



DiaSorin Italia S.p.A.
Via Crescentino snc - 13040 Saluggia (VC) - Italy
www.diasorin.com
Tel. +39.0161.4871



Changes: Update of Legal Manufacturer Name;
Deletions: -

LIAISON® XL Cleaning Tool (REF 310995)

1. INTRODUCTION

The LIAISON® XL Cleaning Tool is useful to improve routine maintenance of the LIAISON® XL Analyzer family. It intervenes to clean the washer needles and tubes, according to the indications provided in the user documentation or in the kit specific package insert. The kit can only be used with LIAISON® XL Analyzer family.

The kit is sufficient for 20 maintenance sessions.

Maintenance with LIAISON® XL Cleaning Tool does not replace routine maintenance of the LIAISON® XL analyzer family.

2. STORAGE

Upon receipt (), store the kit in an upright position at room temperature (15-30°C). Reagents should not be used past the expiry date indicated on the kit label. The expiry date of each component is reported on the respective vial label.

After first opening, the CLEAN solution vial is stable for seven days at room temperature (15-30°C).

After removing the seals, the reagent integral is stable for four weeks at room temperature (15-30°C).

3. WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.

For Professional Use Only.

Handle the kit components in accordance with the usual precautions specified for laboratory reagents.

Do not eat, drink, smoke or apply cosmetics in the assay laboratory.

Do not pipette by mouth.

Handle the waste liquids of the analyzer as potentially hazardous biological material. They must be considered potentially able to transmit infectious agents and should therefore be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each Country. Liquid waste must be decontaminated with a chemical use sodium hypochlorite solution with 0.1% active chlorine (e.g. dilution 1:50 of a solution at 5% active chlorine) for at least half an hour.

Do not use kits or components beyond the expiration date given on the label.

Pursuant to EC Regulation 1272/2008 (CLP), **SOLB** is labelled as EUH210 safety data sheets available on request.

For additional information see Safety Data Sheets available on www.diasorin.com.

4. LIAISON® XL Cleaning Tool

4.1. INTENDED USE

The LIAISON® XL Cleaning Tool is intended to clean the washer needles and tubes after a routine involving assays potentially prone to cause clogging of washer needles and tubes, according to the indications provided in the user documentation or in the kit specific package insert.

A sodium hypochlorite solution cleanses the washer needles and tubes. They are rinsed afterwards by the mean of a wash solution.

LIAISON® XL Cleaning Tool is to be used after the completion of the daily routine, as the last operation of the day (prior to possible maintenance sessions) or as the first operation of the next day, before the daily routine.

The frequency of use is detailed in the user documentation or in the kit package insert.

4.2. MATERIALS PROVIDED

LIAISON® XL Cleaning Tool consists of the following components:

CLEAN|INTG **LIAISON® XL CLEAN Integrals** (two units): sufficient for 20 Clean tests (10 Clean tests per integral). One Clean test requires 5 determinations of the integral.

It consists of two vials containing a wash solution (**SOLB** 21 mL).

CLEAN|SOL **CLEAN Solution vial** (10 units, each 3.5 mL): contains a sodium hypochlorite solution. The CLEAN Solution is not intended as a bactericide agent. 1 CLEAN solution vial is sufficient for 2 Clean tests.

4.3. SYSTEM SET-UP

Before using the LIAISON® XL Cleaning Tool **the first time**, the assay protocol has to be imported: see the instrument guide.

Insert **CLEAN** test in a suitable assay group.

4.4. HOW TO USE THE LIAISON® XL Cleaning Tool

Insert the LIAISON® XL CLEAN Integral in the reagent area, handling it like any integral. No resuspension step is required.

Insert a CLEAN Solution vial in an L tube rack and remove the cap.

Insert the L rack in any position of the sample area.

Associate the CLEAN sample to the CLEAN test. Start the test.

The CLEAN test lasts about 14 minutes.

When it finishes, extract the integral, extract and recap or dispose the CLEAN solution vial as applicable. The CLEAN solution vial is intended to support a maximum of two runs. Remnants should not be pooled.

Store reagents as described.

Note: the user should not:

- start a CLEAN test while an analytical routine is running,
- increase the number of replicates (5) provided by default,
- start a further run of CLEAN test while the previous one is already running,
- leave the CLEAN solution vial uncapped after the completion of the run.

4.5. EXPECTED RESULTS

After running the CLEAN test, the RLU (relative light units) results associated to the CLEAN test in the Results list of the User Software (GUI), are not significant.

For EU only: please be aware that any serious incident that has occurred in relation to this IVD medical device should be reported to DiaSorin and the competent authority of the EU Member State in which the user and/or patient is established.

200/007-986, 05 - 2022-07

For Customer service in the U.S. and Canada call toll-free: 1-800-328-1482

Distributed in the U.S. by DiaSorin Inc., Stillwater, MN, USA.