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Changes: § 6,7,8
Deletions: § 4

LIAISON® Control HSV-1 IgG (REF 310831)

1. INTENDED USE

The LIAISON® Control HSV-1 IgG (REF 310831) are to be used to provide daily quality control of the LIAISON® HSV-1 Type Specific IgG chemiluminescent immunoassay (CLIA). The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON®, LIAISON® XL and LIAISON® XS.

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. MATERIALS PROVIDED

Negative Control (0.7 mL) 2 vials	CONTROL -	Human serum/defibrinated plasma, non-reactive for HSV-1 IgG antibodies 0.2% ProClin® 300.
Positive Control (0.7 mL) 2 vials	CONTROL +	Human serum/defibrinated plasma reactive for HSV-1 IgG antibodies, 0.2% ProClin® 300.

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 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 - CONTROL +
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
Upon receipt, the controls must be stored at 2-8°C in an upright position to prevent adherence of the solution to the vial cap. Do not freeze. When controls are stored sealed and kept upright, they are stable at 2-8°C up to the expiry date. Once opened controls are stable for 4 weeks when properly stored at 2-8°C between 2 successive uses. Avoid bacterial contamination of controls. The controls should not be used past the expiry date indicated on the vial labels.

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® HSV-1 controls are intended to monitor for substantial reagent failure. Whenever 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® HSV-1 Type Specific IgG assay is necessary to obtain reliable results.

6. PREPARATION AND USE
The LIAISON® Control HSV-1 IgG is provided liquid. Transfer a minimum of 160 µL to a glass or plastic tube. Affix the appropriate bar code label to the tube and place onto 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.

7. LIMITATIONS
Control values for assays other than the LIAISON® HSV-1 Type Specific IgG 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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