BioCLIA® Sample Diluent I

Chemiluminescent Microparticle Immunoassay

Key to Symbols Used

REF	Catalog Number		Expiration Date
IVD	For *In Vitro* Diagnostic Use	LOT	Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in European Union
ANTIGEN BIOT	Biotinylated Antigen	Σ	ContainsSufficient for < *n* > Tests
CONJ AP G	Conjugate		Chemical Risk Warning
M STREP	Microparticle		Biological Risk Warning

BioCLIA® Sample Diluent I

Intended Use

The BioCLIA Sample Diluent I is a common reagent intended for diluting specimens in BioCLIA chemiluminescent microparticle immunoassay performed on BioCLIA instruments. For *in vitro* diagnostic use only.

Catalog Numbers

MY00965 (100ml)

Materials supplied

• Ready to use PBS buffer (pH 7.4) containing casein, surfactant and preservatives. DIL | SPE | I

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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.

Storage Conditions

The BioCLIA Sample Diluent I should be kept in refrigerator (2 - 8 ^{o}C). It is stable until the expiration date when stored and handled as directed. Vial opened reagents or onboard reagents are valid within 28 running days (2 - 8 ^{o}C).

Assay Procedure

Note that, it is important to perform all routine maintenance procedures as defined in the BioCLIA® 1200 and BioCLIA® 6500 User Manual for optimal performance.

See the BioCLIA® 1200 and BioCLIA® 6500 User Manual for preparation, setup, dilutions, adjustment, assay and quality control procedures.

Warnings and Precautions

• This product is for *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 added in the reagent at concentration between 0.0015% - 0.6%.

References

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.

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EC REP

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Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019
Revision 6