







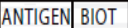



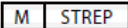



BioCLIA[®] System Substrate

Chemiluminescent Microparticle Immunoassay

Key to Symbols Used

	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Biotinylated Antigen		Contains Sufficient for < n > Tests
	Conjugate		Chemical Risk Warning
	Microparticle		Biological Risk Warning

BioCLIA® System Substrate

Intended Use

The BioCLIA System Substrate is a common reagent intended for enhancing chemiluminescence based on alkaline phosphatase (AP) immunoassay system on BioCLIA instruments. For *in vitro* diagnostic use only.

Catalog Numbers

MY00405 (4 X 600 Tests)

Materials supplied

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

SUBS | AMPPD

Preservatives: NaN₃ < 0.1%.

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).

Storage Conditions

The BioCLIA System Substrate should be stored in refrigerator (2 - 8 °C) and kept in dark. It is stable until the expiration date if stored and handled as directed. Vial opened reagents or onboard reagents are valid within 28 running days (18 - 25 °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 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.
- Do not use contaminated reagent.

References

1. Bronstein 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.



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Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019
Revision 7