Prepared by: D. Napert

Adopted: 12/4/13 David Morris PhD\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Revisions:

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| --- | --- | --- | --- |
| New 12/4/13 |  |  |  |
| 9/2019 rev Na Critical Value |  |  |  |
| 11/2023 K interference, WBC |  |  |  |
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Lifespan AMC-Department of Pathology

The Miriam Hospital \_\_\_ \_\_\_ Rhode Island Hospital

164 Summit Avenue 593 Eddy Street

Providence, Rhode Island 02906 Providence, Rhode Island 02903

This procedure is valid for the following chemistry analyzers:

|  |  |
| --- | --- |
| * AU480 | * AU680 |
| * AU5800 |  |

# PRINCIPLE:

The determination of electrolytes (sodium, potassium, and chloride) is one of the most important functions in the clinical laboratory.

Electrolytes affect most metabolic processes. They serve to maintain osmotic pressure and hydration of various body fluid compartments, proper body pH, and regulation of appropriate heart and muscle functions. Electrolytes are also involved in oxidation-reduction reactions and participate as essential parts or cofactors in enzyme reactions.1

# INTENDED USE:

System reagent for the quantitative determination of Sodium, Potassium, and Chloride concentrations in human serum, plasma, or urine on Beckman Coulter AU Clinical Chemistry analyzers.

# METHODOLOGY:

The Beckman Coulter AU System ISE module for Na+, K+, and Cl- employs crown ether membrane electrodes for sodium and potassium; and a molecular oriented PVC membrane for chloride that are specific for each ion of interest in the sample. An electrical potential is developed according to the Nernst Equation for a specific ion. When compared to the Internal Reference Solution, this electrical potential is translated into voltage and then into the ion concentration of the sample.1

Methods of determining electrolytes include emissions spectrophotometry, flame spectrophotometry, neutron activation analysis, atomic absorption spectroscopy, and ion selective electrodes.

# SPECIMEN:

## Patient Preparation:

None required. Serum/plasma collected by standard venipuncture techniques

## Type:

Serum or plasma, free from hemolysis, is the recommended specimen. Separate serum from red blood cells as soon as possible. If plasma must be used, the recommended anticoagulants are lithium heparin and ammonium heparin. Avoid hemolysis, which may falsely elevate potassium values.

Urine samples should be collected in a clean, leak-proof container and should not be acidified. If transport is delayed, specimens should be kept refrigerated at 2-8°C.

A 24-hour collection2 is the recommended specimen to determine the urine sodium, potassium or chloride.

## Handling Conditions:

Use fresh sample for analysis when possible. Sodium and potassium are stable in serum for at least one week when stored at 2-8°C. Chloride is stable in serum for one week when stored 2-30°C. Store the samples in a stoppered tube if analysis is delayed. 2

Urine specimens should be stored at 2-8°C.

Ammonia (shared tube)- If requested, it is acceptable to run Potassium on the ammonia sample (on ice) if it was spun within 90 minutes.

## Criteria for Unacceptable Specimens

The sample must be properly labeled with the minimum of the patient’s name and date of birth. For more information on the acceptability of samples, see Specimen Rejection Policy in Administrative Manual.

Hemolyzed samples- Refer to policy *Hemolysis, Lipemia and Other Interferences & Hemolysis Grid Appendix H1* to review when to report or cancel based on hemoglobin concentration and HEMO index.

# EQUIPMENT AND MATERIALS:

## Equipment:

Beckman Coulter AU400/AU400e, AU480, AU600, AU640/AU640e, AU680, AU2700, AU5400 and AU5800 analyzers.

## Materials:

Na+ Electrode: Cat No. MU9194

K+ Electrode: Cat No. MU9195

Cl- Electrode: Cat No. MU9196

Reference Electrode: Cat No. MU9197

*Reactive Components:*

|  |  |  |  |
| --- | --- | --- | --- |
| **ISE Buffer (AUH1011)** |  | **ISE Reference (AUH1013)** |  |
| Triethanolamine | 0.1 mol/L | Potassium Chloride | 1.0 mol/L |
| Preservatives |  | Preservatives |  |
|  |  |  |  |
| **ISE Mid Standard (AUH1012)** |  | **Internal Reference Solution (AUH1017)** |  |
| Sodium | 4.3 mmol/L | Potassium Chloride | 3.3 mol/L |
| Potassium | 0.13 mmol/L | Silver Chloride | Saturated |
| Chloride | 3.1 mmol/L | Preservatives |  |
| Preservatives |  |  |  |
|  |  |  |  |
| **ISE Low Serum Standard (AUH1014)** |  | **ISE High Serum Standard (AUH1015)** |  |
| Sodium | 130 mmol/L | Sodium | 160 mmol/L |
| Potassium | 3.5 mmol/L | Potassium | 6.0 mmol/L |
| Chloride | 85 mmol/L | Chloride | 120 mmol/L |
| Preservatives |  | Preservatives |  |
|  |  |  |  |
| **Note: Urine standards are packages as a set (AU1016)** | | | |
| **ISE Low Urine Standard** |  | **ISE High Urine Standard** |  |
| Sodium | 50 mmol/L | Sodium | 200 mmol/L |
| Potassium | 10 mmol/L | Potassium | 100 mmol/L |
| Chloride | 50 mmol/L | Chloride | 180 mmol/L |
| Preservatives |  | Preservatives |  |
|  |  |  |  |
| **Note: Selectivity solutions are packages as a set (AUH1018)** | | | |
| **Na+ Selectivity Check Solution** |  | **K+ Selectivity Check Solution** |  |
| Sodium | 150 mmol/L | Potassium | 5.0 mmol/L |
| Preservatives |  | Preservatives |  |

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| Reagent storage location in this laboratory: Reagents are stored in the Chemistry refrigerator |

Test tubes 12 -16 mm in diameter or sample cups (Cat No. AU1063).

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| Storage location of test tubes or sample cups in this laboratory: Sample tubes and cups are stored in the main chemistry lab area |

|  |  |
| --- | --- |
| ISE Low Serum Standard | (Cat No. AUH1014) |
| ISE High Serum Standard | (Cat No. AUH1015) |
| ISE Low/High Urine Standard | (Cat No. AUH1016) |

|  |
| --- |
| Storage location of the Chemistry Calibrator in this laboratory: Calibrators are stored in the Chemistry refrigerator |

### Precautions:

1. The ISE Reagents and Standards are for *in vitro* diagnostic use.
2. Do not ingest. Harmful if swallowed.

## Preparation:

The Beckman Coulter AU System ISE reagents are liquid, ready for use. No preparation is needed. ISE electrodes come prepared and ready to install on board the analyzer.

### Storage Requirements:

1. The unopened reagents and standards are stable until the expiration date printed on the label when stored at 2 - 25°C with the exception of the Internal Reference Solution (Cat No. AUH1017), which is stored 15-25°C.

1. ISE Buffer (Cat No. AUH1011), ISE Mid-Standard (Cat No. AUH1012), and ISE Reference Solution (Cat No. AUH1013) are stable for 90 days when opened and stored in the ISE reagent compartment of the analyzer.
2. After opening, ISE Low and High Serum Standards (Cat No. AUH1014 and AUH1015), ISE Urine Low/High Standard (Cat No. AUH1016), and Na/K Selectivity Check Solutions (Cat No. AUH1018) may be stored at 2 - 25°C for up to 90 days provided the cap is replaced immediately after use. ISE Internal Reference Solution (Cat No. AUH1017) may be stored at 15- 25°C for up to 90 days provided the cap is replaced immediately after use.

### Indications of Deterioration:

Discoloration of the reagent, visible signs of microbial growth, turbidity or precipitation in reagent may indicate degradation and warrant discontinuance of use.

# PERFORMANCE PARAMETERS:

The following data was obtained using the ISE Reagents Beckman Coulter AU analyzers according to established procedures. Results obtained at individual facilities may differ.

## Precision5:

Estimates of precision, based on CLSI recommendations4, are consistent with typical performance. The within run precision is less than 3%CV and total precision is less than 5%CV. Assays of control sera and pooled urine samples were carried out and data reduced following CLSI guidelines.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SERUM, N=100 | | **Within run** | | **Total** | |
| **Mean, mEq/L** | | **SD** | **CV%** | **SD** | **CV%** |
| Na+ Level 1 | 124.4 | 0.5 | 0.4 | 0.8 | 0.6 |
| Na+ Level 2 | 143.0 | 0.5 | 0.3 | 0.8 | 0.5 |
| K+ Level 1 | 2.9 | 0.2 | 0.6 | 0.02 | 0.7 |
| K+ Level 2 | 5.7 | 0.04 | 0.8 | 0.05 | 0.9 |
| **Cl**- **Level 1** | 85.9 | 0.4 | 0.5 | 0.6 | 0.6 |
| **Cl**- **Level 2** | 112.3 | 0.5 | 0.5 | 0.6 | 0.6 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| URINE, N=100 | | **Within run** | | **Total** | |
| **Mean, mEq/L** | | **SD** | **CV%** | **SD** | **CV%** |
| Na+ Level 1 | 88 | 0.6 | 0.7 | 0.8 | 0.9 |
| Na+ Level 2 | 182.3 | 0.7 | 0.4 | 1.5 | 0.8 |
| K+ Level 1 | 32.1 | 0.3 | 0.8 | 0.3 | 1.0 |
| K+ Level 2 | 85.8 | 0.5 | 0.6 | 0.9 | 1.1 |
| **Cl**- **Level 1** | 111.3 | 0.7 | 0.6 | 0.9 | 0.8 |
| **Cl**- **Level 2** | 238.8 | 0.9 | 0.4 | 1.4 | 0.6 |

## Method Comparison5:

Patient samples were used to compare the Beckman Coulter AU System ISE. Representative performance data on AU analyzers is shown in the next table.

|  |  |  |  |
| --- | --- | --- | --- |
| Y Method | AU640 / AU640e | | |
| X Method | AU600 | | |
|  | Na+ | K+ | Cl- |
| Slope | 1.01 | 0.99 | 1.01 |
| Intercept | 0.3 | 0.12 | 0.7 |
| Corr. Coeff. (r) | 0.998 | 0.999 | 0.999 |
| No. of Samples (n) | 230 | 230 | 230 |

### Serum:

### Urine:

|  |  |  |  |
| --- | --- | --- | --- |
| Y Method | AU640 / AU640e | | |
| X Method | AU600 | | |
|  | Na+ | K+ | Cl- |
| Slope | 1.01 | 0.99 | 0.99 |
| Intercept | 1.5 | 4.7 | -0.4 |
| Corr. Coeff. (r) | 0.999 | 0.999 | 0.999 |
| No. of Samples (n) | 184 | 184 | 184 |

# CALIBRATION:

## Standard Preparation:

Perform a multipoint calibration by using the automated ISE calibration with the appropriate standards placed in the labeled positions on the STAT table or designated ISE Standard Solution area. The frequency of calibration is daily. Calibration of the ISE methods is accomplished by the use of the Beckman Coulter ISE standards for serum or urine.

Refer to the ISE section of the appropriate AU User Guide for a complete listing of calibration procedures.

## Calibration Procedure:

Recalibration of this test is required when any of these conditions exist:

1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.

3. A critical part was replaced.

# QUALITY CONTROL:

During operation of the Beckman Coulter AU analyzer at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition, controls should be performed after calibration, with each new lot of reagents, and after specific maintenance or troubleshooting steps described in the appropriate AU User’s Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory’s standard procedure.

|  |
| --- |
| Location of controls used at this laboratory. Controls are located in Chemistry refrigerator |

# ANALYZER PARAMETERS:

A complete list of test parameters and operating procedures can be found in the appropriate User’s Guide and at [www.beckmancoulter.com](http://www.beckmancoulter.com).

# CALCULATIONS:

For SI Units mmol/L is equivalent to mEq/L.

# REPORTING RESULTS:

## Reference Ranges:

Serum1: Urine1:

Na+: 136 – 145 mEq/L Na+: 40 – 220 mEq/day

K+: 3.5 – 5.1 mEq/L K+: 25 – 125 mEq/day

Cl-: 98 – 107 mEq/L Cl-: 110 – 250 mEq/day

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

**Lifespan Reference Ranges established by Normal Value study**

|  |  |  |  |
| --- | --- | --- | --- |
| **INTERVAL** | **Assay** | **SAMPLE TYPE** | **CONVENTIONAL UNITS** |
| Lifespan AMC | **Sodium** | Serum or Plasma | * 1. month 131-143 mEq/L   1mo-1 yr 131-145 mEq/L  1-5 yr 132-143 mEq/L  5-10 yr 135-143 mEq/L  10-15 yr 133-143 mEq/L  15-150 yr 135-145 mEq/L |
|  | Urine | None Established |
| Lifespan AMC | **Potassium** | **Serum or Plasma** | Birth-1 mo = 3.7 to 5.9 meq/L  1 mo-1 year= 4.1-5.3 meq/L  1year-12 years = 3.4-4.7 meq/L  >12 years= 3.6-5.1 meq/L |
|  | Urine | None Established |
| Lifespan AMC | **Chloride** | **Serum or Plasma** | * 1. mo 99- 116 mEq/L   one mo-1 yr 98-118 mEq/L  1-5 yr 98-116 mEq/L  5-10 yr 99-114 mEq/L  10-15 yr 98-115 mEq/L  15-150 yr 98-110 mEq/L |
|  |  | Urine | None Established |

## Procedures for Abnormal Results:

Abnormal results are flagged by the listed analyzers according to the normal values entered by the user into the instrument parameters.

**Critical Values established by Lifespan**

|  |  |  |
| --- | --- | --- |
|  | Sample Type | Critical Values (Orange/Red) |
| Sodium | Serum or Plasma | <120 mEq/L |
| >160 mEq/L |
|  |  |  |
| Chloride | Serum or Plasma | < 85 mEq/L |
| >120 mEq/L |
|  |  |  |
| Potassium | Serum or Plasma | <3.0 mEq/L |
| >6.0 mEq/L |

## Critical Results

All Critical results must be called back to the requesting location and reported as soon as the result is available. All Critical Orange results must be called back and reported within 8 hours, Critical Red must be called within 1 hour. A footnote/comment must be entered into the patient record which includes the person to whom the result was reported, the date and time the result was reported and the tech who reported the value. Communication of the results must include the full name of the patient along with the DOB must be read back to the caller and this action noted in the footnote.

## Reporting Format:

Results are automatically printed for each sample in mEq/L at 37°C.

The AU analyzers are interfaced with the LIS system through the Remisol Advance Data manager. All results are transmitted electronically and rules for Autovalidation, flagging, critical, etc have been validated through testing.

# LIMITATIONS:

The Beckman Coulter AU System ISE procedures are linear as follows:

Serum: Na+: 50 – 200 mEq/L Urine: Na+: 10 – 400 mEq/L

K+: 1.0 – 10.0 mEq/L K+: 2.0 – 200 mEq/L

Cl-: 50 – 200 mEq/L Cl-: 15 – 400 mEq/L

Samples exceeding the dynamic range of the assay should be diluted with deionized water and re-assayed. The results obtained must be multiplied by the dilution factor to obtain the correct concentration for the undiluted sample.

## Interfering Substances:

Certain anticoagulants, preservatives, drugs and organophilic compounds may affect electrolyte determinations. For further information on interfering substances, refer to Young3 for a compilation of reported interferences with these tests. Visually turbid urine samples should be centrifuged prior to analysis2.

Pseudohyperkalemia may be indicated in certain patients’ chronic lymphocytic leukemia (CLL). In these instances, a patient’s plasma potassium result is falsely elevated into the critical range of >6.0 mEq/L. Such samples should be reviewed, for hemolysis and elevated white blood cell (WBC) count. If the hemolysis index is ≤1 and the WBC count is >20x10^9/L the result should be entered as SEE\_NOTE with the comment @WBCK. The result should be communicated to the provider and a whole blood potassium should be recommended to remove the interference from the elevated WBC.

Grossly lipemic samples may show an inappropriate decrease in sodium, potassium, and chloride results due to volume displacement. Such samples should be ultracentrifuged ad the analysis performed on the infranatant. (middle clear layer).

Hemolyzed samples- Refer to *Hemolysis Grid Appendix H1.*

HEMO index ≤2 reported with comment @HEM1

HEMO index ≥3 cancel with comment @HEML and call

The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc., makes no representation about the completeness or accuracy of results generated by future studies.

# REFERENCES:

1. Tietz, N.W. editor. Fundamentals of Clinical Chemistry. 3rd Edition, W.B. Saunders, 1987.

2. Pesce, A.J. Kaplan, L.A. editors, Methods in Clinical Chemistry. C.V. Mosby Company. 1996.

3. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 5th Edition, AACC Press. 2000.

4. CLSI/NCCLS Evaluation Protocol EP5-T2, 1992.

5. Data on file for specific AU analyzers.