MEDICA

IVD CE

EASYLYTE $Na^+/K^+/Ca^{++}$/pH SOLUTIONS PACK
REF 2114 400mL
REF 2123 800mL

INTENDED USE
The EasyLyte $Na^+/K^+/Ca^{++}$/pH Solutions Pack is intended for the quantitative determination of sodium (Na^+), potassium (K^+) and ionized calcium (iCa^{++}) in human serum, plasma and whole blood using the MEDICA EasyLyte® Analyzer.

Measurements of pH are used only to normalize ionized calcium results to pH of 7.40 units and not for diagnostic purposes.

For professional use only. For *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION
Electrolyte measurements in biological fluids were traditionally performed using flame photometry. The development of selective organic compounds for sodium, potassium, ionized calcium and other electrolytes has permitted the development of sensors capable of the direct measurement of biological fluids throughout the physiological range. These sensors are known as ion-selective sensors.

Sodium is the major cation in extracellular fluid and has a major effect on osmotic pressure and water distribution between cells, plasma and interstitial fluid. Low sodium imbalance (Hyponatremia) is associated with diarrhea, server polyuria, metabolic acidosis, Addison's disease and renal tubular disease. High sodium imbalance (Hypernatremia) is associated with hyperadrenalism, severe dehydration, brain injury, diabetic coma and excess treatment with sodium salts.

Potassium is a major cation in intracellular liquid. Potassium imbalance has a direct effect on muscle irritability, myocardial function and respiration. Some conditions that effect potassium levels in blood include hypoaldosternism, diarrhea, vomiting and therapy with diuretics for hypertension or cardiac disease. Unlike sodium, there is no mechanism to maintain a threshold potassium level in the body.

Ionized calcium is the only physiologically active form of calcium. Increased or decreased levels of ionized calcium are directly related to hyperparathyroidism and hyperparathyroidism respectively. Calcium regulates muscle contraction, hormone secretion and membrane permeability. Acidosis (low pH) causes and increase in the amount of ionized calcium and alkalosis (high pH) causes a decrease in the amount of ionized calcium.

PRINCIPLE OF THE PROCEDURE
The EasyLyte analyzer measures sodium, potassium, ionized calcium in human serum, plasma and whole blood using ion-selective electrode technology. The flow-through pH electrodes contain glass tubing, specially formulated to be sensitive to hydrogen ions. The flow-through sodium, potassium and calcium electrodes employ a plastic tube, incorporating neutral carrier ionophores. The potential of each electrode is measured relative to a fixed and stable voltage that is established by the double-junction silver/silver chloride reference electrode. An ion-selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic, as expressed by the Nerst equation:

$$E = E^{o} + \frac{RT}{nF} \text{Log (g C)}$$

where: E = The potential of the electrode in sample solution
E^o = The potential developed under standard conditions
RT/nF = A temperature dependent “constant”, termed the slope(s)
n = 1 for sodium, potassium, pH
n = 2 for calcium
Log = Base ten logarithm function
g = Activity coefficient of the measured ion in the solution
C = Concentration of the measured ion in the solution

REAGENTS

400mL Solutions Pack (REF 2114)	800mL Solutions Pack (REF 2123)
Standard A Solution, 400mL	**Standard A Solution, 800mL**
145.0 mmol/L Na^+	145.0 mmol/L Na^+
4.0 mmol/L K^+	4.0 mmol/L K^+
1.25 mmol/L Ca^{++}	1.25 mmol/L Ca^{++}
7.40 units pH	7.40 units pH
Buffer	Buffer
Preservative	Preservative
Wetting Agent	Wetting Agent
Standard B Solution, 130mL	**Standard B Solution, 180mL**
80.0 mmol/L Na^+	80.0 mmol/L Na^+
10.0 mmol/L K^+	10.0 mmol/L K^+
2.50 mmol/L Ca^{++}	2.50 mmol/L Ca^{++}
6.80 units of pH	6.80 units of pH
Buffer	Buffer
Preservative	Preservative
Wetting Agent	Wetting Agent
Waste Container	**Waste Container**

PRECAUTIONARY STATEMENTS

When used, the Solutions Pack contains human body fluids and is considered biohazardous. Handle and dispose of the Solutions Pack using the same precautions as with any biohazardous material. Discard according to local regulations.

INSTRUCTIONS FOR SOLUTIONS PACK HANDLING, STORAGE AND STABILITY

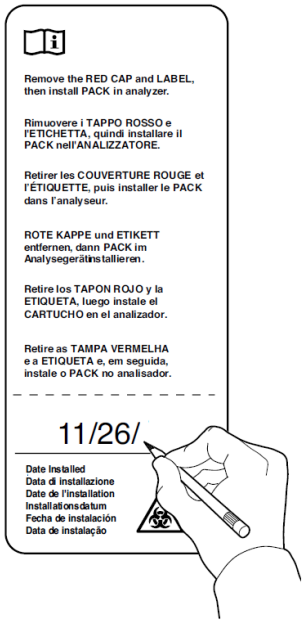
The Solutions Pack is ready to use as supplied. Unopened, the Solutions Pack is stable until the expiration date listed on the label if stored at 4–25°C. After installation, the Solutions Pack is stable on-board the EasyLyte analyzer until the expiration date listed on the label. DO NOT FREEZE.

REMOVAL OF USED SOLUTIONS PACK

Following standard laboratory precautions, grasp the Solutions Pack firmly and pull away from the analyzer. DO NOT SQUEEZE SOLUTIONS PACK. Place the red cap over the four connectors and discard according to local regulations.

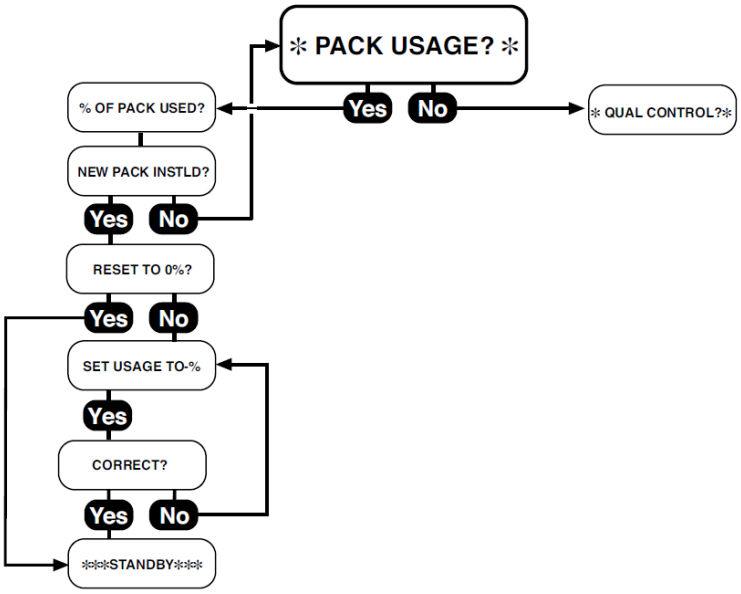
INSTALLATION OF NEW SOLUTIONS PACK

Remove the new Solutions Pack from the shipping container. Remove the orange label, record the date on the tear off tab and affix to the front of the Solutions Pack. This records the Solutions Pack installation date. Remove the red cap. Install the new Solutions Pack until it fits firmly into the solutions valve.



RESET COUNTER INSTRUCTIONS

The EasyLyte analyzer has an internal counter, which keeps track of the Solutions Pack usage. The % counter must be set to zero (0) each time a new Solutions Pack is installed. When installing a new Solutions Pack, enter the **SECOND MENU** and select the ***PACK USAGE?*** option. Upon answering YES to ***PACK USAGE?***, the EasyLyte analyzer displays and prints the percentage of the Solutions Pack. Press YES again and the EasyLyte analyzer software automatically recognizes and selects the pack size (400mL or 800mL). Answer YES to **RESET TO 0%?** for the Solutions Pack you are installing. The EasyLyte analyzer will then automatically enter *****STANDBY*****. When the EasyLyte analyzer is recalibrated, it will automatically purge the fluid lines of the new Solutions Pack to insure a successful calibration.



ADDITIONAL INFORMATION

See EasyLyte Operator's Manual for detailed information and performance data.

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