KAISER PERMANENTE®
COLORADO LABORATORY

iSTAT BNP PROCEDURE

PRINCIPLE:
The iSTAT ® System incorporates comprehensive components needed to perform blood analysis in the laboratory. The i-STAT B-type natriuretic peptide (BNP) test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure (CHF). The System consists of the following primary components.

a. Cartridges – A single-use disposable cartridge contains microfabricated sensors for BNP, a calibrant solution, fluidics system, and a waste chamber. A whole blood sample of approximately 17 uL (1 to 3 drops) is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

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 Lakewood Laboratory

SPECIMEN REQUIREMENTS
1. Whole blood or plasma collected in EDTA anticoagulant.
2. Other anticoagulant is not acceptable.
3. Clotted samples are not acceptable and should be rejected and redrawn
4. Capillary samples (finger stick or heel stick) are not acceptable as it contains excess tissue fluid as it will affect the result.
5. Other specimen types such as Urine, body fluids, etc. are not acceptable samples.
6. Test whole blood or plasma sample within 30 minutes of collection. If it cannot be tested within 30 minutes, spin and refrigerated the plasma for up to 24 hours or frozen if >24 hours.

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EQUIPMENT AND MATERIALS

Instrument: iSTAT1 Analyzer

Cartridge: iSTAT BNP cartridge

1. Store at 2 to 8°C.
2. May be stored at room temperature (18 to 30°C) for 14 days.
3. Do not return to the refrigerator once they have been at room temperature.
4. Do not expose to temperatures above 30°C or below 2ºC.
5. When removed from the refrigerator, write the new 14 day expiration date on each pouch. Do not use after the new written expiration date.
6. Allow to come to room temperature for at least 5 minutes.
7. Should remain in pouches until time of use.

Controls: BNP controls Level 1 and Level 3

1. Levels 1 and 3 controls are stable until the expiration date on the vial when stored unopened at 2 to 8°C. Cat no. 06P17-05 (L1) & 06P17-06 (L2)
2. Once opened, the controls are stable for 30 days when stored tightly capped at 2 to 8°C.
3. Remove QC vials from the refrigerator and allow to come to room temperature (about 15 minutes).
4. Do not use after expiration date on the box and vials.

Calibrators: iSTAT BNP Calibration verification Control Set levels 1-3. Cat no. 06P17-08.

1. Levels 1-3 are stable until the expiration date on the vial when stored unopened at 2 to 8°C. Cat no. 06P17-08.
2. Once opened, the controls are stable for 30 days when stored tightly capped at 2 to 8°C.

SPECIMEN COLLECTION

- See phlebotomy venipuncture procedure

REAGENTS

All reagents are contained in the cartridges.

CALIBRATION

1. Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.
2. 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 three levels and will verify the calibration of iSTAT cartridges throughout the reportable range. The set is kept in the refrigerator at 2-8 ºC. The analyzer, cartridges and calibrators must be at the same temperature for best results. Allow 30 minutes for the vials to equilibrate to room temperature.
3. See the iSTAT BNP / cTnL calibration verification worksheet in the forms section of the Laboratory website.
4. Calibration verification stepwise procedure
    a. Perform the simulator test before doing the calibration verification procedure.
    b. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.

c. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
d. 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 control vial and store it at 2-8ºC (35-46ºF) which is stable for up to 30 days.
e. Seal the cartridge and immediately insert it into the i-STAT 1 handheld.
f. See Value Assignment Sheets posted on the APOC website at www.abbottpointofcare.com. The Value Assignment Sheet displays target values and ranges expected when cartridges, controls, and equipment are performing properly.
g. 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 handheld.
h. Target values are specific to the i-STAT System. Results may differ if used with other methods.
i. Analyze the data to verify linearity. Attach the iSTAT printout on the back of the calibration worksheet and staple the value assignment sheets to it. Submit to the Laboratory supervisor for review and signature.
j. File paperwork in the calibration verification section of the iSTAT maintenance binder.

QUALITY CONTROL

Controls:

1. Run Level 1 and 3 QC and document on the New/lot or Weekly QC log
    a. At least once per week
    b. With each new cartridge and QC lot and shipment
2. Quality Control stepwise procedure
    a. Remove vial from refrigerator and allow to come to room temperature (18-30°) for 15 minutes.
    b. Gently invert the vial 10 times, and then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
    c. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
    d. Open the vial and transfer a drop of solution directly into the BNP
    e. Seal the cartridge and insert into the i-STAT 1 Analyzer.
    f. Write the results on the iSTAT BNP / cTnL QC log
    g. See Value Assignment Sheets posted on the APOC website at www.abbottpointofcare.com The Value Assignment Sheet displays target values and ranges expected when cartridges, controls, and equipment are performing properly.
    h. 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 handheld.
    i. Target values are specific to the iSTAT System. Results may differ if used with other methods.

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. 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.
13. In Cerner, at Accession Result Entry, ARE, retrieve the patient and Perform and Verify.
14. Perform and verify all results that are <100 pg / mL.
15. For BNP results of 100 pg / mL or higher, give a verbal result of >100 pg / mL and notify the ordering provider that the test will be sent on to the FR lab for re-testing and result verification by the next business day.
    a. Cancel and reorder the original order in the ORV application of Cerner using the "reordered, test rescheduled" cancel code. The LIS will cancel the current order and a new order will be placed in collections inquiry.
    b. Dispatch the open BNP order in Collections inquiry
    c. Separate the plasma and keep it refrigerated (or frozen >24 hours) and send on to the FR lab on the first morning courier (M-F). Freeze plasma on weekends and send first thing on Monday morning.

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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.

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C. CALCULATIONS

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

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.
    a. See step #15 above on how to process results of 100 pg / mL or higher
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:
    a. From the main test Menu of the iSTAT1 analyzer:
    b. Select the "Menu" key
    c. Select Option 6 - Transmit data
    d. Select from the list, the result you want to re-transmit

REFERENCE RANGES

<15 – 100 pg / mL

Analytical Measurement Range

15 – 5000 pg / mL

CriticalValues

Result of 100 pg / mL or higher

LIMITATIONS OF THE PROCEDURE

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.

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