BioCLIA Autoimmune Control Set, Ro60

Cat.No.	Kit Size
MY00302	2 X 1 mL
MY00353	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, Ro60 is intended for the quality control purposes of the BioCLIA Ro60 performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Anti-nuclear antibodies (ANAs) are 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 ANAs has significant correlation to the diagnosis of Sharp Syndrome, SLE, Sjogren'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 Control N** Barcode labeled tubes with buffer containing human antibodies to Ro60 in stabilizers and preservatives. Ready to use, 1 mL.

Control | N

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

Control | P

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

Control N	Negative Control
Control P	Positive Control

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	Σ	Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning

REFERENCE

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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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