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LIAISON® TrimericS IgG Diluent Accessory (REF 311512)

1. INTENDED USE

The LIAISON® TrimericS IgG Diluent Accessory is intended for diluting specimens with high levels of anti-trimeric spike protein specific IgG antibodies to SARS-CoV-2 above the assay measuring range > 2080 BAU/mL for use with the LIAISON® SARS-CoV-2 TrimericS IgG assay. The device is intended for *in vitro* diagnostic use in a professional laboratory setting on the automated LIAISON® Analyzer family.

2. MATERIALS PROVIDED

Specimen Diluent 1 x 50 mL		Phosphate buffer containing BSA, non-specific recombinant protein (produced in <i>E. coli</i>), detergent, EDTA, 0.2% ProClin® 300, preservatives.
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ProClin® is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

All lots of LIAISON® TrimericS IgG Diluent Accessory are interchangeable between LIAISON® SARS-CoV-2 TrimericS IgG lots.

3. 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 pipette 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:

	ProClin®
CAS No.:	55965-84-9
Reagents:	DILSPE
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3
Signal Word:	Warning
Pictogram:	 GHS07 – Exclamation mark
Hazard Statements:	H317 – May cause an allergic skin reaction. H412 – Harmful to aquatic life with long lasting effects
Precautionary Statements:	P261 – Avoid breathing dust, fumes, gas, mist, vapors or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves, protective clothing, eye protection, and face protection.

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

4. PREPARATION AND USE

The LIAISON® TrimericS IgG Diluent Accessory is provided ready to use. The LIAISON® TrimericS IgG Diluent Accessory must be loaded onto the analyzer in the ancillary reagent area. After use, recap the vial promptly and store at 2-8°C in an upright position.

Each LIAISON® TrimericS IgG Diluent Accessory bottle is identified via information encoded in the reagent Radio Frequency Identification transponder (RFID tag). In the event that the RFID Tag cannot be read by the analyzer, the diluent accessory bottle cannot be used. Do not discard the reagent: contact your local DiaSorin technical support for instruction.

In order to maintain reagent traceability on the analyzer, do not separate the LIAISON® TrimericS IgG Diluent Accessory bottle from the ancillary holder.

Refer to the analyzer operators manual for details on the reagent use in the ancillary reagent area on board the analyzer.

5. STORAGE

Store the LIAISON® TrimericS IgG Diluent Accessory at 2-8°C upon receipt. The LIAISON® TrimericS IgG Diluent Accessory is stable until the expiration date on the vials when stored unopened at 2-8°C. Once opened, the diluent is stable for 4 weeks.

6. LIMITATIONS

1. The LIAISON® TrimericS IgG Diluent Accessory is designed for use with the LIAISON® SARS-CoV-2 TrimericS IgG assay on the LIAISON® XL and LIAISON® XS Analyzer.
2. Improper reagent storage or technical errors may result in discordant results.
3. Indications of possible deterioration include the presence of particulate matter in the liquid or significant deviation from previous results.
4. Patient antibodies to SARS-CoV-2 are heterogeneous, which may lead to a non-linear dilution response.

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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