CHEM.NOVA.ASSAY.1.0 IONIZED CALCIUM ON THE NOVA 8 ANALYZER

PRINCIPLE

The Nova 8 Analyzer is an analyzer for in vitro measurement of Ionized Calcium in whole blood, serum or plasma blood samples. The ion selective sensor measures an electrical potential or current in proportion to the amount of the specific analyte in the serum that fills the electrode train. A reference electrode supplies a continuous electrical potential to act as a baseline.

RELATED DOCUMENTS

CHEM.NOVA.1.0 NOVA 8 Maintenance

DOCUMENT OWNER

Manager, Chemistry and Special Chemistry

SPECIMEN

A. Specimen Type:
   1. Whole blood (sodium or lithium heparin)
      a. Do not collect specimen in plasma separator tubes.
   2. Plasma: (sodium or lithium heparin)
      a. Specimens collected in separator tubes are acceptable.
   3. Serum (unopened SST)
      a. Complete clot formation should be allowed to take place before centrifugation to obtain serum samples.
      b. Specimens should be free of particulate matter.
      c. Specimens collected in separator tubes are acceptable.

B. Storage and Stability:
   1. Whole blood: Ensure that samples are well mixed. Whole blood samples are not to be chilled. Must be received on ice and run within 1 hour of collection.
   2. Plasma: Centrifuge within 1 hour of collection. If assay will not be completed within 8 hours, the plasma should be stored refrigerated at 2 to 8°C. If assays will not be completed within 48 hours or if the plasma sample is to be stored beyond 48 hours, the sample is to be stored frozen at -20°C.
   3. Serum
      a. Room temperature (22°C) - 8 hours
      b. Refrigerated (2-8°) - 48 hours
      c. Testing that is delayed for more than 48 hours should be frozen (-20°C) –
   4. Minimum volume – 180 µL
   5. Special instructions

a. It is important that the sample not be exposed to air during or after collection.
b. Patient Preparation: No patient preparation is required

REAGENTS

A. All reagents are purchased from Nova Biomedical
   1. Calibrator Pack: stable until the expiration date on the box
      a. Refer to the Operator's Manual for replacing the Calibrator Pack
      b. The concentrations of the internal standards are printed on the calibration pack. In addition to the calibrators and solutions, the pack has a self-contained waste bag for safe disposal of waste.
   2. Conditioning solution
   3. Cleaning solution

B. Reagent Preparation:
   All reagents are ready for use and require no preparation.

C. Reagent storage and Stability
   1. Reagents should be stored in their original package, which lists the expiration date.
      a. Each box of reagent should be dated upon receipt.
      b. Store at the temperature indicated on the package
   2. Do not use if reagent appears discolored, cracked or disfigured, or if the reagent appears to have evaporated or become contaminated.

D. Reagent Performance:
   Reagents are acceptable if:
   1. The three levels of quality control results are within the established range after the reagents are placed on the analyzer and the analyzer is calibrated.
   2. The in use time has not been exceeded.

EQUIPMENT

A. Analyzer: Nova 8 System

B. Supplies:
   1. 2 mL sample cups
   2. Printer paper

CALIBRATION

A. Automatic/Scheduled Calibrations:
   In general, calibrations on the Nova 8 are automatic and no intervention by the user is required.
   1. An auto calibration occurs 30 minutes after power-up and at 2 hour intervals, thereafter, or 2 hours after the last manual calibration. (calibration time is 203 seconds)
   2. A manual calibration can be initiated at any time by pressing CALIBRATE on the CRT screen when the system is idle.

3. Calibration must be performed after changing the Calibrator pack, after performing any maintenance or troubleshooting.
4. Some analytes are dependent upon other analytes. In order to function properly, the analyte (source of dependence) must be properly calibrated before the dependent analyte can function/report. Magnesium depends on Ionized Calcium in the Nova 8.

QUALITY CONTROL

A. A minimum of three levels of external QC are run daily.
   1. Day shift will run all three levels of controls.
   2. Evening shift will run level 2
   3. Night shift will run level 3

B. The controls are ready to use and do not require any preparation. Mix the QC vial gently before use.

C. Quality control results must fall within the limits established for each of the controls.

D. Analyzing QC samples:
   1. Select sample type: Select the sample type, serum/plasma, for control levels 1, 2 or 3.
   2. Select the stat position: Place the sampler in the STAT position by lifting the sample assembly.
   3. Press ANALYZE
   4. ID as QC sample:
      a. Using the arrow keys, position the cursor in the Sample ID field.
      b. Press the QC key on the keypad.
      c. Select the QC ID number designated for the control being analyzed and press ENTER.
   5. Open a control vial after mixing gently.
   6. Press ANALYZE to begin analysis.
      a. The probe will extend.
      b. Place the tip of the probe into the control sample.
      c. On completion of the analysis, results will appear on the screen and on the printout.
      d. Document the results in SQ and verify the result is within the acceptable limits established.

PROCEDURE

A. Ready screen:
   1. Samples can be analyzed when the CRT screen shows that all analytes are calibrated (designated by the letter C).
   2. There should be no Check Status message in the upper right hand corner.

3. Check the sample type in the upper left hand corner. Change if necessary. You must select the sample type before you program a worklist or begin an analysis.
    a. Press the SAMPLE TYPE key to access the Sample Type menu if the desired sample type is different from the one shown on the status line in the upper left corner of the display.
    b. Press the number of the sample type to be analyzed. The sample type will be displayed in the status area at the top of the display screen.
    c. Press EXIT to return to the previous screen.
4. Select the analysis Mode, STAT or TRAY.
5. With the sampler in the UP position, the instrument accepts hand held or STAT samples. With the sampler in the DOWN position, the instrument accepts samples from the tray.

B. STAT ANALYSIS

1. Pull the sampler up to analyze samples in the STAT position.
2. Enter a STAT Sample ID. (A STAT Sample can be identified with up to 15 alphanumeric characters before analysis is initiated).
    a. Press WORKLIST to access the Sample Data Input screen. The Sample ID field will be highlighted.
    b. To enter numbers, press the desired number on the keypad to place it in the ID field.
    c. To enter letters, Press TEXT to access the TEXT Input window. The letter “A” is highlighted. Press the arrow keys to move the cursor to the desired letter. Press ENTER to place the highlighted letter in the ID field. Both text and numbers can be entered when the TEXT window is active. Press ENTER to lock in the sample ID. The cursor now highlights the test field.
    d. To correct an erroneous ID, press ENTER until the cursor returns to the ID field and then press CLEAR. The entire ID will be deleted.
    e. If a Barcode wand is present, Barcode the Specimen ID when the ID field is highlighted.
3. Select a test for STAT Sample:
    a. This analyzer will only be reporting Ionized Calcium results.
    b. Press the number on the keypad that corresponds to the test on the keypad replica to select tests.
    c. Press EXIT to remove the Sample Date Input screen thus cancelling all sample data entries.
4. Fill a 2 mL sample cup with sample or you can directly sample from the original tube.
5. Begin analysis
    a. Press ANALYZE, the probe will extend.
    b. Place the tip of the probe into the specimen
    c. Press ANALYZE again , wait until the probe retracts

NOTE: If the probe is exposed to the gel from SST tubes, this will cause the instrument to need extensive service if gel enters the probe and enters the electrode train.

C. Tray Analysis

A sample tray is run from a worklist which contains information for each sample on the tray. A tray can hold up to 40 samples and all cups must contain the same sample type. The tray accepts 0.5 or 2.0 mL sample cups.

1. Check the sample type
   a. Press the SAMPLE TYPE key to display the Sample Type Menu.
   b. Press the number of the sample type that you want to analyze.
      1.) Serum/Plasma
      2.) Whole Blood
   c. Press EXIT

      NOTE: make sure the sampler is in the down position.
2. Display the Worklist by pressing the Worklist button on the keypad.
3. Press ANALYZE to display the Worklist screen.
4. Edit the worklist
   a. Select the desired cup. If different from the one highlighted, move the cursor with the arrow keys to the appropriate cup.
   b. Press ENTER to access the Worklist Editor screen.
   c. Enter ID.
   d. Press ENTER.
   e. Select Test. Press the number on the keypad that corresponds to the test on the keypad shown on the right side of the screen.
   f. Press ENTER to lock in test and move the cursor to the cup # field.
   g. Place sample in a 2 mL cup and place in the correct cup location on the tray.
   h. Enter the next cup # and program ID and tests as described in a through f above.
   i. If you want to review the worklist before analysis, go the Worklist Review screen.
   j. After all the cups are in the tray, push the tray firmly until closed.
   k. Press ANALYZE when the cup programming is completed. The tray will be processed automatically.

D. RESULTS

1. Results will print automatically.
2. View results.

   If an error is encountered during the analysis, the results will flash on the screen. On the printout, the results appear with the code ERR or CR (Control Error). Under ERRORS on the printout, a numerical error code and short description appears.

3. Results should be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.
4. The analyzer can save the last 80 stat results in memory.
5. The analyzer saves all results from only the LAST tray analyzed.
6. A tray worklist needs to be cleared before running another tray or sample.
    a. Press WORKLIST (sampler needs to be in the down positions).
    b. Press CLEAR.
    c. Press ENTER: an empty worklist will appear.

REPORTING RESULTS

A. Reference Range: 1.13 - 1.32 mmol/L
B. Critical Range: <0.68 mmol/L or > 1.58 mmol/L
C. AMR: 0.40-2.60 mmol/L
D. Sunquest Computer Entry:
    1. Manual Entry
        Function: MEM
        Worksheet: BGRE
        Test Code: ICA
    2. Online Entry
        Function: OEM
        Worksheet: BGRE
        Test Code: ICA
E. QLS Computer Entry
    1. Enter: 3,3,1
    2. Worksheet: BGRE
    3. Accession number: Enter JI number from the tube or printout
F. If the HIS or LIS system is down, see the appropriate Laboratory Computer Downtime Procedure.

PROCEDURE NOTES

A. Backup method: When testing cannot be performed, the testing site's backup policy should be followed.
B. Maintenance:
    1. Refer to the maintenance sheet for specific tasks to be performed.
    2. Refer to the NOVA 8 "Instructions for Use Manual" for detailed instructions for performing maintenance procedures.
C. Troubleshooting:
    Refer to the NOVA 8 "Instructions for Use Manual" for detailed instructions for performing troubleshooting procedures.

D. Interfering Substances:
   1. Sodium and potassium perchlorate (1.0 mmol/L) has been shown to decrease the iCA concentration by 0.1 mmol/L.
   2. Drugs containing perchlorate, such as Irenat, may interfere with iCA measurements.

CLINICAL SIGNIFICANCE

Ionized Calcium is the free (unbound) fraction of total calcium and is the only fraction that can be readily used by the body for vital processes, such as muscular contraction, cardiac function, and transmission of nerve impulses and blood clotting. The ionized calcium value may be used in the diagnosis and treatment of hypertension, renal disease and vitamin D related disorders. Also useful in the diagnosis and treatment of patients with increased total protein and/or albumin levels as in dehydration.

REFERENCES

A. Nova Instructions for Use Manual #38333, rev 2004-01, Nova Biomedical, Waltham, MA 02454-9141.
B. NOVA CRT Training Manual, #16485, rev. L 10/99, Nova Biomedical, Waltham, MA 02454-9141.