# Hướng dẫn sử dụng tiếng Anh

*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 23 tháng 11 năm 2022*

**Người đại diện hợp pháp của cơ sở**

**GIÁM ĐỐC**

M.S.D.N: 0106162113 - C.T.T.N.H.H
CÔNG TY TRÁCH NHIỆM HỮU HẠN THIẾT BỊ NHẬT ANH
THÀNH PHỐ HÀ NỘI

**Lương Tuấn Phương**

Changes: §2, §4, §6;
Deletions: -

## LIAISON® Control Insulin (REF 310361)

### 1. INTENDED USE

The LIAISON® Insulin 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® Insulin controls have not been established in connection with any other assays or instrument platforms.

**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.

### 2. MATERIALS PROVIDED

**2 x 2 vials**

| | | |
|---|---|---|
| Control 1 (2 x 1.0 mL) | CONTROL 1 | LIAISON® Control Insulin (level 1): semisynthetic human insulin (prepared enzymatically from pig insulin), human insulin-free serum, 0.2% ProClin™ 300, < 1% gentamycin sulfate salt. (lyophilized reagent) |
| Control 2 (2 x 1.0 mL) | CONTROL 2 | LIAISON® Control Insulin (level 2): semisynthetic human insulin (prepared enzymatically from pig insulin), human insulin-free serum, an inert blue dye, 0.2% ProClin™ 300, < 1% gentamycin sulfate salt. (lyophilized reagent) |
| 2 bar-coded labels for Control Insulin (level 1). | | |
| 2 bar-coded labels for Control Insulin (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.
- Controls are not kit lot specific and may be safely interchanged even from different 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 labeled as follow:

| | |
|---|---|
| **REAGENTS:** | CONTROL 1 (lyophilized), CONTROL 2 (lyophilized) |
| **CLASSIFICATION:** | Eye irrit. 2 H319<br>Skin irrit. 2 H315<br>Skin sens. 1A H317<br>Aquatic Acute 1 H400<br>Aquatic Chronic 1 H410 |
| **SIGNAL WORD:** | Warning |
| **SYMBOLS / PICTOGRAMS:** |  GHS07 Exclamation mark  GHS09 Environment |
| **HAZARD STATEMENTS:** | H315 Causes skin irritation.<br>H317 May cause an allergic skin reaction.<br>H319 Causes serious eye irritation.<br>H410 Very toxic to aquatic life with long lasting effects. |
| **PRECAUTIONARY STATEMENTS:** | P261 Avoid breathing dust/fume/gas/mist/vapours/spray.<br>P280 Wear protective gloves/protective clothing/eye protection/face protection.<br>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P273 avoid release to the environment.<br>P391 Collect spillage. |
| **CONTAINS:**<br>(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); gentamycin sulfate salt. |

Pursuant to EC Regulation 1272/2008 (CLP), after reconstitution CONTROL 1 and CONTROL 2 are classified and labeled as follow:

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

**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 lyophil to the vial cap.
- **Reconstituted**: Stable for four weeks when properly stored at 2-8°C either in their sealed vials or in stoppered transfer tubes. After reconstitution the controls must be stored at 2-8°C in an upright position to prevent adherence of the solution to the vial or tube cap. Do not freeze. Performance characteristics after storage at –20°C or below have not been established.

## 6. PREPARATION OF REAGENTS

– Reconstitute the vial contents with 1.0 mL deionized or distilled water.
– Allow the vials to stand for 10-15 minutes at 18-25°C to achieve complete dissolution.
– Mix vials thoroughly by gentle inversion; avoid foaming.
– The reconstituted solution of each control must be transferred to a 12 x 75mm polystyrene tube. Affix the proper bar-coded label to the control tube and load on to the instrument specimen area. Each control solution allows at least 14 tests to be performed.
– The minimum volume required is 210 µL (60 µL control + 150 µL dead volume).
– Keep the controls on board the instrument only for the amount of time required for quality control testing.
– After use, stopper transfer tubes promptly and store them at 2-8°C in an upright position.
– During handling, use appropriate precautions to avoid bacterial contamination of controls.

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

## 7. HANDLING

– Place bar-coded transfer tubes in one of the patient racks on the analyzer.
– Make sure that identical controls are not placed directly one after another.
– For proper handling please refer to the relevant Analyzer Operator's Manual.

## 8. TARGET VALUES

The target values and ranges of insulin 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.

For Customer Service in Canada call toll free: 1-800-328-1482