Acceptance Criteria

Any results that do not meet the following criteria should not be reported.

Item	Criteria
Total Area range	• 1.0 million to 3.5 million • If the area is outside this range, the sample should be manually diluted and reanalyzed.
Quality Control	Values should be in range
HbA_{1c} reportable range	• NGSP: 3.4–20.6% • IFCC: 14–203 mmol/mol • Any sample with >15% or >140 mmol/mol HbA_{1c} should be suspected of having a hemoglobin variant.
HbF	• ≤25% does not interfere with test • Any sample with HbF >5% should be suspected of having a hemoglobinopathy.
Labile A_{1c} (LA1c)	No interference
Carbamylated hemoglobin (CHb)	• No interference • CHb elutes in the LA1c window
P3 or P4 peak	• P3 peak ≤5% for hemoglobin variant samples (i.e., HbS-, HbC-, HbD-, and HbE-trait) • P3 peak ≤10% for non-variant samples • P4 peak ≤10% • If either peak exceeds the cutoff, a fresh sample should be obtained for analysis.
Heterozygous hemoglobins E, D, S, and C	HbA_{1c} result is reportable.
Variant and/or C windows	Combined area of <50%
"Unknown" peaks	No interference

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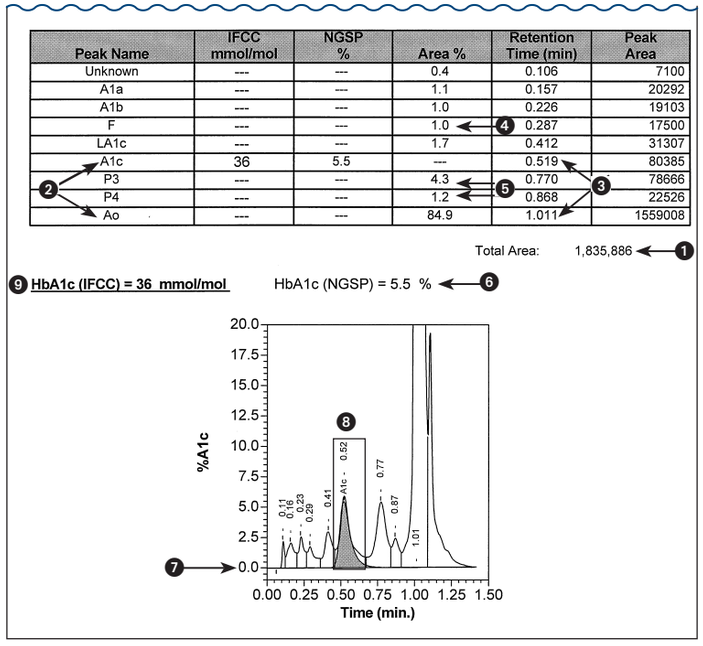
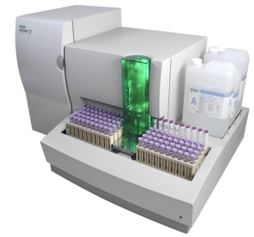
Result Review

	Item	Observation
1	Total Area	1.0 million to 3.5 million
2	A1c and Ao peaks	Correctly identified
3	A1c and Ao retention times	Consistently in range
4	F peak	≤25%
5	P3 and P4 peaks	≤10% each for non-variant sample
6	HbA_{1c} result	Within reportable range
7	Baseline	Starts at 0.0 on Y-axis; stable with no ramping.
8	A1c peak shape	Sharp and uniform (i.e., NOT broad, shouldered, or tailing)
9	Primary Reporting Unit	The standardized HbA_{1c} master equation for the primary reporting unit appears in the Summary Report.



VARIANT™ II TURBO HbA_{1c} Kit - 2.0 Quick Guide 12000447



CE IVD

- *This Quick Guide is for reference use only; for detailed information, see the Instructions For Use and Operation Manual.*
- *Consider any materials of human origin as infectious and handle them using typical biosafety procedures.*
- *Wear personal protective equipment while handling all reagents and samples and while operating the VARIANT II TURBO system.*

Reagent / Sample Preparation

Whole Blood Primer:

- Reconstitute each vial with 1 mL of DI water.
- Allow to stand for 10 minutes; swirl gently to dissolve.
- Stable for 1 day at 2–8 °C.

Calibrators:

- 2 Calibrators (Level 1 and Level 2).
- Reconstitute each vial with 7 mL of cold Calibrator Diluent.
- Allow to stand for 2 minutes; swirl gently to dissolve.
- Stable for 24 hours at 2–8 °C; do not freeze.

Controls:

- Reconstitute and store the controls according to the manufacturer's package insert.
- If no dilution instructions are provided, predilute the controls as directed in the *Prediluted Samples* section of this Quick Guide.

Whole Blood Samples:

- Samples should be collected in vacuum collection tubes containing K2-EDTA or K3-EDTA. Samples are stable for 7 days at 2–8 °C, 1 day at room temperature (15–30 °C), or 12 months at –70 °C.
- Capillary blood should be collected in HCCS (Hemoglobin Capillary Collection System).
- No sample preparation required.

Prediluted Samples:

- If abnormal tube type or height of sample is less than 25 mm, then predilute 1:300 (5 µL of sample in 1.5 mL of Wash/Diluent Solution) prior to analysis.
- Samples with total areas outside of the expected range should be rediluted and rerun to achieve values within the 1.0–3.5 million total area count range.

Installing the Update Kit CD-ROM

1. Go to the **Setup/Test** screen. Verify that **V2TURBO_A1c** is selected in the Select New Test drop-down list.
2. Insert the Update Kit CD-ROM and click **Update Kit**.
3. In the Update Kit dialog box, select drive e:\. Select the V2TURBO_A1c file.
4. Click **OK**.

Installing Reagents

1. Install new Elution Buffers and Wash/Diluent Solution:
   - Remove the reagent bottles one at a time.
   - Do not touch the lines below the caps.
   - Do not wipe the lines.
   - Place each bottle in the proper position on the reagent reservoir module.
   - At 15–30 °C, open bottles are stable for: Elution Buffer A = 30 days, Elution Buffer B = 90 days, and Wash/Diluent Solution = 60 days.
2. Manually enter new lot information and expiration dates in the **Setup/Test** screen or use Update Kit CD-ROM.
3. Perform a **System Flush** (**Setup/Test/Reagents** screen) if a different lot of reagent is installed.

Installing a New Analytical Cartridge

Priming is performed only for a new analytical cartridge. The prefilter must be replaced when a new analytical cartridge is installed.

1. Replace cartridge (install with arrow pointing up).
2. Go to the **Maintain/Instruments** screen. Select **Do Startup Actions** from the Execute Commands list. Click **Start**.
3. After the startup actions are completed, return the instrument to Ready state by clicking **Return to READY state**.
4. Place the following in a sample rack:

Tube Position	Adapter Label	Sample Type	Reagent
1	PRIMER	PR	Whole Blood Primer (1 mL)
2	PRIMER	PR	Whole Blood Primer (1 mL)
3	BLANK	BL	DI water
4	BLANK	BL	DI water
5	BLANK	BL	DI water
6	STOP	----	----

5. Ensure microvial adapter barcodes are facing the instrument. Place rack on the right side of the VSS conveyor belt.
6. Verify that the system is in Ready state. Go to the **Run/Worklist** screen and click **Start/Stop** to start the run.
7. Calibration is required after priming is completed.

NOTE: *An Automatic Priming option is available beginning with CDM software version 5.1. This option allows you to run racks containing calibrators, controls, and patient samples within the same run as the priming rack without operator intervention. To use this option, set up the Priming and Calibration racks exactly as specified in this Quick Guide (including properly barcoded BLANK and STOP microvial adapters). Select the* ***Automatic Priming*** *checkbox in the Worklist Control dialog box before starting the run.*

Calibration

Calibration is performed after priming a new analytical cartridge.

1. Go to the **Setup/Sample Types/Calibrator** screen. Verify that **Enable Delta Factor** is selected. Verify that **Stop Worklist** is selected in the "Action if outside limits" drop-down list.
2. Place the following in a sample rack:

Tube Position	Adapter Label	Sample Type	Reagent
1	BLANK	BL	Prediluted sample/control (1 mL)
2	Calibrator Level 1	C1	Calibrator Level 1 (1 mL)
3	Calibrator Level 2	C2	Calibrator Level 2 (1 mL)
4	Control Level 1	LC	Low QC
5	Control Level 2	HC	High QC
6 to N	----	P	Patient Samples
N + 1	Control Level 1	LC	Low QC (optional)
N + 2	Control Level 2	HC	High QC (optional)
N + 3	STOP	----	----

3. Ensure microvial adapter barcodes are facing the instrument. Place rack on the right side of the VSS conveyor belt.
4. Verify that the system is in Ready state. Go to the **Run/Worklist** screen and click **Start/Stop** to start the run.
5. Review the Calibrator Averaging/Summary Report, verifying that the new slope and intercept values are within range (i.e., not flagged).

Installing a New Prefilter

Replace the prefilter at 500 injections.

1. The prefilter can be installed in either direction. Push the prefilter firmly over the Stainless Steel Prefilter Adapter.
2. Place the PEEK Housing into the inlet cap with the arrow pointing in the direction of flow (bottom to top). Hand-tighten it clockwise, ensuring it does not leak.

Update the prefilter injection counter in CDM:

1. Go to the **Setup/Test/Cartridges** screen.
2. Change the **In Use** column entry from **Yes** to **No** for the used prefilter; a new line is generated for the new prefilter.
3. In the new prefilter line, enter "**N/A**" in the **Lot #** column and **500** in the **Inj. Limit** column.
4. In the **In Use** column, select **Yes**.

Daily Warm-Up Procedure

The following procedure must be performed only if the CDM Automatic Warming Up option is not being used. The Automatic Warming Up option can be used with CDM software version 5.1 or later. See the applicable CDM Software Operation Manual for information.

1. Go to the **Maintain/Instruments** screen.
2. Click **Return to Active**.
3. In the dialog box, click **Yes** (perform automatic warm-up operations).
4. After the warm-up is completed, return the instrument to Ready state by clicking **Return to READY state**.

Daily Maintenance

- **Check that the correct test (V2TURBO_A1c) is installed.**
- **Check buffer/wash levels and line positions.**
- **Check cartridge injection count.**
- **Check prefilter injection count.**
- **Check waste container level.**
- **Check piston seal wash tubing for liquid.**
- **Check pump pressure on both pumps (with pumps running):**
  - Flow rate at 2.0 mL/min
  - If pressure fluctuation (> ±5%) or low pressure is observed, remove air from pumps.
- **Check for leaks during pressure check.**
- **Check printer paper supply.**

Routine Sample Run

1. Place the following in a sample rack:

Tube Position	Adapter Label	Sample Type	Reagent
1	BLANK	BL	Prediluted sample/control (1 mL)
2	Control Level 1	LC	Low QC
3	Control Level 2	HC	High QC
4 to N	----	P	Patient Samples
N + 1	Control Level 1	LC	Low QC (optional)
N + 2	Control Level 2	HC	High QC (optional)
N + 3	STOP	----	----

2. Ensure microvial adapter barcodes are facing the instrument. Place rack on the right side of the VSS conveyor belt.
3. Verify that the system is in Ready State. Go to the **Run/Worklist** screen and click **Start/Stop** to start the run.

NOTE: *When the run is complete, the system will perform an automatic wash and remain in Ready state for 30 minutes; more samples can be run at this time.*

After being idle for 30 minutes, the system goes to Inactive state.