



MAGLUMI® Starter 1+2

INTENDED USE

The Starter 1+2 is for triggering chemiluminescence reaction to produce the light signal, and it is used in conjunction with MAGLUMI assay reagents on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

SUMMARY


The Starter 1 provides the alkaline environment, and then the Starter 2 triggers ABEI (N-(4-Aminobutyl)-N-ethylisoluminol) to produce the light signal, which will be captured by the analyzer.

MATERIALS PROVIDED

REF	Description	Specification
130299004M	1.5% NaOH (Starter 1)	Starter 1: 1x230 mL Starter 2: 1x230 mL
130299027M	0.18% H ₂ O ₂ (Starter 2)	Starter 1: 1x1.5 L Starter 2: 1x1.5 L

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For professional use only.
- Do not use the product beyond the expiration date indicated on the label.
- Exercise the normal precautions required for handling all laboratory reagents.
- Avoid ingestion and contact with skin and eyes, if you unfortunately experience it, please drink or rinse with plenty of water, and seek emergency medical treatment.
- All waste should be considered potentially infectious and should be disposed of in accordance with local guidelines.
- Safety data sheets are available on request.
- Note: If any serious incident has occurred in relation to the device, please report to Shenzhen New Industries Biomedical Engineering Co., Ltd. (Snibe) or our authorized representative and the competent authority of the Member State in which you are established.
- Pursuant to EC Regulation 1272/2008 (CLP) hazardous reagents are classified and labeled as follow:

REAGENTS:	Starter 1
CLASSIFICATION:	Skin Irritant, Category 2
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark
HAZARD STATEMENTS:	H315 Causes skin irritation.
PRECAUTIONARY STATEMENTS:	P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing. P362+P364: Take off contaminated clothing and wash before reuse. P302+P352: IF ON SKIN: Wash with plenty of soap and water.
CONTAINS: (only substances prescribed pursuant to Article 18 of EC Regulation 1272/2008).	Sodium hydroxide; caustic soda (Starter 1)

PROCEDURE

Materials Provided

Starter 1+2

Materials Required (But Not Provided)

130299004M: Maglumi 600, Maglumi 800, Maglumi 1000, Maglumi 1000 Plus, Maglumi 2000, Maglumi 2000 Plus, Maglumi 4000, Maglumi 4000 Plus, MAGLUMI X3 and Biolumi 8000.

130299027M: MAGLUMI X8, MAGLUMI X6 and Biolumi CX8.

Handling









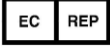





Whenever the starter reagents are replaced, follow the procedure described in the Operators Manual.

- Place Starter 1 and Starter 2 into the loading position in "1" and "2". To avoid any mix-up, the tubings for the starter reagents are marked. Correct positioning is absolutely essential.
- Do not shake violently to avoid bubble formation.
- Always close starter cover after loading reagents.
- Never leave starter reagent vials open.
- Do not exchange the cover of starter reagent vials 1 and 2.
- For further information, please refer to the appropriate Operators Manual.

STORAGE AND STABILITY

- Unopened at 2-30°C: until the expiry date as stated on the labels.
- Opened at 2-30°C: 45 days.
- On board stability: 4 weeks.
- Keep away from direct sunlight.

SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
	Temperature limit (Store at 2-30°C)		Keep away from sunlight
	Catalogue number		Use-by date
	<i>In vitro</i> diagnostic medical device		Batch code
	Authorized representative in the European Community		Kit components
	CE marking		This way up
	Unique device identifier		Importer

MAGLUMI® and Biolumi® are trademarks of Snibe. All other product names and trademarks are the property of their respective owners.



Shenzhen New Industries Biomedical Engineering Co., Ltd.
 No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China
 Tel: +86-755-21536601 Fax: +86-755-28292740



Shanghai International Holding Corp. GmbH (Europe)
 Eiffestrasse 80, 20537 Hamburg, Germany
 Tel: +49-40-2513175 Fax: +49-40-255726