














BioCLIA[®] Autoimmune Calibrator Set

Ro60

Ro60 Assay Calibrators

Key to Symbols Used			
	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Calibrator 1		Contains Sufficient for $< n >$ Tests
	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator

Set, Ro60

Intended Use

The BioCLIA® Autoimmune Calibrator Set, Ro60 is intended for the calibration of the BioCLIA Ro60 performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00200 (2 X 1 mL)

MY00251 (4 X 1 mL)

Summary and Principles of the Procedure

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 Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator contains human antibodies to Ro60 in 0.1 M Tris (pH7.4) buffer.

Ro60	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **Ro60 Calibrator 2** A tube contains 1mL, ready to use reagent. Calibrator contains human antibodies to Ro60 in 0.1 M Tris (pH7.4) buffer.

Ro60	CAL	2
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

Precautions:



Human serum is added in the calibrators.



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

- 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. Ro60 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 Ro60. 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

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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.
5. Scofield RH. Autoantibodies as predictors of disease. The Lancet 2004;363:1544-46.
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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Technical Assistance

For technical assistance, contact your National Distributor.

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Revision 9



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