

PIT-SOL-EN-v1 (05/2022)

INTENDED USE

These solutions are intended for washing Selectra Pro Series analyzers.
These accessories for an *in vitro* diagnostic device are for professional use only.

COMPOSITION

Acid Solution: Acidic solution (pH 1).
System Cleaning Solution: Alkaline sodium hypochlorite solution.

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

- **Acid solution** and **System Cleaning Solution** are classified as hazardous



- Consult Safety Data Sheet (SDS) for a proper handling.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.

STABILITY

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

Do not use after expiration date indicated on the vial labels.
Open vial stability for both solutions : until product's expiry date.

On board-stability:

Acid Solution (pure) : 2 weeks
System Cleaning Solution (diluted) : 2 weeks

PREPARATION

Acid Solution is ready to use.
System Cleaning Solution needs to be diluted 1/10 in distilled or deionized water, as indicated in the analyzer's user manual.

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

Special programming instructions: Verify if the Probe and Test incompatibilities settings in the Selectra Pro instrument are set as indicated in the Special Programming Instructions table on page 2 of this instructions for use.

Consult the Selectra Pro operator manual on how to program these Probe and Test incompatibilities.

LIMITATIONS

The use of ACID SOLUTION and SYSTEM CLEANING SOLUTION has been validated for the Selectra Pro analyzer.
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.

TECHNICAL ASSISTANCE

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

SYMBOLS

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

CONT	Content
SOL	Solution
	Modification from previous version
CE	European Conformity

SPECIAL PROGRAMMING INSTRUCTIONS TABLE

Program the Probe & Test incompatibilities in the Selectra Pro instrument as indicated in the table below

TOUCHPRO SOFTWARE

Probe Incompatibilities

TEST	Type	Reagent
CHOLESTEROL HDL 2G SL	Link	Acid Solution
HDL CHOLESTEROL	Link	Acid Solution
VITAMIN D	Link	Acid Solution
TOTAL PROTEIN PLUS	Incompatibility	MAGNESIUM XYLIDYL
CHOLESTEROL SL	Incompatibility	MAGNESIUM XB

Test Incompatibilities

TEST	Type	Reagent
TRIGLYCERIDES SL	Link	Acid Solution*
VITAMIN D	Link	Acid Solution

*To be programmed only if LIPASE reagent is installed on-board

LIPASE and TRIGLYCERIDES must be run in separate routines.

OTHER SOFTWARE

Needle Incompatibility

CHOLESTEROL HDL 2G SL	Link <<	HCl
HDL CHOLESTEROL	Link <<	HCl
VITAMIN D	Link <<	HCl
TOTAL PROTEIN PLUS	Incompatibility :	MAGNESIUM XYLIDYL
CHOLESTEROL SL	Incompatibility :	MAGNESIUM XB

Cuvette Incompatibility

TRIGLYCERIDES SL	Link <<	HCl*
VITAMIN D	Link <<	HCl

*To be programmed only if LIPASE reagent is installed on-board

LIPASE and TRIGLYCERIDES must be run in separate routines.

