## Document History:

**Title: i-STAT Alinity System SOP** **Site(s): Kidney Check Program**

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|---|---|---|---|
| **Document #:** | **100-140-01** | **Version #:** | **01** |
| **Section:** | **General Operations** | **Subsection:** | **Non-DSM POCT** |

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| **Approved by:** | A Sokoro | **Date:** | 22 Oct 2020 |

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| **Approved by:** | L Thorlacius | **Date:** | 15 Jan 2021 |
| **Signature:** | (Signature on File) | | |
| | | **Effective Date:** | 19 Jan 2021 |

| # | Details of Revisions: | Approval: | Date: |
|---|---|---|---|
| 1 | New document | A Sokoro | 22 Oct 2020 |
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## 1.0 PURPOSE:

1.1. To provide instruction for use of the i-STAT Alinity analyzer
1.2. Non-Shared Health sites may use this SOP if they have a Memorandum of Understanding (MOU) with Shared Health. The MOU will clarify the responsibilities of both the external organization and Shared Health.

## 2.0 GENERAL INFORMATION:

2.1. The intended use of the i-STAT Alinity is to provide an analyzer that can be run by trained non-technologist staff in collaboration with Shared Health. It is designed to function consistently and dependably from day to day.
2.2. External Proficiency Testing (EPT) must be done for each analyte being tested for on the i-STAT Alinity analyzer; if no EPT is available, then a suitable alternative must be used as advised by the applicable provincial discipline team. See section 17.0 for further information regarding EPT.
2.3. Training of new operators will be provided by a previously trained technologist or designate.
2.4. All operators must be provided with a unique Operator ID number; ID must not be shared.
2.5. All staff utilizing the i-STAT analyzer must have initial training and annual competency assessments.
2.6. All staff must be re-certified annually.

## 3.0 SYSTEM OVERVIEW:

3.1. The i-STAT system incorporates comprehensive components needed to perform blood analysis at the point of care level.
3.2. The system consists of the following components:
  3.2.1. Analyzer into which a sample-filled cartridge is inserted for analysis; the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous monitoring.
  3.2.2. Cartridges which are single use and disposable and contain micro-fabricated sensors, a calibrant solution, fluidics system and waste chamber. Cartridges available at each site will depend on the site test menu and the intended use of the analyzer at the site.

## 4.0 SAFETY PRECAUTIONS:

4.1. As per Routine Practices (Standard Precautions).
4.2. Mandatory use of gloves and safety glasses.
4.3. Cartridges should be disposed of as biohazard waste, not in general waste.

## 5.0 VALIDATIONS OF NEW OR REPLACEMENT ANALZYERS:

5.1. These requirements are to validate that new analyzers are functioning as expected.
5.2. Calibration verification and Integrity Testing must be performed on all new or replacement analyzers as well as on each analyzer when it is moved or transported from one site to another.
  - See Section 17.0 for instructions on performing calibration verification.
  - See Section 16.0 for instructions on performing integrity testing with liquid controls.
5.3. Results must be within the acceptable ranges provided by the manufacturer prior to using the analyzers to report patient results.
5.4. Results of calibration verification and liquid controls should be recorded in the workbook.

## 6.0 SUPPLIES AND STORAGE REQUIREMENTS:

### 6.1. Cartridges:

6.1.1. General Information:

- Sealed in individual pouches or portion packs
- Individual pouches must be warmed to room temperature (between 18 ºC and 30 ºC) for 5 minutes prior to testing; entire boxes must be warmed for one (1) hour prior to use.
- **DO NOT** allow cartridges to freeze.
- **DO NOT** return cartridges to the fridge once they have been at room temperature.
- **DO NOT** use cartridge if pouch has been punctured.
- **DO NOT** use after the labeled expiration date.

6.1.2. Storage:

- Store main supply of cartridges at fridge temperature (between 2 ºC and 8 ºC).

6.1.3. Room temperature storage:

- Between 18 ºC and 30 ºC is acceptable but will shorten the expiry dating:
  - Creatinine cartridges = 14 days
- Shortened expiry date must be written on the package when taken out of the fridge.

### 6.2. Calibration Verifiers and Liquid Controls:

6.2.1. General Information:

- i-STAT Aqueous Calibration Verifiers and Quality Control materials are used for all chemistry quality testing
- All products are stored at fridge temperature (between 2 ºC and 8 ºC); do not allow to freeze.
- **DO NOT** use after expiration date on the box and ampules.

6.2.2. Calibration verifiers and controls must come to room temperature (between 18 ºC and 30 ºC) for at least 30 minutes prior to use for creatinine testing.

6.2.3. Room temperature storage (between 18 ºC and 30 ºC) is acceptable but will shorten expiry dating:

- I-STAT Aqueous Calibration Verifiers and Controls = 5 days

6.2.4. Shortened expiry date must be written on the vials or box when taken out of the fridge.

### 6.3. Electronic Simulator:

6.2.1. Store at room temperature (between 18 ºC and 30 ºC).

6.2.2. Protect contact pads from contamination by replacing the plastic cap and placing the e-simulator in its protective case after use.

## 7.0 SPECIMEN COLLECTION AND HANDLING:

### 7.1. Finger Stick Specimens:

7.1.1. First drop of blood will contain excess tissue fluid and must be wiped away.

7.1.2. Avoid strong repetitive pressure (“milking”), as it may cause hemolysis or tissue fluid contamination of the sample.

7.1.3. Draw blood into capillary tube while avoiding creating air bubble in the tube.

7.1.4. Once tube is completely filled, tap sample into Lithium Heparin-filled microtainer.

7.1.5. Mix blood and anticoagulant by inverting tube gently at least 10 times immediately following collection.

7.1.6. Testing must be performed within 30 minutes of collection.

7.1.7. **DO NOT** run clotted samples.

**8.0 DAILY QUALITY CONTROLS:**

8.1. Verify the performance of each i-STAT Alinity running the external electronic simulator every 24 hours of use.
8.2. All analyzers will lock and not report results if the e-simulator has not been run in the last 24 hours; running the e-simulator will unlock the analyzer.

| Electronic Simulator | |
|---|---|
| Step 1 | Turn on i-STAT (small button on right side of analyzer) |
| Step 2 | Press **More Options** |
| Step 3 | Press **Quality Options** |
| Step 4 | Press **Perform Electronic Simulator Test** |
| Step 5 | Scan or enter unique operator ID |
| Step 6 | Scan Simulator ID (found on the sticker on the front of the simulator) |
| Step 7 | Insert Simulator |
| Step 8 | Document results in Kidney Check QC Workbook (document # WB01). |

| *If,* | *Then,* | |
|---|---|---|
| ***PASS*** is displayed on the screen | Remove the Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen; use the analyzer as required. | |
| ***FAIL*** is displayed on the screen (analyzer will lock and not report results if the electronic simulator has failed) | Follow the prompts on the screen. | |
| | ***If,*** | ***Then,*** |
| | ***PASS*** is displayed | Document results in Kidney Check QC Workbook; use the |
| | ***FAIL*** is displayed | Document results in QC Workbook; call Abbott Tech Support 1-800-387-8378 (prompt 1 then 3). |

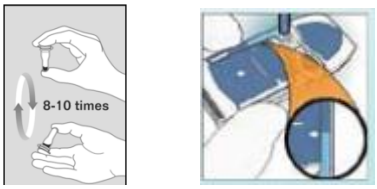
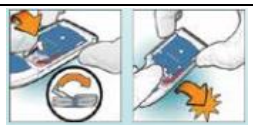
**9.0 RECHARGING:**

9.1. Each site will have a downloader/recharger; it is recommended that the analyzer be left on the recharger when not in use.
9.2. Docking the i-STAT on this will recharge the batteries.
9.3. Each unit also comes with lithium 9V batteries that should be stored on site for use in the event of a power outage.
9.4. Refer to vendor manual for more information/instructions.

**10.0 PROCEDURE FOR ANALYSIS:**

**10.1. Preparation for Use:**

10.1.1. An individual cartridge may be used after standing 5 minutes in its pouch at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.
10.1.2. DO NOT open cartridge pouch before scanning the barcode.
10.1.3. DO NOT pre-load cartridges.
10.1.4. Re-mix specimen before loading the next cartridge.

| Specimen Analysis | | |
|---|---|---|
| **Step 1** | Use universal precautions when handling samples | |
| **Step 2** | Place analyzer on a flat surface; DO NOT MOVE until analysis is complete. | |
| **Step 3** | Turn the analyzer on and press **Perform Patient Test** | |
| **Step 4** | Scan or enter the Unique Operator ID and Patient ID. Repeat if prompted | |
| **Step 5** | Scan or enter cartridge lot number barcode from the cartridge pouch. |  |
| **Step 6** | Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge. | |
| **Step 7** | Following thorough mixing of the sample (8 figure 8 motions), draw up sample into dispensing device discard the first 1-2 drops of blood, direct the dispensing tip containing the blood into the sample well and dispense the sample until it reaches the fill mark on the cartridge; the well will be about half full. |   |
| **Step 8** | Holding the cartridge by its edges, close the cover over the sample well until it snaps into place. DO NOT press over the sample well. DO NOT touch metal contact pads. |  |
| **Step 9** | Insert the cartridge into the cartridge port using the Gentle Insertion technique.<br>• Hold the analyzer in place with one hand.<br>• Handling the cartridge by its edges, gently guide the sealed cartridge into the handheld port until it clicks into place. |  |
| **Step 10** | The "*Time to Results*" countdown bar will be displayed; once time has elapsed results can be viewed on the display. | |
| **Step 11** | To print result place on downloader/recharger, review all the results and press print. Do not move analyzer or printer until printing is complete. Report results as per protocol. | |
| **Step 12** | Remove cartridge after "Cartridge Locked" message disappears; the analyzer is ready for the next test immediately. | |
| **Step 13** | Attach analyzer printout to requisition/report; sign and date; enter results into laboratory electronic information system, if applicable. Photocopy requisition with attached report. Save copy as per retention guidelines. | |

**10.2. Calculations:**

10.2.1. The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

**10.3. Suppressed Results:**

10.3.1. Conditions under which the i-STAT will not display results:

| *If,* | *Then,* |
|---|---|
| Results outside the System's reportable ranges are flagged with a **<** or **>**, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The **< >** flag indicates that the results for this test were dependent on the result of a test flagged as either **>** or **<**. | Send specimen(s) to laboratory for analysis, if necessary. |

**10.4. Troubleshooting Quality Check Error Messages:**

10.4.1. The i-STAT Alinity performs quality checks throughout the testing cycle.

10.4.2. If any quality checks fail, the i-STAT will halt testing and display a Failure Codes or Alert

10.4.3. Quality Check Failures:

- Displayed instead of results if the analyzer detects a problem.
- Four (4) types of quality check failures:
  - Instrument
  - Cartridge
  - Sample
  - Software
- The type of failure will be displayed on the screen along with resolution instructions. Take the action displayed by following the instructions on the screen.

10.4.4. Startup Alerts:

- Displayed before the Home screen appears.
- The screen displays instruction for resolution.

10.4.5. Alerts:

- The alert button provides access to alert's description.
- Indicated a change in instrument status during testing.

10.4.6. A full list of Quality Check Failure Codes can be found in Appendix 5 with causes and resolutions for each failure.

10.4.7. If the problem cannot be resolved using Appendix 5, contact Abbott Technical Support and provide the Quality Check Code number for assistance.

## 11.0 REFERENCE RANGES AND REPORTABLE RANGES:

11.1. Reference ranges may differ from those use for the same test at a site when it is run on different instrumentation.

11.2. When reporting i-STAT results, use i-STAT reference ranges.

11.2.1. Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy.

11.2.2. Reportable range means the range of test values throughout which the measurement systems results have been shown to be valid.

11.3. **The i-STAT Alinity only displays adult reference ranges; reference values in pediatric patients may differ.**

| ANALYTE | UNIT | ADULT REFERENCE RANGES venous & capillary | REPORTABLE RANGE |
|---|---|---|---|
| Creatinine | µmol/L | 53 – 115 | 18- 1768 |
| eGFR | mL/min/1.73m$^2$ | ≥ 90 | 0 – 60* |

***A calculated eGFR >60mL/min/1.73m^2 does not exclude the possibility of mild renal disease. Further laboratory testing may be necessary to distinguish normal renal function from mild renal disease.***

## 12.0 CRITICAL RESULTS:

12.1. Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test.
12.2. Critical results represent an emergency condition and must be reported immediately to the appropriate person in charge of patient care.
12.3. In Manitoba, contact the Nephrologist on call at Seven Oaks General Hospital. If the Nephrologist can't be contacted, results can be given directly to Dr. Paul Komenda.
12.4. Other provinces must establish a protocol for delivering critical results within their Health Authority.

| ANALYTE (units) | ADULT | | CHILDREN | | NEONATES** | |
|---|---|---|---|---|---|---|
| | low | high | low | high | low | high |
| Creatinine (µmol/L) | - | ≥ 654 | - | ≥ 336 | - | - |

## 13.0 RESULTS REPORTING:

13.1. Results are displayed numerically with their units and reference ranges.
13.2. Results outside the reference range should be evaluated for critical results. These results will be highlighted by both colour and an arrow.
- Yellow indicates the results is outside reference range but not critical
- Red indicates the result is critical.
- ⇧ and ⇩ will indicate if the result is high or low.

13.3. Print results by pressing Print on the right side of the screen
13.4. Print-outs from the i-STAT Alinity are on thermal paper and will fade with time, there result reports must be either photocopies or recorded another way.
13.5. Both the physician/chart and the testing site should retain a copy of the results as per Shared Health SOP # 100-10-05 Lab Records and Materials Retention Policy.
13.6. Reports generated by the testing site must include:
- Patient demographics (name, DOB, Gender, Unique ID such as PHIN).
- Test results, units and reference ranges.
- Unique Operator ID.
- Time and date test was performed.
- Clear indication that testing was done on the i-STAT.

## 14.0 VERIFICATION OF CARTRIDGE STORAGE CONDITIONS:

### 14.1. Refrigerated Conditions:

14.1.1. Verify that the cartridges, calibration verifiers and QC fluids are all within the expiration date printed on the boxes; if not, DO NOT USE and initiate ordering replacements.
14.1.2. Verify the refrigerator did not exceed the limits of 2 ºC and 8 ºC, and record temperature in the appropriate section of the Kidney Check QC Workbook.

| Refrigerated Cartridge Temperature Verification | |
|---|---|
| ***If,*** | ***Then,*** |
| Temperature of cartridge storage refrigerator is within range of 2°C to 8°C | Use cartridges as required. |
| Temperature of cartridge storage refrigerator is outside the range of 2°C to 8°C | Quarantine the cartridges in the storage fridge.<br>Notify supervisor/designate immediately.<br>**DO NOT USE** the cartridges from this fridge.<br>Document all actions in the workbook. |

**14.2. Room Temperature Conditions:**

14.2.1. Verify that any materials at room temperature have been out of the refrigerator less than their shortened expiry date (see section 5.0 Supplies and Storage Requirements)

14.2.2. Verify that room temperature has not exceeded 30 ºC, and record temperature in the appropriate section of the Kidney Check QC Workbook.

| Room Temperature Cartridge Verification | |
|---|---|
| ***If,*** | ***Then,*** |
| Measured room temperature has been continuously below 30°C | Use cartridges as required. |
| Measured room temperature has exceeded 30°C for any period of time | Quarantine the cartridges.<br>Notify supervisor/designate immediately.<br>**DO NOT USE** the cartridges.<br>Document all actions in the workbook. |

## 15.0 PROCEDURE FOR NEW SHIPMENTS OF CARTRIDGES:

15.1. For new shipments of cartridges (must be done at receiving site), check the Temperature Monitor and perform integrity testing with QC materials (see section 15.0).

**15.1.1. Temperature Monitor**

- i-STAT cartridges are shipped refrigerated with a four-window indicator used to monitor temperature during transit.
- Fill out the record of receipt and forward materials to the refrigerator.

| Temperature Monitor – New Shipments of Cartridges | |
|---|---|
| ***If,*** | ***Then,*** |
| All windows are white or if only the A or B windows are blue or the 1 or 2 windows are red | Record result in the workbook.<br>Transit temperatures were satisfactory and the cartridges can be used. |
| The C or D windows are blue, or the 3 or 4 windows are red | Quarantine the suspect cartons.<br>Notify supervisor/designate immediately.<br>**DO NOT USE** cartridges from the suspect carton.<br>Document all actions in the Kidney Check QC Workbook.<br>Notify Abbott and request replacement. |

## 16.0 INTEGRITY TESTING:

16.1. Performed using liquid quality control materials listed in section 5.2.

16.2. Integrity testing is required on each new lot and each new shipment of cartridges and for instrument validation following calibration verification (see section 16.0).

16.3. Compare results to the Value Assignment Sheets (VAS), available on the Abbott POC website: https://www.pointofcare.abbott/int/en/offerings/support/istat-alinity/value-assignment-sheets

16.4. Check that the lot number on the control ampule matches the lot number on the VAS and that the software version listed on the VAS matches the software installed in the analyzer.

16.5. The VAS displays target values and ranges expected when materials and equipment are performing properly.

16.6. Always remember to analyze the control material in the control pathway under the Quality Tests option of the i-STAT Alinity Analyzer menu.

| Integrity Testing – Creatinine Cartridges | |
|---|---|
| **Step 1** | Power On |
| **Step 2** | **More Options → Quality Options → Quality Control** |
| **Step 3** | Enter required information on screen and press **Perform Unscheduled** |
| **Step 4** | Prior to testing cartridges, ampules must stand out at room temperature for approximately 30 minutes. For best results, ampules, cartridges, and analyzers should be at the same temperature. |
| **Step 6** | Immediately before use, shake the ampoule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the scored neck. |
| **Step 7** | Using a plain capillary tube or plain syringe, immediately transfer the solution from the ampule into a cartridge. Seal the cartridge and insert it into an analyzer. It is important not to expose the solution to room air since this will alter the results. |
| **Step 8** | Compare results to the Value Assessment Sheets (VAS). If all results are within expected ranges, use the cartridges as needed. Document results in Kidney Check QC Workbook. |

| ***If,*** | ***Then,*** |
|---|---|
| All results ***PASS*** | Document QC results.<br>Use cartridges as needed. |
| Any results are outside the published expected ranges | **DO NOT USE** cartridges from the suspect lot.<br>Quarantine the suspect lot.<br>Notify supervisor/designate immediately.<br>Record QC results/failure and actions in workbook. |

## 17.0 CALIBRATION:

### 17.1. Routine calibration

17.1.1. For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type; operator intervention is not necessary.

### 17.2. Calibration Verification

17.2.1. Calibration verification must be performed using on all new or replacement analyzers, or any analyzer that has been moved from one site to another, with i-STAT Calibration Verification (Cal/Ver) sets which are designed to verify the calibration of each assay through the reportable range.

17.2.2. Five (5) levels of verification solution are run and compared to the Value Assignment Sheet available on the i-STAT Alinity website: https://www.pointofcare.abbott/int/en/offerings/support/istat-alinity/value-assignment-sheets

17.2.3. Cal/Ver samples are handled using the same pre-analytical techniques as quality control materials. The calibration should always be analyzed in the Cal/Ver pathway under the Quality Tests option of the i-STAT Alinity Analyzer menu.

| Calibration Verification | |
|---|---|
| **Step 1** | Power On |
| **Step 2** | **More Options → Quality Options → Cal/Ver** |
| **Step 3** | Enter required information on screen |
| **Step 4** | Prior to testing cartridges, ampules must stand out at room temperature for approximately 30 minutes. For best results, ampules, cartridges, and analyzers should be at the same temperature. |
| **Step 6** | Immediately before use, shake the ampoule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the scored neck. |

| | |
|---|---|
| **Step 7** | Using a plain capillary tube or plain syringe, immediately transfer the solution from the ampule into a cartridge. Seal the cartridge and insert it into an analyzer. It is important not to expose the solution to room air since this will alter the results. |
| **Step 8** | Compare results to the Value Assessment Sheets (VAS). If all results are within expected ranges, use the cartridges as needed. Document results in Kidney Check QC Workbook.<br>Repeat above steps for all 5 levels. |
| **Step 9** | Confirm results by performing integrity testing and running the e-simulator. |

## 18.0 EXTERNAL PROFICIENCY TESTING (EPT):

18.1. Each site should subscribe to an external proficiency testing program for all analytes being tested at the site; programs can be ordered through the College of American Pathologists. https://www.cap.org
18.2. Samples must be tested according to instructions included with each kit, and treated the same as all patient samples.
18.3. Each region/program must have a system for maintaining documentation and verifying that sites are performing required quality control.
18.4. Program required:
- Chemistry – College of American Pathologists (CAP) AQ4

## 19.0 UPDATING SOFTWARE – CLEW:

19.1. The i-STAT system does not require lot-specific calibration information, however Abbott re-issues standardization values periodically to maintain long term consistency of results over a range of lot numbers; this is equivalent to adjusting calibration on a traditional analyzer.
19.2. New CLEW (software) re-establishes the standardization and incorporates refinements to the internal quality monitoring system.
19.3. These software updates occur every 6 months.
19.4. Document CLEW updates on equipment action log.
19.5. After doing CLEW updates, perform daily QC with the e-simulator to ensure analyzer is functioning correctly.

| Step | Action |
|---|---|
| 1 | Go to: https://www.pointofcare.abbott/int/en/i-stat-alinity-support<br>Fill out your contact information. Select **Submit** when finished |
| 2 | Navigate to i-STAT Alinity System Software<br>Note: File is not MAC compatible; Microsoft Windows 7 or 10 and Internet Explorer web browser is recommended |
| 3 | Save software to USB<br>Note: Requires FAT32 formatted USB 2.0 memory stick; file must be saved on the top-level directory of the USB |
| 4 | Place analyzer into the base station and power up. |
| 5 | Insert USB into the USB port in the base station |
| 6 | From the Home screen, press **More Options → Instrument Options → Software Installation → Install from USB** |
| 7 | Follow on-screen prompts until transfer is complete |
| 8 | If installation is successful, an on-screen message will appear “New Software Installed” |
| 9 | If installation is not successful, and on-screen message will appear “Installation Failed”<br>• Contact Abbott Technical Support for Customer at 1-800-387-8378 (prompt 1 then 3).<br>• Support is available 24 hours, 7 days a week |

**20.0 CUSTOMIZATIONS:**

20.1. Customizations (SI units, exceptions, requirements) must be entered into each i-STAT analyzer prior to being used for patient testing.
- 20.1.1. If an i-STAT is sent for repair, customizations will need to be re-entered prior to sample testing.
- 20.1.2. If a different unit is received, customizations will need to be entered prior to sample testing.
- 20.1.3. For detailed information refer to the i-STAT technical manual for customization settings.
- 20.1.4. For each new or replacement i-STAT, Calibration Verification and Integrity Testing must be performed and units verified prior to reporting results.
- 20.1.5. All customizations must be made through the More Options menu.

| Customization Action | Explanation |
|---|---|
| **CLEWS and JAMS**<br>More Options; Instrument Status | **Current software**<br>Verify software version is up-to-date. Analyzer will not run if software is expired. |
| **Date and Time**<br>More Options; Instrument Options; Instrument Settings; Set Clock/Set Date Format | **Correct time/date** |
| **Creatinine**<br>More Options; Instrument Options; Instrument Settings; Set Units | **Creatinine – change to SI**<br>Reports results in µmol/L |

**21.0 CLINICAL SIGNIFICANCE:**

| Analyte | Some Causes of Increased Values | Some Causes of Decreased Values |
|---|---|---|
| **Creatinine** | Impaired renal function<br>High muscle mass | Low muscle mass |
| **eGFR** | The rate is an index of kidney function, used to screen for and detect early kidney damage, to help diagnose chronic kidney disease, and to monitor kidney status.<br><br>Creatinine-based estimating equations are not recommended for use with individuals with unstable creatinine concentrations, not with persons with extremes in muscle mass and diet. | |

**22.0 PRINCIPLES OF MEASUREMENT:**

| Analyte | Principles of Measurement |
|---|---|
| **Creatinine** | Is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration. |
| **eGFR** | Is a calculated result when a creatinine test result is obtained. The calculation options are:<br>• The Modification of Diet in Renal Disease (MDRD) Study equation:<br>○ **eGFR= 175 x $(S_{cr})^{-1.154}$ x (Age) $^{-0.203}$ x (0.742 if female) x (1.212 if African American)**, *where $S_{cr}$ is serum creatinine (mg/dL), and age is expressed in years* |

| Analyte | Principles of Measurement |
|---|---|
| **eGFR, cont.** | • The Chronic Kidney Disease Epidemiology Collaboration formula (CKD-EPI):<br>○ **eGFR= 141 x min ($S_{cr}$/k,1)$^a$x max ($S_{cr}$/k,1)-1.209 x 0.993 $^{Age}$ x 1.018 (if female) x 1.159 (if Black)**, *where $S_{cr}$ is serum creatinine (mg/dL) k is 0.7 for females and 0.9 for males, a is -0.329 for females and -0.411 for males, min indicates the minimum of $S_{cr}$/k or 1, and max indicates maximum of $S_{cr}$/k or 1.* |

**23.0 INTEREFERENCES:**

23.1. An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured.

| ANALYTE | INTERFERENT | INTERFERENT CONCENTRATION | EFFECT ON ANALYTE RESULT |
|---|---|---|---|
| **Creatinine** | Acetaminophen | For every 1 mmol/L acetaminophen | Increase (↑) creatinine by 22 µmol/L |
| | Ascorbate | 0.227 mmol/L | Increase (↑) creatinine by 62 µmol/L |
| | Bromide | 12.5 mmol/L (100 mg/dL) | Increase (↑) creatinine by 71 µmol/L from an initial Creatinine concentration of 88 µmol/L |
| **<177 µmol/L** | ***P***$CO_2$ | Above 40 mmHg | Increase (↑) creatinine by 6.9% per 10 mmHg ***P***$CO_2$ |
| | | Below 40 mmHg | Decrease (↓) creatinine by 6.9% per 10 mmHg ***P***$CO_2$ |
| **>177 µmol/L** | ***P***$CO_2$ | Above 40 mmHg | Decrease (↓) creatinine by 3.7% per 10 mmHg ***P***$CO_2$ |
| | | Below 40 mmHg | Increase (↑) creatinine by 3.7% per 10 mmHg ***P***$CO_2$ |
| | Hydroxyurea | 100 µmol/L | Increase (↑) 164 µmol/L |
| | Creatine | 5 mg/dL creatine | Increase (↑) creatinine by 18 µmol/L |
| | N-acetylcysteine | 16.6 mmol/L | Increase (↑) creatinine by 35 µmol/L |
| **eGFR** | The formula is only valid for adults between the ages of 18 and 120 years | | |

**24.0 REFERENCES:**

24.1. i-STAT Alinity System Operations Manual, Abbott Point of Care, 4 May 2020
24.2. Statland, B.E., Clinical Decision Levels for Lab Tests. Medical Economics Books, 1987
24.3. Tietz, N.W., Tietz Textbook of Clinical Chemistry, third edition, Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders Company, Philadelphia, 1999. Table 50 – 20, Appendix
24.4. Kost, Gerald J., Using critical limits to improve patient outcome. Medical Laboratory Observer. March 1993; 25(3): 22–27

**25.0 APPENDICES:**

Appendix 1 – Blood Collection – Skin Puncture
Appendix 2 – i-STAT Alinity System – CREA Job Aid
Appendix 3 – i-STAT Alinity System - Troubleshooting
Appendix 4 – i-STAT Alinity System – Quality Check Failure Codes, Causes and Resolutions

## Appendix 1: *Blood Collection – Skin Puncture*

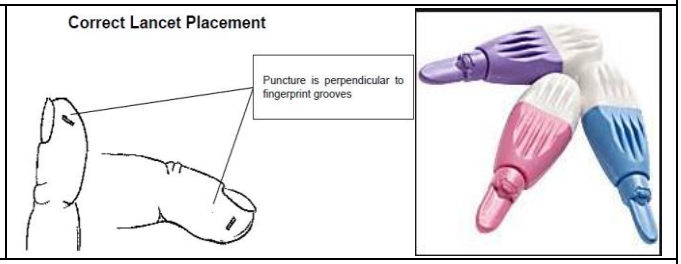
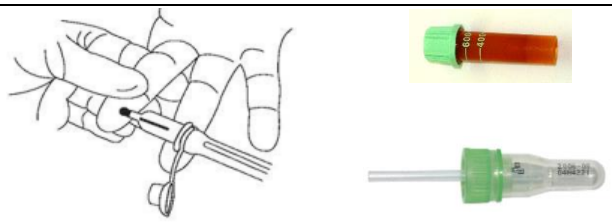
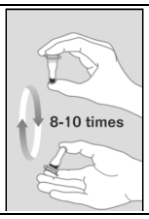
**Skin Puncture Blood Collection:**

- Ideal site for puncture is the inside surface of the ring or middle finger on the non-dominant hand; if this is not possible, index finger may be used; AVOID using pinky finger or thumb
- Avoid puncturing directly on pad, as it is more sensitive; choose a site medial or lateral to the pad whenever possible

**Ensuring correct patient ID is CRUCIAL AND MANDATORY**

- If patient does not have PHN or MB Health Card, alternative identifiers can be used, including First Nation Inuit & Aboriginal Health, Treaty Card, etc.
    - The info must be unique to that patient

Have patient state and spell first and last name and birthday; resolve any discrepancies before initiating collection

| Step | Action |
|---|---|
| 1 | Have patient place hand, palm up, comfortably on a sold surface; select site for puncture. |
| 2 | Cleanse site with an alcohol swab; allow to air dry, do not wipe dry with cotton. |
| 3 | Grasp finger with firm even pressure between your thumb and index finger; remove tab from lancet by twisting gently; position lancet so puncture will be perpendicular to fingerprint grooves; press lancet into finger to release the blade.   |
| 4 | Wipe away the first drop of blood, as it is presumed to be contaminated with tissue fluid. |
| 5 | Position finger downward and allow the blood drops to flow freely into the collection vessel (SAFE-T-FILL/microtainer/capillary rod). Scoop drops into the container, tapping and/or gently mixing as needed to distribute anti-coagulant.  |
| 6 | **Do not vigorously squeeze or massage the finger; DO NOT MILK THE FINGER.** This will cause tissue fluid to contaminate the sample, which will affect results. |
| 7 | Cap container, and invert gently 8-10 times to mix.   |
| 8 | Place gauze on finger; have patient apply pressure until bleeding stops; apply bandage if needed/requested. |
| 9 | Unless analyzing immediately and discarding any remaining sample, label all tubes with patient information including name and unique identifier. **Do not walk away from the sample unless it is labeled.** |

**NOTE:** Puncture site may be warmed prior to collection to promote increased blood flow.
Dangling of the hand below the level of the heart will also increase blood flow to the fingers.

# Appendix 2: *i-STAT Alinity System – CREA Testing*

**Specimen Requirements for Chemistry CREA Testing:**

- Skin Puncture:
  - Specimen must be collected in a Lithium Heparin collection device (i.e. SAFE-T-FILL microtube or Lithium Heparin MicroContainer)

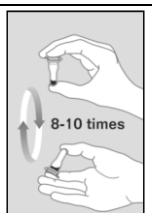
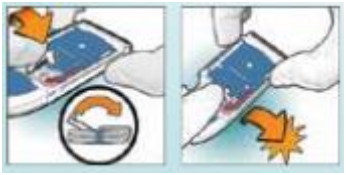
  - Follow Blood **Collection – Skin Puncture Job Aid** for collection procedure to ensure high quality samples and results.
    **IMPORTANT:** Do not "milk" finger while collecting sample

**Quality Control**

- Electronic simulator must be run every 24 hours, or before running patient samples if analyzer is not in use every day

**Note:** Instrument and/or Reagent validations must be performed every time the analyzer or reagents have been moved off site.

Equilibrate cartridge to room temperature for five (5) minutes prior to use; **DO NOT open cartridge pouch before scanning the barcode.**

| Step | Action | |
|---|---|---|
| 1 | Place analyzer on a flat surface; **DO NOT MOVE ANALYZER** until testing is complete | |
| 2 | Turn the analyzer on and press Perform Patient Test | |
| 3 | Scan or enter Operator ID. Repeat if prompted. Enter the patient ID. | |
| 4 | Scan the lot number on the cartridge pouch |  |
| 5 | Remove cartridge from portion pack. **Handle the cartridge by its edges.**<br>**Note:** Avoid touching the contact pads or exerting pressure over the centre of the cartridge. | |
| 6 | Mix the sample by holding tube between thumb and forefinger and inverting 8-10 times.<br>Using a capillary rod or a syringe, draw up a small amount of sample and slowly dispense into cartridge sample well, being careful not to over- or under-fill (either scenario will result in an error); sample should reach the arrow as indicated on the cartridge |   |
| 7 | Holding the cartridge by its edges. Close the cover over the sample well until it snaps into place. DO NOT press over the sample well |  |
| 8 | Hold the analyzer in place with one hand.<br>Handling the cartridge by its edges, gently guide the sealed cartridge into the handheld port until it clicks into place. |  |
| 9 | The "*Time to Results*" countdown bar will then be displayed. Once time has elapsed, results can be viewed on analyzer's display. | |
| 10 | To print result, review all results, then place on base station and press **Print.** Do NOT move analyzer or printer until printing is complete. Scan results for error message and critical results. Take appropriate actions. | |
| 11 | Remove cartridge after "*Cartridge Locked*" message disappears. The analyzer is ready for the next test immediately. | |
| 12 | Attach analyzer printout to requisition/report; sign and date; enter results into laboratory electronic information system, if applicable. Photocopy requisition with attached report. Save copy as per retention guidelines. | |

## Appendix 3: *i-STAT Alinity System – Troubleshooting*

***NOTE:*** *any time a new sample is run or a new cartridge is used, document with a comment on the patient log*

| If… | Then, |
|---|---|
| Results do not reflect the patient's condition (unexpected results) | Repeat the test using a fresh cartridge and sample |
| Results are still suspect | Send sample to the lab |
| The analyzer fails to provide a test result or displays an error code message | Repeat the test using a fresh cartridge and sample |
| The condition persists | DO NOT use the analyzer<br>Log the error condition in the equipment log<br>Call vendor support for assistance<br>Send sample to the lab |
| "Cartridge Locked" does not disappear on the i-STAT after the test cycle is completed | Wait until device turns off; turn back on. If it resets, remove the cartridge; if no, recharge the battery and then turn the device on |
| **i-STAT Alinity Messages / Codes** | **Operator Action** |
| Dead batteries / replace batteries | Recharge device |
| Cartridge Error | Use a fresh cartridge |
| Cartridge Preburst | Use a fresh cartridge |
| Unable to Position Sample | Use a fresh cartridge |
| Sample Positioned Short of Fill Mark | Use a fresh cartridge |
| Sample Positioned Beyond Fill Mark | Use a fresh cartridge |
| **Test Flags** | **Operator Action** |
| Results are not reportable due to sensor errors or interfering substances | Collect a new sample and repeat test; document all results on log<br>**Note:** if results flag again, send a sample to the lab |
| Results above or below the reportable range for the analyzer | Send sample to the lab for testing |
| Results are above or below the action range | Follow procedure for samples with critical values |
| **QC Failures** | **Operator Action** |
| Control results fall outside the values stated in the package insert | **DO NOT** test patient samples until all control results are within acceptable range<br>See below for possible sources of error |
| **Sources of Random QC Error** | **Sources of Systemic QC Error** |
| Bubbles in reagent | Replacement of reagent or reagent lot change |
| Sampling or reagent syringes | Improperly prepared reagents |
| Improperly mixed/dissolved reagents | Inadequate storage of reagents or calibrators |
| Clog in sampling device | Calibration (not performed or did not pass; calibration drift) |
| Power supply/fluctuations | Calibrator lot change or wrong calibrator values |
| Unstable temperature and incubation | Change in procedure from one operator to another |
| Individual operator variation | Environmental issues affecting reagents or instruments |

*Abbott i-STAT Alinity Technical Support: 1-800-387-8378 Option 1*

## Appendix 4: *i-STAT Alinity System – Quality Check Failure Codes, Causes and Resolutions*

Quality Check Failure Codes (QCFs) indicate an issue was detected with the instrument, cartridge, sample or software. The failure of any quality check causes the instrument to display a quality check failure code consisting of a numeric code, a cause, and resolution message, and suggested corrective action.

Use the following tables to the *Quality Check Failure code* and determine the cause and resolution.
In the table below, in the first column, find the **QCF code** as found in **Review Results** on the analyzer.
Identify the pathway in which the failure occurred, and
In the **Cause** column find the cause number, then see the *Quality Check Failure Causes* table for the description
In the **Resolution** column find the resolution letter, then see the *Quality Check Failure Resolutions* table for corrective action.

### Quality Check Failure Codes:

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 2-01-1.1.1 | 1 | A | 1 | A | | | 2-01 |
| 2-02-1.1.2 | 1 | A | 1 | A | | | 2-02 |
| 8-01-2.1.8 | | I | | I | | P / BB | 8-01 |
| 11-01-2.13.32 | | B | | B | | D | 11-01 |
| 13-01-1.6.1 | | S | | S | | S | 13-01 |
| 17-01-8.2.1 | 2 | E | 2 | F | | | 17-01 |
| 18-01-8.2.2 | 2 | E | 2 | F | | | 18-01 |
| 19-01-6.2.5 | 2 | E | 2 | F | | | 19-01 |
| 20-01-3.1.1[1] | | G | | F | | | 20-01 |
| 21-01-3.1.3 | 3 | G | 3 | F | | | 21-01 |
| 22-01-6.1.3 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.5 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.8 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.9 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.10 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.11 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.12 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.15 | 4 | X | 4 | F | | | 22-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 23-01-3.3.2[1] | | G | | F | | | 23-01 |
| 24-01-3.1.5 | | G | | F | | | 24-01 |
| 25-01-6.1.13 | 5 | X | 5 | F | | | 25-01 |
| 25-01-6.1.14 | 5 | X | 5 | F | | | 25-01 |
| 26-01-6.2.1 | | X | | F | | | 26-01 |
| 26-01-6.2.2 | | X | | F | | | 26-01 |
| 26-01-6.2.3 | | X | | F | | | 26-01 |
| 26-01-6.2.4 | | X | | F | | | 26-01 |
| 27-01-4.1.1[1] | | G | | F | | | 27-01 |
| 28-01-4.1.2 | | G | | F | | | 28-01 |
| 29-01-4.1.3 | | G | | F | | | 29-01 |
| 30-01-6.1.4 | 6 | W | 12 | F | | | 30-01 |
| 30-01-6.1.7 | 6 | W | 12 | F | | | 30-01 |
| 30-02-4.1.4 | 6 | H | 12 | F | | | 30-02 |
| 31-01-4.1.5 | 7 | G | 7 | F | | | 31-01 |
| 31-02-6.1.16 | 7 | X | 7 | F | | | 31-02 |
| 32-01-4.1.6 | | G | | F | | | 32-01 |
| 33-01-4.1.8 | | G | | F | | | 33-01 |
| 34-01-4.1.11 | 7 | G | 7 | F | | | 34-01 |
| 20-01-3.1.1[1] | | G | | F | | | 20-01 |
| 21-01-3.1.3 | 3 | G | 3 | F | | | 21-01 |
| 22-01-6.1.3 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.5 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.8 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.9 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.10 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.11 | 4 | X | 4 | F | | | 22-01 |
| 22-01-6.1.12 | 4 | X | 4 | F | | | 22-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 22-01-6.1.15 | 4 | X | 4 | F | | | 22-01 |
| 23-01-3.3.2[1] | | G | | F | | | 23-01 |
| 24-01-3.1.5 | | G | | F | | | 24-01 |
| 25-01-6.1.13 | 5 | X | 5 | F | | | 25-01 |
| 25-01-6.1.14 | 5 | X | 5 | F | | | 25-01 |
| 26-01-6.2.1 | | X | | F | | | 26-01 |
| 26-01-6.2.2 | | X | | F | | | 26-01 |
| 26-01-6.2.3 | | X | | F | | | 26-01 |
| 26-01-6.2.4 | | X | | F | | | 26-01 |
| 27-01-4.1.1[1] | | G | | F | | | 27-01 |
| 28-01-4.1.2 | | G | | F | | | 28-01 |
| 29-01-4.1.3 | | G | | F | | | 29-01 |
| 30-01-6.1.4 | 6 | W | 12 | F | | | 30-01 |
| 30-01-6.1.7 | 6 | W | 12 | F | | | 30-01 |
| 30-02-4.1.4 | 6 | H | 12 | F | | | 30-02 |
| 31-01-4.1.5 | 7 | G | 7 | F | | | 31-01 |
| 31-02-6.1.16 | 7 | X | 7 | F | | | 31-02 |
| 32-01-4.1.6 | | G | | F | | | 32-01 |
| 33-01-4.1.8 | | G | | F | | | 33-01 |
| 34-01-4.1.11 | 7 | G | 7 | F | | | 34-01 |
| 35-01-4.1.7 | 8 | H | 13 | F | | | 35-01 |
| 36-01-4.1.10 | 8 | H | 13 | F | | | 36-01 |
| 37-01-4.1.9 | 6 | H | 12 | F | | | 37-01 |
| 38-01-4.1.12 | 9 | G | 9 | F | | | 38-01 |
| 39-01-6.1.6 | 9 | G | 9 | F | | | 39-01 |
| 40-01-3.3.3 | | G | | F | | | 40-01 |
| 41-01-3.1.21 | | G | | F | | | 41-01 |
| 42-01-3.1.6 | | G | | F | | | 42-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 44-01-6.1.1 | 5 | X | 5 | F | | | 44-01 |
| 46-01-6.1.2 | 5 | X | 5 | F | | | 46-01 |
| 47-01-2.1.7 | | N | | N | | J / Z | 47-01 |
| 48-01-2.13.2 | | B | | B | | C / AA | 48-01 |
| 49-01-3.3.1 | 14 | U | 14 | V | | | 49-01 |
| 50-01-2.1.1 | | G | | F | | C / AA | 50-01 |
| 50-01-2.1.2 | | G | | F | | C / AA | 50-01 |
| 50-01-2.1.3 | | G | | F | | C / AA | 50-01 |
| 50-01-2.1.6 | | G | | F | | C / AA | 50-01 |
| 51-01-2.1.4 | | G | | F | | C / AA | 51-01 |
| 51-01-2.1.9 | | G | | F | | C / AA | 51-01 |
| 52-01-2.1.5 | | G | | F | | C / AA | 52-01 |
| 53-01-2.9.3 | | T | | T | | T | 53-01 |
| 57-01-2.4.1 | | B | | B | | D | 57-01 |
| 59-01-4.5.1 | | B | | B | | D | 59-01 |
| 60-01-1.6.2 | | B | | B | | C / AA | 60-01 |
| 63-01-2.9.1 | | D | | D | | D | 63-01 |
| 63-01-2.9.2 | | D | | D | | D | 63-01 |
| 66-01-2.2.1 | | B | | B | | D | 66-01 |
| 66-01-2.2.2 | | B | | B | | D | 66-01 |
| 66-01-2.2.3 | | B | | B | | D | 66-01 |
| 68-01-2.4.2 | | B | | B | | D | 68-01 |
| 69-01-4.6.1 | | G | | F | | | 69-01 |
| 69-01-4.6.2 | | G | | F | | | 69-01 |
| 69-01-5.6.1 | | G | | F | | | 69-01 |
| 69-01-5.6.2 | | G | | F | | | 69-01 |
| 69-01-6.6.1 | | G | | F | | | 69-01 |
| 69-01-6.6.2 | | G | | F | | | 69-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 69-02-4.6.3 | | K | | K | | | 69-02 |
| 69-02-4.6.4 | | K | | K | | | 69-02 |
| 69-02-5.6.3 | | K | | K | | | 69-02 |
| 69-02-5.6.4 | | K | | K | | | 69-02 |
| 69-02-5.6.5 | | K | | K | | | 69-02 |
| 69-02-6.6.3 | | K | | K | | | 69-02 |
| 69-02-6.6.4 | | K | | K | | | 69-02 |
| 69-03-7.6.1 | | | | | | C / AA | 69-03 |
| 69-03-7.6.2 | | | | | | C / AA | 69-03 |
| 69-04-7.6.3 | | | | | | L / CC | 69-04 |
| 70-01-1.6.3 | | B | | B | | D | 70-01 |
| 72-01-2.1.10 | | D | | D | | D | 72-01 |
| 72-01-2.1.11 | | D | | D | | D | 72-01 |
| 79-01-2.3.1 | 15 | U | 15 | V | | | 79-01 |
| 80-01-3.4.1 | | G | | F | | | 80-01 |
| 80-01-3.4.2 | | G | | F | | | 80-01 |
| 80-01-3.4.3 | | G | | F | | | 80-01 |
| 80-01-3.4.4 | | G | | F | | | 80-01 |
| 82-01-1.2.1 | | B | | B | | D | 82-01 |
| 82-01-2.10.3 | | B | | B | | D | 82-01 |
| 87-01-3.2.1 | | G | | F | | | 87-01 |
| 88-01-1.6.33 | | B | | B | | C / AA | 88-01 |
| 89-01-2.7.32 | | B | | B | | C / AA | 89-01 |
| 90-01-2.4.3 | | D | | D | | D | 90-01 |
| 90-01-2.4.4 | | D | | D | | D | 90-01 |
| 90-01-2.4.5 | | D | | D | | D | 90-01 |
| 90-01-2.4.6 | | D | | D | | D | 90-01 |
| 90-01-2.4.7 | | D | | D | | D | 90-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 90-01-2.4.8 | | D | | D | | D | 90-01 |
| 90-01-2.4.9 | | D | | D | | D | 90-01 |
| 90-01-2.4.10 | | D | | D | | D | 90-01 |
| 90-01-2.4.11 | | D | | D | | D | 90-01 |
| 90-01-2.4.12 | | D | | D | | D | 90-01 |
| 90-01-2.4.13 | | D | | D | | D | 90-01 |
| 90-02-2.4.14 | | B | | B | | D | 90-02 |
| 90-02-2.4.16 | | B | | B | | D | 90-02 |
| 90-02-2.4.17 | | B | | B | | D | 90-02 |
| 90-02-2.4.18 | | B | | B | | D | 90-02 |
| 90-03-2.4.15 | 19 | Y | 19 | Y | | | 90-03 |
| 90-04-2.4.19 | | | | | | D | 90-04 |
| 91-01-2.6.32 | | B | | B | | D | 91-01 |
| 92-01-2.10.1 | | B | | B | | D | 92-01 |
| 92-01-2.10.2 | | B | | B | | D | 92-01 |
| 93-01-2.5.32 | | B | | B | | D | 93-01 |
| 93-01-2.5.33 | | B | | B | | D | 93-01 |
| 94-01-1.6.32 | | B | | B | | D | 94-01 |
| 95-01-1.7.1 | | R | | R | | | 95-01 |
| 99-01-2.13.1 | | G | | F | | C / AA | 99-01 |
| 99-02-2.2.4 | | | | | | C / AA | 99-02 |
| 117-01-5.1.30 | | G | | F | | | 117-01 |
| 118-01-5.1.28 | | G | | F | | | 118-01 |
| 119-01-5.1.29 | | G | | F | | | 119-01 |
| 120-01-5.1.21 | | G | | F | | | 120-01 |
| 121-01-5.1.22 | | G | | F | | | 121-01 |
| 122-01-5.1.23 | | G | | F | | | 122-01 |
| 123-01-5.1.24 | | G | | F | | | 123-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 124-01-5.1.25 | | G | | F | | | 124-01 |
| 125-01-5.1.26 | | G | | F | | | 125-01 |
| 126-01-5.1.27 | | G | | F | | | 126-01 |
| 127-01-5.1.1 | 17 | G | 17 | F | | | 127-01 |
| 127-01-5.1.3 | 17 | G | 17 | F | | | 127-01 |
| 128-01-5.1.5 | 16 | G | 16 | F | | | 128-01 |
| 129-01-5.1.7 | | G | | F | | | 129-01 |
| 130-01-5.1.8 | 9 | G | 9 | F | | | 130-01 |
| 131-01-5.1.10 | 8 | H | 13 | F | | | 131-01 |
| 132-01-5.1.15 | 9 | G | 9 | F | | | 132-01 |
| 133-01-5.1.20 | | G | | F | | | 133-01 |
| 134-01-5.1.16 | 9 | G | 9 | F | | | 134-01 |
| 134-01-5.1.17 | 9 | G | 9 | F | | | 134-01 |
| 135-01-5.1.12 | 9 | G | 9 | F | | | 135-01 |
| 136-01-5.1.13 | 9 | G | 9 | F | | | 136-01 |
| 136-01-5.1.14 | 9 | G | 9 | F | | | 136-01 |
| 137-01-5.1.11 | 9 | G | 9 | F | | | 137-01 |
| 138-01-5.1.9 | 9 | G | 9 | F | | | 138-01 |
| 142-01-5.2.1 | 3 | G | 3 | F | | | 142-01 |
| 142-01-5.2.7 | 3 | G | 3 | F | | | 142-01 |
| 143-01-5.2.2 | 3 | G | 3 | F | | | 143-01 |
| 143-01-5.2.6 | 3 | G | 3 | F | | | 143-01 |
| 144-01-5.1.19 | | G | | F | | | 144-01 |
| 145-01-5.1.2 | 7 | G | 7 | F | | | 145-01 |
| 146-01-5.1.4 | 6 | H | 12 | F | | | 146-01 |
| 146-01-5.1.6 | 6 | H | 12 | F | | | 146-01 |
| 148-01-5.1.18 | | G | | F | | | 148-01 |
| 149-01-5.2.3 | | G | | F | | | 149-01 |

| QCF Code shown in Review Results | Patient Pathway | | Quality Control Pathway | | Electronic Simulator/ Conditioning Cartridge Pathway | | QCF Code shown on screen |
|---|---|---|---|---|---|---|---|
| | Cause | Resolution | Cause | Resolution | Cause | Resolution | |
| 149-01-5.2.8 | | G | | F | | | 149-01 |
| 150-01-5.2.4 | | G | | F | | | 150-01 |
| 150-01-5.2.9 | | G | | F | | | 150-01 |
| 151-01-5.2.5 | | G | | F | | | 151-01 |
| 151-01-5.2.10 | | G | | F | | | 151-01 |
| 152-01-5.2.11 | | G | | F | | | 152-01 |
| 165-01-8.1.1 | 17 | X | 17 | F | | | 165-01 |
| 166-01-8.1.2 | 18 | X | 18 | F | | | 166-01 |
| 167-01-8.1.3 | 6 | W | 12 | F | | | 167-01 |
| 170-01-8.1.4 | | X | | F | | | 170-01 |
| 171-01-8.1.5 | | X | | F | | | 171-01 |
| 172-01-8.1.6 | | X | | F | | | 172-01 |
| 173-01-8.1.7 | | X | | F | | | 173-01 |
| 174-01-8.1.8 | | X | | F | | | 174-01 |
| 175-01-8.1.9 | | X | | F | | | 175-01 |

## Quality Check Failure Causes:

| Causes | |
|---|---|
| **1** | The internal temperature is not within 16 to 30$^{O}$C (61 to 86$^{O}$F). |
| **2** | No clot was detected during testing. |
| **3** | Cartridge was rejected during the testing cycle. Probable causes:<br>• Operator pressed too hard on the center of the cartridge<br>• Used cartridge inserted<br>• Cartridge was frozen and thawed before testing |
| **4** | Sample was rejected during the testing cycle. Probable causes:<br>• Bubbles in the sample<br>• Microclots in the sample<br>• Used cartridge inserted<br>• Snap closure not secure |

| Causes | |
|---|---|
| **5** | Sample was rejected during the testing cycle. Probable causes:<br>• Bubbles in the sample<br>• Too little sample used to fill the cartridge<br>• Clots in the sample |
| **6** | Excess blood was added to the cartridge. When filling the cartridge, the blood advanced past the level indicated by the 'fill to' arrow. |
| **7** | Sample was rejected during the testing cycle. Probable cause:<br>• Snap closure not secure. |
| **8** | An insufficient amount of blood was used to fill the cartridge. When filling the cartridge, the blood did not reach the level indicated by the 'fill to' arrow. |
| **9** | Sample was rejected during the testing cycle. Probable causes:<br>• Bubbles in the sample<br>• Insufficient amount of sample used to fill the cartridge |
| **10** | Sample was rejected during the testing cycle. Probable causes:<br>• Microclots in the sample<br>• Snap closure not secure |
| **11** | Reserved for future use. |
| **12** | Excess sample was added to the cartridge. When filling the cartridge, the sample advanced past the level indicated by the 'fill to' arrow. |
| **13** | An insufficient amount of sample was used to fill the cartridge. When filling the cartridge, the sample did not reach the level indicated by the 'fill to' arrow. |
| **14** | Cartridge was rejected. Probable cause:<br>• Instrument cannot lock cartridge in place to begin testing |
| **15** | Cartridge was rejected. Probable causes:<br>• Instrument cannot lock cartridge in place to begin testing<br>• Debris on cartridge |
| **16** | Sample was rejected during the testing cycle. Probable causes:<br>• Bubbles in the sample<br>• Insufficient mixing of sample used to fill the cartridge<br>• Wrong sample type |
| **17** | Cartridge was rejected during the testing cycle. Probable causes:<br>• Excess sample was added to the cartridge<br>• Used cartridge inserted |
| **18** | Cartridge was rejected during the testing cycle. Probable causes:<br>• Bubbles in the sample<br>• Microclots in the sample<br>• Used cartridge inserted<br>• Snap closure not secure<br>• Too little sample used to fill the cartridge |
| **19** | Cartridge was rejected during the testing cycle. Probable causes:<br>• Cartridge pouch opened too soon after removal from refrigerator<br>• Cartridge not filled immediately after opening pouch |

## Quality Check Failure Resolutions:

| Resolutions | |
|---|---|
| A | Navigate to the Home Screen, then touch More Options. Touch Instrument Status and assess the instrument's temperature. Move the instrument to an appropriate environment. |
| B | Perform an Electronic Simulator test. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction. |
| C | Repeat Electronic Simulator testing. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction. |
| D | Contact the system administrator for further instruction. |
| E | Do not collect the sample for this cartridge in a device that contains anticoagulant. Draw new sample. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| F | Prepare a new bottle of material per the manufacturer's instruction. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| G | Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| H | When filling a cartridge, use care to advance blood to the level indicated by the 'fill to' arrow. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| I | Instrument did not reset correctly. Perform an electronic simulator test. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction. |
| J | The simulator was not fully inserted. Repeat testing. Make sure that the cover retaining ring does not interfere with Electronic Simulator insertion. Ensure the Simulator is fully inserted. The Simulator is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction. |
| K | Always scan the barcode found on the pouch that contained the cartridge in use. Scanning any other barcode can cause this error. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| L | A cartridge was detected when an Electronic Simulator was expected. Repeat testing ensuring to insert an Electronic Simulator. Make sure that the cover retaining ring does not interfere with Simulator insertion. Ensure the Simulator is fully inserted. The Simulator is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction. |
| M | Reserved for future use. |
| N | The cartridge was not fully inserted. Repeat testing with a freshly filled cartridge. Ensure the cartridge is fully inserted. The cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction. |
| P | The instrument did not reset correctly. Repeat electronic simulator testing. If the test results in a PASS, the instrument is ready for use otherwise contact the system administrator for further instruction. |
| R | Test has been successfully cancelled. |

| Resolutions | |
|---|---|
| S | OSi software installation required. Contact the system administrator for further instructions |
| T | Install the most recent OSi software. Contact the system administrator for further instructions. |
| U | Power off the instrument. Insert the Latch Return Tool into the cartridge port until it stops. Immediately remove the tool from the instrument. Repeat testing with a freshly filled cartridge. If the same quality check failure displays, contact the system administrator for further instruction. |
| V | Power off the instrument. Insert the Latch Return Tool into the cartridge port until it stops. Immediately remove the tool from the instrument. Prepare a new bottle of material per the manufacturer's instruction. Repeat testing with a freshly filled cartridge. If the same quality check failure displays, contact the system administrator for further instruction. |
| W | When filling a cartridge, use care to advance blood to the level indicated by the 'fill to' arrow. Draw new sample. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| X | Draw new sample. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction. |
| Y | Cartridge pouch must be out of the refrigerator for a minimum of 5 minutes before opening. After opening the pouch, immediately begin to follow the prompts on the screen. If the same quality check failure displays, contact the system administrator for further instruction. |
| Z | The Conditioning Cartridge was not fully inserted. Repeat conditioning. Ensure the Conditioning Cartridge is fully inserted. The Conditioning Cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction. |
| AA | Repeat conditioning with Conditioning Cartridge testing. If conditioning completes successfully, the instrument is ready for use, otherwise contact the system administrator for further instruction. |
| BB | Instrument did not reset correctly. Repeat conditioning with Conditioning Cartridge. If conditioning completes successfully, the instrument is ready for use, otherwise contact the system administrator for further instruction. |
| CC | A cartridge was detected when a Conditioning Cartridge was expected. Repeat conditioning ensuring to insert a Conditioning Cartridge. Ensure the Conditioning Cartridge is fully inserted. The Conditioning Cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction. |