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Changes: Update of Legal Manufacturer name
Deletions: -

LIAISON® Control S100 (REF 319112)

1. INTENDED USE

The LIAISON® S100 controls (low and high) are to be used in LIAISON® chemiluminescent immunoassays (CLIA) as a means of checking reliability of assay runs. The performance characteristics of LIAISON® Control S100 have not been established for any other assays or instrument platforms different from LIAISON® and LIAISON® XL.

2. MATERIALS PROVIDED

Control reagent for 6 determinations in singlicate per vial:		
2 x 1.0 mL	CONTROL 1	Control low: containing S-100B antigen from bovine brain, Ovalbumin (chicken), 0.09% sodium azide.
2 x 1.0 mL	CONTROL 2	Control high: containing S-100B antigen from bovine brain, Ovalbumin (chicken), 0.09% sodium azide.

The controls are provided lyophilized. Reconstituted reagents are slightly turbid.

The controls consist of S-100 protein. This S-100 protein originates from purified and well-characterized material. Controls are calibrated against in-house reference S-100 material.

The range of concentrations of each control indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.
LIAISON® Analyzer. The Certificate of Analysis reports specific information on the lot of controls, which have to be manually inserted in the analyzer's software prior to loading the control vials onboard. For details, refer to the analyzer operator's manual.

LIAISON® XL Analyzer. The Certificate of Analysis reports barcodes containing specific information on the lot of controls, which are to be read by the hand-held barcode scanner of the LIAISON® XL Analyzer prior to loading the control vials onboard. For details, refer to the analyzer operator's manual.
Each laboratory is responsible for adopting different limits to meet individual requirements.

3. WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.
Controls are not kit lot specific and may be safely interchanged even from different lots.
Observe the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Observe quality control guidelines for medical laboratories.
As, however, no absolute assurance can be given that pathogens are absent, all components of human and animal origin should be considered potentially infectious and handled with care.

4. SAFETY PRECAUTIONS

Do not eat, drink, smoke or apply cosmetics during the assay.
Do not pipette by mouth.
Avoid direct contact with all potentially infectious materials by wearing laboratory clothing, protective goggles and disposable gloves. Wash hands thoroughly at the end of each assay.
Avoid splashing or forming an aerosol. Any drops of biological reagent must be removed with a sodium hypochlorite solution with 0.5% active chlorine, and the means used must be treated as infected waste.
All samples and reagents containing biological materials used for the assay must be considered potentially able to transmit infectious agents; the waste must be handled with care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country. Any materials for reuse must be appropriately sterilized in compliance with the local laws and guidelines. Check the effectiveness of the sterilization/decontamination cycle.

Do not use kits or components beyond the expiration date given on the label.

Reagents containing sodium azide (< 0.1%) [EC no: 247-852-1]:

DIRECTIVE	**EC No. 1272/2008**
HAZARD / RISK STATEMENTS	**EUH 210 -** Safety data sheet available on request

5. PREPARATION OF REAGENTS

Reconstitute with 1.0 mL deionized or distilled water.
Allow the vials to stand for 15 minutes, at approximately 18-25 °C.
Mix thoroughly by gentle inversion, avoid foaming.
The minimum volume required is 500 µL (100 µL control + 400 µL dead volume).
Keep the controls onboard the instrument only for the amount of time required for quality control testing.
After use, stopper the vials promptly and store them at 2-8 °C in an upright position.
During handling, use appropriate precautions to avoid bacterial contamination of controls.

6. STORAGE AND STABILITY

Upon receipt, the controls must be stored at 2-8 °C in an upright position to prevent adherence to the vial cap.
Unopened: at 2-8 °C until the expiry date.
Reconstituted: 2 hours onboard. Stored at -20 °C or + 2-8 °C during 12 weeks.
The controls may not be frozen and thawed more than three (3) times.
The controls must be used within the expiry date printed on the label.

7. HANDLING

For proper handling please refer to the analyzer operator´s manual.

8. TARGET VALUES

The target values and ranges of S100 concentrations in the controls are printed on the Certificate of Analysis. They have been established after taking into account run variability with respect to the stored master curve, in order to guarantee accuracy of analytical results and to obtain indications on stability or deterioration of reagents. If controls values lie repeatedly outside the expected ranges, the test has most probably been performed incorrectly.