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Changes: § 4  
Deletions: § 4

## LIAISON® Q.S.E.T. Device Plus ([REF] 319060)

### 1. INTENDED USE

The LIAISON® Q.S.E.T. Device Plus (Quantitative Stool Extraction and Test) is intended for use in the preparation of human stool specimens for testing in designated stool assays. The device is intended for *in vitro* diagnostic use in a professional laboratory setting on the automated LIAISON® Analyzer family.

### 2. MATERIALS PROVIDED

|                                |      |                                                                                                                                                                                                                           |
|--------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| LIAISON® Q.S.E.T. Device Plus* | TUBE | Polypropylene mixing tube with black funnel, screw cap, and white sampling wand with blue cap. The tube contains 6.0 mL of a buffered solution containing BSA, surfactant, 0.1% ProClin®300 and 0.05% gentamicin sulfate. |
| Number of Devices              |      | 100                                                                                                                                                                                                                       |

\*Device does not contain Bisphenol A (BPA), latex or Di (2-ethylhexyl)phthalate (DEHP).  
ProClin® is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

The LIAISON® Q.S.E.T. Device Plus is suitable for use with track lines, however it is the responsibility of each laboratory to perform their own validation.

### 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 pipette 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.
- Failure to fully coat sample onto the grooves of the device may result in falsely low assay results.

**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:                 | TUBE                                                                                                                                                                                                                                  |
| Classification:           | Skin sensitization, Category 1<br>Aquatic Chronic, Category 3                                                                                                                                                                         |
| Signal Word:              | Warning                                                                                                                                                                                                                               |
| Pictogram:                | <br>GHS07 – Exclamation mark                                                                                                                         |
| Hazard Statements:        | H317 – May cause an allergic skin reaction.<br>H412 – Harmful to aquatic life with long lasting effects.                                                                                                                              |
| Precautionary Statements: | P261 – Avoid breathing mist or spray.<br>P272 – Contaminated work clothing should not be allowed out of the workplace.<br>P273 – Avoid release to the environment.<br>P280 – Wear protective gloves and clothing, and eye protection. |

The Symbols Glossary and Safety Data Sheet are provided electronically at [www.diasorin.com](http://www.diasorin.com).

**4. STORAGE**

Store the LIAISON® Q.S.E.T. Device Plus at 2-24°C upon receipt and prior to use. Unopened LIAISON® Q.S.E.T. Device Plus is stable until the expiration date on the tubes when stored at 2-24 °C.

**5. PROCEDURE**

Refer to the respective DiaSorin stool assay Instructions for Use for stool extraction device usage instructions.

**6. LIMITATIONS OF USE**

- Each device is for one use and not to be reused.
- Very solid stools should not be extracted using this device.
- The LIAISON® Q.S.E.T. Device Plus is to be used by trained laboratory personnel only.
- Analyte in stool may not be evenly distributed throughout the sample. Without proper homogenization of the sample, variations can occur.

**7. REPRODUCIBILITY**

LIAISON® Q.S.E.T. Device Plus sampling reproducibility was tested using 5 human stool specimens ranging from 2 – 7 on the Bristol Stool Form Scale (BSFS) which were sampled by 3 operators with 5 replicates per specimen per operator on 3 lots of devices for a total of 225 sampling events. The weight of each sample collected by the Q.S.E.T. Device Plus was determined by comparison against the empty device. Repeatability was assessed across all 5 specimens, replicates, operators, and lots.

Sample collection performance of LIAISON® Q.S.E.T. Device Plus

|                      |              |
|----------------------|--------------|
| Mean Sample Weight   | 11.3 mg      |
| Median Sample Weight | 11.4 mg      |
| Range                | 8.5-13.5 mg  |
| 95% CI               | 11.2-11.4 mg |
| SD                   | 1.06         |
| %CV                  | 9.38%        |

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 and the competent authority of the EU Member State in which the user and/or patient is established.



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