KAISER PERMANENTE®
COLORADO LABORATORY

iSTAT 1 CHEMISTRY ANALYZER

PRINCIPLE

The iSTAT® System incorporates comprehensive components needed to perform blood analysis at the point of care or in the laboratory.

- Cartridges: A single-use disposable cartridge contains a microfabricated sensor array, a calibrant solution. The CHEM8+ cartridge has sensors for analysis of sodium, potassium, chloride, TCO_2, urea nitrogen (BUN), Creatinine (CREA), and glucose. The "G" cartridge has a sensor for glucose.
- 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.

SCOPE

- Performed by Medical Technologists, Laboratory Technicians, and Phlebotomists.

SPECIMEN REQUIREMENTS

- **Venipuncture Specimens**
  - Fresh whole blood collected in a properly filled vacutainer blood collection tube with lithium or sodium heparin anticoagulant.
  - Mix blood and anticoagulant by inverting tube at least 5 times**.**

  NOTE: Samples must be tested within 10 minutes.

- **Finger and Heelstick Specimens**
  - Fresh whole blood collected in a capillary tube without anticoagulant.
  - Fresh whole blood collected in a capillary tube or "bullet" with lithium or sodium heparin anticoagulant.

  NOTE: Test within 3 minutes of collection.

- **Collection of Finger and Heelstick Specimens**
  - Wipe away the first drop of blood which contains excess tissue fluid which can increase the potassium result and dilute other analytes.
  - Avoid drawing air into the plastic capillary tube.
  - Use balanced heparin or plain plastic capillary tubes for collection.
  - Test samples immediately to avoid clotting (especially in neonates).

EQUIPMENT AND MATERIALS

- **Instrument - iSTAT1 Analyzer**
- **Cartridges**
  - ❖ **iSTAT Chem 8+** Cartridges – this cartridge is waived.
  - ❖ **iSTAT G** Cartridge – Glucose (Rock Creek only) this cartridge is waived.
    - o Store the main supply of cartridges at 2 to 8°C.
    - o **Do not** allow to freeze.
    - o May be stored at room temperature (18 to 30°C) for 14 days.
    - o Do not return to the refrigerator once they have been at room temperature.
    - o Do not expose to temperatures above 30°C (86°F).
    - o When removed from the refrigerator, write the new 14 day expiration date on each pouch. Do not use after written expiration date on pouch.
    - o Allow to warm to room temperature for a minimum of 5 minutes before use
    - o Should remain in the foil pouch until time of use.
    - o The Chem8+ cartridge (Sodium, Potassium, Chloride, TCO2, BUN, Glucose, Creatinine) is a thermal cartridge.
    - o The "G" cartridge is a thermal cartridge.

- **Controls**
  - o Level **1** control for **Chem8+** cartridges
  - o Level **3** Control for "**G**" cartridge.
  - o Store at 2 to 8°C (35 to 46°F)
  - o Allow each ampule to warm to room temperature for a minimum of 30 minutes before use.
  - o Do not use after the expiration date.

- **Specimen Collection**
  - ❖ Capillary Specimen Collection:
    - o Skin puncture lancets
    - o Plastic capillary tubes

  - ❖ Venipuncture Specimen Collection:
    - o Vacutainer holders and needles
    - o Lithium and/or sodium heparin evacuated vacutainer blood collection tubes.
    - o Mint green - lithium heparin gel separator tubes are acceptable if left **unspun.**

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.

NOTE: Calibration Verification is not required for tests performed on waived cartridges.

QUALITY CONTROL

Controls

- QC is performed monthly with the current lot# of cartridges and current lot# of control
- Remove a cartridge, current lot#, from the refrigerator, allow to warm for 5 minutes.
- Remove an ampule of the appropriate control, allow to warm for 30 minutes.
- Hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
- 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 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 fresh capillary tube or pipette.
- Turn on the iSTAT, → press MENU → press #3 Quality Test → press #1 Control
- Run Level 1 control for Chem8+ cartridges.
- Run Level 3 for "G" cartridges.
- Follow the procedure below for testing patient specimens.
- Record the results on the QC log sheet.
- Staple the instrument printout to the back of the QC log sheet.

NOTE: See separate procedures for the following:

1. **Incoming Shipments of Cartridges and Controls**
2. **Electronic Simulator Check**
3. **Thermal Probe Check: Performed bi-annually**

PROCEDURES

A. TESTING PATIENT SPECIMENS

1. Remove the iSTAT from the Network Downloader Cradle.
2. Turn on, at the Test Menu page press #2, iSTAT 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. Direct the dispensing tip or plastic capillary tube containing the blood into the sample well.
8. Dispense the sample until it reaches the FILL TO mark on the cartridge. Leave some sample in the well.
9. Close the cover over the sample well until it snaps into place. (Do not press over the sample well)
10. Insert the cartridge into the cartridge door until it clicks into place.
11. Leave iSTAT on the flat surface of the counter while it is testing.

12. When testing is complete and results are ready, print results and then return the iSTAT 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.

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 a Network Downloader.
2. Turn the printer on (printer light green).
3. Press the Print key on the 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. Do not put scotch tape over any of the printing – this will cause the printing to disappear.

REPORTING RESULTS

- **TEST RESULTS**
  1. In Cerner LIS, in Function - Accession Result Entry, (ARE), retrieve the patient.
  2. Compare the patient's name and HRN to ensure the correct patient.
  3. Compare the accn # on the iSTAT printout with the accn # in the LIS.
  4. Compare the results on the instrument printout to the results in the LIS.
  5. Perform and Verify.
  6. On rare occasions the results will need to be re-transmitted due to interface errors.
  7. To re-transmit test results, perform the following:
     From main test Menu of the iSTAT1 analyzer:
     1. Select the "Menu" key
     2. Select Option 6 - Transmit data
  8. **DO NOT enter results manually in the LIS.**

- **RESULT NOTES**

1. Report only those analyte values that are specifically requested by the provider.
2. If an abnormal (not an alert value) is obtained on an analyte that has NOT been requested by the provider, contact the provider and request that the provider order a Chem 7.
3. Proceed as per protocol for alert values.

- **FLAGGED/SUPPRESSED RESULTS**

1. Results outside the system's reportable ranges are flagged with a "<" or ">", indicating that the result is below the lower or above the upper limit of the reportable range respectively. See the table of reportable ranges posted in the laboratory. Results which are un-reportable based on internal QC rejection criteria are flagged with "****".

ACTION: Analyze the specimen again(repeat test) using another cartridge. Any result that is **NOT** flagged should be reported in the usual manner.

After repeat, results with "<" and/or ">" **can** be reported. Report the "<" or ">" of AMR results for that particular analyte. (See the chart below for reference ranges, critical results and AMR)

Do not report any i-STAT results flagged " **"**

If the result is still flagged with "****" after repeat, transfer the accession number to Arapahoe, Franklin, or Rock Creek so they can verify the flagged "****" analyte.

Call and notify the provider of the delay of results for the flagged analyte.

2. 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.

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

- **HEMLYOSIS RESULTS**

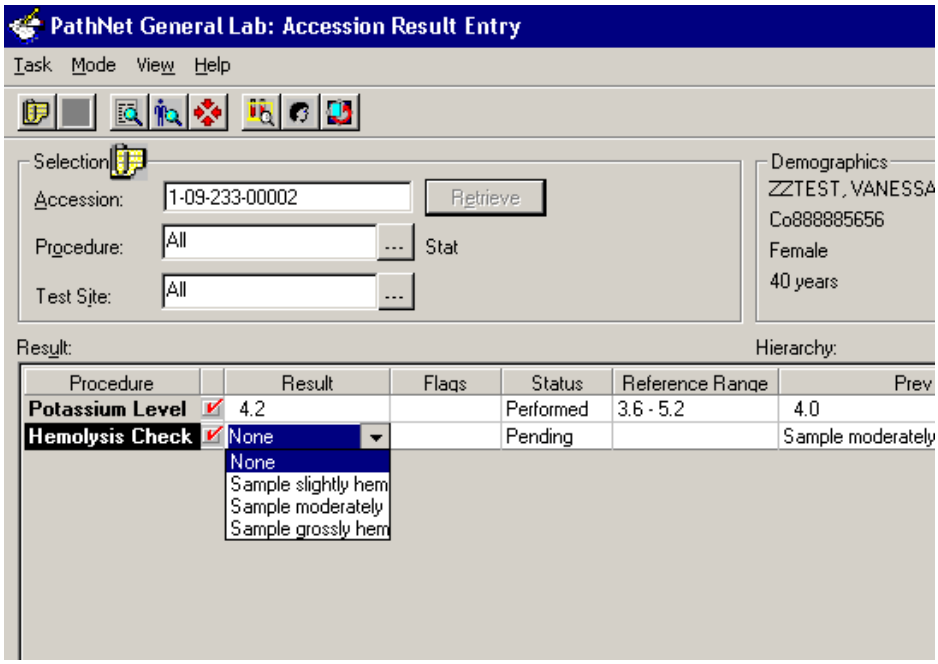
MANDATORY: Before reporting a potassium result on a patient: - check the specimen for **hemolysis.**

1. Centrifuge the specimen or a specimen aliquot for 3 minutes at 3000 RPM.

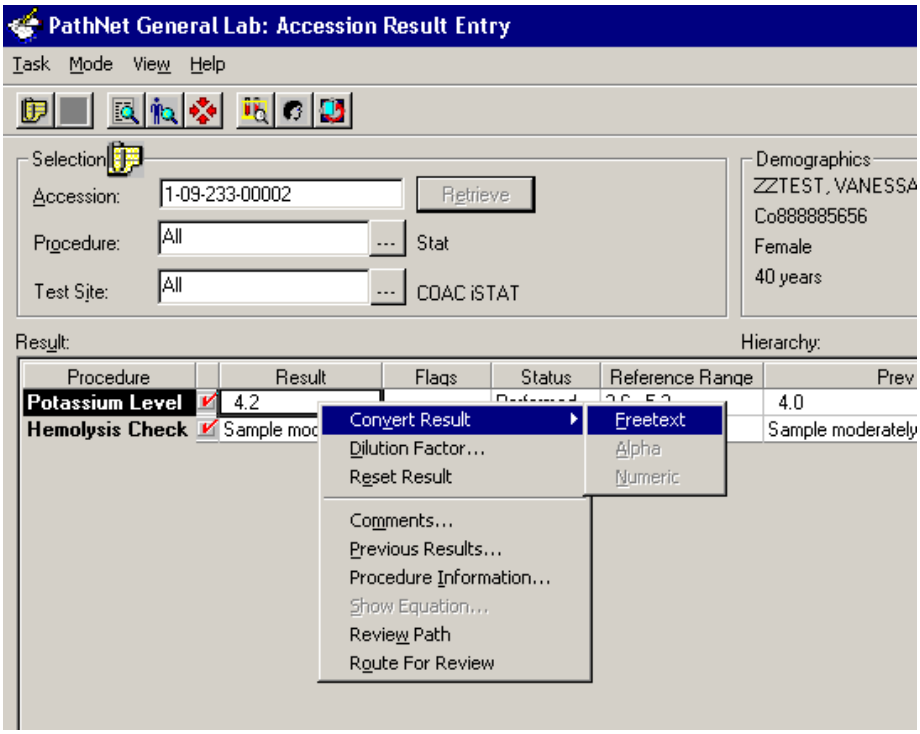
nter t r the Hem LIS i \RE"

2. Click on "Perform"
3. Retrieve the ACCN in order to activate (fire) the rule for the hemolysis check.

4. If you “Verify” **before** “Perform” – the rule will not activate and will not appear with the numeric result.

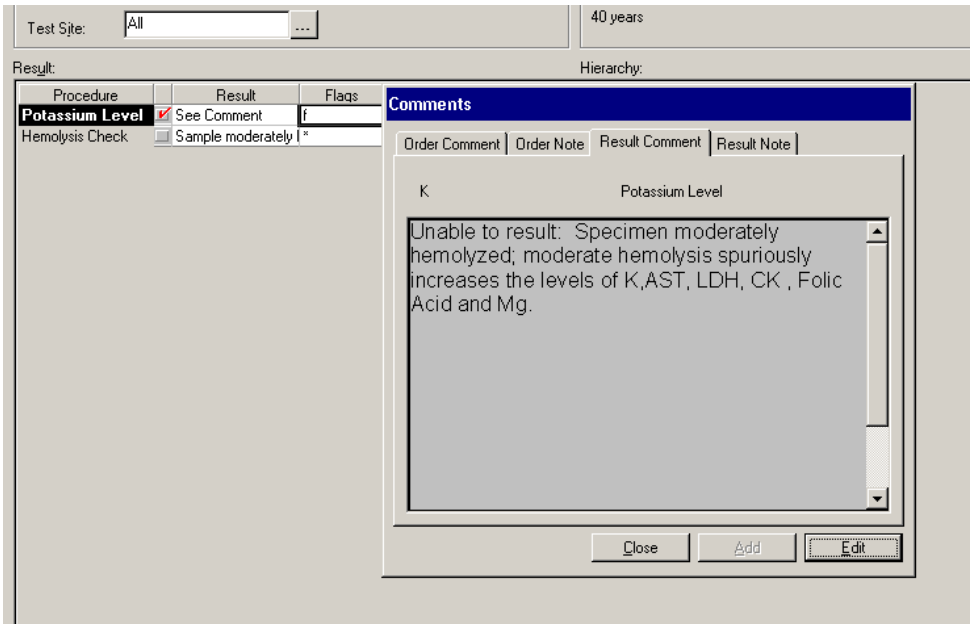


5. A result of moderate or grossly hemolyzed will affect the potassium level.
6. **DO NOT REPORT** a potassium result when the specimen has moderate or gross hemolysis.
7. To report Moderate or Gross hemolysis - Right click on the potassium result and convert the field to free text.



8. Click on the paperclip button to add a comment. Type in “See Comment.”

9. Click on Edit
10. To enter **moderate hemolysis type in: mh and push F9**
11. To enter **gross hemolysis type in: gh and push F9**



12. Close the Comment box.
13. Retrieve the ACCN # and click "Verify".

REFERENCE RANGES

Test	Units	Reference Range	Alert Values	AMR
Glucose-Fasting	mg/dL	60 – 99	<40 female < 50 male >400	20 – 700
Glucose-Random	mg/dL	60-200	<40 females < 50 males >400	20 – 700
BUN	mg/dL	8-26	>100	3 – 140
Creatinine	mg/dL	0.6-1.3	>4.9	0.2 – 20.0
Sodium	mmol/L	138 – 146	<120 >160	100 - 180
Potassium	mmol/L	3.5 - 4.9	<3.0 >6.0	2.0 – 9.0

Chloride	mmol/L	98-109		60 – 140
CO2	mmol/L	24 - 29	<15 >40	9 – 50

LIMITATIONS OF THE PROCEDURE

- **Abnormal Creatinine Results**
  - The medication Hydroxyurea (Droxia®, Hydrea®) can cause significant errors in the measurement of creatinine.
  - If the creatinine level is greater than 2.0 mg/dl. Cerner will add a comment indicating that the elevated level may be due to the above medication.
  - It is important to click on "Perform" **before** verifying the creatinine results to fire the rule that adds the comment.

- **Criteria for Specimen Rejection**
  - Evidence of clotting
  - Specimens collected with anticoagulant other than lithium or sodium heparin
  - Other sample types such as urine, CSF and pleural fluid.

REFERENCES

- iSTAT package inserts and iSTAT System Manual
- Fundamentals of Clinical Chemistry, N. Tietz, Third Edition, Pages:426-435, 614-616, 676-678.
- Clinical Chemistry Theory, Analysis & Correlation, Kaplan/Pesce, 2nd Edition, Pages 850-856, 872-875, 884-888, and 1021-1024
- iSTAT Technical Bulletin: The iSTAT System and Waived Status