

VARIANT II TURBO Hemoglobin Testing System

For Demanding Workloads



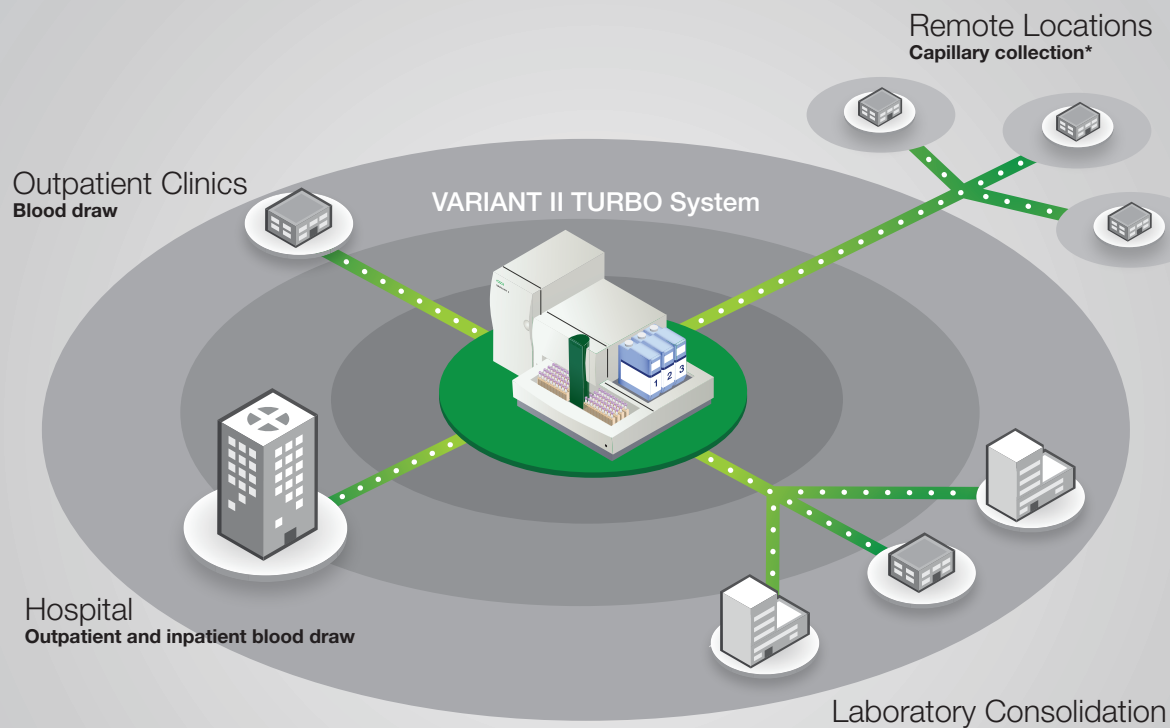


At the core of your demanding workload are your patients and providers

Clinicians use HbA1c results as an aid to diagnose and monitor patients with diabetes. Because there are more and more patients living with diabetes, laboratories are experiencing increased HbA1c sample volumes. Bio-Rad understands your challenge to meet this growing demand and is committed to helping you provide timely, reliable HbA1c results.

Is your laboratory experiencing increased HbA1c demand?

Over the years, population growth, laboratory consolidation, and dependence on capillary collection samples* have led to increased testing demands. Growing labs need systems that can safely and effectively tackle larger sample loads. For labs outgrowing their smaller systems, the VARIANT II TURBO Hemoglobin Testing System could be the next step in providing speed and modularity for increasing sample volumes. [Learn more >](#)



”

Customer Testimonial

“Over the past 4 years, our HbA1c testing volume has increased from 20,000 to 50,000 HbA1c tests annually. The TURBO System has made this growth transition easy for our lab. It also helps us meet our 24-hour turnaround time. Using Bio-Rad’s gold standard ion-exchange HPLC assay has kept our clinicians satisfied and has reduced questions from the clinics. I love the TURBO and would like others to know how much it could make their lives easier and simpler. We are extremely happy with our choice to use the TURBO System and would recommend it to anyone.”

*Customer review by medical technologist
Connecticut, USA*

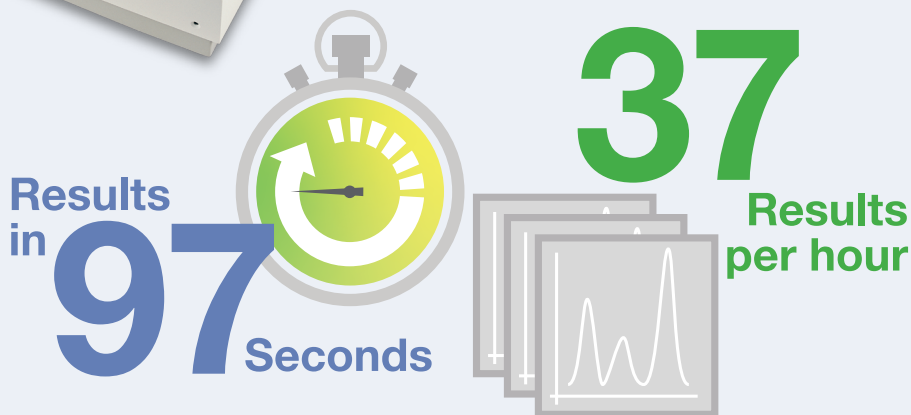
The VARIANT II TURBO System for demanding HbA_{1c} workloads



VARIANT II TURBO Hemoglobin Testing System

Perform up to 100 samples per run

The VARIANT II TURBO Hemoglobin Testing System uses ion-exchange High Performance Liquid Chromatography (HPLC) with a dual pump and buffer gradient to provide well-defined HbA_{1c} peak separation that helps deliver a full patient picture to clinicians. Meet your 24-hour HbA_{1c} turnaround time requirement by generating an HbA_{1c} result every 97 seconds. [Learn more >](#)



VARIANT II TURBO 2.0 HbA_{1c} Kit - 2.0

For optimized workflow

The VARIANT II TURBO HbA_{1c} Kit - 2.0 streamlines inventory management by using interchangeable kit components with long shelf lives. Your operator's hands-on time is greatly reduced with 2,500 tests per kit, one calibration per cartridge, and QC management included in the software. Once the samples are loaded, simply press "Start" for fully automated walk-away operation.

For better patient care

Ion-exchange HPLC technology is the method of choice for clinicians seeking accurate results without common hemoglobin variant interference.*

Be confident in reporting high quality, clinically-relevant HbA_{1c} results to aid physicians in diagnosing those who have diabetes, identifying people at risk for developing the disease, or monitoring the progress of those living with diabetes.

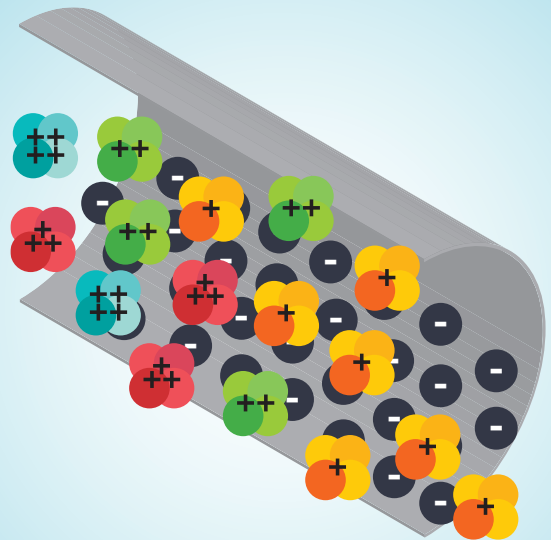


*Interferences from common hemoglobin variants: HbAS, HbAC, HbAD, and HbAE were tested. Based on net performance criteria the results were acceptable.

Bio-Rad HPLC Technology is the difference for patients and clinicians

Given our history and experience in HbA1c testing, it's no wonder that many of your peers around the world have chosen the VARIANT II TURBO System over other methods.

Using Bio-Rad's ion-exchange HPLC separation technology, you can optimize your lab's performance. With our technology, separation of different hemoglobin fractions helps you generate quality reportable HbA1c results and reduces time wasted on investigating questionable results. [Learn more >](#)



Uncovering the ion-exchange HPLC advantage

HbA1c accuracy in the presence of:

	Lipemia	Elevated HbF (up to 25%)	Elevated HbF (> 25%)	Common Hemoglobin Variants	Homozygous & Double Heterozygous Variants
Bio-Rad Ion-Exchange HPLC	Results released (up to 6,000 mg/dl)	Results released	Results not released	Results released	Results not released
Immunoassay	Results released (variable claims between 500 mg/dl to 3,000 mg/dl ^{1,2})	Results released	Results released	Results released	Results released
Enzymatic					
Boronate Affinity					

- Clinically accurate with patient chromatogram
- Manufacturers' package inserts have variable claims for resistance to interference from lipemia
- Clinical accuracy due to potential interferences cannot be confirmed without patient chromatogram
- Clinically accurate: HbA1c cannot be released when HbF > 25%
- 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 reported

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

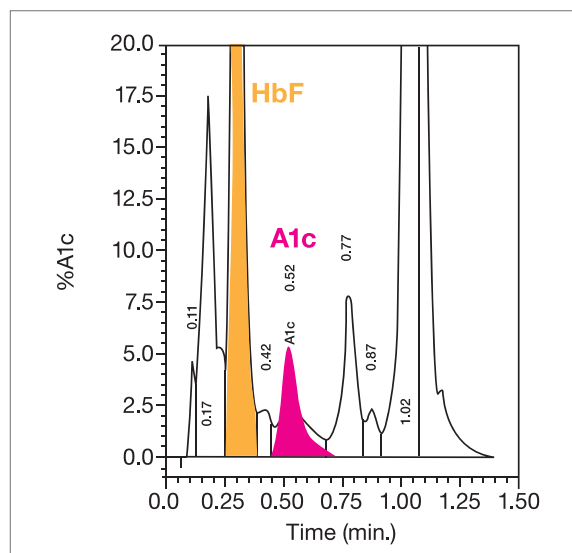
REFERENCES

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>.

How does your HbA1c method perform?

Bio-Rad HPLC reveals HbF to deliver HbA1c values you can trust

This is an example of an adult patient that has elevated Fetal Hemoglobin (HbF), often exhibited in patients with Hereditary Persistence of Fetal Hemoglobin (HPFH). The chromatogram shows that HbF is separated at a different elution time than Hemoglobin A1c. This separation means that the A1c result can be released correctly without HbF interference up to 25%.



Bio-Rad HPLC reveals HbF for a diagnosis you can trust

Are you reporting valid HbA1c results?

HbA1c testing methods that don't see common hemoglobin variants or elevated levels of hemoglobin F might lead to misdiagnosis and unnecessary or delayed patient treatment.

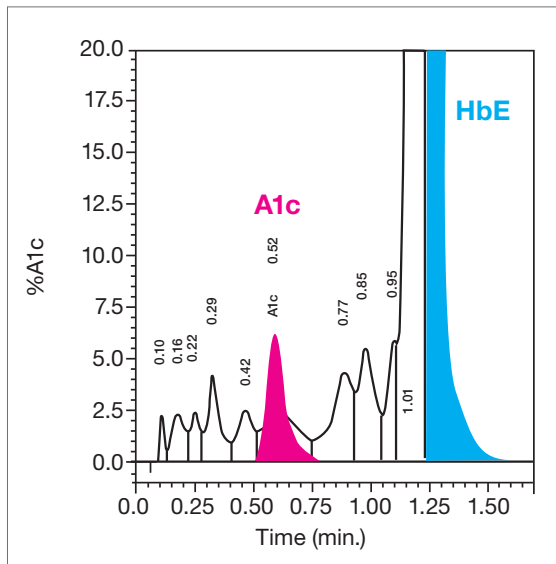
Case study results:*

Bio-Rad VARIANT II TURBO System reveals the presence of HbF so you can confidently report HbA1c results to your clinicians.

Immunoassays do not reveal the presence of HbF. So you might not know the result was invalid and unknowingly report incorrect results. [Download case study >](#)



*Data on file at investigating laboratory



Chromatogram of patient with heterozygous Hemoglobin E (HbE) trait

HPLC separates HbE from HbA1c

The chromatogram shows that HbE is separated at a different elution time than Hemoglobin A1c. This separation means that HbA1c can be released correctly without HbE interference.

Lipemia does not interfere with ion-exchange HPLC

Are your HbA1c samples lipemic?

Many people living with diabetes may also have high cholesterol as defined by elevated triglycerides. Samples from this group tend to be lipemic. You are probably running more lipemic samples than you realize.

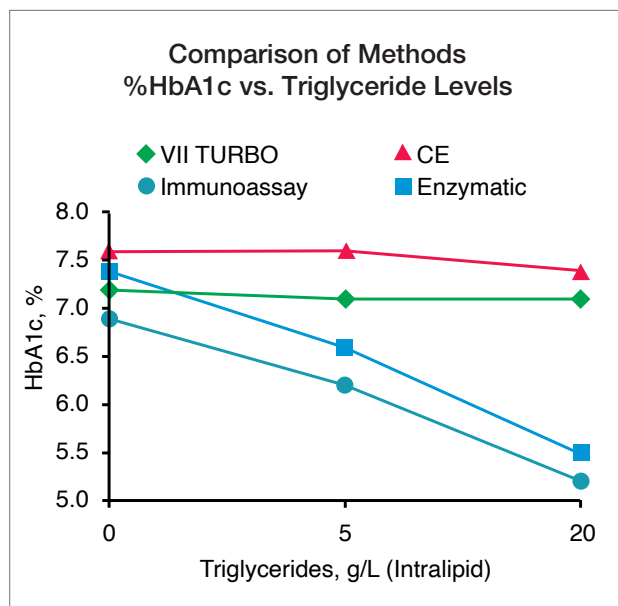
Do your samples appear milky or cloudy?

This is an indication of a lipemic sample. Lipemic samples can interfere with HbA1c results with certain methods.

VARIANT II TURBO advantage

In a study titled "HbA1c Platforms are Variably Affected by Increasing Lipemia," presented at the AACC in 2018, the performances of nine routine HbA1c platforms were evaluated using clinically lipemic specimens. The study revealed that most immunoassays and the enzymatic method for HbA1c are susceptible to negative interference from elevated triglycerides. This negative interference from elevated triglycerides would generate a falsely low HbA1c result.

The Bio-Rad VARIANT II TURBO System reported HbA1c values without significant change from baseline in the presence of triglycerides. [Learn more >](#)



The negative bias observed with immunoassay and the enzymatic method was approximately 10% (5 g/l) and 25% (20 g/l), respectively. The Bio-Rad VARIANT II TURBO System tested samples in the presence of triglycerides up to 20 g/l.

REFERENCES

1. Parker ML et al. (2018). HbA1c Platforms are Variably Affected by Increasing Lipemia. Abstract A-288. 70th AACC Annual Scientific Meeting Abstracts

VARIANT II TURBO HbA_{1c} Kit - 2.0

A Case to Reduce User Interactions

Introduction

As laboratories struggle with resources and staffing, it becomes increasingly important to ensure that laboratorians focus on value-added tasks. Comparing user interactions between HbA_{1c} analyzers can help laboratories choose the most efficient system.

Testing methods

The instructions for use (IFU) of the VARIANT II TURBO HbA_{1c} Kit - 2.0 was compared with IFUs for capillary electrophoresis, boronate affinity, and two HPLC HbA_{1c} analyzers to evaluate user interactions required to keep an analyzer running. User interactions evaluated included those required for reagent replacements, calibrations, and maintenance. The reagent replacements included cartridge, prefilter, Buffer #1, Buffer #2, Buffer #3 (if used), and wash/diluent replacements.

NOTE: The capillary electrophoresis HbA_{1c} analyzer has an additional maintenance activity to clean the capillaries every 500 injections and was included in the evaluation.

Analysis

The following analysis, evaluating five HbA_{1c} analyzers, demonstrates how the VARIANT II TURBO HbA_{1c} Kit - 2.0 requires the fewest number of user interactions, reagent replacements, calibrations, and maintenance activities.

Results*

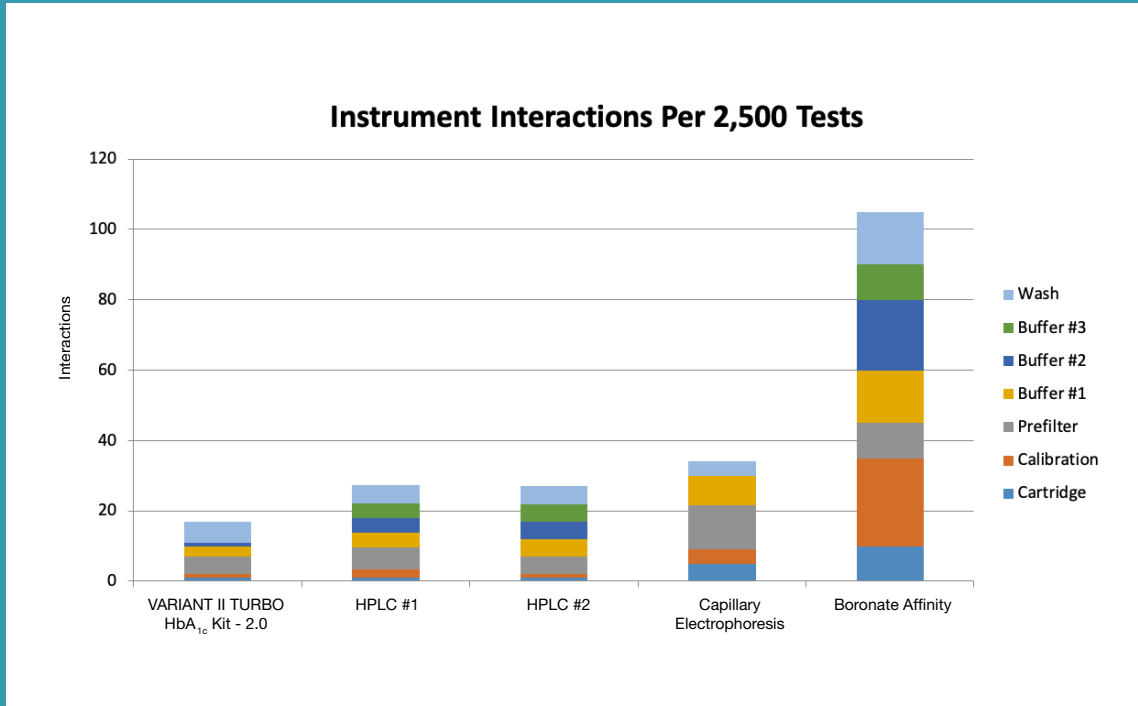
For every 2,500 samples tested:

- VARIANT II TURBO HbA_{1c} Kit - 2.0 required 16 user interactions
- Two HPLC HbA_{1c} analyzers required 27 user interactions each
- Capillary electrophoresis HbA_{1c} analyzer required 34 user interactions
- Boronate affinity HbA_{1c} analyzer required 105 user interactions

Conclusion

Based on this evaluation, the VARIANT II TURBO HbA_{1c} Kit - 2.0 offers reduced user interactions such as maintenance activities, calibrations, and reagent replacements.

VARIANT II TURBO System requires the fewest operator interactions



VARIANT II TURBO HbA_{1c} Kit - 2.0
has fewer

Reagent changes

System calibrations

Cartridge replacements

Maintenance interactions

Bio-Rad is a Trusted Partner

Who is Bio-Rad?

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.

Why is our HbA1c technology the gold standard?

Bio-Rad's ion-exchange high performance liquid chromatography (HPLC) is the gold standard for HbA1c testing because of the role our technology and methodology played 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.

Give your clinicians HbA1c results they can trust

Backed by over 40 years of research in diabetes, hemoglobinopathies, and β -thalassemia, the VARIANT II TURBO 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.

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. [Learn more >](#)

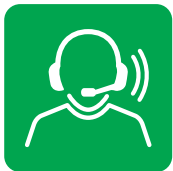
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1. DCCT Research Group (1996). The absence of a glycemic threshold for the development of long-term complications: the perspective of the Diabetes Control and Complications Trial. *Diabetes* 45(10), 1289–1298.
2. Nathan DM et al. (1993). The effect 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.



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. Should you need immediate assistance, our hemoglobin testing systems can be connected to BRiCare, Bio-Rad's remote support application, that keeps your system running smoothly. Less downtime for your laboratory means more uptime for generating high-quality results.



Cybersecurity

Rest assured, your laboratory and the VARIANT II TURBO System are protected. The AppLocker utility locks down the VARIANT II TURBO System software configuration so only known and approved programs can be executed. Microsoft Windows 10 OS guarantees support for security updates and our optional AI (artificial intelligence)-driven BlackBerry® Protect antivirus software defends against online threats. [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 >](#)

Labs worldwide use Bio-Rad ion-exchange HPLC systems



Ordering Information

Catalog No.	Description	
270-2600	VARIANT II TURBO Hemoglobin Testing System	1 unit
270-2601	VARIANT II TURBO Hemoglobin Testing System without computer	1 unit
12000447	VARIANT II TURBO HbA1c kit - 2.0.....	2,500 tests
740	Lyphocek Diabetes Control, Bilevel (3 each of 2 levels).....	6 x 0.5 mL
12000070	Lyphocek Hemoglobin A1c Linearity Set (1 each of 6 levels).....	6 x 0.5 mL
BC80	EQAS Hemoglobin Program (3 levels)	12 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
196-2051	Hemoglobin Capillary Collection System (HCCS).....	5 tests
196-2052	Hemoglobin Capillary Collection System (HCCS).....	100 tests
196-2053	Hemoglobin Capillary Collection System (HCCS).....	5,000 tests
196-2100	Plastic Capillaries, 100 per dispenser	20 dispensers
196-1054	Capillary Holder.....	20 holders
270-2220-10	Capillary Collection Adapter	1 unit
11000759	BlackBerry® Protect 5 yr Subscription.....	1 each

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