DiaSorin Inc.
1951 Northwestern Ave – Stillwater, MN 55082 – USA
Tel 1.651.439.9710 – Fax 1.651.351.5669

Changes: § 3
Deletions: §

LIAISON® Rotavirus Control Set (REF 318941)

1. INTENDED USE

The DiaSorin LIAISON® Rotavirus Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® Rotavirus assay. The performance characteristics of the LIAISON® Rotavirus Controls have not been established for any other assay or instrument platforms different from the 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 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 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

The following materials are provided in the control set.

Negative Control 2 x 6 mL Ready to use	CONTROL -	BSA, surfactant, 0.1% ProClin® 300 and 0.05% gentamicin sulfate.
Positive Control 6 x 2 mL Lyophilized	CONTROL +	Inactivated rotavirus, BSA, surfactant, 0.1% ProClin® 300 and 0.05% gentamicin sulfate. Reconstitute in 2 mL distilled or deionized water.

ProClin is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

- Bar Code Labels for Positive Control

Materials required but not provided:

- Pipette capable of delivering 1-2 mL for reconstituting controls
- Glass or polypropylene sample tubes
- Transfer pipette capable of delivering 400 µL

Controls are not kit lot specific and may be safely interchanged between different LIAISON® Rotavirus Reagent Integral lots.

3. WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE – Not for internal or external use in humans or animals.

GENERAL SAFETY:

- All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Avoid contact with skin, eyes or mucous membranes. Follow good industrial hygiene practices during testing.
- Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
- Do not pipet solutions by mouth.
- Avoid direct contact with all potentially infectious materials by wearing lab coat, protective eye/face wear and disposable gloves.
- Wash hands thoroughly at the end of each assay.
- Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
- Waste materials should be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country.
- Do not use kits or components beyond the expiration date given on the label.

CHEMICAL HAZARD AND SAFETY INFORMATION: Reagents in this kit are classified in accordance with US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and applicable European Union directives (see Material Safety Data Sheet for additional information).

GHS/CLP:

	ProClin®
CAS No.:	55965-84-9
Reagents:	CONTROL - CONTROL +
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3
Signal Word:	Warning
Pictogram:	 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 mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves and clothing, and eye protection.

4. STORAGE AND STABILITY

Store the LIAISON® Rotavirus Control Set at 2-8°C upon receipt and prior to reconstitution. The Rotavirus Control Set is stable until the expiration date on the vials when stored at 2-8°C. The controls have been shown to be stable for 2 hours when stored at room temperature (18-25 °C). The reconstituted positive control may be stored capped at 2-8°C for 7 days, or aliquot and freeze remaining positive control at –20°C for up to 16 weeks. These can be used through 1 freeze-thaw cycle.

5. QUALITY CONTROL

Quality control is required to be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. It is recommended that the user refer to CLSI C24-A3, and 42 CFR 493.1256 (c) for guidance on appropriate quality control practices.

LIAISON® Rotavirus controls are intended to monitor for substantial reagent failure. Whenever controls lie outside the expected ranges, calibration should be repeated and controls and samples retested.

Do not report patient results until control results are within expected ranges. Strict adherence to the instructions of the LIAISON® Rotavirus assay is necessary to obtain reliable results.

6. PREPARATION AND USE

The LIAISON® Rotavirus Positive Control is provided in a lyophilized form and should be stored at 2-8°C. Reconstitute positive control with 2 mL of distilled or deionized water. Allow control to dissolve on bench top for 5 minutes. Mix thoroughly by gentle inversion to ensure complete reconstitution for a minimum of 10 minutes. If using a frozen aliquot, mix thoroughly by gentle inversion prior to use. Transfer a minimum of 400 µL to a sample tube. Affix the appropriate bar code label to the tube and place in appropriate sized rack and load onto the Analyzer. Discard any unused portion of the control remaining in the tube after assaying.

The LIAISON® Rotavirus Negative Control is liquid and ready to use. Store at 2-8°C. Remove caps from the controls and place controls into the appropriate sample rack with the barcode showing outward and slide rack into the patient sample area. Return controls to the refrigerator immediately after each use.

Control identification is detected by the barcode label or may be manually programmed into the analyzer. Follow the analyzer operator's manual to start the run.

7. LIMITATIONS

Control values for assays other than the LIAISON® Rotavirus assay have not been established. If users wish to use this control material with other assays, it is their responsibility to establish appropriate ranges.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate reference ranges should be established for all quality control materials used.

If control values obtained after successful calibration lie repeatedly outside the expect ranges, the test should be repeated using an unopened control vial.

8. ASSIGNED VALUES

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.

DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082
USA

UK Responsible Person:
DiaSorin Italia S.p.A.
UK Branch
Central Road
Dartford Kent DA1 5LR
UK

EC REP
DiaSorin Italia S.p.A.
Via Crescentino snc
13040 Saluggia (VC)
Italy