

# ENVOY® 500 ISE CALIBRATOR KIT

## Product no. 55117

For *in vitro* diagnostic use

**CAUTION : Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)**

### INTENDED USE

Envoy 500 ISE CALIBRATOR KIT is intended for the calibration of Sodium (Na<sup>+</sup>), Potassium (K<sup>+</sup>), Chloride (Cl<sup>-</sup>) and Carbon Dioxide (Total CO<sub>2</sub>) on ENVOY 500 series Analyzers equipped with ISE module.

### SUMMARY AND PRINCIPLE

These calibrators contain sodium, potassium, chloride and carbon dioxide in an aqueous solution. The set point values are traceable to NIST reference materials.

### REAGENTS

#### COMPOSITION

The Envoy 500 ISE Calibrators contain sodium, potassium, chloride and carbon dioxide with non-reactive preservatives and stabilizers. The set point values for each level are printed on the respective calibrator bottle labels.

#### WARNINGS AND PRECAUTIONS

- These calibrators are for professional *in vitro* diagnostic use only.
- The calibrators should be handled in the same manner as patient samples.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.
- Dispose of contents in accordance with all local, state and federal regulations.

#### PREPARATION

ISE Calibrator is ready for use as packaged.

#### STORAGE AND STABILITY

Store the Envoy 500 ISE Calibrators at 2 to 30 °C. Do not freeze. Do not use ISE Calibrators beyond the expiration date printed on the label. After opening, the calibrator is stable for 30 days when stored at 2 to 30 °C.

### PROCEDURE

#### MATERIALS PROVIDED

The Envoy 500 ISE Calibrator Kit includes the following components:  
 6 x 20 mL Envoy High ISE Calibrator  
 6 x 20 mL Envoy Low ISE Calibrator

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Envoy 500 ISE System.
- Envoy 500 ISE Reference Solution (product no. 55382).
- Envoy 500 ISE Baseline Solution (product no. 55381).
- Envoy 500 Serum Controls (product no. 55131).
- Envoy 500 ISE Cleaner (product no. 55154).
- Envoy 500 ISE Conditioner (product no. 55153).

#### ENVOY ISE CALIBRATOR USE

Do not open the calibrator until you are ready to use it. Before opening the bottle for the first time, mix the calibrator by gently inverting it ten times and write the date on the label. Remove the calibrator sample and immediately cap the calibrator vial.

Gently mix the calibrator prior to each subsequent use. Refer to the operator manual for instructions on entering set points and calibrating the analyzer.

Envoy ISE Calibrators should be used at the beginning of each test day. Fresh calibrator should be dispensed into the sample cup just prior to calibration. Once calibration material has been placed in sample cups, it should be read within 15 minutes and then discarded. ISE Calibration on the Envoy 500 Chemistry System should be performed every four hours or whenever control results are out of range. Recalibration should also be done whenever service is performed or whenever there is a question regarding ISE test performance.









#### CALCULATIONS

All calculations are performed by the instrument.

#### LIMITATIONS

The set points for the Envoy 500 ISE Calibrators are valid only for the Envoy 500 ISE Solutions used on the Envoy 500 Series Analyzers equipped with ISE module.

### GLOSSARY OF SYMBOLS

	Contents		Manufacturer		Catalog No.
	Batch Code		See instruction for use		Use by
	<i>In vitro</i> diagnostic device		Temperature Limitation		

 : Modification from previous version