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

Changes: § 3
Deletions: §

LIAISON® Androstenedione Control Set (REF 318871)

1. INTENDED USE

The DiaSorin LIAISON® Androstenedione Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Androstenedione assay. The performance characteristics of the LIAISON® Androstenedione controls have not been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL.

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 calibration verifier vials on board. For details, refer to the analyzer operator's manual.

2. MATERIALS PROVIDED

Control Level 1 (2 x 2 mL)	CONTROL 1	Human hormone free serum containing androstenedione, 0.2% ProClin® 300 and 0.01% gentamicin sulfate.
Control Level 2 (2 x 2 mL)	CONTROL 2	Human hormone free serum containing androstenedione, 0.2% ProClin® 300 and 0.01% gentamicin sulfate.

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

All reagents are supplied ready to use.

Controls are not kit lot specific and may be safely interchanged between different LIAISON® Androstenedione 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 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.

4. STORAGE AND STABILITY
Store the controls at 2-8°C upon receipt. Controls are stable until the expiration date on the vial labels when stored at 2-8°C. Once opened, controls are stable for 4 weeks when properly stored at 2-8°C between uses. 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® Androstenedione 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® Androstenedione is necessary to obtain reliable results.

6. PREPARATION AND USE
The LIAISON® Androstenedione Control Set is provided ready to use. Allow controls to reach room temperature prior to use and mix thoroughly by gentle inversion. Remove caps from the controls and place controls intoappropriate sample rack type with the barcode showing outward and slide rack into the patient sample area. Control identification is detected by the bar code label or may be manually programmed into the instrument. Follow the analyzer operator's manual to start the run. Return controls to the refrigerator immediately after each use.

7. LIMITATIONS

Control values for assays other than the LIAISON® Androstenedione 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.

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