

BioCLIA System Wash Buffer

Cat. No.	GTIN Code	Kit Size
MY00404	06924030405199	6 x 1 L

INTENDED USE

The BioCLIA System Wash Buffer is a common reagent intended for washing steps in BioCLIA chemiluminescent microparticle immunoassay performed on the BioCLIA 6500 and BioCLIA 500.

For professional *in vitro* diagnostic use only.

DETECTION PRINCIPLE

The BioCLIA System Wash Buffer is used for washing the solid phase immune complex to remove the free reagent, which ensures the correct testing results. It is also used for the washing protocol for BioCLIA instrument to minimize or prevent the carrying over of sample and reagent from the previous test.

MATERIALS SUPPLIED

- Wash buffer, composed of Tris buffer (pH 8.7) containing surfactant and preservatives.

Surfactant: Tween 20 < 0.3%,

Triton X-100 < 0.3%,

Preservatives: 5-Bromo-5-Nitro-1, 3-Dioxane (BND) < 1%.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use any reagents beyond their expiration dates.
- Instructions must be carefully followed for reagent use and storage. Any modification in procedure may interfere with the results. Contaminated vials/cuvettes must be handled strictly with safety guidelines or rules of biological hazards to ensure the safety of users and environment.
- This product contains chemical components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with the reagent happens, rinse the contact area with plenty of water immediately and see a doctor if necessary.

Precautions:



- Tween 20 is added in the reagent at concentration less than 0.3%.

- Triton X-100 is added in the reagent at concentration less than 0.3%.
- 5-Bromo-5-Nitro-1, 3-Dioxane (BND) is added in the reagent at concentration less than 1%.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

STORAGE CONDITIONS













- Store the kit at 0-35 °C.
- It is stable until the expiration date when stored and handled as directed.
- Opened reagents or onboard reagents may be used for 14 successive days (18-25 °C). The software of the BioCLIA instruments monitors the onboard (in-use) expiration of the reagent cartridge. The system will not allow use of a reagent which has expired.

ASSAY PROCEDURE

Detailed information about operating the BioCLIA instruments can be taken from the Instrument User's Manual.

Note that, it is important to perform all routine maintenance procedures for optimal performance.

SYMBOLS

	Catalog Number		Use-by date
	In Vitro diagnostic medical device		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in the European Community
	CE Marking		Contains Sufficient for <n> Tests
	Biological Risk		GH507 Warning

REFERENCE

- David Wild. The Immunoassay Handbook. Elsevier, 2005: 185.
- US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens. Jan 2001
- US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition. Washington, DC: US Government Printing Office, May 1999.
- World Health Organization. Laboratory Biosafety Manual. Geneva: World Health Organization. 2004.

5. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline - Third Edition. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute, 2005.



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The eIFU is available on Website:

<http://en.hob-biotech.com/usercenter/login.aspx>

TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

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