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Changes: § 3
Deletions: §

LIAISON® XL 1,25 Dihydroxyvitamin D Controls (REF 310984)

1. INTENDED USE

The DiaSorin LIAISON® XL 1,25 Dihydroxyvitamin D Controls are intended for use as assayed quality control samples to monitor the performance of the DiaSorin LIAISON® XL 1,25 Dihydroxyvitamin D assay. The performance characteristics of LIAISON® XL 1,25 Dihydroxyvitamin D Controls have not been established for any other assays or instrument platforms different from the LIAISON® XL and LIAISON® XS.

LIAISON® XL Analyzer The certificate of analysis bar codes give specific information on the lot of controls and should be read by the hand-held bar code scanner of the LIAISON® XL Analyzer prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

LIAISON® XS Analyzer The certificate of analysis bar codes give specific information on the lot of controls and should be read by the hand-held bar code scanner of the LIAISON® XS Analyzer prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

2. MATERIALS PROVIDED

Control Level 1 (2 x 2 mL) lyophilized	CONTROL 1	Low level of $1,25(OH)_2D$ in human serum, 0.01% gentamicin sulfate and 0.2% ProClin® 300 and < 0.09% sodium azide.
Control Level 2 (2 x 2 mL) lyophilized	CONTROL 2	High level of $1,25(OH)_2D$ in human serum 0.01% gentamicin sulfate and 0.2% ProClin® 300.

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

Bar Code Labels for Controls 1 and 2

Materials Required But Not Provided

- Pipettes capable of delivering 1-2 mL
- Pipettes capable of delivering 75 - 225 µL
- Glass or plastic (polypropylene) 12 x 75 mm sample tubes

Controls are not kit lot specific and may be safely interchanged between different LIAISON® 1,25 Dihydroxyvitamin D Reagent Integral 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).

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 an 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:

	ProClin®	Sodium Azide
CAS No.:	55965-84-9	26628-22-8
Reagents:	CONTROL 1 CONTROL 2	CONTROL 1
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3	None required
Signal Word:	Warning	None required
Pictogram:	 GHS07 – Exclamation mark	None required
Hazard Statements:	H317 – May cause an allergic skin reaction. H412 – Harmful to aquatic life with long lasting effects.	None required
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.	None required

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. STORAGE AND STABILITY

Store the LIAISON® XL 1,25 Dihydroxyvitamin D Controls at 2-8°C upon receipt and prior to reconstitution. The lyophilized controls are stable until the expiration date on the vials when stored at 2-8°C. Reconstituted controls are stable for 8 hours at room temperature or 6 weeks at 2-8°C. Aliquot and freeze remaining controls at -20°C. Controls are stable through 4 freeze thaw cycles. Indications of possible deterioration include the presence of particulate matter in the liquid or significant deviation from previous results.

5. QUALITY CONTROL

Quality control is required to be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. It is recommended that the user refer to CLSI C24-A3 and 42 CFR 493.1256 (c) for guidance on appropriate quality control practices.

LIAISON® XL 1,25 Dihydroxyvitamin D controls are intended to monitor for substantial reagent failure. If controls lie outside the expected ranges, calibration should be repeated, and controls and samples retested.

Do not report patient results until control results are within expected ranges. Strict adherence to the instructions of the LIAISON® XL 1,25 Dihydroxyvitamin D assay is necessary to obtain reliable results.

6. PREPARATION AND USE

The LIAISON® XL 1,25 Dihydroxyvitamin D Controls are provided lyophilized. Reconstitute controls with 2 mL of distilled or deionized water. Allow controls to dissolve on bench top for **15** minutes. Mix thoroughly by gentle inversion to ensure complete reconstitution. If using frozen aliquot, mix by gentle inversion prior to use. Transfer a minimum of 225 µL to a sample tube. Affix the appropriate bar code label to the tube and place onto the appropriate sample rack with barcode label facing outward. Slide rack into the patient sample area. Control identification is detected by the barcode label or may be manually programmed into the analyzer. Follow the analyzer operator's manual to start the run. Discard any unused portion of the control remaining in the tube after assaying.

7. LIMITATIONS

Control values for assays other than the LIAISON® XL 1,25 Dihydroxyvitamin D assay have not been established. If users wish to use this control material with other assays, it is their responsibility to establish appropriate ranges.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate reference ranges should be established for all quality control materials used.

If control values obtained after successful calibration lie repeatedly outside the expect ranges, the test should be repeated using an unopened control vial.

8. ASSIGNED VALUES

The range of concentrations of each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.

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