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Changes: Update of Legal Manufacturer name
Deletions: -

LIAISON® Starter Kit (REF 319102)
LIAISON® XL Starter Kit (REF 319200)

1. INTENDED USE

Starter kit reagents produce the chemiluminescence signal that allows the photomultiplier of LIAISON® Analyzer family to detect an immunological reaction. LIAISON® Starter Kit (REF 319102) is intended to be used on LIAISON® Analyzer, while LIAISON® XL Starter Kit (REF 319200) is intended to be used on LIAISON® and LIAISON® XL Analyzers.

2. MATERIALS PROVIDED

Reagent for 1000 determinations per bottle	
3 x 230 mL Starter 1	Starter 1: containing < 5 µg/mL deuteroferriheme in 4% sodium hydroxide solution
3 x 230 mL Starter 2	Starter 2: containing approx. 0.12% hydrogen peroxide solution.

All reagents are provided ready-to-use in optimized concentrations to be used for the LIAISON® Analyzer family.
For additional details such as proper test performance of LIAISON® assays consult instructions for use of the assay to be performed.

3. WARNINGS AND PRECAUTIONS

For in vitro diagnostic use. For laboratory professional use only.
Observe the normal precautions required for handling all laboratory reagents.
Observe quality control guidelines for medical laboratories.
Strict adherence to the instructions are necessary to obtain reliable results.
Disposal of all waste material should be in accordance with local guidelines

4. SAFETY PRECAUTIONS

Do not eat, drink, smoke or apply cosmetics during the assay.
Do not pipette by mouth.
Avoid direct contact with all materials by wearing laboratory clothing, protective goggles and disposable gloves. Wash hands thoroughly at the end of each assay.
Avoid splashing.
The LIAISON® Analyzer family should be cleaned and decontaminated on a regular basis. See the Operator's Manual for the procedures.
Do not use kits or components beyond the expiration date given on the label.
The starter reagents also include 4% sodium hydroxide and 0.12% hydrogen peroxide. If sodium hydroxide or peroxide hydrogen solutions splash into your eyes, rinse immediately and thoroughly with plenty of water or a suitable buffer solution. A physician should be consulted as necessary.

Reagents containing sodium hydroxide:

DIRECTIVE	**EC No. 1272/2008**	
REAGENTS	Starter 1	
CLASSIFICATION OF SUBSTANCE	Skin corrosion, category 1B Serious eye damage, category 1 Corrosive to metal, category 1	
SIGNAL WORD	Danger	
SYMBOLS / PICTOGRAMS	 GHS05	Corrosion
HAZARD / RISK STATEMENTS	H290 H314	May be corrosive to metals Causes severe skin burn and eye damage
PRECAUTIONARY / SAFETY STATEMENTS	P260 P264 P280 P301 + P330 + P331 P303 + P361 + P353 P305 + P351 + P338 P308 + P310	Do not breathe dust / fume / gas / mist / vapours / spray Wash hands thoroughly after handling Wear protective gloves and clothing/ eye protection / face protection IF SWALLOWED: rinse mouth. Do NOT induce vomiting IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing IF exposed or concerned: immediately call a POISON CENTER or doctor / physician
CONTAINS: (only substances prescribed pursuant to Article 18 of EC Regulation 1272/2008).	Sodium hydroxide 4% [CAS no. 1310-73-2]	

5. REAGENT STORAGE AND STABILITY

The starter reagents should be stored unopened in their original bottles. Store at 15 - 30 °C up to the expiry date indicated on the label.
Onboard stability: up to the expiry date.
Keep away from direct light.

6. HANDLING

For LIAISON®:
To avoid mix-ups in the tubing for the starter reagents, LIAISON® is marked as: Starter 1: 1/white; Starter 2: 2/green
Correct positioning is crucial!
Place Starter 1 and Starter 2 bottles into the loading positions A1 and A2 for the starter reagents.
Do not pool starter reagents.
Avoid air bubble formation.
Always seal the screw caps of the starter reagent bottles after loading reagents.
Never leave starter reagent bottles open!
Do not exchange the screw caps of starter reagent bottles 1 and 2.

For LIAISON® XL:
To avoid mix-ups in the positions for the starter reagents, the LIAISON® XL starter flap is marked as:
SET A = Starter 1: Starter 1; Starter 2: Starter 2
Correct positioning is crucial!
Lightly pull the “clip-cap” of the correct loading positions on the system to the direction of the user.
Place the “clip-cap” of the system onto the starter bottles ensuring that the tooth of the clip sits below the lower ring of the starter bottles.
Place Starter 1 and Starter 2 bottles into the correct loading positions ensuring that the Identification labels are facing the user (red label facing the back wall of the loading port).
Do not pool starter reagents.
Avoid air bubble formation.
Never leave starter reagent bottles open!
Do not exchange the screw caps of starter reagent bottles 1 and 2.

A brown fine precipitate might occasionally be observed in bottles of Starter 1.
Please note that the precipitate has no impact on the product performance and has no negative influence on the instrument (precipitate does not plug the instrument needles or tubing).
The products can be used without any restrictions on LIAISON® and LIAISON® XL Analyzer instruments.
There is no need to dissolve the precipitate prior to use – although gentle mixing will disperse the precipitate it is likely to reoccur after some time.

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.