

PIT-SLSY-EN-V1 (05/2022)

INTENDED USE

This solution is intended for washing probes and cuvettes of Selectra Pro Series analyzers.

This accessory for an *in vitro* diagnostic device is for professional use only.

COMPOSITION

Sodium azide < 0.1 % (w/w)
Also contains surfactants

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water, as indicated in the analyzer's user manual.
- General Laboratory equipment (e.g. pipette).
- Selectra Pro Family analyzers and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS

- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Solution contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of this solution always flush with copious amounts of water to prevent azide buildup.
- Consult Safety Data Sheet (SDS) for a proper handling.

STABILITY

Store at 15-25 °C and protect from light. Do not freeze.

Do not use after expiration date indicated on the vial labels.

Diluted solution stability: 2 weeks.

Open vial stability: until product's expiry date.

PREPARATION

Solution needs to be diluted 1/400 in distilled or deionized water, as indicated in the analyzer's user manual.

E.g. 5 mL in 2 L or 12.5 mL in 5 L or 25 mL in 10 L.

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the container may impact on product performance. Do not use the solution if there is physical evidence of deterioration (e.g. leakages or punctured container).

INSTALLATION AND USE

Consult Selectra Pro operator manual corresponding.

LIMITATIONS

The use of SYSTEM SOLUTION has been validated for the Selectra Pro Series analyzers.

Using a different analyzer should be validated by the laboratory.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member State of the European union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.

By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

SYMBOLS

Symbols used are defined in ISO 15223-1 standard, except those presented below :

	Content
	Solution
	Modification from previous version
	European Conformity

TECHNICAL ASSISTANCE

Contact your local distributor or ELITech Clinical Systems SAS (ccsupport@elitechgroup.com).