

# MAGLUMI Light Check



130299006M



100 X 5



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Keep upright for storage

## 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 MAGLUMI chemiluminescence immunoassay (CLIA) fully auto analyzer (Including MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 plus), 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. Material provided

5 vials for 100 determinations each  
5 vials for 5x2.0ml MAGLUMI Light Check  
The Light Check reagent is provided lyophilized



For additional details such as proper test performance of MAGLUMI assays consult instructions for use of the assay to be performed.

## FOR PROFESSIONAL USE ONLY

Store at 2--8°C



COMPLETELY READ THE INSTRUCTIONS  
BEFORE PROCEEDING

en

## SYMBOLS USED ON LABELS



Authorized Representative in Europe



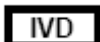
Manufacturer



Attention. See Instructions For Use



Contents of kit



In vitro diagnostic medical device  
(In vitro diagnostic use)



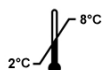
Lot number



Catalogue Code



Expiry date (Use by...)



Temperature limitation  
(store at 2--8 °C)



Number of tests



Keep away from sunlight

## 3. Preparation of Reagents

- Carefully open the vial containing the lyophilized material (vacuum).
- Reconstitute lyophilisate by pipetteing precisely 2 ml ( $\pm 20 \mu\text{l}$ ) 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 15 min.

## 4. Storage and Stability

- Unopened in the original vial: at 2 – 8°C until the expiry date given on the label.
- Reconstituted: 1 week at 2 – 8°C (closed).  
**After use, immediately close the MAGLUMI Light Check vial and store it in a refrigerator at 2 – 8°C.**
- Keep away from direct sunlight.
- Aliquot and store at -20 °C can be steady for 36 month. Avoid repeated freezing and thawing.

## 5. Handling

- Pipette the MAGLUMI Light Check into a tube, and then place the tube into the matched patient rack.
- Seal the tube and store the rest of the Light Check at 2 – 8°C immediately after been used.

## 6. Target values for Light Check and Background\*

- Light Check: 500,000-600,000 RLU
- Background: 200 - 1000 RLU

(\* Target values may differ due to analyzer setting, contact SNIBE authorized technician for further information)

## 7. Warning and precautions for users

- Observe the normal precautions required for handling all laboratory reagents.
- Disposal of all waste material should be in accordance with local guidelines.