ISEPak

REF FG000013

Product Code : AGD-ISE620

Intended Use :

ISEPak is used for the quantitative determination of Sodium, Potassium, Chloride and Calcium concentrations in human serum and urine on the EL-120 Electrolyte analyzer.

Product Description :

Reagent pack for EL-120 Electrolyte analyzer.

Assay Principle :

EL-120 is an electrolyte analyzer that uses Ion selective electrode measurement principle to accurately determine the electrolyte values. It consist of Sodium, Potassium, Chloride, Calcium and Reference Electrodes. Each electrode has membrane which is selective for the specific ions moving across the membrane. The membrane is an ion exchanger resulting in the membrane potential, or measuring voltage, which is built-up between the sample and the membrane. A difference in ion concentrations between the inner electrolyte and the sample causes an electro-chemical potential to form across the membrane of the active electrode. The potential is conducted by a highly conductive, inner electrode to an amplifier. The reference electrode is connected to ground as well as to the amplifier.

Contents :

Each ISEPak contains the following :

CAL A : 350mL

Sodium (Na^+)	150.0mmol/L
Potassium (K^+)	5.00mmol/L
Chloride (Cl^-)	115.0mmol/L
Calcium (iCa^{++})	0.90mmol/L

CAL B : 150mL

Sodium (Na^+)	100.0mmol/L
Potassium (K^+)	1.80mmol/L
Chloride (Cl^-)	72.0mmol/L
Calcium (iCa^{++})	1.50mmol/L

Precautions:

1. For in vitro diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Toxic preserver are added, which can cause skin irritation. Therefore, if the reagent comes into contact with the skin or garments rinse with water and consult the doctor if skin irritation develops.
4. Do not freeze.
5. When used the ISEPak contains human body fluids.
6. Handle with appropriate care.

Preparation of Reagents :

The reagents are ready to use. No preparation is required.

Storage and Stability :

When stored hermetically sealed at a temperature of 15 to 30°C, protected from light and contamination avoided during use; reagents are stable up to expiry date stated on the label.

Indications of Deterioration :

Turbidity or precipitation in the unopened liquids and working reagents may indicate decomposition and warrant discontinuance of use. Refer to the corresponding operators manual.

Sample :

Whole blood, Plasma, Urine, Serum, free from hemolysis is the recommended specimen.

Procedure :

1. Removal of used ISEPak :

- Go to Main menu - Setup - Reagent status.
- Remove the used ISEPak.
- Use the red nozzle seal to close the connector nipples of the used ISEPak to prevent any leakage.
- Dispose of used ISEPak properly according to local regulations.

2. Preparation of New ISEPak :

- Before using the new ISEPak, remove the red nozzle seal from the connector nipples. This can be done by gently pulling the seal off the nipples. Save the red nozzle seal cover for future use to close the connector nipples of the used ISEPak.
- Write the date of installation on the label side of the new ISEPak to keep track of its usage.

3. Install New ISEPak:

- Go to Main menu - Setup - Reagent status.
- Place the ISEPak on the left side of the analyzer.
- Check Reagent pack status - New pack detected and Pack remaining - 100% on Reagent status screen.

Range :

Measuring Range:

Parameter	Serum/Plasma/Blood/Aqueous
Sodium (Na^+)	40 - 205mmol/L
Potassium (K^+)	1.5 - 15.0mmol/L
Chloride (Cl^-)	50 - 200mmol/L
Calcium (iCa^{++})	0.2 - 5.0mmol/L

Reference Range :

Parameter	Serum/Plasma/Blood
Sodium (Na^+)	136 - 145mmol/L
Potassium (K^+)	3.5 - 5.1mmol/L
Chloride (Cl^-)	97 - 108mmol/L
Calcium (iCa^{++})	1.15 - 1.35mmol/L 4.6 - 5.4mg/dL

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Performance characteristics :

The following data was obtained using the ISE reagents on Electrolyte Analyzer ISE modules according to established procedures. Results obtained in individual laboratories may differ.

Quality Control :

The following data was obtained using the ISE reagents on Electrolyte Analyzer ISE modules according to established procedures. Results obtained in individual laboratories may differ.

Disposal :

The Bio Hazard waste should be disposed of in compliance with your local or national regulations for Biohazard Waste Disposal method.

References:

1) Tietz, Norbert W.,Ed.,Textbook of Clinical Chemistry, 2nd Ed.

2) Clinical and Laboratory Standards Institute. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- second edition;CLSI documents EP5- A2, (2004).

AGD Biomedicals uses the below recognized symbols given in ISO 15223 : 2020

	Use by date	IVD	In Vitro diagnostic medical device
LOT	Batch Code	EC REP	Authorized Representative in the European Community
	Caution is necessary when operating the device		Limit of Temperature
	Name of the manufacturer	REF	Catalogue Number
	Date when the medical device was manufactured	CE	European Conformity
	Contains Sufficient for <n> tests	NON STERILE	Non-sterile conditions
	Biohazard	UDI	Unique Device Identification
	Protection from light source sources		Consult the instructions for use
	Do not use if package is damaged		

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ISO 13485 : 2016

EC REP

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