

BioCLIA Autoimmune Control Set, RF Screen

Cat.No.	Kit Size
MY00335	2 X 1 mL
MY00386	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, RF Screen is intended for the quality control purposes of the BioCLIA RF Screen performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

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}

MATERIALS SUPPLIED

- RF Screen Control N** Barcode labeled tubes with buffer containing human antibodies to RF in stabilizers and preservatives. Ready to use, 1 mL.

Control	N
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

- RF Screen Control P** Barcode labeled tubes with buffer containing human antibodies to RF in stabilizers and preservatives. Ready to use, 1 mL.

Control	P
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Control Code contains controls' information is provided in each kit.

Target value and acceptance range for the controls are indicated on the card provided in each kit.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use any controls beyond their expiration dates.
- Do not mix controls from different lots unless specified.
- Instructions must be carefully followed for using and storing of controls. Any modification in procedure may interfere with the results.
- Controls and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- 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!

Precautions:



Human serum is added in the controls.

- 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. 7 Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.



- Proclin 300 is added in the controls at concentration between 0.0015% - 0.6%.
- Controls contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with controls happens, rinse the contact surface with plenty of water immediately and see a doctor if necessary.

STORAGE CONDITIONS

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened controls could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 35 controls, after which the reagent must be discarded.
- Avoid repeated freezing and thawing.

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.

Control

The control procedure should be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency. Each Laboratory should establish its own reference ranges.

Programming and Running samples

1. Put the kit into the corresponding position of the reagent chamber of the fully automatic chemiluminescence analyzer. The information of the kit 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.

TRACEABILITY

The reported values were determined over multiple runs on the BioCLIA 6500 and BioCLIA 500 using specific lots of reagents against an in-house standard. DGP 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

- The controls are designed for control of the same lot of BioCLIA Autoimmune Reagent Kit.
- The controls can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 35 controls are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper results.

SYMBOLS

	Catalog Number		Use-by date
	In Vitro diagnostic medical device		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in the European Community
	CE Marking		Contains Sufficient for <n> Tests
	Biological Risk		GHS07 Warning

	Negative Control
	Positive Control

REFERENCE

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. Fallet GH. [Early diagnosis of rheumatoid arthritis]. Journal of Internal Medicine 1954;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.



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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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