DiaSorin Inc.
1951 Northwestern Ave – Stillwater, MN 55082 – USA
www.diasorin.com
Tel 1.651.439.9710 – Fax 1.651.351.5669

Changes: § 1, 3, 4
Deletions: § 3

LIAISON® Calcitonin II-Gen Control Set (REF 310651)

1. INTENDED PURPOSE

The DiaSorin LIAISON® Calcitonin II-Gen Control Set is intended for use as assayed quality control samples to monitor the DiaSorin LIAISON® Calcitonin II-Gen Assay.
The performance characteristics of LIAISON® Calcitonin II-Gen controls have not been established for any other assays or instrument platforms different from LIAISON® Analyzer family*.

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.

2. SUMMARY AND EXPLANATION OF THE TEST

The DiaSorin LIAISON® Calcitonin II-Gen Control Set contains human serum-based samples. The controls will assist in the evaluation of proper performance of the LIAISON® Calcitonin II-Gen Assay when performed on the LIAISON® Analyzer.

3. MATERIALS PROVIDED

The following materials are provided in the Control Set:

Control Level 1 4 vials – 2 mL each Lyophilized	CONTROL 1	Human serum, 0.2% ProClin™ 300 and calcitonin. Reconstitute in 2 mL distilled or deionized water. Store and aliquot reconstituted control at -20°C.
Control Level 2 4 vials – 2 mL each Lyophilized	CONTROL 2	Human serum, 0.2% ProClin™ 300 and calcitonin. Reconstitute in 2 mL distilled or deionized water. Store and aliquot reconstituted control at -20°C.

ProClin is a trademark of the LANXESS Corp.

20 Barcode labels for each level of Control

Materials required but not provided:

- Transfer pipette capable of delivering 400 µL.
- Glass or polypropylene sample tubes

* LIAISON®, LIAISON® XL, LIAISON® XS

4. 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).

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™
CAS No.:	55965-84-9
Reagents:	CONTROL 1 CONTROL 2
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.

5. 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 vials when stored at 2-8°C. Reconstituted controls should be stored frozen at -20°C and are stable up to six (6) weeks. The aliquoted frozen controls can be used after one (1) freeze-thaw cycle. Indications of possible deterioration include the presence of particulate matter in the liquid or significant deviation from previous results.

6. 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® Calcitonin II Gen 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® Calcitonin II Gen is necessary to obtain reliable results.

7. PREPARATION AND USE

The LIAISON® Calcitonin II-Gen Control Set is provided in lyophilized form to be stored at 2-8°C. Reconstitute each vial with 2.0 mL of distilled or deionized water. Allow the vials to stand for 5-10 minutes at room temperature; mix gently by inversion. Transfer approximately 350 µL to a glass or plastic tube. Affix the appropriate bar code label to the tube and place onto the LIAISON® Analyzer. Discard any unused portion of the control remaining in the tube after assaying. Calcitonin is a labile peptide and controls should be placed on ice after reconstitution if not immediately assayed. Calcitonin controls have been shown to be stable for 2 hours when stored on ice or 1 hour when stored at room temperature. Remaining reconstituted controls should be aliquoted into a minimum of 400 µL and frozen immediately at -20°C. When thawing frozen aliquot, mixing is required.

8. LIMITATIONS

Control values for assays other than the LIAISON® Calicitonin II Gen 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.

9. 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.

DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082
USA

UK Responsible Person:
DiaSorin Italia S.p.A.
UK Branch
Central Road
Dartford Kent DA1 5LR
UK

EC REP
DiaSorin Italia S.p.A.
Via Crescentino snc
13040 Saluggia (VC)
Italy