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☆ : Note changes

In Vitro Diagnostic Use

Chemiluminescent Enzyme Immunoassay Reagent

Lumipulse® *G*

Wash Solution

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8:00 – 17:00 GMT+1

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Read this insert carefully before performing the assay and keep for future reference.
The reliability of assay procedures other than those described in this package insert cannot be guaranteed.

■ NAME

Lumipulse ***G*** Wash Solution

■ INTENDED USE

For *in vitro* diagnostic use: This product is a common reagent used for washing in the LUMIPULSE ***G*** System.

■ EXPLANATION OF THE REAGENT

LUMIPULSE ***G*** System is an assay system including its specific reagents and consumables, and it is based on chemiluminescent enzyme immunoassay (CLEIA) technology. This reagent is used for washing the particles to remove unbound materials in the LUMIPULSE ***G*** System. For other reagents' information of LUMIPULSE ***G*** System, refer to their package inserts.

■ MATERIAL PROVIDED

Lumipulse *G* Wash Solution: Concentrate,

1 × 1000 mL REF 231173

Contains 342 mM Sodium chloride in Tris buffer with a detergent. Preservative: sodium azide.

■ WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only.

1. SAFETY PRECAUTIONS

Sodium azide: NaN_3 1.0% (w/v)

R25: Toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S28: After contact with skin, wash immediately with plenty of water.
S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S60: This material and its container must be disposed of as hazardous waste.
S61: Avoid release to the environment. Refer to special instructions/safety data sheets.

2. PRECAUTIONS FOR HANDLING

1) Lumipulse ***G*** Wash Solution contains 1.0% (w/v) sodium azide before dilution. Handle carefully to avoid contact with skin, eyes, or mouth.
2) In the event of accidental contact with this reagent with skin, eyes, or mouth, immediately rinse thoroughly with water and seek medical attention if necessary.
3) When handling this reagent, refer to the directions of Lumipulse ***G*** reagents package inserts and LUMIPULSE ***G*** System Operation Manual.

3. PRECAUTIONS FOR USE

1) Read through this package insert and the LUMIPULSE ***G*** System Operation Manual. Follow the instructions. Incorrect use of the reagent may result in false data or accident hazard.
2) Do not use expired reagent.
3) Avoid using the reagent which may have been stored in an improper way.
4) This reagent is diluted and shall be brought to the room temperature (15-25 °C) before use.

4. PRECAUTIONS FOR WASTE

1) The Wash Solution and diluted Wash Solution contain 1.0% and 0.1% (w/v) sodium azide as a preservative, respectively. Follow any applicable regulations for disposal. If flushing down the drain, use generous amounts of water when discarding to prevent the formation of explosive metal azides.
2) Handle any medical wastes produced by the assay in compliance with waste-related regulations in each country or region.
3) When any liquid such as specimen or assay waste is splashed, wipe and disinfect the whole area with an appropriate disinfectant such as sodium hypochlorite or glutaric aldehyde.

■ STORAGE INSTRUCTIONS

Store at 2-10 °C. DO NOT FREEZE.
When stored and handled properly, the reagent remains stable until the expiration date. Refer to the expiration date shown on the immediate container label.

■ INSTRUMENT

This reagent is designed for a fully automated chemiluminescent enzyme immunoassay (CLEIA) on the LUMIPULSE ***G*** System. Refer to the LUMIPULSE ***G*** System Operation Manual for further information.

■ REAGENT PREPARATION

10 × concentrated solution. Prior to use, dilute 10 × with purified water and mix thoroughly. The diluted Wash Solution shall be brought to room temperature (15-25 °C) before use. To load the diluted Wash Solution onto the LUMIPULSE ***G*** System, follow the instructions in the LUMIPULSE ***G*** System Operation Manual.

■ GLOSSARY OF SYMBOLS

CE	CE Marking (European directive 98/79/EC on *in vitro* diagnostic medical devices)		
EC REP	Authorised Representative in the European Community		
IVD	*In Vitro* Diagnostic Medical Device	LOT	Batch Code
	Manufacturer		Consult Instructions for Use
REF	Catalogue Number		Use by
	Toxic		Temperature Limitation
CONTENTS	Content of the Kit		

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CE