KAISER PERMANENTE®
COLORADO LABORATORY

iSTAT ARTERIAL BLOOD GASSES

PRINCIPLE

The iSTAT ® System incorporates comprehensive components needed to perform blood analysis in the laboratory. The System consists of the following primary components.

a. Cartridges – a single use disposable cartridge contains microfabricated sensor array, a calibrant solution, fluidic system, and a waste chamber. Sensors for analysis of pH, PCO2, and PO2 are available on the G3+ cartridge. Lakewood laboratory will be using the CG4+ cartridge with an additional sensor for Lactate testing. A whole blood sample of approximately 2 to 4 drops is dispensed into the cartridge sample well.

b. Analyzer – a hand-held analyzer into which the blood filled cartridge is placed for analysis automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. Analyzers with thermal control capability for testing at 37° C and cartridges requiring thermal control are labeled with a 37° symbol.

SCOPE

Only performed by Medical Technologists and Laboratory Technicians at the Franklin, Rock Creek and Lakewood Medical Office Laboratories

SPECIMEN REQUIREMENTS

1. Fresh whole blood collected in a syringe with lithium or sodium heparin anticoagulant. Test within 10 minutes of collection because it is **not** a closed system.
2. Arterial specimens collected in a syringe containing sodium or lithium heparin anticoagulant. Fill syringes with the correct blood to heparin ratio. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeatedly for at least 5 seconds. If possible, test samples immediately after drawn; samples should be tested within 10 minutes (remix before testing).

EQUIPMENT AND MATERIALS

Instrument: iSTAT1 Analyzer

Cartridges

- G3+ or CG4+ cartridge
- Store at 2 to 8°C.

- May be stored at room temperature (18 to 30°C) for 14 days.
- Do not return to the refrigerator once they have been at room temperature.
- Do not expose to temperatures above 30°C or below 2ºC.
- When removed from the refrigerator, write the new 14 day expiration date on each pouch. Do not use after the new written expiration date.
- Allow to come to room temperature for at least 5 minutes.
- Should remain in pouches until time of use.

Controls

- Levels 1 and 3 control ampules should be stored at 2 to 8°C.
- Remove QC ampules from the refrigerator and allow to come to room temperature (minimum of 4 hours).
- Do not use after expiration date on the box and ampules.

Specimen Collection

- Heparinized blood gas syringe.

REAGENTS

All reagents are contained in the cartridges.

CALIBRATION

- Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.
- Calibration verification is a procedure that verifies the accuracy of results across the entire measurement range of a test and is performed every 6 months as required by the CAP (College of American Pathologists).

  The Calibration Verification set contains five levels and will verify the calibration of iSTAT cartridges throughout the reportable range. Each set contains four 1.7 mL glass ampules of each level (1-5). Store the set in the refrigerator 2-8 ºC.

  The analyzer, cartridges and ampules must be at the same temperature for best results. Allow 30 minutes for the ampules to equilibrate to room temperature.

  1. Place the iSTAT into the Calibration Verification mode.
  2. Press Menu > option #3 – Quality Tests > option #3 – Cal Ver
  3. A separate ampule must be used for each cartridge.
  4. Hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution and shake the control ampule vigorously for 10 seconds to equilibrate the liquid and gas phases.
  5. Tap the top of the ampule to send any solution back into body of the ampule. Cover the neck of the ampule with a tissue or gauze pad and carefully snap off the neck of the ampule.
  6. Immediately draw solution from the body of the ampule using a fresh capillary tube or pipette.
  7. It is only necessary to run each level one time, unless a result falls outside of the manufacturer's stated range.

NOTE: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

8. Place two to four drops of the solution into the cartridge. Be sure that the solution reaches the "FILL TO" line.
9. Close the cartridge and insert into the analyzer.
10. Analyze the data to verify linearity.

QUALITY CONTROL

Controls:

- Hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution and shake the control ampule vigorously for 10 seconds to equilibrate the liquid and gas phases.
- Tap the top of the ampule to send any solution back into the body of the ampule.
- Cover the neck of the ampule with a tissue or gauze pad and ***carefully*** snap off the neck of the ampule.
- Immediately draw solution from the body of the ampule using a pipette.
- It is important not to expose the solution to room air since this will alter the results.
- Use care not to draw bubbles into the pipette.
- Run both levels once per week and at change of lot.

NOTE: Use one ampoule for each cartridge tested. An ampoule should not be used more than once

- Continue with the standard procedure for testing patient samples. Enter the patient identification number assigned to the control.
- Compare results to the package insert values. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges use the cartridges as needed.
- Record QC on the log sheet.

See separate procedures for the following:

1. Electronic Simulator
2. Incoming Cartridges and Incoming controls
3. Thermal Probe Check

PROCEDURE

A. TESTING PATIENT SPECIMENS

1. Remove the iSTAT from the Network Downloader Cradle.
2. Turn on, at the Test Menu page press #2, iSTAT1 Cartridge.
3. Enter your 6 digit NUID without the leading letter.
4. Scan the barcode label of the patient when prompted.
5. Scan the barcode label of the cartridge when prompted.

6. Remove Cartridge from the pouch. Avoid touching pads or exerting pressure over the calibrant pack in the center of the cartridge.
7. Syringe samples: mix the blood in the syringe by rolling between the palms of the hand and inverting gently.
8. Direct the dispensing tip or plastic capillary tube containing the blood into the sample well.
9. Dispense the sample until it reaches the FILL TO mark on the cartridge. Leave some sample in the well.
10. Close the cover over the sample well until it snaps into place. (Do not press over the sample well)
11. Insert the cartridge into the cartridge door until it clicks into place.
12. Leave iSTAT1 on the flat surface of the counter while it is testing.
13. When testing is complete and results are ready, Print results and then return the iSTAT1 to the Network Downloader Cradle to allow it to interface automatically to Cerner. "Communication in Process" will appear on the screen indicating that the interface is occurring. (This may take more than a few seconds.)
14. In Cerner, at Accession Result Entry, ARE, retrieve the patient and Perform and Verify.

B. PRINTING RESULTS

1. Align the IR window of the iSTAT1 analyzer and the portable printer within 1 to 6 inches of each other or place analyzer in the Network Downloader.
2. Turn the printer on (printer light green).
3. Press the Print key on the iSTAT1 analyzer to print the displayed test record.
4. Attach the printout to the worksheet or if not using a worksheet, save the printout in the daily work sheets.

C. CALCULATIONS

The iSTAT1 analyzer contains a microprocessor that performs all calculations required for reporting results.

Correction of PO2 at extreme altitude

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solution than in whole blood due to the absence of red blood cells containing hemoglobin which binds the oxygen molecules. 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 flowpath of the analyzer.

The ranges for iSTAT aqueous solutions are established for the degree of oxygen equilibration which occurs in the cartridges at or near sea level. PO2 results for aqueous solutions, including iSTAT controls and Calibration Verification Sets and proficiency testing (external QC) samples, can be corrected for higher altitude environments using the following equations. Observed PO2 values should be corrected before comparing them to the values assignment sheet included with each box of iSTAT controls.

For PO2 values below 150 mmHg:

PO2 corrected = PO2 observed + (0.067 X (760-BP))
Where BP = 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 PO2 values above 150 mmHg:

PO2 corrected = PO2 observed + (0.029 X (760 – BP))
Where BP = 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)

REPORTING RESULTS

1. In the Cerner LIS, in Function - Accession Result Entry, (ARE), retrieve the patient.
2. Check the patient's name and HRN to ensure the correct patient.
3. Compare the results on the instrument printout to the results in the LIS.
4. Perform and Verify.
5. On rare occasions the results will need to be re-transmitted due to interface errors.
6. To re-transmit test results, perform the following:
   From the main test Menu of the iSTAT1 analyzer:
   Select the "Menu" key
   Select Option 6 - Transmit data
   Select from the list, the result you want to re-transmit

Note: Report only those analyte values that are specifically requested by the provider. If an abnormal (not an alert value) is obtained on an analyte that has NOT been requested by the provider, contact the provider and ask if they would like the result reported. If yes, the provider must order the test in HealthConnect.
Proceed as per protocol for alert values

REFERENCE RANGES

Tests	Units	Analytical Measurement Range	Reference Range	Critical Values
pH		6.8-8.8	7.35-7.45	<7.20 or >7.55
pCO2	mmHg	10-100	35-45	<20 or >60
pO2	mmHg	5-800	80-105	<40
TCO2	mmol/L	5-50	24-29	n/a
HCO3	mmol/L	5-50	23-28	n/a
Base Excess	mmol/L	n/a	-2 to +3	n/a
O2 Saturation	%	n/a	95-98	n/a
Lactate	See separate Lactate procedure			

LIMITATIONS OF THE PROCEDURE

Criteria for Specimen Rejection

- Evidence of Clotting
- Syringe containing more than 30% air.
    - Samples with 10-30% air should have their results appended with the following comment: “Air bubbles in sample, questionable results”.

Suppressed Results

There are three conditions under which the iSTAT1 analyzer will not display results:

1. Results outside of the iSTATs 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. However, if results are outside the verified ranges, do not report, send specimen to St. Joseph or Good Samaritan laboratory.

2. Results which are un-reportable based on internal QC rejection criteria are flagged with “****”. Analyze the specimen again using another cartridge. The results that are not suppressed should be reported in the usual manner. If the results are suppressed again, send the specimen to St. Joseph or Good Samaritan laboratory.

3. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, sensors, mechanical or electrical functions of the analyzer.

Take the action displayed with the message that identifies the problem. Refer to the iSTAT System Manual’s Troubleshooting section if necessary.

REFERENCES

iSTAT package inserts

iSTAT System Manual

Fundamentals of Clinical Chemistry, N. Tietz. 3rd Edition, pages 426-435, 614-616, and 676-678.

Clinical Chemistry Theory, Analysis & Correlation, Kaplan and Pesce, 2nd Edition, pages 850-856, 872-875, 884-888, and 1021-1024.