

PIT-SOL-EN-v3 (11/2023)

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: To prevent on-board contaminations of tests, specific installation and programming instructions are required. Please refer to the tables on page 2/3 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 on our documentation are defined on ISO-15223-1 standard, except for some presented in the symbols glossary available on the ELITech Website. (Symbols glossary).

SPECIAL PROGRAMMING INSTRUCTION TABLES

To prevent on-board contaminations of tests, it is recommended that links and incompatibilities are programmed as per the tables below:

1. PREVENTION OF REAGENT NEEDLE CONTAMINATIONS

- **All SELECTRA Pro analyzers:** repeat any strange result after programming a needle wash.

- **SELECTRA ProM**

a. MENU “PROBE/NEEDLE INCOMPATIBILITIES”

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING		
		Test	Type	Reagent
HDL CHOLESTEROL (CHDL)	TRIGLYCERIDES SL (TGML) URIC ACID MONO SL (AUML) URIC ACID SL (AUSL)	HDL CHOLESTEROL (CHDL)	Link / <<	Acid Solution/HCl
TOTAL BILIRUBIN (BITO)	HDL CHOLESTEROL (CHDL)	TOTAL BILIRUBIN (BITO) R1	Link / <<	Acid Solution/HCl
CHOLESTEROL HDL 2G (HDLL)	TRIGLYCERIDES SL (TGML)	CHOLESTEROL HDL 2G (HDLL)	Link / <<	Acid Solution/HCl
VITAMIN D R2 (VITD)	VITAMIN D (VITD)	VITAMIN D (VITD)	Link / <<	Acid Solution/HCl
TOTAL PROTEIN PLUS (PROB)	MAGNESIUM XYLIDYL (MAGX)	TOTAL PROTEIN PLUS (PROB)	Incompatibility / :	MAGNESIUM XYLIDYL (MAGX)
CHOLESTEROL SL (CHSL)	MAGNESIUM XB (MGXB)	CHOLESTEROL SL (CHSL)	Incompatibility / :	MAGNESIUM XB (MGXB)

b. MENU “TEST ORDER/TEST NAME ORDER”

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING
TOTAL BILIRUBIN (BITO)	HDL CHOLESTEROL (CHDL)	CHOLESTEROL (CHSL) must be programmed just before HDL CHOLESTEROL (CHDL)

c. ROUTINE PROGRAMMING

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING
TRIGLYCERIDES SL (TGML)	LIPASE (LPSL)	TRIGLYCERIDES SL (TGML) and LIPASE (LPSL) <u>must be run in separate routines</u>

- **SELECTRA ProS/ProXS**

a. MENU “TEST ORDER/TEST NAME ORDER”

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING
TOTAL BILIRUBIN (BITO)	HDL CHOLESTEROL (CHDL)	CHOLESTEROL (CHSL) must be programmed just before HDL CHOLESTEROL (CHDL)

b. ROUTINE PROGRAMMING

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING
TRIGLYCERIDES SL (TGML)	LIPASE (LPSL)	TRIGLYCERIDES SL (TGML) and LIPASE (LPSL) <u>must be run in separate routines</u>

- **SELECTRA ProXL**

a. REAGENT INSTALLATION: DO NOT INSTALL the following reagents on the same reagent rotor

CONTAMINATING REAGENT	CONTAMINATED REAGENT
TOTAL BILIRUBIN (BITO)	HDL CHOLESTEROL (CHDL)
CHOLESTEROL HDL 2G (HDLL)	TRIGLYCERIDES SL (TGML)
HDL CHOLESTEROL (CHDL)	TRIGLYCERIDES SL (TGML) URIC ACID MONO SL (AUML) URIC ACID SL (AUSL)
TOTAL PROTEIN PLUS (PROB)	MAGNESIUM XYLIDYL (MAGX)
CHOLESTEROL SL (CHSL)	MAGNESIUM XB (MGXB)
TRIGLYCERIDES SL (TGML)	LIPASE (LPSL)

b. MENU “PROBE/NEEDLE INCOMPATIBILITIES”

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING		
		Test	Type	Reagent
VITAMIN D R2 (VITD)	VITAMIN D (VITD)	VITAMIN D (VITD)	Link / <<	Acid Solution/HCl

2. PREVENTION OF CUVETTE CONTAMINATIONS

- MENU “TEST/CUVETTE INCOMPATIBILITIES” for SELECTRA ProM, ProS, ProXL.

CONTAMINATING REAGENT	CONTAMINATED REAGENT	SETTING		
		Test	Type	Reagent
TRIGLYCERIDES SL (TGML)	LIPASE (LPSL)	TRIGLYCERIDES SL (TGML)	Link / <<	Acid Solution/HCl *
MICROALBUMIN (IMAL)	MICROALBUMIN (IMAL)	MICROALBUMIN (IMAL)	Link / <<	Acid Solution/HCl
VITAMIN D (VITD)	(Prevention from latex cuvette staining)	VITAMIN D (VITD)	Link / <<	Acid Solution/HCl
RHEUMATOID FACTOR (IRFA)	(Prevention from latex cuvette staining)	RHEUMATOID FACTOR (IRFA)	Link / <<	Acid Solution/HCl

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

