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Changes: §
Deletions: §

LIAISON® Thymidine Kinase Specimen Diluent Set (REF 310962)

1. INTENDED USE

The LIAISON® Thymidine Kinase Specimen Diluent is intended for use with the LIAISON® Thymidine Kinase assay for diluting specimens with high levels of Thymidine Kinase > 100 U/L. 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	Human serum with additives for stability and 0.09% NaN_3

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).

Reagents Containing Human Source Material:
Warning – Treat as potentially infectious. Each serum/plasma donor unit used in the preparation of this product has been tested by a U.S. FDA approved method and found non-reactive for the presence of the antibody to Human Immunodeficiency Virus 1 and 2 (HIV 1/2), the Hepatitis B surface antigen (HBsAg), and the antibody to Hepatitis C (HCV). While these methods are highly accurate, they do not guarantee that all infected units will be detected. This product may also contain other human source diseases for which there is no approved test. Because no known test method can offer complete assurance that HIV, Hepatitis B Virus (HBV) and HCV or other infectious agents are absent, all products containing human source material should be handled following universal precautions; and as applicable in accordance with good laboratory practices as described in the Centers for Disease Control and the National Institutes of Health current manual, Biosafety in Microbiological and Biomedical Laboratories (BMBL); or the World Health Organization current edition, Laboratory Biosafety Manual.

GHS/CLP:

	Sodium Azide
CAS No.:	26628-22-8
Reagents:	DIL SPE
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.

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 1:3. Final sample result must be corrected for the dilution factor.
Example of 1:3 dilution:
200 µL diluent + 100 µL high patient sample.

All lots of sample diluent are interchangeable among all LIAISON® Thymidine Kinase integral lots.

5. STORAGE

Store the LIAISON® Thymidine Kinase 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.
Once opened, the sample diluent is stable for 2 weeks.

6. LIMITATIONS

The DiaSorin LIAISON® Thymidine Kinase Specimen Diluent is designed for use with the LIAISON® Thymidine Kinase assay and the LIAISON® Analyzer family.

Improper reagent storage or technical errors may result in erroneous 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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