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Deletions: §

LIAISON® Wash/System Liquid ([REF] 319100)

1. INTENDED USE

LIAISON® Wash/System Liquid is required on the LIAISON® and LIAISON® XL analyzers to wash the magnetic particles used in LIAISON® immunoassays. The LIAISON® Wash/System Liquid is also required for rinsing the pipetting needles and tubing system of the LIAISON® Analyzer. The device is intended for *in vitro* diagnostic use in a professional laboratory setting on the automated LIAISON® Analyzer family.

CONTENTS

MATERIAL PROVIDED

[REF] 319100

6 bottles for approximately 1000 determinations each

6 x 1 L LIAISON® Wash/System Liquid (10 x concentrate) :
phosphate buffer solution, < 0.1% sodium azide



For additional details such as proper test performance of LIAISON® assays consult instructions for use of the assay to be performed.

2. PREPARATION

NOTE: Prepare LIAISON® Wash/System Liquid at least 6 hours prior to use.

- Use only the DiaSorin approved 10 L containers provided with the LIAISON® and LIAISON® XL analyzers.
- Fill the 10 L container with purified water up to the 9 L filling mark.

NOTE: Use only water defined according to CLSI guidelines for laboratory “Instrument Feed Water” as indicated in the corresponding LIAISON® or LIAISON® XL user manual.

- Add the contents of 1 bottle of LIAISON® Wash/System Liquid slowly to avoid the formation of foam.
- Gently mix the Wash/System Liquid and water solution continuing to avoid the formation of foam.
- Place the cap on the container. Keep the cap loose (do not screw the cap down completely) to allow proper degassing of the Wash/System Liquid solution.
- The prepared Wash/System Liquid container must sit (without being connected to the analyzer) for a period of no less than 6 hours until degassing is complete.

NOTE: When pooling remaining degassed Wash/System Liquid from 1 container to another, the pooled container must sit isolated (without being connected to the analyzer) for a period of no less than 6 hours until degassing is complete.

Once the 6 hour degassing period has passed, screw the cap down completely on the container and connect the container to the analyzer following the corresponding LIAISON® or LIAISON® XL user manual.

3. STORAGE AND SHELF-LIFE

- Storage of Wash/System Liquid concentrate: At 15 – 30°C until the expiration date on the label.
- Shelf-life of prepared Wash/System Liquid: 4 weeks at 15 – 30°C.
- **Keep away from direct light.**

4. WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE – Not for internal or external use in humans or animals.

GENERAL SAFETY

- All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Avoid contact with skin, eyes or mucous membranes. Follow good industrial hygiene practices during testing.
- Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
- Do not pipet solutions by mouth.
- Avoid direct contact with all potentially infectious materials by wearing lab coat, protective eye/face wear and disposable gloves.
- Wash hands thoroughly at the end of each assay.
- Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
- Waste materials should 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.
- Do not use kits or components beyond the expiration date given on the label.

Chemical Hazard and Safety Information: Reagents in this kit are classified in accordance with US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and applicable European Union directives (see Material Safety Data Sheet for additional information).

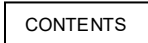
GHS/CLP:

	Sodium Azide
CAS No.:	26628-22-8
Reagents:	BUF WASH 10X
Classification:	None required
Signal Word:	None required
Pictogram:	None required
Hazard Statements:	None required
Precautionary Statements:	None required

The Symbols Glossary and Safety Data Sheet are provided electronically at www.diasorin.com.

REAGENTS CONTAINING SODIUM AZIDE: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976.

SYMBOLS USED WITH DEVICES

	English
	European Conformity
	Expiration Date
	Manufacturer
	Consult Instructions for Use
	<i>In vitro</i> diagnostic.
	Lot No.
	Temperature limitation.
	Material Provided
	Keep away from direct light.
	Keep upright for storage.

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.



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