BioCLIA System Substrate

Cat. No.	GTIN Code	Kit Size
MY00405	06924030405205	4 X 600 Tests

INTENDED USE

The BioCLIA System Substrate is a common reagent intended for enhancing chemiluminescence based on alkaline phosphatase (AP) immunoassay system on the BioCLIA 6500 and BioCLIA 500.

For professional *in vitro* diagnostic use only.

DETECTION PRINCIPLE

AMPPD solution is stable under storage condition. It will be catalyzed by alkaline phosphatase (AP) and produce a kind of unstable intermediate. This intermediate will immediately decay into small molecules and along with photons emitted. This chemiluminescent intensity is positively correlated to the amount of AP reacted, and the analyte concentration can be calculated by determining the relatively luminescent unit (RLU).

MATERIALS SUPPLIED

- Ready to use AMPPD solution (3-[2-spiroadamatane]-4-methoxy-4-[3-phosphoryloxy]-phenyl-1, 2-diox).

Preservatives: NaN_3 < 0.1%.

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 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:

- NaN_3 is added in the reagent at concentration less than 0.1%.
- 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 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 (1 -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

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		Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning

REFERENCE

1. Bronsteln JC, Voyta GH, Thorpe G, et al. Chemiluminescent Assay of Alkaline Phosphatase Applied in an Ultrasensitive Enzyme Immunoassay of Thyrotropin. Clin Chem. 1989, 35, (7):1441.

2. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens. Jan 2001.

3. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition. Washington, DC: US Government Printing Office, May 1999.

4. 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.

CE IVD

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EC REP

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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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