

Changes: Update of Legal Manufacturer name

Deletions: -

LIAISON® Light Check 12 (REF 319150) for 12 x 100 tests

1. INTENDED USE

Light Check reagent required to check the validity of starter reagents Starter 1 and 2 as well as the functioning of the measurement and pipetting units. A Light Check has to be carried out on the LIAISON® Analyzer either once daily prior to starting the first measurement series or each time a new lot of starter reagents is used. This control program concomitantly checks the proper functioning of the instrument and of the starter reagents to avoid data loss due to instrument defects or inadvertently placed or expired starter reagents.

2. MATERIALS PROVIDED

12 vials for 100 determinations each	
12	x 2.0 mL LIAISON® Light Check 12 (REF 319150): contains < 25 ng/mL isoluminol conjugate

The Light Check reagent is provided lyophilized

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 is 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 potentially infectious materials by wearing laboratory clothing, protective goggles and disposable gloves.
Wash hands thoroughly at the end of each assay.
Avoid splashing or forming an aerosol. Any 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 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.

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.

5. PREPARATION OF REAGENTS

- Carefully open the vial containing the lyophilized material (vacuum).
- Reconstitute lyophilizate by pipetting precisely 2 mL (± 20 μ L) water, into the original vial.
- Use only water defined according to CLSI guidelines for laboratory water (Type III).
- Shake carefully (avoid foam formation). Make sure that lyophilized material adherent to the caps is also dissolved.
- Prior to use, let it stand for 5 min.
- Only the original vial is allowed in the analyzer.

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 the reagent.

6. STORAGE AND STABILITY

Upon receipt, the LIAISON® Light Check must be stored at 2-8 °C in an upright position to prevent adherence to the vial cap.

- **Lyophilized (unopened):** Stable at 2-8 °C until the expiry date given on the label.
 - **Reconstituted:** one (1) week at 2-8 °C (closed).
- After use, immediately close the LIAISON® Light Check vial and store it in a refrigerator at 2-8 °C.**
- Keep away from direct light.

7. HANDLING

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

Place the LIAISON® Light Check vial into the patient rack "L" only.

8. TARGET VALUES FOR LIGHT CHECK AND BACKGROUND

Light Check: 120,000 – 180,000 RLU (relative light units)

Background: 120 – 320 RLU (relative light units)

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.