

BioCLIA Autoimmune Calibrator Set, Ro60

Cat.No.	Kit Size
MY00200	2 X 1 mL
MY00251	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Calibrator Set, Ro60 is intended for the calibration of the BioCLIA Ro60 performed on the BioCLIA 6500 and BioCLIA 500.

For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Anti-nuclear antibody (ANA) is a class of auto-antibodies with different binding affinities specific to different nuclear antigens. Generally, ANAs include extractable nuclear antigen (ENA) antibodies and un-extractable nuclear antigen antibodies.¹ Determination of ANA has significant correlation to the diagnosis of Sharp syndrome (MCTD), systemic lupus erythematosus (SLE), Sjögren's syndrome, progressive systemic sclerosis, polymyositis/dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

Anti-Ro60 antibodies, also known as anti-Ro antibodies, are commonly found in primary Sjögren's Syndrome, an autoimmune disorder that affects the exocrine glands. The presence of anti-Ro60 antibodies are found in 50–70% of Sjögren's Syndrome and 30% of SLE with cutaneous involvement.^{2,3} Anti-Ro antibodies are also found less frequently in other disorders including autoimmune liver diseases, coeliac diseases, autoimmune rheumatic diseases, cardiac neonatal lupus erythematosus and polymyositis.^{4,5}

During pregnancy, anti-Ro60 antibodies can cross the placenta and cause neonatal lupus in babies.⁶ In Sjögren's Syndrome, anti-Ro60 antibodies correlate with early onset, increased disease duration, parotid gland enlargement, disease outside the glands and infiltration of glands by lymphocytes.⁷ Anti-Ro60 antibodies are specific to components of the Ro-RNP complex, comprising 45 kDa, 52 kDa, 54 kDa and 60kDa proteins and RNA. The 60 kDa DNA/RNA binding protein and 52 kDa T-cell regulatory proteins are the best characterized antigens of anti-Ro antibodies. Collectively, these proteins are part of a ribonucleoprotein (RNP) complex that associated with the hYRNAs, hY1-hY5.

The Ro antigens are expressed on the surface of cells undergoing apoptosis and may cause the inflammation within the salivary gland by interaction with cells of the immune system. The antibodies may also be produced through molecular mimicry, where cross reactive antibodies bind to both virus and human proteins. This may occur with the Ro antigens and may subsequently produce antibodies to other proteins through a process known as epitope spreading.⁷

MATERIALS SUPPLIED

- **Ro60 Calibrator 1** Barcode labeled tubes with buffer containing human antibodies to Ro60 in stabilizers and preservatives. Ready to use, 1 mL.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **Ro60 Calibrator 2** Barcode labeled tubes with buffer containing human antibodies to Ro60 in stabilizers and preservatives. Ready to use, 1 mL.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Calibrator Code contains calibrators' information is provided in each kit.

WARNINGS AND PRECAUTIONS

- For professional *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.
- 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 calibrators.

- 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 gloves and clothing.



- Proclin 300 is added in the calibrators at concentration between 0.0015% - 0.6%.
- 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

- Store the kit at 2-8 °C.

- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened calibrators could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 20 calibrations, 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.

Assay Calibration

The BioCLIA Autoimmune Reagent Kit utilizes a predefined lot specific Master Curve which is uploaded into the instrument via the barcode provided in the main reagent kit. The Calibrator Code contains calibrator information is then scanned. Based on the results of running two calibrators, the instrument specific Working Calibration Curve is generated and is used to calculate the concentration 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 met.

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 calibrators are designed for calibration of the same lot of BioCLIA Autoimmune Reagent Kit.
- The calibrators can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 20

calibrations are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper calibration of the assay and which can give 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
	Calibrator 1		
	Calibrator 2		

REFERENCE

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2. Hernández-Molina G, Leal-Alegre G, Michel-Peregrina M. The meaning of anti-Ro and anti-La antibodies in primary Sjögren's syndrome. *Autoimmunity reviews* 2011;10:123-25.
3. Defendenti C, Atzeni F, Spina MF, Grosso S, Cereda A, Guercilena G, et al. Clinical and laboratory aspects of Ro/SSA-52 autoantibodies. *Autoimmunity reviews* 2011;10:150-54.
4. Venables PJ. Sjögren's syndrome. *Best Practice & Research Clinical Rheumatology* 2004;18:313-29.
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6. Yamamoto K. Pathogenesis of Sjögren's syndrome. *Autoimmunity reviews* 2003;2:13-18.
7. 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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