

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

Chemistry by iSTAT

Principle

The Abbott iSTAT provides quantitative determinations of sodium, potassium, Chloride, ionized calcium, TCO₂, glucose, BUN, creatinine, hemoglobin, and hematocrit in whole blood. Each single-use disposable reagent cartridge is composed of multiple reaction sensors for test-specific readings. The chemical reactions carried out within each cuvette are designed to produce a reaction that absorbs light at known wavelengths. Analyte concentrations are then calculated from this light absorbance data.

Each of these reagent cartridges will test the following analytes:

Sodium	Chloride	Potassium	Hematocrit
BUN (Urea Nitrogen)	Creatinine	Ionized Calcium	
TCO ₂	Glucose	Hemoglobin	

Specimen Requirements

1. Whole blood collected in a non- heparinized syringe or Lithium- Heparin vacutainer tube is the only acceptable specimen.
2. Specimens must be tested immediately after collection to avoid clotting.
3. A sample size of 65µL is required.

Interferences

1. If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time.
2. Potassium values obtained from a finger stick may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.
3. Hemodilution of the sample by more than 20% (associated with priming cardiopulmonary bypass pumps) may cause clinically significant errors in sodium, chloride, and ionized calcium results.

Interferent	Concentration	Effect
Acetaminophen	1 mmol/L	Creatinine will be falsely increased by 0.25mg/dL.
	1.32 mm/L	iCA will be falsely decreased.
	1.32 mm/L	Creatinine will be falsely increased.
Acetylcysteine	10.2 mmol/L	Chloride will be falsely decreased.
	10.2 mmol/L	iCA will be falsely decreased.
	10.2 mmol/L	Creatinine will be falsely increased.
Ascorbate	0.34 mmol/L	Creatinine will increase 0.3 mg/dL.
β- hydroxybutyrate	16mmol/L	Decrease sodium by 5 mmol/L, increase chloride by 3 mmol/L
	20 mmol/L	Decrease iCA by 0.1 mmol/L
Bromide	12.5 mmol/L	Increase chloride by 30 mmol/L. Use another method
	37.5 mmol/L	Increase sodium by 5 mmol/L. Use another method.
	37.5 mmol/L	Decrease glucose by 30 mg/dL. Use another method.
	37.5 mmol/L	iCA will be falsely increased.
	37.5 mmol/L	Creatinine will be falsely increased
CO2		Creatinine (>2 mg/dL) values are decreased by 3.7% for every 10mmHg of pCO2.
		Creatinine (>2 mg/dL) values are increased by 3.7% for every 10mmHg of pCO2.
	pCO2 >40 mmHg	Creatinine (<2mg/dL) values are increased by 6.9% for every 10mmHg of pCO2.
	pCO2<40 mmHg	Creatinine (<2mg/dL) values are decreased by 6.9% for every 10mmHg of pCO2.
Creatine	5mg/dL	Creatinine will increase by 0.20 mg/dl
Hydroxyurea		May cause significant errors in glucose. Use alternate method for testing for glucose.
		Creatinine will be falsely increased. Use alternate method.
Lactate	11 mmol/L	Increase chloride by 3.5 mmol/L
	20 mmol/L	Increase sodium by 5 mmol/L
	20 mmol/L	Decrease iCA by 0.05 mmol/L
Lipids	Abnormally elevated	May slightly increase hemoglobin results.
Magnesium	6.6 mmol/L	iCA will be falsely increased.
Salicylate	4 mmol/L	Increase chloride by 5 mmol/L. Use another method.
	4.34 mmol/L	Decrease iCA by 0.1 mmol/L
Thiocyanate		May cause falsely elevated chloride results, or may cause chloride results to be suppressed ('star out'). Use another method.
	6.9 mmol/L	Decrease glucose approximately 7 mg/dL.
	140 mg/dL	BUN will decrease by 21%

4. Specimens with any level of hemolysis (HEM 1+, 2+, or 3+) may demonstrate falsely elevated potassium (K+) results. If results are suspect, a new specimen should be obtained and rerun on the iSTAT.
5. Samples with a hematocrit in excess of 60% may have certain analyte results reported on the result card as "****". These specimens must be sent to the Core Lab for proper testing.

6. A result may be suppressed when any of the internal QC steps detect an abnormal condition or analyte concentrations outside of the linear range of the assay. Suppressed results due to abnormal conditions are displayed as either '<' (less than) or '>' (greater than). If a < or > is displayed, rerun the test using a new cartridge or send the specimen to the core lab for testing.
7. A result which is not reportable based on internal QC rejection criteria are flagged as '***'. Analyze the specimen again with a fresh cartridge. If the results are suppressed again send the sample to the Core Lab.

Anytime a result is suppressed and a specimen is sent to the Core Lab, the testing done on the iSTAT cannot be billed for. A Basic metabolic panel (BMP) should be ordered for Core Lab testing.

For Hemoglobin and Hematocrit only:

8. If WBC is greater than 50,000 the H&H may be falsely increased.
9. Hematocrit results are affected by the level of total protein as follows:

Displayed Result	TP <6.5 g/dL	TP > 8.0 g/dL
HCT < 40 %	Hct is decreased by ~1% for each decrease of 1 g/dL TP	HCT is increased by ~1% for each increase of 1 g/dL TP
HCT > 40%	Hct is decreased by ~0.75 % for each decrease of 1 g/dL TP	Hct increased by ~0.75% for each increase of 1 g/dL TP

10. Abnormally high lipids may increase results.
11. The electrolyte concentration is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also affect hematocrit.

Analytical Measurement Range (Linearity)

Analyte	AMR
Sodium	100-180 mmol/L
Potassium (K)	2.0-9.0 mmol/L
Chloride	65-140 mmol/L
Ionized Calcium	0.25-2.50 mmol/L
TCO2	5-50 mmol/L
Glucose	20-700 mg/dL
Urea Nitrogen (BUN)	3-140 mg/dL
Creatinine (Cre)	0.2-20 mg/dL
Hemoglobin	3.4 – 25.5 g/dL
Hematocrit	10-75 %

Results exceeding the iSTAT's measurable range are displayed as either a greater than (>) or less than (<) symbol. Any result for a particular test that exceeds the iSTAT's measurable range is to be sent to the Core Lab for testing.

Reference Range

Analyte		Male	Female	Neonate
Sodium	mmol/L	134-143	134-143	134-143
Potassium	mmol/L	3.4-5.0	3.4-5.0	3.4-5.0
Chloride	mmol/L	97-108	97-108	97-108
Ionized Calcium	mmol/L	1.14-1.32	1.14-1.32	1.14-1.32
TCO2	mmol/L	22-29	22-29	N/A
Glucose	mg/dL	60-99	60-99	41-60
BUN	mg/dL	6-20	6-20	4-15
Creatinine	mg/dL			
	0 - 2 mos.	0.3 - 0.9	0.3 - 0.9	N/A
	2 mos - 1 yr.	0.2 - 0.4	0.2 - 0.4	N/A
	1 - 3 yrs.	0.2 - 0.4	0.2 - 0.4	N/A
	3 - 5 yrs.	0.3 - 0.4	0.3 - 0.4	N/A
	5 - 7 yrs.	0.3 - 0.5	0.3 - 0.5	N/A
	7 - 9 yrs.	0.3 - 0.6	0.3 - 0.6	N/A
	9 - 11 yrs.	0.3 - 0.6	0.3 - 0.6	N/A
	11 - 13 yrs.	0.4 - 0.7	0.4 - 0.7	N/A
	13 - 18 yrs.	0.5 - 0.8	0.5 - 0.8	N/A
	18 - 150 yrs.	0.7 - 1.3	0.6 - 1.1	N/A
Hemoglobin	g/dL			
	0-30 days	10.0-18.0	10.0-18.0	N/A
	1-6 mos.	9.5-14.0	9.5-14.0	
	6 mo.- 2 yrs.	10.5-13.5	10.5-13.5	
	2-6 yrs.	11.5-13.5	11.5-13.5	
	6-12 yrs.	11.5-15.5	11.5-15.5	
	12-18 yrs.	13.0-16.0	12.0-16.0	
	18-150 yrs.	13.5-17.5	12.0-16.0	
Hematocrit	%			
	0-30 days	31.0-55.0	31.0-55.0	N/A
	1-6 mo.	28.0-42.0	28.0-42.0	
	6 mo.- 2 yrs.	33.0-39.0	33.0-39.0	
	2-6 yrs.	34.0-40.0	34.0-40.0	
	6-12 yrs.	35.0-45.0	35.0-45.0	
	12-18 yrs.	37.0-49.0	36.0-46.0	
	18-150 yrs.	41.0-53.0	36.0-46.0	

Critical/Alert Values

Critical alert values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider and be documented in the test record as to who was contacted, the time of contact, the person making contact, and if relevant, that the results were read back.

Critical/Alert Value			
		Low	High
Sodium	mmol/L	≤120	≥160
Potassium	mmol/L	≤2.5	≥6.0
Chloride	mmol/L	None	None
Ionized CA	mmol/L	None	None
TCO ₂	mmol/L	None	None
Glucose 0-1D	mg/dL	≤40	≥300
Glucose 1D-150yr	mg/dL	≤50	≥500
BUN	mg/dL	None	None
Creatinine	mg/dL	None	None
Hemoglobin	g/dL	≤6.5	≥19.0
Hematocrit	%	≤20	≥60

Quality Control

Internal Electronic Simulator (Daily)

The performance of the analyzer is verified by using the Internal Electronic Simulator every 8 hours of use. The Internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the 8-hour interval is reached.

1. If the analyzer passes, the cartridge test cycle proceeds.

NOTE: "PASS" message will not be displayed on the analyzer screen. The "PASS" record will appear in the analyzer's stored results.

2. If the analyzer displays "ELECTRONIC SIMULATOR FAIL," the instrument is programmed to lock out patient testing until an Electronic simulator test passes.
 - a. Run the External Electronic Simulator test.
 - b. If External Simulator fails twice, send Chem 8 samples to the Core Lab for testing and call the Hotline at 1-800-366-8020 for assistance.

External Electronic Simulator

External Electronic Simulator should be run if Internal Electronic Simulator fails. External Electronic Simulator should also be run if operator suspects damage to the analyzer (for example, if analyzer is dropped). If External Electronic Simulator passes, run patient test.

1. Allow simulator and analyzer to stand in the same place, out of drafts, at room temperature for 30 minutes. The External Electronic Simulator is stored at room temperature (18-30°C).
2. Turn on analyzer

3. Press Menu key
4. Press 3 for Quality Tests
5. Press 4 for Simulator
6. Type/scan your Operator ID and press enter
7. Type/scan simulator ID and press enter
8. Remove the cover from the Electronic Simulator and insert straight into the analyzer (inserting at an angle may cause a Quality Check message to be displayed)
9. Let the simulator run until the message reads PASS or FAIL.
10. If PASS is displayed then continue to use the analyzer.
11. If FAIL then rerun it. If the rerun fails again, send chemistry samples to the Core Lab for testing and remove the iSTAT from service.

Verification of Cartridge Storage Conditions (Daily)

Refrigerated Cartridges:

1. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes.
2. Dispose of any expired cartridges in the regular trash.
3. Verify that the refrigerator did not exceed the limits of 2-8°C (35-46°F).
4. Document on the Temperature Log.
5. If the temperature of the cartridge storage refrigerator is within the range of 2-8°C (35-46°F), use cartridges as required.
6. If the temperature is outside the range of 2-8°C (35-46°F):
 - a. Quarantine the cartridges in the storage refrigerator.
 - b. Notify Point of Care Department immediately.
 - c. DO NOT USE the cartridges from this refrigerator.
 - d. Record the out-of-control event in the iStat QC logbook, along with the action taken.

Room Temperature Cartridges:

1. Verify that all boxes of cartridges at room temperature (18-30°C) have been out of the refrigerator less than 2 weeks.
2. If the measured room temperature has exceeded 30°C (86°F) for any period of time:
 - a. Quarantine the cartridges.
 - b. Notify Point of Care Department immediately.
 - c. DO NOT USE the cartridges from this location.
 - d. Record the out-of-control event in the iStat QC logbook, along with the action taken.

Liquid quality control

Four levels of liquid quality controls (LQC) (two levels for the Chem 8 portion and two levels for Hematocrit) must be tested when a new lot of reagent cartridges arrive and each month thereafter. To perform LQC testing:

1. Call POC office- (4-5497) for an aliquot of Levels 1 and 2- for Chem 8. The controls are stable for 5 days refrigerated (2-8°C).
2. Levels 3 and 4- for H&H are located in the ED POCT refrigerator. Take one vial of each level out of refrigerator.

Must be out at RT for at least 4 hours.

- a. Before use, hold the ampule at the top and bottom and shake for 10 seconds to mix the solution. Tap the ampule to restore the liquid to the bottom. Snap the top off and dispense fluid into the cartridge.
3. On the i-STAT hit the Menu Key.
4. Press '3' Quality Tests.
5. Press '1' Control.
6. Enter or scan your operator ID using the numeric keys when prompted.
7. Enter the control number (1 – 4) at the Control Lot Number prompt.
8. Scan the Cartridge barcode.
9. Remove the cartridge from the pack.
10. Place cartridge on a flat surface and dispense the LQC slowly and steadily until it reaches the fill mark indicated on the cartridge label.
11. Fold the snap closure over the sample well.
12. Insert the loaded reagent cartridge into the instrument.
The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
13. When test is complete. Document the control values and compare to the control reference ranges.
14. If any results fall outside of reference range, that level of LQC must be reran with a new reagent Cartridge.
15. Repeat above steps for the other level of LQC.
16. All levels of LQC **must have** all results within the reference ranges prior to patient testing. Contact the POC coordinator (4-5497) if results do not fall within the reference limits on the second attempt. Document all action taken on the troubleshooting log sheet.

Cartridge Testing

An operator starts a cartridge test cycle by selecting the iStat Cartridge option 2 from the Test Menu.

1. Enter or scan your Employee ID number (Your 5-digit TACS ID) and press Enter.
2. Enter/scan the patient ID then press Enter.
3. Scan the cartridge barcode by pressing the SCAN button and aim the light over the barcode located on the back side of the cartridge package.
4. Remove the cartridge from its pouch. **Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.**
5. On a flat surface direct the dispensing tip or capillary tube containing the blood into the sample well.
6. Dispense the sample until it reaches the fill mark on the cartridge.
7. Immediately flip the snap closure over the sample well. Insert the cartridge into the instrument until it clicks into place.

The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.

The screen will read “Identifying Cartridge, Please Wait.”

8. Screen will display time remaining until test completion

9. Upon test completion, results are shown on the analyzer’s display screen. **Results are displayed for 2 minutes before the analyzer turns off.**

10. If the analyzer times out, press the On/Off button to restart and select the “Last Result” option from the test menu to review the last result.

11. After use or prior to the next patient, clean the outside of the meter.

- a. Gloves are to be changed and hand hygiene performed between patients.
- b. Clean meter surface when visible blood or bloody fluids are present by wiping with a disposable disinfectant wipe (e.g. PDI Sani-Cloth AF or PDI Sani-Cloth HB) to remove any visible organic material. Cleaning should be followed by disinfection (see #3).
- c. When no visible organic material is present, after each use disinfect the exterior surface following manufacturer’s directions using a disposable bleach wipe (e.g. Clorox Germicidal Wipe or PDI Bleach Wipes).
- d. Ensure that the device remains “wet” for the duration of the contact time listed on the label of the bleach wipe.
- e. Alcohol should never be used because it can damage the light emitting diodes (LED) readout, causing “fogging” of the plastic screens.

Calculations

None

Reporting Results

The results are displayed on the iStat screen. Dock the meter to transmit the results to the patient’s chart.

Patient results displaying an asterisk next to the result indicate results outside of the established normal reference range.

A ‘ ? ’ or ‘****’ may be present in place of a result. This is intended to notify the user of a possibly diluted or otherwise contaminated specimen. Patient specimens demonstrating these marks should be reviewed carefully. A new specimen may be indicated if results are lower than expected.

Review the patient results for any critical/alert values. Report any critical/alert values to the provider immediately and document this in the patient’s record.

Data Transfer

1. The iSTAT will need to be downloaded for the patient results to be charted in Epic.
2. QC monitoring will be performed by POC.

Monthly QA (Performed by Point of Care)

1. Print electronic simulator results

2. POCT will download liquid QC log and monitor for trends/shifts and adjust ranges if needed.

Calibration (Performed by Point of Care)

Calibration Verification and patient correlations are done every 6-months to verify instrument's measurable range for the tested analytes.

Reagents

1. Reagent cartridges:
 - a. No preparation needed.
 - b. Each single-use disposable reagent cartridge contains one reference electrode, sensors for the measurement of the analyte, and a buffered aqueous calibrant solution for the tests. See the package insert provided with each box of reagent cartridges for full details.
 - c. Cartridges stored in the refrigerator (2-8°C or 35-46°F) are stable until the expiration date. If stored at room temperature (18-30°C or 64-86°F), cartridges are stable for two weeks. Label the box of cartridges with the new expiration date. **Do not allow cartridges to freeze.**
2. iSTAT Liquid Assayed Controls (LQC) Levels I and II:
 - a. Aliquots of Liquid controls are obtained through Point of Care. Call 4-5497 for fresh QC.
 - b. Storage:

The aliquots are stable for 5 days if kept at 2-8°C
3. RNA QC for Hematocrit:
 - a. Vials are stored in the ED refrigerator (2-8°C) until the expiration on the vial. Avoid freezing and temperatures greater than 30°C. **Must be out at RT for at least 4 hours.**

References

1. Abbott I STAT Operator's Manual, June 2004.
2. Burtis, Carl A. "Tietz Textbook of Clinical Chemistry," 3rd Ed., W.B. Saunders Company, Philadelphia, 1999, pp. 1241-1245.
3. Adult reference range based on OHSU Internal Reference Range Studies Serum and Burtis, Carl A. "Tietz Textbook of Clinical Chemistry", 3rd Ed., W.B. Saunders Company, Philadelphia, pg. 1809.
4. Ceriotti, Ferruccio. "References Intervals for Serum Creatinine Concentrations: Assessment of Available Data for Global Application", Clinical Chemistry 54:3, 559-566, 2008.

