BioCLIA Allergy Specific IgE Conjugate and Microparticle Set

(Chemiluminescent Microparticle Immunoassay)

REF

MY01311 (100 Test/kit)
MY01312 (150 Test/kit)
MY01313 (200 Test/kit)
MY01314 (300 Test/kit)

INTENDED USE

BioCLIA Specific IgE Conjugate and Microparticle Reagent Kit is a common reagent kit intended for providing magnetic beads and enzyme conjugate to realize quantitative determination of allergen specific IgE in human serum, aiding the clinical diagnosis of Type I hypersensitivity. For professional *in vitro* diagnostic use only.

PRINCIPLE OF THE PROCEDURE

BioCLIA Allergy Reagent Kit is a two-step immunoassay. The allergen of interest is biotinylated, it reacts with the specific IgE in patient sample and form a IgE-allergen complex with streptavidin beads. After incubation, a washing step removes the unbound reagents and sample matrix. Subsequently add enzyme conjugated anti-human IgE antibodies and bind to the IgE-allergen complex. After incubation, a second washing step removes the excess enzyme conjugates. Then addition of substrate results in the emission of light and RLU is measured. RLU is proportional to the amount of allergen specific IgE present in the sample. To evaluate the test results, RLU is transformed to concentration with the use of a calibration curve.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Used on BioCLIA 6500 and BioCLIA 500 instruments only.
- Do not use any reagents beyond the expiration dates.
- Liquid waste and solid waste taken from BioCLIA 6500 and BioCLIA 500 should also be handled in accordance with the appropriate biosafety practices same as stated above.
- Once opened, the reagent cartridge must be stored in the instrument's reagent carousel. For the first placement of reagent into the instrument, please take care to avoid spilling the reagents.
- Spilled reagents should be cleaned up immediately. Comply with all federal, state and local environmental regulations when disposing of wastes.
- Improper cleaning or rinsing of the instrument may lead to chemical contamination of the reagents. Residues from common laboratory chemicals such as formalin, bleach, ethanol, or detergent can cause interference in the assay. Be sure to follow the recommended cleaning procedure as outlined in the BioCLIA 6500 and BioCLIA 500 User's Manual.

Precautions:

- Both Microparticle and Conjugate contain ProClin300 0.1% as preservative and may cause an allergic skin reaction by skin contact. Avoid contact with skin. Wear protective gloves, protective clothing and take eye protection.
- 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.

MATERIALS SUPPLIED

- **Microparticles**

Streptavidin-microparticles in 0.01 M PBS (pH7.4±0.2) buffer with stabilizer.

M	STREP

Preservatives: 0.1% ProClin 300

- **Conjugate**

AP labeled anti-human IgE antibodies in 0.05 M MES (pH6.0±0.2) buffer with stabilizer.

CONJ	AP	E

Preservatives: 0.1% ProClin 300.

Kit size	Microparticles	Conjugate
100 Tests/Kit	1 X 4.5 mL	1 X 13 mL
150 Tests/Kit	1 X 6.75 mL	1 X 19.5 mL
200 Tests/Kit	2 X 4.5 mL	2 X 13 mL
300 Tests/Kit	2 X 6.75 mL	2 X 19.5 mL

STORAGE AND STABILITY

- Store the kit at 2-8 °C. It is stable until the expiration date when stored and handled as directed.
- The shelf life of the unopened kit is 18 months from day of production.
- Vial opened reagents or onboard reagents could 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.

Assay Calibration

The BioCLIA Allergy Reagent Kit utilizes seven points of calibrators to get the Working Calibration Curve. The calibrators information is uploaded into the instrument via the barcode provided in the BioCLIA Allergy Specific IgE Calibrator and Control Set. The Working Calibration Curve is generated and is used to calculate the analyte concentration (IU/mL) from the RLU obtained for each patient.

For each new lot of reagent, please calibrate prior to the first time use, and every 28 days thereafter. The software will not allow the lot to be used if the above requirements are not meet.

Programming and Running Samples

1. Put the reagents into the corresponding position of the reagent chamber of the fully automatic chemiluminescence analyzer. The information of the reagents can be uploaded into the instrument system through the scanning of reagent barcode, and can also be set through the supporting software of the instrument.
2. The information of calibrator / quality control is identified by scanning the calibrator / control barcodes, and the position of calibrator / quality control is assigned in the instrument system.
3. The sample to be tested is placed on the instrument sample rack

chamber, and the corresponding test information is edited through the instrument supporting software.

4. Start the operation procedure, and all calibrator / quality control / sample processing steps will be automatically executed.

Control

The control procedure could be done before running the specimens every day. Users also can adjust the control procedure period according to their own lab frequency.

APPEARENCE

Kit components are complete with no leakage. Conjugate is a clear liquid reagent without any precipitation or floc, microparticle is light to dark brown suspension. Packing labels are clear and easy to be identified.

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
M STREP	Streptavidin coated microparticles		
CONJ AP E	AP labeled anti-human IgE antibody		

REFERENCE

1. Geha RS. Human IgE. J Allergy Clin Immunol 1984;74:109-20.
2. Halpern G. Markers of human allergic disease. J Clin Immunoassay 1983;6:131-39.
3. Homberger H, Yuninger J. Laboratory testing in the diagnosis and management of allergic diseases. Clin Lab 1983;2:351-88.
4. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens.
5. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition. Washington, DC: US Government Printing Office 1999.
6. World Health Organization. Laboratory Biosafety Manual. Geneva: World Health Organization 2004.
7. 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.

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