BioCLIA® Autoimmune Calibrator Set

RF IgA

RF IgA Assay Calibrators

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
		Σ	Contains Sufficient for < *n* > Tests
CAL 1	Calibrator 1		
CAL 2	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator Set, RF IgA

Intended Use

The BioCLIA Autoimmune Calibrator Set, RF IgA is intended for the calibration of the BioCLIA RF IgA performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00230 (2 X 1 mL)
MY00281 (4 X 1 mL)

Summary and Principles of the Procedure

Rheumatoid factors (RFs) are anti-antibodies specific to the degenerated IgG antibodies caused by infection factors (bacteria, viruses, etc.). B cell clones for expressing RFs exist in rheumatoid arthritis (RA) patients and about 50% of healthy human bodies. A large amount of RFs produced under certain pathologic conditions such as degenerated IgG or EB virus directly stimulating the B cells. [1] Commonly, RFs include IgA, IgD, IgE, IgG and IgM types. [2, 3]

The presence of RFs in serum can indicate the occurrence of suspected autoimmune activity unrelated to rheumatoid arthritis, such as that associated with tissue or organ rejection. In such instances, RF may serve as one of the several serological markers for autoimmunity. [4] The sensitivity of RFs for established rheumatoid arthritis is only 60-70% with a specificity of 78%. [5] RFs positive patients are likely to have extra-articular manifestation that includes subcutaneous nodules and vasculitis. Patients with a high concentration of RFs suffer from diseases like rheumatoid arthritis (RA, 50-90%), Sjogren's syndrome (75-95%). [6] In addition, it was also found that RFs are related to systemic lupus erythematosus (SLE, 15-35%), polymyositis (55-10%), systemic sclerosis (20-30%), mixed connective tissue disease (MCTD, 50-60%) or cryoglobulinemia (40-100%). [7, 8] Specifically, RF-IgA is a clinical activity indicator for RA, scleroderma, Felty syndrome and systemic lupus erythematosus.

Materials supplied

- **RF IgA Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator 1 contains anti-RF IgA antibodies in MOPS (PH 6.0-7.0) buffer. RF-A CAL 1

Preservatives: 5-Bromo-5-Nitro-1, 3-Dioxane (BND) < 1%.

- **RF IgA Calibrator 2** A tube contains 1mL, ready to use reagent. Calibrator 2 contains anti-RF IgA antibodies in MOPS (PH 6.0-7.0) buffer. RF-A CAL 2

Preservatives: 5-Bromo-5-Nitro-1, 3-Dioxane (BND) < 1%.

Target value information is indicated in the 2D barcode localized in each kit.

Warnings and Precautions

The human derived material in this product was tested by FDA approved methods and found nonreactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV 1/2 antibodies. Handle as if potentially infectious. [9] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:

 Human serum is added in the calibrators.

• The product is for *in vitro* diagnostic use only.
• Do not use any calibrators beyond their expiration dates. Do not mix calibrators from different lots unless specified.
• Instructions must be carefully followed for using and storing of calibrators. Any modification in procedure may interfere with the results. Calibrators and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
• Calibrators contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with calibrators happens, rinse immediately the contact surface with plenty of water and see a doctor if necessary.

Storage Conditions

The kit is stable until the expiration date, if stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a calibrator tube is opened, it is good for a total of 15 times, no more than 2 hours per time when kept uncapped, onboard the instrument, after which the reagent must be discarded. Three freeze-thaw cycles before testing has no effect on the kit reagents.

Assay Procedure

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

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

Traceability

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA® 6500 using specific lots of reagents against an in-house standard. RF IgA results are reported in RU/mL which is interpreted from relative light unit (RLU). Method comparison test showed good sensitivity and specificity of tested assay.

Limitations

This product is designed as calibrators for

monitoring the performance of the BioCLIA RF IgA. These calibrators are subjected to the limitations of the assay system. Deviations may indicate problems with one or more components in the test system.

References

1. Edkins A, Cushley W. The Jekyll and Hyde nature of antibodies. Biological Sciences Review 2012;25:2.
2. Banchuin N, Janyapoon K, Sarntivijai S, Parivisutt L. Re-evaluation of ELISA and latex agglutination test for rheumatoid factor detection in the diagnosis of rheumatoid arthritis. Asian Pacific Journal of Allergy & Immunology 1992;10:47-54.
3. Herrmann D, Jäger L, Hein G, Henzgen M, Schlenvoigt G. IgE rheumatoid factor. Occurrence and diagnostic importance in comparison with IgM rheumatoid factor and circulating immune complexes. Journal of Investigational Allergology & Clinical Immunology 1991;1:302-7.
4. Rostaing L, Modesto A, Cisterne JM, Izopet J, Oksman F, Duffaut M, et al. Serological markers of autoimmunity in renal transplant patients with chronic hepatitis C. American Journal of Nephrology 1998;18:50-6.
5. Nishimura K, Sugiyama D, Kogata Y, Tsuji G, Nakazawa T, Kawano S, et al. Meta-analysis: diagnostic accuracy of anti-cyclic citrullinated peptide antibody and rheumatoid factor for rheumatoid arthritis. Annals of Internal Medicine 2007;146:797-808.
6. Visser H. Early diagnosis of rheumatoid arthritis. Best Practice & Research Clinical Rheumatology 2005;19:55-72.
7. Wilson D. Rheumatoid factors in patients with rheumatoid arthritis. Canadian Family Physician Médecin De Famille Canadien 2006;52:180-1.
8. Longmore M, Wilkinson IB, Rajagopalan SR. Oxford Handbook of Clinical Medicine. 2004 ;6th ed.
9. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

HOB Biotech Group Co., Ltd

C6 Building, No. 218 Xinghu Road, SuzhouIndustrial Park,

Suzhou, Jiangsu, 215123, China

REGISTRANT/MANUFACTURE: HOB Biotech Group Co., Ltd

ADDRESS/LOCATION:

C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215123 China

CONTACT INFORMATION: TEL (+86)512-69561996 Fax (+86)512-62956652

WEBSITE: www.hob-biotech.com

CUSTOMER SERVICE: HOB Biotech Group Co., Ltd

CUSTOMER SERVICE CONTACT: TEL (+86)4008601202

EUROPE REPRESENTATIVE: Emergo Europe

ADDRESS/LOCATION:

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019

Revision 9