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Electrolyte Controls

Level 1, 2, 3 CONTROLS
 Lot # **XXXXXX** Exp. **YYYY-MM-DD**

Intended Use

The *SelectaLyte*™ Quality Control Kit Tri-Level contains assayed quality control materials used for monitoring the performance of the *SelectaLyte*™ Electrolyte Analyzer. For in-vitro diagnostic use only.

Product Description

Established laboratory practices use stable controls to monitor the performance of diagnostic tests. The *SelectaLyte*™ Quality Control Kit Tri-Level is composed of a buffered aqueous solution. Convenient ready-to-use glass ampules contain 2ml of solution of three (3) levels for monitoring analytes Na+, K+, and Cl- at various points within measuring range. 30 ampules are packaged per box, 10 ampules at each level.

Precautions

Carefully break open the ampule at the scoring, using protection such as an ampule snapper to avoid injury.

Storage and Stability

The *SelectaLyte*™ Quality Control Kit Tri Level has a shelf life of 24 months from the date of manufacture. Store at room temperature. Protect product from freezing and exposure to temperatures greater than 30° C.

General Directions for Use

1. Before opening, hold the glass ampule by the top and shake gently.
2. Lightly tap the ampule to help restore all liquid to the bottom.
3. Carefully break open the ampule at the scoring.
4. For best results, immediately aspirate (within 60 seconds) the liquid into the analyzer. This direct aspiration technique minimizes potential contamination and evaporation of samples.

Expected Results

Refer to the Assigned Values Table for assay ranges. Before use, verify that the lot number on the ampule matches the lot number on the table of assay values. If the instrument is properly calibrated, test data obtained while using this control kit should fall within expected ranges.

The degree of acceptable variation is an individual judgment based upon a test analyte's methodology, clinical significance, and medical decision levels.

For this reason, it is recommended that each laboratory establish its own mean and standard deviation ranges in accordance with daily laboratory practice.

Limitations


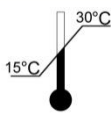










The *SelectaLyte*™ Quality Control Kit Tri Level is intended for use in evaluating the performance of the *SelectaLyte*™ Electrolyte Analyzer, and should not be considered a substitute for other aspects of quality control and good laboratory practices such as calibration, recommended maintenance techniques, and proper record keeping.

Disposal of Materials

Controls contain no blood or blood products. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

Technical Assistance

For technical assistance and customer service contact Awareness Technology Inc. at 772-283-6540 or fax: 772-283-8020 or email: isesupport@awaretech.com.

	A11-310		
	#####		Rx Only
	YYYY-MM-DD		
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SelectaLyte Tri-Level Quality Control Kit

REF A11-310
LOT #####
 YYYY-MM-DD

Assigned Values Table

Instrument or Method	Level 1 Abnormal Low Lot# XXXXXX Exp. YYYY-MM			Level 2 Normal Lot# XXXXXX Exp. YYYY-MM			Level 3 Abnormal High Lot# XXXXXX Exp. YYYY-MM		
	Na ⁺ mmol/L	K ⁺ mmol/L	Cl ⁻ mmol/L	Na ⁺ mmol/L	K ⁺ mmol/L	Cl ⁻ mmol/L	Na ⁺ mmol/L	K ⁺ mmol/L	Cl ⁻ mmol/L
SelectaLyte™	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX
AVL 9180	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX	XXX-XXX
Flame Photometer*	XXX-XXX	XXX-XXX	-	XXX-XXX	XXX-XXX	-	XXX-XXX	XXX-XXX	-
Amperometric Analysis*	-	-	XXX-XXX	-	-	XXX-XXX	-	-	XXX-XXX

* Using a standard calibration with NIST 918c and 919b

Symbol	Standard Title and Number	Title of Symbol	Symbol Ref #	Explanatory Text
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Authorized representative in the European Community	5.1.2	Indicates the Authorized representative in the European Community.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Use-by-date	5.1.4	Indicates the date after which the medical device is not to be used.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Catalog number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Temperature limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Consult instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	In Vitro diagnostic medical device	5.5.1	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Contains sufficient for 10 tests	5.5.5	Indicates the total number of IVD tests that can be performed with the IVD kit reagents.
Rx Only	Guidance for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements	Rx Only	N/A	Caution: Federal law prohibits dispensing without prescription.