CALIBRATION VERIFICATION 15

OVERVIEW

Calibration Verification, also known as a linearity check, is a procedure intended to verify the accuracy of results over the entire measurement range of a test. Because of the inherent stability of the i-STAT System, Abbott Point of Care does not make any specific recommendations for the calibration verification procedure. Therefore, it is the responsibility of the laboratory to determine when and how this procedure should be performed.

Replacement and newly purchased analyzers are delivered with factory calibration. The Electronic Simulator is superior to calibration verification or control solutions in assuring that the analyzer's most important function is within factory specifications.

STABILITY OF CALIBRATION IN THE i-STAT SYSTEM

The i-STAT System is a unit-use testing system. Components that cause shifts and drifts in results in multi-use analyzers: sensors (electrodes), calibration solution, fluid-handling channels and pumps, are housed in a disposable test cartridge. The sensors are exposed to sample only once, so there is no protein build-up which is a major cause for deterioration of sensor slope and the need to calibrate and/or verify calibration on a frequent basis in multi-use analyzers.

The stability and consistency of the manufacturing process allow the slope of the sensors to be programmed into the analyzer's software. A one-point calibration to set the intercept accounts for any day-to-day variation in testing conditions. When stored according to directions, the cartridges are stable up to the expiration date.

The analyzer houses the mechanical and electrical systems necessary to control fluid movement within the cartridge, control the temperature when measurements are performed at 37 °C, measure barometric pressure, measure electrical signals generated by the sensors and display and transmit results. The analyzer's functions are factory calibrated to specifications that are programmed into the analyzer along with acceptability limits, which when exceeded cause the analyzer to display quality check messages or to display *** rather than results.

The accuracy of results and dependability of the internal quality check system depend upon the ability of the analyzer to take accurate and sensitive signal readings from the sensors. To check this function, i-STAT developed an electronic control device. The Electronic Simulator simulates two levels of electronic signals that stress the analyzer's signal detection function both below and above the reportable ranges. Injecting signals directly into the analyzer allows very tight control limits to be set. Control limits for liquid controls are set wide enough to allow for sensor-to-sensor variation. All analyzers that pass the Electronic Simulator test are equivalent and any variations in results are caused by within and between lot variations in the cartridges.

The combination of unit-use cartridges, inherently stable electronics of the analyzer, and reliability of the Electronic Simulator check provides the stability needed for a point-of-care testing system and reduces the need for frequent stability or calibration verification checks.

i-STAT CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	PCO_2	Lactate
Chloride	PO_2	BUN/Urea
Ionized Calcium	TCO_2	Creatinine

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients

See the table "Reactive Ingredients" in the Quality Control section of the i-STAT System Manual for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes.

Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule 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.

3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
5	Immediately 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.

Note: Since aqueous based solutions such as calibration verification material lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 14. Target values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

Correction of PO_2 for Barometric Pressure (BP)

The partial pressure of oxygen in a solution will change as it equilibrates to the ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin, which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flow-path of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Equations:

For PO_2 values below 150 mmHg: PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.
(Approximate change: for every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For PO_2 values 150 mmHg and above: PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.
(Approximate change: for every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

i-STAT CHEM8+ CALIBRATION VERIFICATION LEVEL 1B

Calibration Verification Solution for CHEM8+ Cartridges

i-STAT CHEM8+ Calibration Verification Level 1b is available for purchase to verify the calibration of the i-STAT CHEM8+ TCO_2 at the low end of the reportable range.

There are ten 1.7 mL glass ampules in each box.

Note: For testing all CHEM8+ cartridge analytes, use either the i-STAT TriControls Calibration Verification Set (includes hematocrit) or the i-STAT Calibration Verification Set (does not include hematocrit).

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

i-STAT CHEM8+ Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes.

Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

A separate ampule must be used for each cartridge being tested.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

Equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule 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.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately 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.

Note: Since aqueous based solutions such as calibration verification material lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 14. Target values are specific to the i-STAT System. Results obtained when testing these aqueous calibration verification materials with other methods may differ due to matrix effects.

i-STAT TRICONTROLS CALIBRATION VERIFICATION FOR BLOOD GAS/ ELECTROLYTE/ METABOLITE CARTRIDGES

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	$\boldsymbol{P}CO_2$	Lactate
Chloride	$\boldsymbol{P}O_2$	BUN/Urea
Ionized Calcium	TCO_2	Creatinine
pH		

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
$\boldsymbol{P}CO_2$ (mmHg)	96	65	40	26	12
$\boldsymbol{P}O_2$ (mmHg)	40	63	120	163	500
H^+ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 ºC (35-46 ºF) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 ºC; 64-86 ºF) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not ***P***O_2 is to be measured. If ***P***O_2 is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If ***P***O_2 is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule 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.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately 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.

Note: Since aqueous based solutions such as calibration verification material lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous calibration verification solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes (fresh 1 mL or 3 mL sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous calibration verification solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 14. Target values are specific to the i-STAT System. Results obtained when testing these aqueous calibration verification materials with other methods may differ due to matrix effects.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

Correction of PO_2 for Barometric Pressure (BP)

The partial pressure of oxygen in a solution will change as it equilibrates to the ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin, which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flow-path of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. $\boldsymbol{P}O_2$ results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed $\boldsymbol{P}O_2$ values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott .

Equations:

For $\boldsymbol{P}O_2$ values below 150 mmHg: $\boldsymbol{P}O_2$ corrected = $\boldsymbol{P}O_2$ observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen. (Approximate change: for every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For $\boldsymbol{P}O_2$ values 150 mmHg and above: $\boldsymbol{P}O_2$ corrected = $\boldsymbol{P}O_2$ observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen. (Approximate change: for every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

HEMATOCRIT VERIFICATION PROCEDURE

Preparation of Hematocrit Sample

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7 mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.
2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.
3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.
4. Transfer all of the plasma from tube 4 to tube 1.
5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.
6. Gently invert tubes 1, 2 and 3 to resuspend the cells.
7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 15 %. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75 %.

Measurement

1. Gently invert tubes 1, 2, and 3 to resuspend the cells.
2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.
3. Inspect the data for outliers. Repeat a measurement if necessary.
4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results

The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K_3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.
2. The adjusted i-STAT hematocrit mean should be within ±3 %PCV of the microhematocrit mean.

   For example: the microhematocrit method mean for the mid level sample is 36 %PCV. The i-STAT method mean is 34 %PCV. 34 x 1.0425 = 35.445. Acceptable range for the adjusted i-STAT mean: 33 - 39 %PCV.

Note: If your analyzers are customized for K_2EDTA/Heparin/None, the above calculation is unneccessary.

Notes on the Procedure

1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.
2. The highest hematocrit that should be tested on the i-STAT System is 75 %. Whole blood samples with hematocrit values greater than 75 % will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 15 %. Whole blood samples with hematocrit values less than 15 % will be flagged as <15.

Using Another Comparative Method

Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:

- Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.
- Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method

CLSI recommends that the blood samples anticoagulated with Na_2EDTA or K_2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.

* CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard–Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

ACT VERIFICATION PROCEDURE

See Technical Bulletin "i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure."

i-STAT cTnI, BNP, CK-MB, β-hCG CALIBRATION VERIFICATION

Intended Use

The i-STAT cTnI, BNP, CK-MB and β–hCG Calibration Verification Sets are intended for use as assayed materials to verify the greater portion of the Reportable Range for i-STAT cTnI, BNP, CK-MB and β–hCG cartridges.

There are two 1.0 mL plastic vials of each of the three levels in each set.

Notes:

- cTnI, BNP and CK-MB calibration verification materials contain ≤0.09 % sodium azide as a preservative, and β–hCG calibration verification material contains <0.09 % sodium azide as a preservative.
- These calibration verification materials do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of cTnI, BNP and CK-MB and human serum for β–hCG has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the calibration verifiation material can cause an increase in turbidity. Do not use the calibration verification material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Calibration Verification material is ready to use and requires no reconstitution or frozen storage. The calibration verification materials are stable until the expiration date on the vial label when stored unopened at 2-8 ºC (35-46 ºF). Once opened, these calibration verification materials are stable for 30 days when stored tightly capped at 2-8 ºC (35-46 ºF).

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, gently mix the contents of the vial to ensure homogeneity. Avoid foaming of the sample.
3	Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the vial and store it at 2-8 ºC (35-46 ºF).
4	Seal the cartridge and immediately insert it into the i-STAT 1 analyzer.

Acceptable Criteria

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

The Value Assignment Sheet displays target values and ranges expected when cartridges, calibration verification materials and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

Should results outside these ranges be obtained, refer to **TROUBLESHOOTING OUT-OF-RANGE CONTROL OR CALIBRATION VERIFICATION RESULTS ON CARTRIDGES** in Section 14 of the i STAT 1 System Manual.

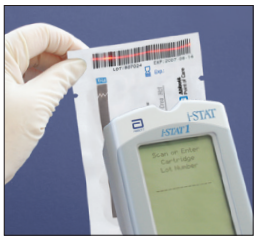
PROCEDURE FOR TESTING CALIBRATION VERIFICATION

Prerequisites

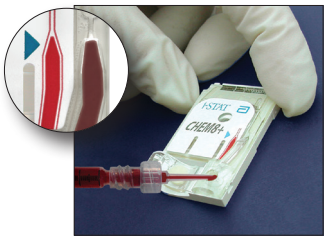
- Ensure that calibration verification testing is performed from the Quality Test Menu for the purpose of documentation and review.
- Scan the cartridge barcode before opening the cartridge pouch.
- Ensure calibration verification ampules, cartridges and analyzers are at room temperature.
- Measurement limits are not applied to results in the calibration verification test path. Results above and below the measurement ranges will be reported.

Procedure

1. Press ⏻ to turn on analyzer.
2. Press MENU → 3 → 3 for Cal Ver Samples.
3. Follow analyzer prompts.
4. Scan the lot number on the cartridge pouch.
   - Position barcode 3 - 9 inches from scanner window on the analyzer.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The analyzer will beep when it reads the barcode successfully.

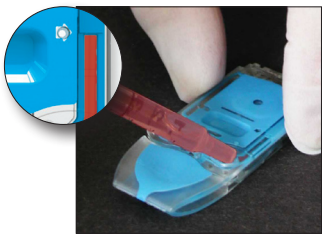


5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.



6. Push the sealed cartridge into the analyzer port until it clicks into place. Wait for the test to complete.

   Note: For Hct and immunoassay testing, the analyzer must remain on a level surface with the display facing up during testing. A level surface includes running the analyzer in the downloader/recharger.



7. Review results.

Troubleshooting Cartridge Tests

Should results outside these ranges be obtained, refer to **TROUBLESHOOTING OUT-OF-RANGE CONTROL OR CALIBRATION VERIFICATION RESULTS ON CARTRIDGES** in Section 14 of the i STAT 1 System Manual.