














BioCLIA[®] Autoimmune Calibrator Set

Ro52

Ro52 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, Ro52

Intended Use

The BioCLIA Autoimmune Calibrator Set, Ro52 is intended for the calibration of the BioCLIA Ro52 performed on the BioCLIA®1200 and BioCLIA®6500.

Catalog Numbers

MY00206 (2 X 1mL)

MY00257(4 X 1mL)

Summary and Principles of the Procedure

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), sjogren's syndrome, progressive systemic sclerosis, polymyositis/dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

Ro52 is a 52 kDa protein detected in autoimmune diseases patients' sera include sjogren's syndrome, systemic lupus erythematosus (SLE), dermatomyositis, etc. It belongs to the TRIM protein family (TRIM21) with different functional structure domain like RING finger, B-box or curly spiral.^{2,3} The effect of Ro52 on immune defense is increasingly concerned, such as the interaction between Ro52 and IgG molecules, or how the Ro52 being an E3 ubiquitin ligase and act on signal molecules. So far, the pathogenic mechanism of Ro52 in autoimmune diseases is not clear. Ro52 proteins are confirmed to be associated with SS-A/Ro complex function.⁴

Due to the appearance of anti-Ro52 antibodies in a variety of autoimmune diseases, it should not be taken as a specific indicator of SLE or sjogren's syndrome but should combine with other clinical findings.

Materials supplied

• **Ro52 Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Ro52 in stabilizers and preservatives.

Ro52	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

• **Ro52 Calibrator 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Ro52 in stabilizers and preservatives.

Ro52	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.⁵ 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, on board 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. Ro52 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 Ro52 Reagents. 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. Tan EM. Autoantibodies to nuclear antigens (ANA): their immunobiology and medicine. *Advances in Immunology* 1982;33:167-240.
2. Frank M, Itoh K, Fujisaku A, Pontarotti P, Mattei M, Neas B. The mapping of the human 52-kD Ro/SSA autoantigen gene to human chromosome 11, and its polymorphisms. *American journal of human genetics* 1993;52:183.
3. James LC, Keeble AH, Khan Z, Rhodes DA, Trowsdale J. Structural basis for PRYSPRY-mediated tripartite motif (TRIM) protein function. *Proceedings of the National Academy of Sciences* 2007;104:6200-05.
4. Mallery DL, McEwan WA, Bidgood SR, Towers GJ, Johnson CM, James LC. Antibodies mediate intracellular immunity through tripartite motif-containing 21 (TRIM21). *Proceedings of the National Academy of Sciences* 2010;107:19985-90.
5. Richmond JY, McKinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

Technical Assistance

For technical assistance, contact your National Distributor.

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Revision 9



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