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Changes: §1;
Deletions: -

LIAISON® Control LymeDetect® (REF 311031)

1. INTENDED PURPOSE

The LIAISON® LymeDetect® controls (IgG/IgM negative, IgG positive, IgM positive, QFL level 1 and QFL level 2) are to be used in LIAISON® chemiluminescence immunoassays (CLIA) as a means of checking reliability of assay runs. The performance characteristics of LIAISON® LymeDetect® controls have not been established for any other assays or instrument platforms different from LIAISON® XL and LIAISON® XS analyzers.

The Controls are intended to monitor the reliability of the assays of the individual markers, and not for the reliability of the combination thereof for final interpretation and patient classification.

LIAISON® XL Analyzer. The certificate of analysis bar codes provides, in the relevant area, 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 provides, in the relevant area, 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

Included in the kit

IgG/IgM Negative control (2 x 0.9 mL)	CONTROL - IgG/IgM	Human serum or defibrinated plasma non-reactive for both *Borrelia burgdorferi* IgG and IgM antibodies, 0.2% ProClin® 300 and gentamicin sulfate as preservatives.
IgG Positive control (2 x 0.7 mL)	CONTROL + IgG	Human serum/plasma reactive for *Borrelia burgdorferi* IgG antibodies, stabilized in PBS buffer, BSA, 0.2% ProClin® 300, an inert yellow dye.
IgM Positive control (2 x 0.9 mL)	CONTROL + IgM	Human serum/plasma reactive for *Borrelia burgdorferi* IgM antibodies, stabilized in PBS buffer, BSA, 0.2% ProClin® 300, an inert yellow dye.
QFL Control level 1 (lyophilized, 2 x 2 mL)	CONTROL 1 QFL	Recombinant human IFN-γ (produced in *E. coli*), HEPES buffer, BSA, bovine serum, 0.4% ProClin® 300, 0.2 g/L gentamicin sulfate.
QFL Control level 2 (lyophilized, 2 x 2 mL)	CONTROL 2 QFL	Recombinant human IFN-γ (produced in *E. coli*), HEPES buffer, BSA, bovine serum, 0.4% ProClin® 300, 0.2 g/L gentamicin sulfate.
2 Barcode labels for reconstituted QFL control level 1.		
2 Barcode labels for reconstituted QFL control level 2.		

IgG and IgM controls are provided in liquid form and ready to use.

QuantiFERON® controls are provided lyophilized.

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. Each laboratory is responsible for adopting different limits to meet individual requirements.

3. WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For Laboratory Professional Use Only.
- Visually inspect the vials for leaking. If the vials are found to be leaking, the local customer service should be notified immediately.
- Controls are not kit lot specific and may be safely interchanged even with different reagent integral lots.
- All materials used to produce the components provided in this kit have been tested for the presence of HBsAg, anti-HCV, anti-HIV-1, anti-HIV-2 and found to be non-reactive. However, as no test method can offer absolute assurance of the absence of pathogens, all specimens of human origin should be considered potentially infectious and handled with care.
- The controls are not calibrators and should not be used for assay calibration.
- Observe the normal precautions required for handling all laboratory reagents.
- Disposal of all waste material should be in accordance with local guidelines.

4. SAFETY PRECAUTIONS

Do not eat, drink, smoke or apply cosmetics in the assay laboratory. Do not pipette by mouth.
Avoid direct contact with potentially infected material by wearing laboratory clothing, protective goggles and disposable gloves. Wash hands thoroughly at the end of each assay.
Avoid splashing or forming an aerosol. All 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 as potentially able to transmit infectious agents. Waste must be handled with care and disposed of in compliance with 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 after the expiration date given on the label.
Pursuant to EC Regulation 1272/2008 (CLP), hazardous reagents are classified and labelled as follows:

REAGENTS:	CONTROL - IgG/IgM, CONTROL + IgG, CONTROL + IgM
CLASSIFICATION:	Skin sens. 1A H317 Aquatic chronic 3 H412
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 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 dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P273 Avoid release to the environment. P362 Take off contaminated clothing and wash 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 n. 247-500-7] and 2- methyl-2H -isothiazol-3-one [EC n. 220-239-6] (3:1). (ProClin® 300).

REAGENTS:	CONTROL 1 QFL (lyophilized), CONTROL 2 QFL (lyophilized)
CLASSIFICATION:	Eye irrit. 2 H319 Skin irrit. 2 H315 Skin sens. 1 H317 Aquatic Chronic 3 H412
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark
HAZARD STATEMENTS:	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. Aquatic Acute 1 H400 Aquatic Chronic 1 H410
PRECAUTIONARY STATEMENTS:	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P273 Avoid release to the environment. P391 Collect spillage.
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); Gentamicin sulfate salt.

Note: after reconstitution, CONTROL 1 QFL and CONTROL 2 QFL are classified as indicated below:

REAGENTS:	CONTROL 1 QFL (reconstituted), CONTROL 2 QFL (reconstituted)
CLASSIFICATION:	Skin sens. 1A H317 Aquatic chronic 3 H412
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 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 dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P273 Avoid release to the environment. P362 Take off contaminated clothing and wash 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).

For additional information, see the Safety Data Sheets available on www.diasorin.com.

5. STORAGE AND STABILITY

5.1. IgG and IgM Controls (CONTROL - IgG/IgM, CONTROL + IgG, CONTROL + IgM)

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 four (4) weeks when properly stored at 2-8°C between two successive uses. Avoid bacterial contamination of controls. The controls should not be used past the expiry date indicated on the vial labels.

5.2. QuantiFERON® Controls (CONTROL 1 QFL, CONTROL 2 QFL)

Do not leave the reconstituted controls at room temperature longer than the time required to process them on the analyzer.

- **Lyophilized**: stable at 2-8°C until the expiry date. Upon receipt, the controls must be stored at 2-8°C in an upright position to prevent adherence of the lyophilizate to the vial cap.
- **Reconstituted**: stable for four (4) weeks when properly stored at 2-8°C in capped vials. After reconstitution, the controls must be stored at 2-8°C in an upright position to prevent adherence of the solution to the vial cap.

6. PREPARATION OF REAGENTS

6.1. IgG and IgM Controls (CONTROL - IgG/IgM, CONTROL + IgG, CONTROL + IgM)

- Place the control vials on a suitable rack on the analyzer. Each control vial allows at least 20 tests to be performed.
- The dead volume is 400 µL.
- The minimum volume required for CONTROL - IgG/IgM is 420 µL (15 µL for IgG test + 5 µL for IgM test + 400 µL dead volume).
- The minimum volume required for CONTROL + IgG is 415 µL (15 µL control + 400 µL dead volume).
- The minimum volume required for CONTROL + IgM is 405 µL (5 µL control + 400 µL dead volume).
- At the time of use, equilibrate controls to room temperature (20-25°C) before opening the vials and keep them on board 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.

6.2. QuantiFERON® Controls (CONTROL 1 QFL, CONTROL 2 QFL)

- Reconstitute the vial contents with 2.0 mL of deionized or distilled water.
- Allow the vials to stand for 15 minutes at 18-25°C to achieve complete dissolution.
- Affix the appropriate, additionally provided barcode label to the vial.
- Mix vials thoroughly by gentle inversion; avoid foaming.
- The minimum volume required is 460 µL (60 µL control + 400 µL dead volume).
- Place the control vials on a suitable rack on the analyzer. Each control vial allows at least 20 tests to be performed.
- At the time of use, equilibrate controls to room temperature (20-25°C) before opening the vials and keep them on board the instrument only for the amount of time required for quality control testing.
- After use, close the vials and store them at 2-8°C in an upright position.
- During handling, use appropriate precautions to avoid bacterial contamination of controls.

Original vial labels refer only to lyophilized controls. Once reconstituted, pursuant to EC Regulation 1272/2008 (CLP), controls are classified Skin sens.1A H317 and Aquatic chronic 3 H412. For more details, refer to paragraph 4.

7. HANDLING

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

8. TARGET VALUES

The range of concentration 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. If control values obtained after successful calibration lie repeatedly outside the expected ranges, the test should be repeated using an unopened control vial.

For EU only: please be aware that any serious incident that has occurred in relation to this IVD medical device should be reported to DiaSorin Italia S.p.A. and to the Competent Authority of the EU Member State in which the user and/or the patient is established.

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