this patient case study, only one A1c result is clinically accurate – the 6.9% Bio-Rad HPLC result.

* Data on file at investigating laboratory.

† Source: American Diabetes Association Guidelines



Click to
view video >

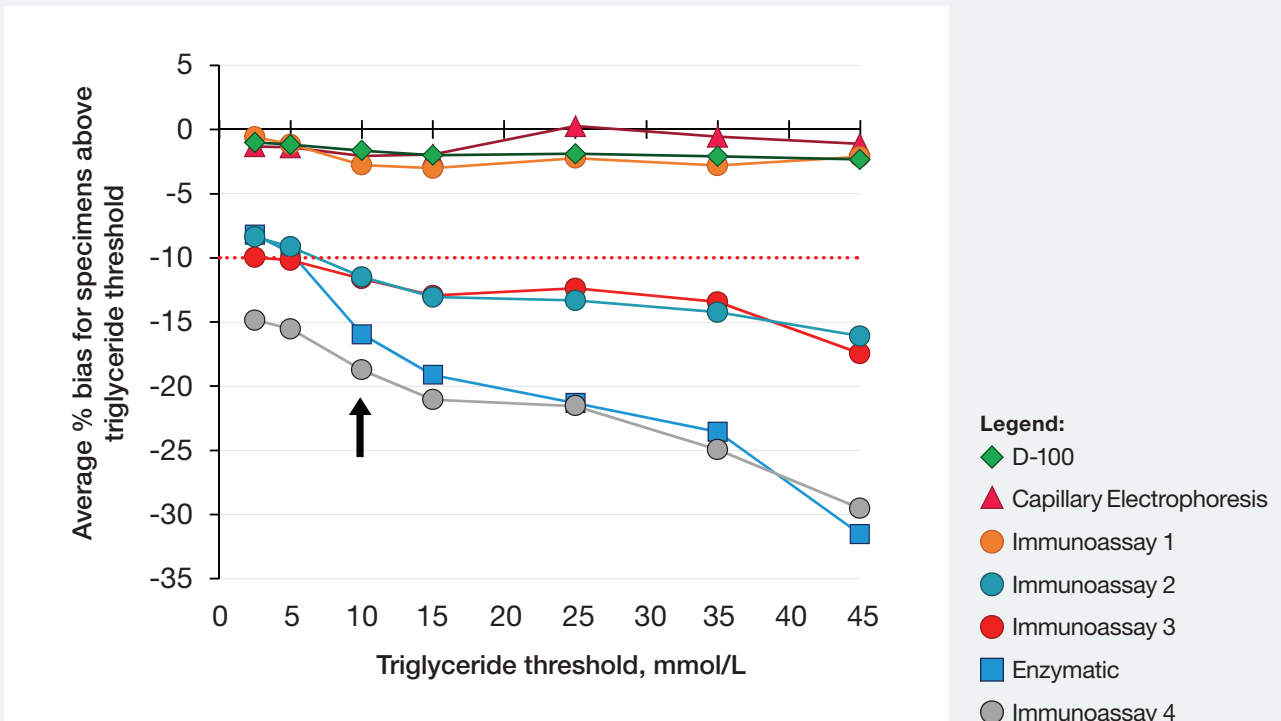
Learn the science behind how Bio-Rad HPLC handles HbF better than immunoassay and other methods.

bio-rad.com/d100/TYK/a1c

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 are 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 D-100 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.



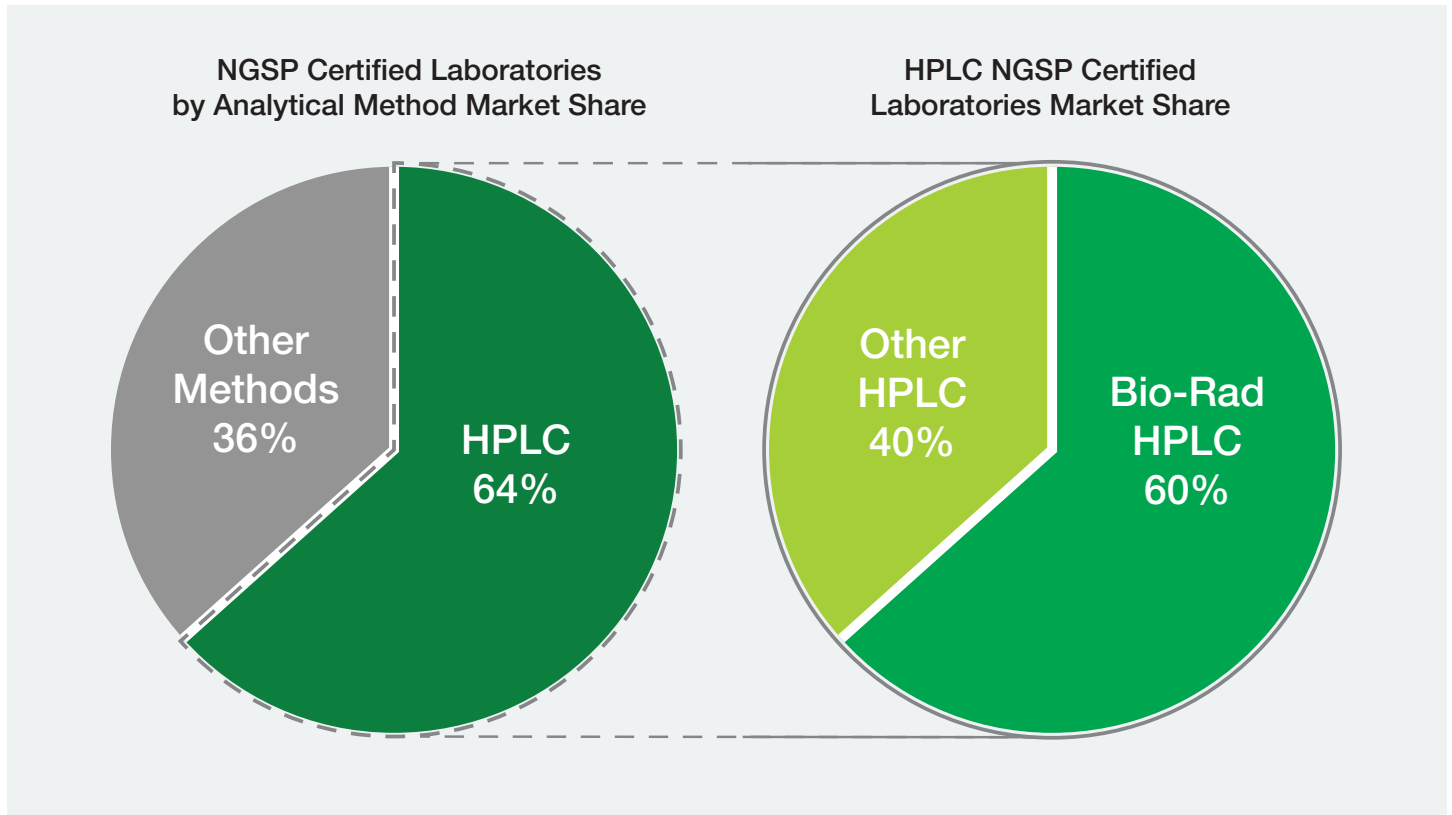
[Learn more >](#)

REFERENCES

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

Bio-Rad's 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-100 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



Customer Testimonial

“Above all, I appreciate its [D-100 System] analytical performance. In terms of reproducibility, I have moved to 0.6%! This leaves me a good margin to determine total error and wins over our trust in regard to renewing our certification.”

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.



A1c Support

Bio-Rad products are recognized as the gold standard for diabetes testing, hemoglobinopathy screening, and quality control systems. To support your D-100 System, we offer additional resources to help you maximize efficiency and productivity.

Partnering with Bio-Rad, you will have access to 24/7 technical support, BRiCare remote service, and CylancePROTECT® cybersecurity to keep you up and running. To educate your team, we provide educational resources through the Library of Variants, Test Your Knowledge Program, and user training videos.



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.



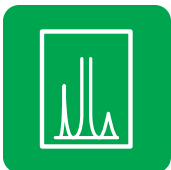
Unparalleled Support

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. [Learn more >](#)



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. Visit the Library of Variants portal. [Learn more >](#)

Access Remote Service and Support With BRiCare

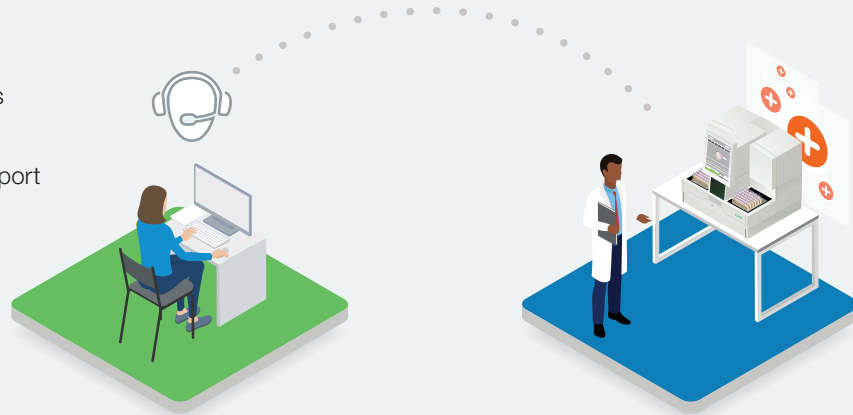
Rounding out our tools to control and manage your D-100 System are BRiCare Remote Service and Support and Bio-Rad's Product Cybersecurity Program to provide services that help you maintain the integrity of your instruments and stay on top of the latest cybersecurity threats.

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-100 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 math 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.

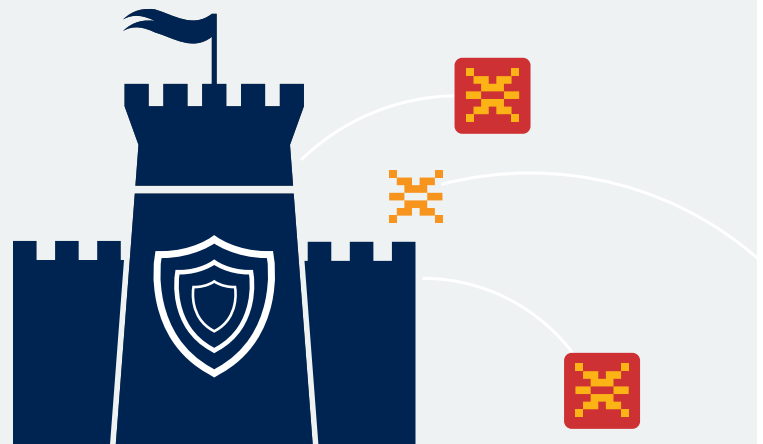


Microsoft AppLocker

Protection against malicious software

AppLocker is validated and deployed on the D-100 Hemoglobin Testing System. This helps control which programs and executable services can be run, preventing unwanted applications.

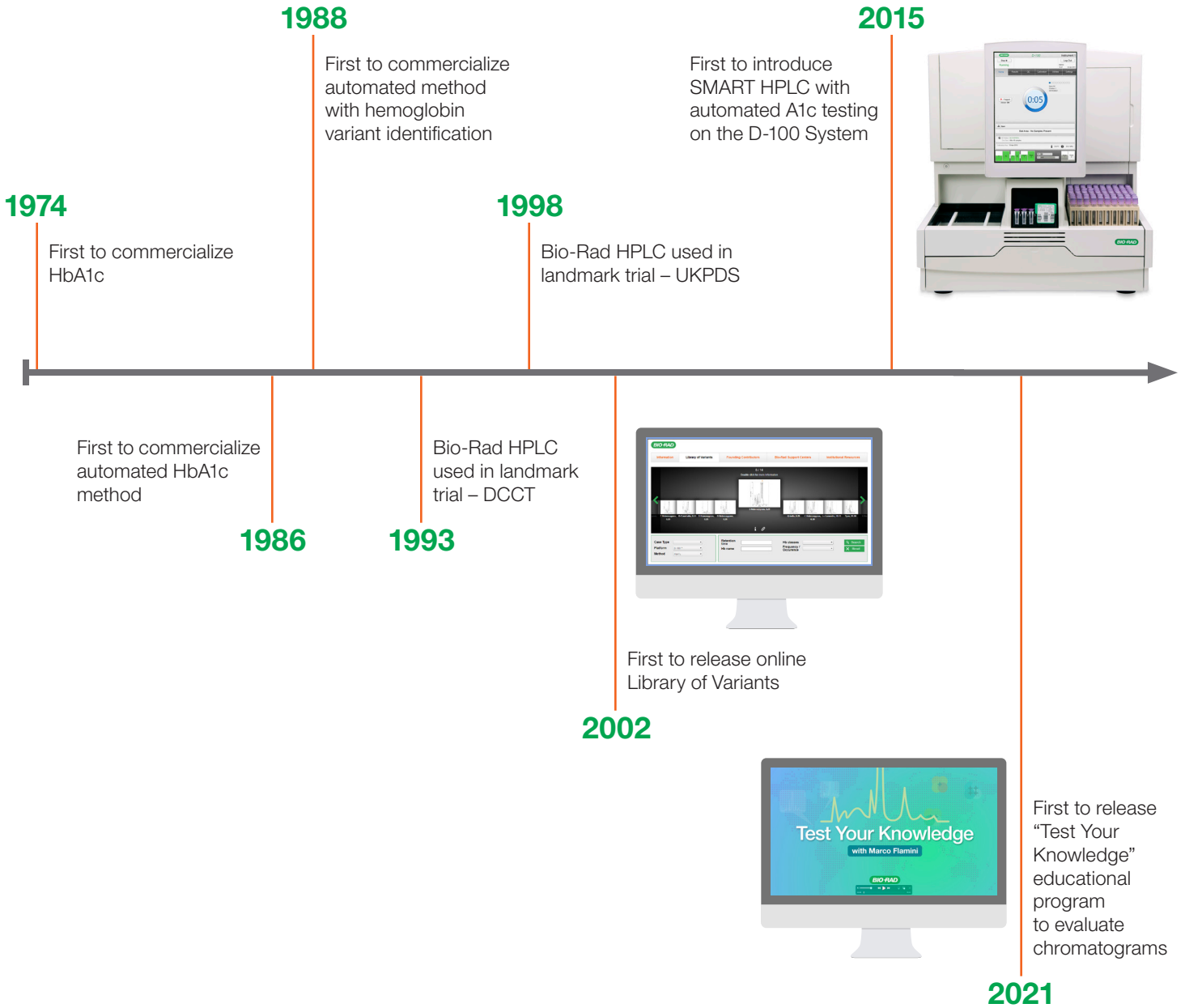
The Microsoft Windows 10 built-in "whitelist" protection feature specifies exactly which applications are allowed to run in order to protect the D-100 System and your laboratory network from cybersecurity threats. For instance, predefined Bio-Rad D-100 executable files and Windows executable files are allowed to run, while all other non-system executable files, including malware, cannot run.



Get More Done. Work Smarter. Be Confident. A1c Support.

Trust the D-100 SMART HPLC Technology

No other company shares our history or track record of firsts



Labs worldwide use Bio-Rad cation-exchange HPLC systems



Ordering Information

Catalog No.	Description	
12008984	D-100 Hemoglobin Testing System.....	1 unit
290-1004	D-100 HbA1c Analytical Cartridge/Calibrator Pack (10,000 tests)	1 each
290-1006	D-100 HbA1c Calibrator Pack	1 each
290-1007	D-100 Prefilters (5-pack)	1 each
290-1008	D-100 Cleaning Tube	1 each
290-1009	D-100 HbA1c Sample Diluent, 1L.....	1 each
290-1010	D-100 HbA1c Elution Buffer A, 2,600 mL	1 each
290-1011	D-100 HbA1c Elution Buffer B, 2,600 mL.....	1 each
290-1012	D-100 Wash Solution, 3,300 mL	1 each

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