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Changes: § 1, 2
Deletions: -

LIAISON® IGF-I Control (REF 319134)

1. INTENDED USE

The LIAISON® IGF-I 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® IGF-I Control have not been established for any other assays or instrument platforms different from LIAISON® and LIAISON® XL and LIAISON® XS.

2. MATERIALS PROVIDED

Control reagent for 20 determinations in singlicate per vial:				
2	x 1.0	mL	CONTROL 1	Control low: contains IGF-I (human, recombinant) in bovine serum albumin solution, 0.1% ProClin® 300
2	x 1.0	mL	CONTROL 2	Control high: contains IGF-I (human, recombinant) in bovine serum albumin solution, 0.1% ProClin® 300
12	x white		CONTROL 1 Barcode label, small	For labeling the aliquoted control tubes for application on the LIAISON® Analyzer family
12	x white		CONTROL 2 Barcode label, small	For labeling the aliquoted control tubes for application on the LIAISON® Analyzer family

The controls are provided lyophilized.

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 on board. 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 on board. For details refer to the analyzer operator's manual.

LIAISON® XS 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® XS Analyzer prior to loading the control vials onboard. For details, refer to the analyzer operator's manual.

3. WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.
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.
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.

4. SAFETY PRECAUTIONS

Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
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 ProClin®:

DIRECTIVE	**EC No. 1272/2008**
REAGENTS	CONTROL 1 CONTROL 2
CLASSIFICATION OF SUBSTANCE	Skin sensitizer, Category 1
SIGNAL WORD	Warning!
SYMBOLS / PICTOGRAMS	 GHS07 - Exclamation mark
HAZARD / RISK STATEMENTS	H317 - May cause an allergic skin reaction.
PRECAUTIONARY / SAFETY STATEMENTS	P261 - Avoid breathing mist or spray. P280 - Wear protective gloves and clothing and eye protection. P363 - Wash contaminated clothing before reuse
CONTAINS: (only substances prescribed pursuant to Article 18 of EC Regulation 1272/2008).	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (ProClin® 300).

5. PREPARATION OF REAGENTS

Reconstitute with 1.0 mL deionized or distilled water.
Allow the vials to stand for 10 minutes, at approximately 18-25 °C.
Mix thoroughly by gentle inversion, avoid foaming.
The minimum volume required is 420 µL (20 µL control + 400 µL dead volume).
Immediately after complete reconstitution it is possible to aliquot the controls in plastic or siliconized tubes and deep-freeze them. The minimum volume of the aliquot is 170 µL (20 µL control + 150 µL dead volume).
Only one freeze and thaw cycle is allowed for each aliquot.
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

Lyophilized: Stable at 2-8 °C until the expiry date.
Reconstituted: Stable for 1 day at 18-25 °C; 5 days when properly stored at 2-8 °C.
Frozen: Aliquots can be stored at -20 °C for up to one month. After thawing the controls must be used up in the same day.

7. HANDLING

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

8. TARGET VALUES

The target values and ranges of IGF-I 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.