Afinion™ AS100 and Afinion™ 2 Analyzers

Fast Facts

- **Reagent Requirements**

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Afinion™ HbA1c Controls</th>
<th>Afinion™ HbA1c Test Kits</th>
</tr>
</thead>
<tbody>
<tr>
<td>2° - 8°C</td>
<td>2° - 8°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15° - 25°C</td>
<td></td>
</tr>
</tbody>
</table>

- **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**
  - Record “Open Date” and “Expiration Date” in the designated areas on the QC box.
  - Bring to room temp before use (~45 minutes).
  - Do not 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.

- **Handling Precautions**
  - Wear proper PPE when handling controls.

- **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.

**Handling Precautions**

- Wear proper PPE when handling controls.

- Once the capillary is filled, analysis must start within 1 minute.
• Maintenance
  o 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.
  o 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)

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

- 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
  o 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.
  o Complete MyLearning module(s) with at least an 80% on the Post-Test at initial training and annually thereafter.
  o Both levels of QC must be performed successfully at initial training and at least once annually thereafter.