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Changes: § 3
Deletions: §

LIAISON® 1-84 PTH Specimen Diluent (REF 310632)

1. INTENDED USE

The LIAISON® 1-84 PTH Specimen Diluent is intended for use with the LIAISON® 1-84 PTH Assay for diluting patient specimens with high levels of 1-84 PTH > 1800 pg/mL. The LIAISON® 1-84 PTH Specimen Diluent Set is designed for use with the LIAISON® 1-84 PTH Assay (310630). 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 4 x 3.0 mL	DIL SPE	Equine serum with additives for stability and 0.2% ProClin® 300.

ProClin is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

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 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:

	ProClin®
CAS No.:	55965-84-9
Reagents:	DIL SPE
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 mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves and clothing, and eye protection.

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

4. PREPARATION AND USE

The specimen diluent is provided in liquid form and is ready to use. The suggested dilution for high patient samples is either 1:2 or 1:4 dilutions. Final sample results must be corrected for the dilution factor.

Example 1:2:
200 µL High patient sample + 200 µL Diluent.

Example 1:4:
100 µL High patient sample+ 300 µL Diluent.

5. STORAGE

Store the Specimen Diluent at 2-8°C upon receipt. The Specimen Diluent is stable until the expiration date on the vials when stored at 2-8°C. The Specimen Diluent is stable for 4 weeks once opened when stored at 2-8°C. Indications of possible deterioration include the presence of particulate matter in the liquid or significant deviation from previous results.

6. LIMITATIONS

EDTA plasma samples diluted with Specimen Diluent should be placed on ice after dilution and tested immediately (within 60 minutes).

The LIAISON® 1-84 PTH Specimen Diluent is designed for use with the LIAISON® 1-84 PTH Assay and the LIAISON® Analyzer family.

Improper reagent storage or technical errors may result in discordant results.

Indications of possible deterioration include the presence of particulate matter in the liquid or significant deviation from previous results.

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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