ENVOY® 500 ISE CLEANER KIT

REF

55154

For *in vitro* diagnostic use, for professional use only



INTENDED USE

Envoy 500 ISE Cleaner Kit is used as a deproteinizer solution for cleaning electrodes on the Envoy 500 Analyzer.

SUMMARY AND PRINCIPLE

Protein build up in the lumen of the chloride and other electrodes can occur over time. If protein build up becomes excessive, flow times and electrode performance can deteriorate and manual cleaning or electrode replacement may be required.

At the end of the working day, the cleaning solution is loaded on the system where it is aspirated into the ISE flow path during the system shut down procedure. The internal surfaces of the electrodes are in contact with the cleaner for five minutes. During this time, the pepsin digests any protein that may have been deposited during the day. After the cleaning process is completed, the solution is automatically washed out of the system and electrodes are left in a conditioned state.

REAGENTS

COMPOSITION

55154A - 1 X 75 mL 0.1N Hydrochloric Acid Diluent 55154B - 6 x > 75 kU Pepsin (porcine)

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use

55154A - Hydrochloric Acid



Warning

May be corrosive to metals. Keep only in original container. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

55154B - Pepsin





Warning

Causes skin irritation. May cause respiratory irritation. Avoid breathing dust. Wash hands thoroughly after handling. Wear protective gloves, eye protection, face protection. If on skin: Wash with plenty of water.

PREPARATION

- 1. Open one small bottle containing Pepsin powder.
- Add ten (10) mL of Hydrochloric Acid Diluent to the powder in the small bottle
- Replace the cap and mix by gentle inversion for at least 1 hour or until dissolved.
- 4. Record the date prepared on the bottle.

STORAGE AND STABILITY

Store the Envoy ISE Cleaner Kit at $2-30\,^{\circ}\text{C}$ (35.6 - 86°F). When properly stored, the reagent is stable until the expiration date on the bottle label. Following reconstitution the reagent is stable for 14 days refrigerated. Bring to room temperature before use on the instrument.

PROCEDURE

MATERIALS PROVIDED

1 X 75 mL 0.1N Hydrochloric Acid Diluent 6 x > 75 kU Pepsin

CLEANING PROCEDURE

- Place the reconstituted cleaning solution in its assigned position on the ISE reagent bar. Allow to come to room temperature.
- The system is programmed to clean, rinse, and condition the electrodes during the shut-down procedure.
- In addition to the reconstituted cleaning solution, make sure there is adequate ISE Diluent and ISE Conditioner on the ISE reagent bar.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local and legal requirements.

DAMAGED PACKAGING

Do not use the solution if the packaging is damaged as this might have an effect on product performance (leakages, pierced/punctured bottle, etc.).

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GLOSSARY OF SYMBOLS

	Manufacturer	LOT	Batch code / Lot number	IVD	In vitro diagnostic medical device
CONT	Contents	M	Use by / Expiration date	[i]	Consult instructions for use
REF	Catalog Number	X	Temperature limitation		