BioCLIA Sample Diluent I

Cat. No.	GTIN Code	Kit Size
MY00965	06924030405274	100 mL

INTENDED USE

The BioCLIA Sample Diluent I is intended for diluting specimens in BioCLIA chemiluminescent microparticle immunoassay performed on the BioCLIA 6500 and BioCLIA 500.

For professional *in vitro* diagnostic use only.

DETECTION PRINCIPLE

The BioCLIA Sample Diluent I is used for diluting specimens including human serum and plasma in BioCLIA autoimmune assays, which ensures to obtain accurate testing results.

MATERIALS SUPPLIED

- Ready to use PBS buffer (pH 7.4) containing casein, surfactant and preservatives.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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 interferes 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: 

- Proclin 300 is added in the reagent at concentration between 0.0015% - 0.6%.
- 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 2-8 °C.
- It is stable until the expiration date when stored and handled as directed.
- Opened reagents or onboard reagents may be used for 28 successive days. 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

REF	Catalog Number		Use-by date
IVD	In Vitro diagnostic medical device	LOT	Lot Number
+2°C +8°C	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Marking	Σ	Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning

REFERENCE

1. Blanchard JS. Buffer for Enzymes. Meth. Enzyrnol. 1984, 04: 404.
2. Gueffroy DE. Calbiochem Buffer: A Guide for the Preparation and Use of Buffer in Biological Systems. 1975.
3. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens. Jan 2001.
4. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition. Washington, DC: US Government Printing Office, May 1999.
5. World Health Organization. Laboratory Biosafety Manual. Geneva: World Health Organization. 2004.
6. 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.

CE IVD

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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.

Date of issue: 17th March 2019

Date of revision: 18th May 2022

Change Control Number: CN22052E

Version: A/2 (EN)