

REF 77483

Intended Use

Eon ISE Reagent Pack is for the quantitative determination of sodium, potassium and chloride in serum and plasma using the Eon 100 Analyzer.

Summary ^{1,2}

The maintenance of water distribution and osmotic pressure in bodily fluid compartments is primarily a function of electrolytes. In addition, electrolytes play a major role in all muscle function, redox reactions and as enzyme co-factors.

Electrolytes can be either positively charged cations or negatively charged anions and are present in bodily fluids as free ions or bound to proteins such as albumin. The three main electrolytes present in bodily fluids as free ions are sodium (Na), potassium (K) and chloride (Cl). Measurement of these three ions is commonly referred to as an electrolyte profile and is one of the most important functions of the clinical laboratory, and therefore is also one of the most common tests performed.

The Eon 100 ISE module for Na, K and Cl utilizes electrodes with selective membranes for each individual ion. In the presence of sample, the potential of each electrode is measured, relative to a reference electrode. The voltage created is dependent on the activity of the ion present in the sample and can be expressed in terms of concentration using the Nernst equation. The sample is aspirated by the Eon 100 into the sample entry port on top of the ISE module after which, the sample is then positioned in front of the electrodes for measurement.

Reagents

CAL A, required for one and two point calibration as well as Pump and Bubble Calibration.

Contains: 140 mmol/L Na⁺, 4.0 mmol/L K⁺ and 125 mmol/L Cl⁻.

CAL B, required for two point calibration.

Contains: 70 mmol/L Na⁺, 8.0 mmol/L K⁺ and 41 mmol/L Cl⁻.

Warnings and Precautions

For *in vitro* diagnostic use.

Handle and dispose of all human source materials as though capable of transmitting infectious agents using the universal precautions³ recommended by the Centers for Disease Control and Prevention (CDC). Do not pipette by mouth; do not eat, drink, smoke or apply cosmetics in areas where specimens are handled. Clean up spills immediately with a 0.5% sodium hypochlorite solution.

Preparation

The Eon ISE Reagent Pack containing is supplied ready to use on the Eon 100 Analyzer.

Storage and Stability

Store the reagent pack between 2-25°C. The reagent pack is stable until the expiry date on the Eon ISE Reagent Pack label.

Specimens

Serum and Plasma Collection and Storage

Serum or plasma (lithium heparin) is the preferred specimen. Do not analyze whole blood. Collect specimens by venipuncture according to accepted clinical protocol. Separate the serum or plasma sample from the cells as soon as possible.

Sodium and potassium are stable for at least 2 weeks at 2-30°C. Chloride is stable for 1 week at 2-30°C.⁴

Procedure

Materials Provided

The Eon ISE Reagent Pack includes the following components:

520mL **CAL A**

190mL **CAL B**

Materials Required But Not Provided

Eon ISE Cleaner **REF** 77154

Eon Sodium Electrode **REF** 77478

Eon Potassium Electrode **REF** 77479

Eon Chloride Electrode **REF** 77480

Eon Reference Electrode **REF** 77473

Eon Spacer Electrode **REF** 77485

Eon Serum Control **REF** 77131

Reagent Installation and Use

Refer to the user manual⁵ for additional information on installing the Eon ISE Reagent Pack, programming the analyzer and running samples, calibrators and controls. The Eon ISE Reagent Pack is pre-assembled and ready to use as packaged. Do not open until you are ready to install the Eon ISE Reagent Pack on the Eon 100.

Calibration

Calibration is carried out automatically by the instrument. Refer to the user manual⁵ for calibration procedures.

Quality Control

Assay at least two levels of control daily in accordance with an accepted quality control program. Control materials may be of human or animal origin, but should represent both clinically normal and abnormal levels of Na, K and Cl. Controls should also be assayed after maintaining the instrument, loading of a new Eon ISE Reagent Pack, and changing Electrodes. Controls may be assayed more frequently based on laboratory workflow and the discretion of the user.

Calculations

All calculations are performed by the Eon 100.

Limitations

Interfering Substances

Studies to determine the level of interference from biological compounds that may be normally present in serum or plasma were carried out on the Eon 100.

No significant interference ($\pm 10\%$) was observed up to the levels shown in the table below:

| | Na | K | Cl |
|---|--------------------------------|--------------------------------|--------------------------------|
| Lipemia (Intralipid [®] measured as Triglycerides) | 500 mg/dL | 500 mg/dL | 500 mg/dL |
| Bilirubin | 60 mg/dL (1026 μ mol/L) | 60 mg/dL (1026 μ mol/L) | 60 mg/dL (1026 μ mol/L) |
| Hemoglobin | 1000 mg/dL (10 g/L) | Do not use hemolyzed samples | 1000 mg/dL (10 g/L) |
| Triglycerides | 2000 mg/dL (22.6 mmol/L) | 2000 mg/dL (22.6 mmol/L) | 2000 mg/dL (22.6 mmol/L) |

Many other substances can affect electrolyte results. For additional information, refer to *Effects of Drugs on Clinical Laboratory Tests*⁷ and *Effects of Preanalytical Variables on Clinical Laboratory Tests*⁸.

The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

Limits and Ranges

Measuring Range

The Measuring Range of the assay defines the acceptable upper and lower limits of the range at which values may be reported. When using the Eon ISE Reagent Pack as recommended, the following ranges apply for serum and plasma:

| | |
|-----|------------------|
| Na+ | 100 - 200 mmol/L |
| K+ | 1.0 - 8.0 mmol/L |
| Cl- | 75 - 150 mmol/L |

Expected Values¹

Venous Plasma/Serum:

| | |
|-----|------------------|
| Na* | 136 - 146 mmol/L |
| K* | 3.5 - 5.0 mmol/L |
| Cl* | 98 - 106 mmol/L |

The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the population that it services⁶.

Performance Data

Precision

Imprecision (Repeatability) was determined in accordance with CLSI EP5-A2 guidelines. Three levels of serum were analyzed in duplicate, two times per day, over a period of at least twenty days.

A summary of the results are shown in the table below.

| LEVEL 1 | | Na | K | Cl |
|-------------------------------------|------|---------|---------|---------|
| Number of Data Points / No. of days | | 84 / 21 | 80 / 20 | 84 / 21 |
| Mean (mmol/L) | | 135 | 3.6 | 99 |
| Within Run | SD | 1.4 | 0.03 | 1.1 |
| | CV % | 1.0 | 0.8 | 1.1 |
| Total | SD | 1.7 | 0.04 | 1.4 |
| | CV % | 1.3 | 1.1 | 1.4 |

| LEVEL 2 | | Na | K | Cl |
|-------------------------------------|------|---------|---------|---------|
| Number of Data Points / No. of days | | 84 / 21 | 80 / 20 | 84 / 21 |
| Mean (mmol/L) | | 154 | 5.6 | 120 |
| Within Run | SD | 1.4 | 0.05 | 0.9 |
| | CV % | 0.9 | 0.9 | 0.8 |
| Total | SD | 1.9 | 0.08 | 1.7 |
| | CV % | 1.2 | 1.4 | 1.4 |

| LEVEL 3 | | Na | K | Cl |
|-------------------------------------|------|---------|---------|---------|
| Number of Data Points / No. of days | | 84 / 21 | 80 / 20 | 84 / 21 |
| Mean (mmol/L) | | 112 | 3.0 | 78 |
| Within Run | SD | 0.8 | 0.02 | 0.7 |
| | CV % | 0.7 | 0.9 | 0.9 |
| Total | SD | 1.4 | 0.04 | 1.1 |
| | CV % | 1.3 | 1.3 | 1.4 |

Method Comparison

Was performed based on CLSI EP9-A2 guidelines using human serum samples, with concentrations spanning the following ranges:

| | |
|-----|------------------|
| Na+ | 106 - 197 mmol/L |
| K+ | 1.6 - 7.9 mmol/L |
| Cl- | 81 - 144 mmol/L |

The following statistics were obtained.

| Sodium | Deming Regression |
|-------------------|-------------------|
| Linear Regression | n = 190 |
| n = 190 | y = 1.004x - 2.07 |
| y = 1.004x - 2.07 | R = 0.9943 |
| R = 0.9943 | |

| Potassium | Deming Regression |
|--------------------|--------------------|
| Linear Regression | n = 153 |
| n = 153 | y = 0.953x + 0.066 |
| y = 0.953x + 0.066 | R = 0.9978 |
| R = 0.9978 | |

| Chloride | Deming Regression |
|--------------------|--------------------|
| Linear Regression | n = 186 |
| n = 186 | y = 0.991x - 0.512 |
| y = 0.991x - 0.512 | R = 0.9945 |
| R = 0.9945 | |

References

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GLOSSARY OF SYMBOLS

| | | | | | |
|--|----------------|--|-------------------------|--|---|
| | Manufacturer | | Batch code / Lot number | | In vitro diagnostic medical device |
| | Contents | | Caution | | Consult instructions for use |
| | Catalog number | | Temperature limitation | | Use by / Expiration date |
| | Calibrant A | | Calibrant B | | Authorized Representative in the European Community |
| | | | | | Biological risks |