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LIAISON® Control QuantiFERON®-TB Gold Plus (REF 311051)

1. INTENDED PURPOSE

The LIAISON® QuantiFERON®-TB Gold Plus controls (level 1 and 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® QuantiFERON®-TB Gold Plus controls have not been established for any other assays or instrument platforms different from LIAISON® XL and LIAISON® XS analyzers.

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

Control level 1 (lyophilized, 2 x 2 mL)	CONTROL 1	Recombinant human IFN-γ (produced in *E. coli*) (less than 0.15 IU/mL), HEPES buffer, BSA, bovine serum, 0.4% ProClin™ 300, 0.2 g/L gentamicin sulfate.
Control level 2 (lyophilized, 2 x 2 mL)	CONTROL 2	Recombinant human IFN-γ (produced in *E. coli*) (approx. 1 IU/mL), HEPES buffer, BSA, bovine serum, 0.4% ProClin™ 300, 0.2 g/L gentamicin sulfate.
2 Barcoded labels for reconstituted Control level 1.		
2 Barcoded labels for reconstituted Control level 2.		

The 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 leakage. 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 were found to be non-reactive. As, however, no test method can offer absolute assurance that pathogens are absent, 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.
- All waste material should be disposed of 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 1 (lyophilized), CONTROL 2 (lyophilized)
CLASSIFICATION:	Eye irrit. 2 H319 Skin irrit. 2 H315 Skin sens. 1A H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark  GHS09 Environment
HAZARD STATEMENTS:	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H410 Very toxic 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. 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 and CONTROL 2 are classified as indicated below:

REAGENTS:	CONTROL 1 (reconstituted), CONTROL 2 (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

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 expiration 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

– 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. 1 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.

A Summary of safety and performance is available on EUDAMED.

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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