Procedure: I-STAT PROCEDURE FOR 200 INSTRUMENT

Prepared By: Ann Bengzon, R.N. Date Adopted: 10/19/01

Review Date: Revision Date: Signature:

10/19/01

6/13/02 R. Wenk, M.D.

2/12/03 R. Wenk, M.D.

6/15/04 R. Wenk, M.D.

10/29/04 R. Wenk, M.D.

Removed from active service by:__________ Date:__________
1. **PURPOSE:**
Incorporates a comprehensive group of components needed to perform blood analysis at point of care. Just 2-3 drops of fresh whole blood is all that is required, and a portable, battery-powered analyzer displays quantitative test results in approximately 2 minutes. Infrared communication devices allow all patient information obtained at the bedside to be transmitted to centralized information system for record keeping and billing.

1. Principle: A single-use disposable cartridge contains a microfabricated biosensor array, a calibrant, solution, fluidics system and waste chamber. Sensors for analysis of sodium, potassium, chloride, pH, \( \text{PO}_2 \), \( \text{PCO}_2 \), urea nitrogen (BUN), glucose, hematocrit, and ACT (Activated Clotting time) are available in a variety of panels. A whole blood sample of approximately 2 to 4 drops of blood is dispensed into the cartridge well. 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 testing at 37\(^0\)C. Information is then transmitted from the analyzer to the I-STAT Central Data Station where data can be stored, organized, edited and transferred to a laboratory information system or other computer.

2. **POLICIES:**
1. Tests will be performed by certified operators using correct policies and procedures of Sinai Hospital.
2. Tracking of trends in patient results is the responsibility of clinical personnel.
3. Personnel should compare with caution laboratory and bedside test values. The results may not be directly comparable because of the different methods used. In the patient’s medical record, the bedside test and laboratory test results will be maintained separately.
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3. SUPPLIES AND STORAGE:
   1. Cartridges:
      a. Stored at 2 to 8°C. Do not allow cartridges to freeze.
      b. May be stored at room temperature 18 to 30°C.
      c. Cartridges are never returned to refrigerator once they have been at room temperature, and should not be exposed to temperature above 30°C.
      d. Mark the calendar on the box to indicate the two week room temperature expiration date.
      e. Cartridges should remain in pouches until time of use.
      f. Do not use after expiration date.

4. SPECIMEN:
   1. Specimen type: Whole blood
   2. Patient preparation: N/A
   3. Handling conditions:
      a. Fresh whole blood in a capillary tube or plastic syringe without Anticoagulant: Test immediately after collection.
      b. Fresh whole blood in a capillary tube with lithium or sodium heparin anticoagulant: Test within 3 minutes of collection
      c. Fresh whole blood collected in a collection tube or syringe with Lithium heparin anticoagulant: Fill to capacity: Test within 10 minutes of collection.
   4. Specimen labeling:
      If test are not performed at patient’s beside at time specimen is drawn a patient identification label should be attached to sample.

5. Sample rejection:
   a. Evidence of clotting.
   b. Specimen collected in vacuum tubes which anticoagulant other than lithium or sodium heparin.
   c. Syringe for, pH, PO₂, PCO₂ with air bubbles in sample.
   d. Other sample types such as urine, CSF and pleural fluid.

6. Specimen collection:
   a. In-Dwelling line:
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Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter connector, and needle.

b. Arterial specimens:
Fill blood gas syringe to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution. 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. Avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions. A blood sample should be tested within 10 minutes after it has been obtained. (re-mix before testing).

c. Venous specimens:
If a cartridge cannot be filled immediately, collect sample into a evacuated blood collection tube or a syringe containing heparin (sodium, lithium or balanced) anticoagulant. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeating for at least 5 seconds. If possible, test samples immediately after drawn; samples should be tested within 10 minutes. (remix before testing).

d. Finger and Heelstick specimens:
Wipe away the first drop of blood, which contains excessive tissue fluid which can increase potassium result and dilute other test results. Avoid drawing air into capillary tube. Use balanced heparin capillary tubes for collection. Test samples immediately to avoid clotting (especially neonates).

7. Preparation for specimen collection:
All i-STAT cartridges must stand at room temperature for 5 minutes (individually) or 1 hour (entire box of 25 cartridges) before use.
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5. EQUIPMENT AND MATERIALS:
   1. Equipment: I-STAT analyzer
   2. Materials/supplies:
      1. Alcohol swab
      2. 2X2 gauge
      3. Lancet: heelstick/ fingerstick/ capillary tube
         Tube/syringe: venous/arterial
      4. I-STAT cartridge
      5. Gloves

6. PROCEDURE:
   1. Take analyzer to bedside. Exception: ER-7 will perform tests in specific location.
   2. Patient labels will be taken to the bedside for proper verification with identification band. (See specimen labeling policy).
   3. Remove cartridge from pouch, taking care to hold cartridge by its sides because touching contact pads can damage the cartridge causing “star outs”.
   4. Obtain sample in appropriate container.
   5. Direct the dispensing tip or capillary tube containing the blood into the sample well.
   6. Dispense the sample until it reaches the FILL TO mark on the cartridge. (Do not press on the sample well).
   7. Insert the cartridge into the cartridge door until it clicks into place.
   8. Enter an operator ID number (clock number). Perfusionist who do not have clock numbers will enter the last four digits of their social security number. Repeat process for verification.
   9. Enter the patient’s unit number (first 8 digits of their medical record) taken directly from the patient’s armband. If zeros precede the numbers they must be entered as part of the unit number. Repeat process for verification.
   10. If the patient does not yet have a unit number, a temporary number may be used or the unit’s cost code. Write the results into the patient’s medical record as they will not be available in Cerner.
   11. At this time you can enter parameters when performing blood gases or to enter blood type.
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12. Review the result shown on the analyzer’s screen.
13. View results shown on analyzer’s screen.
14. Record results in the patient’s medical record. Results may be printed out by the I-STAT analyzer but are not a permanent part of the medical record.
15. Transmit results from the I-STAT immediately after completion of each test group on each patient by the following method:
   a. With the analyzer in the infra re (IR) interface cradle, the green light will be lit.
   b. Press the “*” button on the analyzer to transmit the results to the computer in the lab. During the transmission, the IR Interface will blink alternately red and green. If transmission is successful, the interface will emit a single high pitch beep, and the light will return to green. An unsuccessful transmission is indicated by three low tone beeps. In this case repeat the transmission process.
16. Remove cartridge from instrument and discard cartridge and gloves in biohazard container.

Blood Gas testing:
Follow usual anaerobic procedure for drawing blood gases. After Specimen has been obtained, use the following procedure:
1. Obtain blood via heparinized capillary tube (heelstick) or blood Gas syringe.
2. As soon as blood has been collected, mix sample by rolling Syringe between palms at least for 5 minutes than inverting the syringe repeatedly for at least five minutes.
3. Discard first drop of blood which has been exposed to air, fill Cartridge as usual but closes quickly to minimize exposure to air.
4. Continue following routine procedure for testing.

Entering Comments: ( If Respiratory Therapist )
After entering operator and patient ID the analyzer will allow comments to be entered specific for blood gases. :
1. Page forward and enter the following information:
   a. Patient’s temperature, the press enter.
   b. FiO2, enter information, press enter.
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c. Fields 1 and 2 are to enter comments to provide additional information pertaining to treatment of the patient. See comment codes. Select the number of the appropriate comment, press ‘*’ then enter value. You have the option of entering two comments.
d. When you finished your comments, the instrument will ask if you want to save or edit comments. At this time if you enter save the comments will be saved automatically. If you enter edit, it will allow you to go back starting at the top of the comment page to either change or add comments. All comments will then be saved automatically.

7. RESULTS:
   1. Suppressed Results:
      There are two conditions under which the I-STAT will suppress the presentation of results.
      a. Results outside the system’s reportable range are flagged with a < “or” > indicating that the result is outside the reportable range.
         Action:
         Send specimen(s) to laboratory for analysis.
         Clinical action may be appropriate.
      b. Results, which are unreportable, based on internal QC rejection criteria are flagged with ‘****’.
         Action:
         Analyze the specimen using another cartridge. If the results are suppressed again, send specimen(s) to the laboratory for analysis. Clinical action is not appropriate.

   2. Critical Values:
      Adults:
      a. Any test that exceeds a “critical limit” must be repeated by the i-STAT operator. We are encouraging all operators to send a sample to the laboratory rather than repeating it on the I-STAT. Only for reasons due to location of the patient at time of testing or availability to acquire specimens is this not being required.
      b. If the repeat test produces a match to the first test, the patient’s
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Physician should be notified immediately. If there are still questions about the validity of the repeat test, call the Bedside Testing Coordinator or a Pathologist.

c. If the operator has any concerns about the results from the I-STAT call the Bedside Testing Coordinator.

Nursery:

a. The definition of the “C” flag, will depend on the clinical situation in the Nursery. In neonatology, there is danger of harming the patient by repeated phlebotomy, or capillary sampling (anemia, maceration of tissue, reducing vascular access, infection, thrombosis, etc).

b. If there is clinical suspicion of a diagnosis (hyper-natremia, kalemia, glycernia, uremia, anemia, or polycythemia), then a bedside value with a “C” flagged (e.g. the baby had been hyponatremic for some time), the value does not require repeat analysis. The clinician may wish to repeat the value before or after intervention (That is by choice).

c. Similarly, when a neonatal specimen in the Central laboratory is Analyzed and the results are flagged “C” and the specimen is QNS to repeat, the specimen may be considered “irretrievable” and the result may be reported without repeat analysis.

d. The LIS will append a comment box to neonatal specimens that Produce “C” results. The comment box would appear once/patient laboratory record, if possible, even if no “C” flag is encountered. For bedside tests, “C” is defined only as an alert to clinical staff. If clinical impression is confirmed by laboratory data, repeat analysis is unnecessary, but may be elected. Repeat analysis is required prior to intention if laboratory data is unexplained clinically, unless intervention is considered innocuous. Repeat studies may be performed either at bedside or in the clinical laboratory.

8. PATIENT IDENTIFICATION ERRORS:
If an error was made when entering the patient’s unit number into the instrument, a “Documentation Errors” form is to be filled out. This form will contain the incorrect information entered along with the correct patient's unit number, tests
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performed, date, time, and operator’s clock number. This form will be given to the Bedside Testing Coordinator where Correction and Credit will be given to incorrect patient, Incident Report filled out, and the Director of the operator will be informed. The correct results will be documented into the medical record by the operator who performed the test along with notification of the doctor if necessary that a mistake was made.

9. **QUALITY CONTROL:**

1. **Internal Quality Control:**
   The instrument will run quality control every eight hours while testing is being performed. This will be performed with a “PASS” result before a test result will be given. If the instrument should “FAIL” then the cartridge is removed and reinserted into the instrument or the Electronic Simulator can be inserted. Should the instrument “FAIL” when performing a test and using the Electronic Simulator, a new instrument should be obtained and the Bedside Testing Coordinator notified.

2. **Electronic Simulator:**
   a. Insert Electronic Stimulator into the analyzer.
   b. If “PASS” is displayed on the analyzer, remove the Electronic Simulator. In this case transmit this result over the infra red (IR) interface immediately. If “FAIL” is displayed again, replace instrument by going to Specimen Processing and exchange the malfunction instrument with a new one. Inform the Bedside Testing Coordinator if available.
   c. After QC, transmit QC result by pressing the “*” button.

3. **Liquid Controls:**
   Pathology Department, Bedside Testing Coordinator will perform quality control for all cartridges:
   a. Per shipment / lot number to hospital.
      Two levels of controls performed in duplicate on each cartridge lot number per shipment, two cartridges for electronics, Hct,
   b. Documentation of cartridges, lot numbers and controls will be stored in Pathology.
   c. Controls and Calibration fluids:
      Aqueous assayed control fluids are obtained from I-STAT for verifying the integrity of newly received cartridges. Level one and
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three are used. Controls are formulated at clinically relevant levels with known pH and with known concentration of sodium, potassium, chloride, O2, CO2, ionized calcium, urea, glucose, and creatinine. These solutions do not contain human serum or serum products.

1. Storage
   Contained in 1.7mL glass ampules.
   Refrigerated at 2 to 8°C (35-36°F).
   May be stored at room temperature for up to 5 days at 20 to 30°C (68-86°F).
   Can not be used beyond expiration date.

2. Target Ranges:
   Target values (determined by testing multiple ampules of each level using multiple lots of I-STAT cartridges with I-STAT held analyzers that have passed the Electronic Simulator) are printed on an insert included with each box of control ampules. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the ranges obtained, refer to Cartridge Troubleshooting section in the I-STAT manual or call I-STAT Technical Help. Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the table matches the software revision in the analyzer.

10. ANALYZERS:
    1. Cleaning:
       Wear gloves during the following procedure:
       Clean the display screen with a soft dry tissue or detergent soap and water, never alcohol. Clean analyzer using a gauze pad moistened with mild non-abrasive cleaner, detergent soap and water, or alcohol; rinse using another gauze pad moistened with water and dry.
    2. Decontaminate: Use Lysol Professional
       Decontaminate the analyzer whenever a specimen is spilled onto the Analyzer of if the analyzer is to be returned to I-STAT for repair. Wear Gloves during the following procedure:
       a. Soak a few gauze pads with Lysol solution. Before use, squeeze
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pads to remove excessive solution.
b. Soften, and removed any dried blood with one or two of the gauze pads soaked with Lysol solution. Avoid scraping dried blood as contaminated particles may become airborne.
c. Clean the entire surface of the analyzer twice with the gauze pads Soaked with Lysol solution.
d. Rinse the surface of the analyzer with gauze pads moistened with tap water and dry.
e. If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If the liquid enters the electronic compartment, the battery compartment, or the cartridge port, the analyzer may be damaged.

2. Changing Batteries:
Wait until any test in progress is completed before replacing the batteries or results will be lost. Stored results will not be lost when replacing batteries. To change batteries;
a. Place the analyzer upside down and open the battery compartment door.
b. Remove the old batteries. Orient + and – poles of the new batteries and the + and – labels in the battery compartment and slide the new batteries into place.
c. Discard batteries in appropriate container specified by hospital. Note: Lithium batteries can be obtained from Distribution but must specify that you want 9 volt Lithium batteries for the I-STAT analyzers. Alkaline batteries can be used but will not fit as tight nor last as long.

11. REFERENCE RANGES: Reportable Range
Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of the test values throughout which the measurement system’s results have been shown to be valid:
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<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>Reference Range</th>
<th>Reportable Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>mmol/L</td>
<td>138-146</td>
<td>100-180</td>
</tr>
<tr>
<td>Potassium</td>
<td>mmol/L</td>
<td>3.5-4.9</td>
<td>2.0-9.0</td>
</tr>
<tr>
<td>Chloride</td>
<td>mmol/L</td>
<td>98-109</td>
<td>65-140</td>
</tr>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>8-26</td>
<td>3-140</td>
</tr>
<tr>
<td>Glucose</td>
<td>mg/dL</td>
<td>70-105</td>
<td>20-450</td>
</tr>
<tr>
<td>Crea</td>
<td>mg/dL</td>
<td>0.6-1.3</td>
<td>0.2-20.0</td>
</tr>
<tr>
<td>i-CA</td>
<td>mg/dL</td>
<td>4.5-5.5</td>
<td>1.0-10.0</td>
</tr>
<tr>
<td>pH (arterial)</td>
<td></td>
<td>7.35-7.45</td>
<td>6.8-8.0</td>
</tr>
<tr>
<td>PCO₂ (arterial)</td>
<td>mm/Hg</td>
<td>35-45</td>
<td>10-100</td>
</tr>
<tr>
<td>PO₂ (arterial)</td>
<td>mm/Hg</td>
<td>80-105</td>
<td>5-800</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>%PCV</td>
<td>38-51</td>
<td>10-75</td>
</tr>
</tbody>
</table>

12. **Calibration:**
Calibration is automatically performed as part of the test cycle on each cartridge. Operator invention is not necessary.

13. **Interferences:**
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.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Interferent</th>
<th>Interferent Concentration</th>
<th>Effect on Analyte Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>B-hydroxybutyrate</td>
<td>16mmol/L</td>
<td>↓ 4mmol/L</td>
</tr>
<tr>
<td>Chloride</td>
<td>B-hydroxybutyrate</td>
<td>16mmol/L(166mg/dL)</td>
<td>↓ 6mmol/L</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td>12.5 mmol/L(100mg/dL)</td>
<td>↑ 30mmol/L</td>
</tr>
<tr>
<td></td>
<td>Lactate</td>
<td>11mmol/L(100mg/dL)</td>
<td>↑ 3.5mmol/L</td>
</tr>
<tr>
<td></td>
<td>Salicylate</td>
<td>4mmol/L</td>
<td>↑ 3mmol/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>Ammonium</td>
<td>0.5mmol/L</td>
<td>↓ by 20%</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Analyte</th>
<th>Interferent</th>
<th>Concentration</th>
<th>Effect on Analyte Result</th>
</tr>
</thead>
</table>

Bromide 12.5mmol/L ↓ by 55mg/dL

PH 7.2@37°C ↓ by 4mg/dL

7.6@37°C ↑ by 1mg/dL

Oxygen PCO2 20mmHg@37°C may ↓ glucose

Hematocrit Hct

WBC ↑ than 50,000 may ↑ Hct

Total Protein

For measured Hct < 40%

For each g/dL ↓ 7 ↓ by 1% PCV

For each g/dL ↑ 7 ↑ by 1% PCV

For measured Hct ≥ 40%

Interference on I-STAT PCO2 Measurements:

Propofol: Sustained administration at rates in excess of 50 ug/kg/min (3mg/kg/hour) can significantly decrease the PCO2 due to metabolic byproducts. Send specimens to lab for testing.

Thiopental sodium: A single dose administered over a few minutes. As the drug is rapidly absorbed into the body the interference on blood PCO2 readings will be modest approximately 15 minutes after administration for typical doses (<15% at 70 mmHg).
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The interference will continue to diminish as the drug continues to be absorbed. Send specimens to lab for testing.

Hydroxyurea:
Causes a positive interference with creatine, glucose, and lactate tests proportional to its concentration in the sample. The effect per 100 umol/L hydroxyurea is approximately:

- creatine: 1.85 mg/dL 164 µmol/L
- glucose: 8 mg/dL 0.44 mmol/L
- lactate: 0.16 mmol/L

At typical doses ranging from 500 mg/day to 2 g/day, plasma may be sustained at approximately 100-500 umol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses. Obtain specimen and send to lab for testing.

Creatinine
Ascorbate 11mmol/L ↑ by 0.7 mg/dL
Bromide 100mg/dL ↑ by 0.8 mg/dL
CO₂ For Crea values ↓ 2mg/dL
PCO₂ ↑40mmHg ↑ by 6.9% for every 10mmHg
PCO₂ ↓ 40mmHg ↓ by 6.9% for every 10mmHg
For Crea values ↑ 2mg/dL
PCO₂ ↑40mmHg ↓ by 3.7% for every 10mmHg
PCO₂ ↓ 40mmHg ↑ by 3.7% for every 10mmHg
Creatine 5mg/dL ↑ by 0.20 mg/dL

Analyte Interferent Interferent Effect on Analyte
Concentration Result

Hydroxyurea May cause significant error in the measurement of creatinine with the I-STAT system. Use an alternative method to measure creatinine when patients have been administered hydroxyurea.

Acetaminophen up to 20 mg/dL, bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL, calcium up to 5.0 mg/dL, dopamine up to 13mg/dL, methyldopa up to 2.5mg/dL, salicylate up to 7.75
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mg/dL, sarcosine up to 1.0 mmol/L, and uric acid up to 20 mg/dl were tested and found not to interfere with creatinine results.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Value</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>i-Ca</td>
<td>20 mmol/L</td>
<td>↑ by 1.0 mmol/L</td>
</tr>
<tr>
<td>β-hydroxybulyrate</td>
<td>20 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Lactate</td>
<td>20 mmol/L</td>
<td>↓ by 0.05 mmol/L</td>
</tr>
<tr>
<td>Magnesium</td>
<td>1.0 mmol/L</td>
<td>↑ by 0.04 mmol/L</td>
</tr>
<tr>
<td>Salicylate</td>
<td>4.35 mmol/L</td>
<td></td>
</tr>
</tbody>
</table>

10. TROUBLESHOOTING:
In the event of in-operative equipment do the following sequence:
1. Page Bedside Testing Coordinator (Beeper #1546).
2. Go to Specimen Processing in Pathology to exchange analyzers.
3. Call I-STAT (1-800-366-8020) for technical help.

11. COMMUNICATION OF PROBLEMS:
1. Monthly report will be sent to Directors identifying any problems found. The Director will be asked to follow-up and return to Pathology actions taken to resolve problems noted.
2. Additional communications will be sent when problems are identified and need immediate attention.

12. TRAINING:
Purpose: To ensure that each operator using the I-STAT has been trained is competency verified.

Responsibility: Only the Bedside Testing Coordinator or certified trainers have the authority for training and certification.

Policy:
1. Only an employee who is certified by a certified instructor can performed laboratory testing using the I-STAT analyzer.
3. Certification will include an inservice, satisfactory
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2. Re-certification will be performed yearly.

13. RECORDING AND STORAGE OF DATA:
Results are transmitted to the Central Data Station in the Bedside Testing Coordinator’s office. If all information is correct it is then transmitted to the laboratory computer where the unit number entered into the I-STAT is matched with that patient in the hospital. The Central Data Station then test request those tests available on the cartridge, enters results and verify results. The computer in the laboratory then sends this information over to the hospital computer where it is seen in the patient laboratory result section. Each month this data is backed up on computer disc and stored in Pathology. The Central Data Station is then cleared of that information. Done at the beginning of each month by the Bedside Testing Coordinator.

14. REFERENCES:
i-STAT package inserts
i-STAT System Manual

FOOTNOTES:
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