

DEPMEDS LABORATORY PROCEDURES
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MCCS-HCH

STANDING OPERATING PROCEDURE

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CIBA-CORNING 614 ISE Na⁺/K⁺ ANALYZER

I. INTRODUCTION:

A. Sodium is the major cation of the extracellular fluids. The kidneys regulate sodium contents of the body. Low sodium levels may be caused by excessive urine loss, diarrhea, Addison's disease, and renal tubular disease. High sodium levels may occur in severe dehydration, some types of brain injury, diabetic coma, and excessive intake of sodium salts.

B. Potassium is the major cation of intracellular fluids. Hypokalemia (low potassium levels) may be caused by prolonged diarrhea, starvation, stress states, some kidney malfunctions, and malabsorption by the intestines. Hyperkalemia (high potassium levels) may occur with severe cell damage, hypoventilation, and acute kidney failure.

II. PRINCIPLE:

A. When an ion-selective membrane separates two solutions which differ in concentration of the ion, an electrical potential is developed across the membrane; the size of the potential is dependent upon differences in the ion concentration.

B. The sodium ion-selective electrode (ISE) consists of a glass capillary, which is selective to sodium ions. The sample passes through the capillary, with the outer surface in contact with the electrode filling solution. Electrical connection is via a Ag/AgCl wire. The sodium potential from the sodium electrode is compared with a reference electrode.

C. The potassium ISE consists of a valinomycin-based membrane. The valinomycin is in contact with both the sample on one side and the electrode filling solution on the other. The electrical connection is via a Ag/AgCl wire.

D. The reference electrode consists of a shell filled with saturated KCl, separated from the sample by a cellulose membrane. The electrical connection is via a Ag/AgCl wire, coated with Nafion, an ion-permeable polymer.

E. The Ciba-Corning 614 is a direct potentiometric ISE analyzer used for "in-vitro" quantitative measurements

of sodium and potassium, based on measuring the potential developed by the ISE with respect to the reference electrode. The sodium and potassium electrodes are incorporated in a microprocessor-controlled sample fluid handling system. In an electrolyte solution most simple salts dissociate their ions. An electrical exchange reaction occurs between the relevant electrode and the ions, producing a potential between the ISE and reference electrode.

III. SPECIMEN:

A. Serum, plasma, whole blood, or urine can be assayed.

1. Whole blood sample must not be over one hour old.

2. Plasma (anticoagulant of choice is lithium heparin) should be separated from the red cells as soon as possible. Keep sample capped to prevent evaporation until ready to assay.

3. Dilute urine -- one part urine sample to 9 parts Ciba-Corning urine diluent.

B. Minimum sample volume is 35 ul.

IV. REAGENTS AND MATERIALS:

A. Ciba-Corning 614 ISE Analyzer.

B. Calibrating Standard/Flush solution used to calibrate the analyzer and to rinse out the sampling tract:
140 mmol/L sodium, 4.00 mmol/L potassium.

C. Serum slope standard used to determine the sodium and potassium slope during the two point calibration cycle: 110 mmol/L NaCl, 8.00 mmol/L KCl.

D. Urine slope standard used to determine the slope and calibration for urine: 100 mmol/L NaCl, 120 mmol/L KCl.

E. Ciba-Corning urine diluent.

F. Deproteinizing and cleaning solution: 0.075 mol/L HCl, non-ionic detergent and pepsin.

G. Electrode Conditioning Solution: 0.1 mol/L ammonium hydrogen fluoride, sensitized for ISE systems.

H. Na/K electrode filling solution: 140 mmol/L sodium, 4.00 mmol/L potassium.

I. Reference filling solution: 4 mol/L KCl.

V. CALIBRATION:

A. Fully automated (can be manually controlled) to perform a one point calibration every 10 to 60 minutes and a two

point calibration every 4th calibration for the monitoring of cal-drift.

1. To initiate this calibration manually, press "No" to message "Analyze Blood" and press "Yes" for "Standardization" to perform a one or two point calibration.

2. The first step of the cycle is cleaning and calibrating the sample sensor, and checking the voltage of the sample to see if it is within acceptable range. If calibration is unsuccessful, out of range, unstable, or a indicates a drift, the analyzer will automatically recalibrate up to three cycles. After third unsuccessful recalibration, the system will stop with a message "Cal Failed-Repeat?" Recommend conditioning of electrodes.

3. If the measuring concentration is within range, "Calibration OK" will be displayed on the analyzer.

4. After a successful calibration the slope will be checked (two point calibration), and if slope is within range, "Slope OK" will be displayed.

5. If calibration fails on any electrode, the proper error code message will be generated and troubleshooting should begin. Refer to the Ciba- Corning 614 operator's Manual.

VI. QUALITY CONTROL: (CERTAIN ISE AQUEOUS CONTROLS)

A. The Ciba Corning assayed controls come in three levels: low, medium, and high and are used for the Na⁺/K⁺ assays performed to validate quantification of patient samples when necessary. The controls are supplied readytouse and require no reconstitution; treat identically to patient samples. Date and initial the control ampules when initially opened. Certain ISE controls are supplied at three levels to verify the instrument's performance at several points in the clinical range.

B. Assay controls daily (at least once every 8 hours or as frequently as necessary) to monitor the performance of the Ciba-Corning analyzer.

C. Keep control limits within ± 2 SD of established ranges, which are initially provided by Manufacturer's assays. Slight adjustments of the assayed means may be made on a monthly basis by the supervisor according to the functioning of the equipment, providing that these ranges do not exceed manufacturer's assay limits. Store controls in 4-25°C; avoid direct sunlight.

D. Control procedure:

1. Restore all the liquid to the bottom part of the ampule.

2. Snap open ampule; care should be taken to avoid injury.

3. Aspirate contents into analyzer either in Analyze Blood mode or QC Now mode.

4. Operator can set QC prompts and limits (See Operator's Manual for details).

VII. PROCEDURE:

A. To measure serum, plasma and whole blood:

1. Press "Yes" to the "Analyze Blood" display. Wait for the analyzer to read open probe, than place sample in probe.

2. When analyzer is ready "Probe in Sample" will appear on the display; press "Yes". Ensure probe is immersed in the sample/control. Aspiration time is approximately 10 seconds, with display of "Sampling Wait" appearing. If the sample sensor does not detect the sample/control within 15 seconds, a "Sample Fault" message will be displayed.

3. After sampling, wipe probe with a lintless tissue.

4. The system will instruct you to retract the probe. Ten seconds after the "Return Probe," a continuous beep will sound to remind you to return probe.

5. Results will be displayed within 35 seconds. A copy of the results will also be printed out.

6. To analyze urine, see Instruction Manual.

VIII. CALCULATIONS:

The results are recorded in mmol/L. No further calculation is necessary.

IX. RESULTS:

A. Expected values:

Sodium 135-145 mmol/L.

Potassium 3.6-5.0 mmol/L.

B. Panic values:

Sodium <120 mmol/l and >160 mmol/L.

Potassium <2.5 mmol/L and >6.0 mmol/L.

X. MAINTENANCE:

A. Daily maintenance to be performed.

1. Check levels of cal-pak (change weekly).
2. Ensure probe is straight and centered over weir.
3. Clean weir cover.
4. Clean external surfaces, sampling area, and calibration compartment with disinfectant.
5. Deproteinize and condition electrodes every 8 hours.

B. Quarterly maintenance to be performed.

1. Disinfect analyzer.
2. Replace pump tube cassette; clean and lubricate roller assembly.
3. Replace weir cover if necessary.
4. Replace reference electrode cassette.
5. Refill Na⁺/K⁺ electrodes with fill solution as needed.
6. System check as required.

XI. LIMITATIONS:

- A. Sample must be free of hemolysis.
- B. Linear Range: CV 1.5% or less.

Whole blood/serum/plasma: Sodium 80-200 mmol/L.
Potassium 0.50-9.99 mmol/L.

Urine: Sodium 10-350 mmol/L.
Potassium 5-250 mmol/L.

C. Always replace standard and slope solution with fresh cal-pak of reagent. Never add fresh reagent to existing reagent in the old cal-pak.

D. Cleaning solution is irritating to the eyes, nose and respiratory tract and poisonous. Avoid contact with eyes or skin. If contact occurs, flush with a copious amount of water immediately. Refer to MSDS.

E. System should always be run with front cover closed.

F. Water should never be used to clean or flush the sodium, potassium, or reference electrode.

XII. REFERENCES:

- Teitz, N.W. ed., Textbook of Clinical Chemistry.
Philadelphia: W.B. Saunders Co., 1986.
- Ciba Corning 614 Instruction Manual, Ciba Corning Diagnostics,
1989.