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CE 0459

Changes: §1, §3, §6;
Deletions: -

LIAISON® Control EBV IgM (REF 310501)

1. INTENDED PURPOSE

The LIAISON® EBV IgM controls (negative and positive) are intended for use as assayed quality control samples to monitor the performance and reliability of LIAISON® EBV IgM assay. The performance characteristics of LIAISON® EBV IgM 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, 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 give, 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 controlvials on board. For details, refer to the analyzer operator's manual.

2. MATERIALS PROVIDED

Negative control (2 x 0.9 mL)	CONTROL -	Human serum/plasma stabilized in PBS buffer, non-reactive for VCA IgM antibodies, BSA, 0.2% ProClin™ 300.
Positive control (2 x 0.9 mL)	CONTROL +	Human serum/plasma reactive for VCA IgM antibodies, stabilized in PBS buffer, BSA, 0.2% ProClin™ 300, an inert yellow dye.

All reagents are supplied ready to use. 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. 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.
- 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. 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.

Pursuant to EC Regulation 1272/2008 (CLP) hazardous reagents are classified and labelled as follow:

REAGENTS:	CONTROL -, CONTROL +
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 Safety Data Sheets available on www.diasorin.com.

5. 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 eight 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.

6. PREPARATION OF REAGENTS

- Place the control vials into the appropriate rack of the analyzer. Each control vial allows at least 20 tests to be performed.
- The minimum volume required is 420 µL (20 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.

7. HANDLING

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

8. TARGET VALUES

The target values and ranges of VCA IgM 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.

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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.