



Afinion™ AS100 and Afinion™ 2 Analyzers

Fast Facts



• Reagent Requirements

	Afinion™ HbA1c Controls	Afinion™ HbA1c Test Kits
Storage Temperature	2° - 8°C	2° - 8°C 15° - 25°C
Stability	Unopened: Manufacturer's expiration date Opened: 60 days	Refrigerated: Manufacturer's expiration date Opened box(es): 90 days at room temperature (15° - 25°C)
Handling Requirements	<ul style="list-style-type: none"> - Record "Open Date" and "Expiration Date" in the designated areas on the QC box. - Bring to room temp before use (~45 minutes). - <i>Do not</i> use beyond manufacturer's expiration date or more than 60 days after opening. - Mix vigorously for at least 30 seconds, confirming pellet mixes in completely, prior to use. 	<ul style="list-style-type: none"> - Record "Open Date" and "Expiration Date" in the designated areas on each box once opened. - Bring cartridges to room temp before use (~15 minutes), storing upright. - <i>Do not</i> use beyond manufacturer's expiration date or more than 90 days after storage at room temperature. - All cartridges must be used within 10 minutes of removing from the foil pack.
Handling Precautions	<ul style="list-style-type: none"> - <i>Wear proper PPE when handling controls.</i> 	<ul style="list-style-type: none"> - <i>Once the capillary is filled, analysis must start within 1 minute.</i>

• Testing Procedural Notes

- *Do not* use objects with sharp tips to press buttons on the analyzer screen. The screen can be recalibrated if the touchscreen is not accurate with use of fingertips for navigation.
- *Do not* force the lid open; it will open when commanded by buttons on the screen. The lid must be manually closed immediately after completion of testing to prevent accumulation of dust.
- After loading the capillary with QC material or a patient sample, *do not* wipe off the excess from the exterior.
 - Avoid air bubbles and incomplete filling. If either occur, discard the test cartridge and restart the collection and testing process with a new test cartridge.
- If the test cartridge is dropped on the ground after loading with sample, discard and re-collect with a new test cartridge.
- Hold test cartridge by white handle and avoid touching the optical reading area.



● **Maintenance**

- Monthly: Clean the Cartridge Chamber.
 - Analyzer must be powered down with lid open.
 - Wet the supplied Cleaning Swab with 3 drops water, squeezing out excess fluid, then carefully remove particles from the Cartridge Chamber.
 - Ensure chamber is completely dry before powering the analyzer on.
- As Needed: Clean Analyzer Exterior in the Event of a Spill.
 - Analyzer must be powered down; most spills can be removed with water or mild detergent.

● **Troubleshooting – Most Frequently Observed Error Codes (See SOP for Full List)**

Error Code	Description	Troubleshooting
103, 104	<i>Hemoglobin concentration is below or above the acceptable range.</i>	- Hemoglobin outside acceptable range; sample must be sent to Core Lab.
105, 106	<i>HbA1c value is above or below the analyzer’s linear range.</i>	- Result <4.0% or >15.0%; repeat testing using a new sample and Test Cartridge.
201-218	<i>Sample or Test Cartridge Failures</i>	- Repeat the test with a new sample and test cartridge. - If problem persists, restart analyzer and run controls or contact POCT Office.
301-305	<i>Analyzer Failure</i>	- Restart analyzer. - Two consecutive codes in the 300s must be reported to the POCT Office.
404	<i>Operator ID not found</i>	- New operator must be programmed onto authorized users list by a designated “Supervisor”. - If Annual Competency requirements are not met, operators will be locked out.

- If basic troubleshooting fails, contact the POCT Office for additional assistance. If advanced troubleshooting does not resolve the problem, a Loaner will be issued.
 - Office Hours: Monday-Friday 7:00-15:30 (CMSC SB207)
 - POCT General Phone Line: 5-2645
 - Email: POCTGroup@exchange.johnshopkins.edu
- After hours, use a backup analyzer, if one is available on your unit, or send specimens to Core Lab.
 - CORUS: Pathology Staff – POCT Consult (covered 24/7)

● **Operator Competency**

- Review POCTW012 at initial training; responsibility for all contents of the SOP will be acknowledged during MyLearning module completion.
 - Complete review with any additional assigned revision campaigns from HPO.
- Complete MyLearning module(s) with at least an 80% on the Post-Test at initial training and annually thereafter.
- Both levels of QC must be performed successfully at initial training and at least once annually thereafter.