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Changes: § 1, 2, 3
Deletions: §

**LIAISON® Calprotectin Control Set (REF 318961)**

## 1. INTENDED PURPOSE

The LIAISON® Calprotectin Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Calprotectin assay. The performance characteristics of the LIAISON® Calprotectin controls have not been established for any other assay or instrument platforms different from the LIAISON® Analyzer family. The device is intended for in vitro diagnostic use in a professional laboratory setting.

## 2. MATERIALS PROVIDED

| | | |
|---|---|---|
| Control Level 1<br>(2 x 1.0 mL)<br>Lyophilized | CONTROL 1 | Low level of recombinant calprotectin antigen in a buffered solution containing BSA, surfactant, 0.1% ProClin™ 300 and 0.05% gentamicin sulfate. Reconstitute in 1 mL distilled or deionized water. |
| Control Level 2<br>(2 x 1.0 mL)<br>Lyophilized | CONTROL 2 | High level of recombinant calprotectin antigen in a buffered solution containing BSA, surfactant, 0.1% ProClin™ 300 and 0.05% gentamicin sulfate. Reconstitute in 1 mL distilled or deionized water. |

ProClin is a trademark of the LANXESS Corp.

Materials Required But Not Provided:

- Pipette capable of accurately delivering 250 µL
- Glass or polypropylene sample tubes
- Pipette capable of accurately delivering 1.0 mL

Controls are not kit lot specific and may be safely interchanged between different LIAISON® Calprotectin Reagent Integral lots.

## 3. WARNINGS AND PRECAUTIONS

**FOR *IN VITRO* DISAGNOSTIC 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: | CONTROL 1<br>CONTROL 2 |
| Classification: | Skin sensitization, Category 1<br>Aquatic Chronic, Category 3 |
| Signal Word: | Warning |
| Pictogram: |  <br>GHS07 – Exclamation mark |
| Hazard Statements: | H317 – May cause an allergic skin reaction.<br>H412 – Harmful to aquatic life with long lasting effects. |
| Precautionary Statements: | P261 – Avoid breathing mist or spray.<br>P272 – Contaminated work clothing should not be allowed out of the workplace.<br>P273 – Avoid release to the environment.<br>P280 – Wear protective gloves and clothing, and eye protection. |

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

## 4. STORAGE AND STABILITY

Store the controls at 2-8°C upon receipt. Prior to reconstitution the controls are stable until the expiration date on the vial labels when stored at 2-8°C. Reconstituted controls are stable for at least six (6) hours at room temperature or 28 days at 2-8 °C. Aliquot and freeze remaining controls at -20 °C for up to eight (8) weeks. LIAISON® Calprotectin controls are stable for four (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® Calprotectin 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® Calprotectin Assay is necessary to obtain reliable results.

## 6. PREPARATION AND USE

The LIAISON® Calprotectin Control Set is provided lyophilized. Reconstitute each vial with 1.0 mL of distilled or deionized water. Allow the vials to stand for 5 minutes at room temperature and mix gently by inversion. If using a frozen aliquot, mix gently by inversion prior to use. Transfer a minimum of 250 µL to a glass or plastic tube. Affix the appropriate bar code label to the tube and place onto sample rack “A” 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® Calprotectin 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.

**LIAISON® Analyzer**. The certificate of analysis gives specific information on the lot of controls, which should be manually entered in the analyzer software prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

**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.

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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