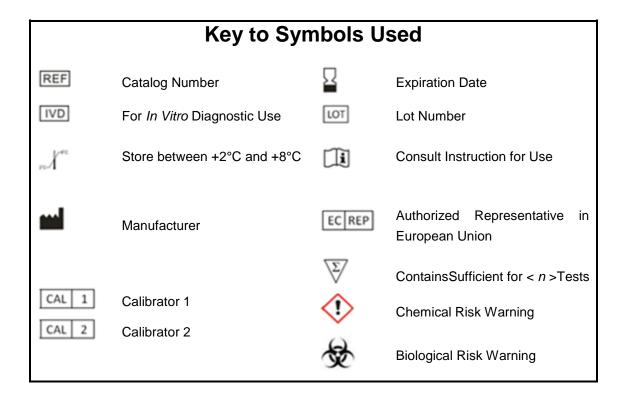
# BioCLIA<sup>®</sup> Autoimmune Calibrator Set

# **Ro52**

# **Ro52 Assay Calibrators**



# 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) antibodiesand un-extractable nuclear antigen antibodie. 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, andlimited 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 7erythematosus (SLE), dermatomyositis, *etc.* It belongs to the TRIM proteinfamily(TRIM21) with different functional structure domain like RING finger, B-box or curly spiral. <sup>2, 3</sup> 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 Ro52in autoimmune diseases is not clear.Ro52 proteins are confirmed to be associated with SS-A/Ro complex function. <sup>4</sup>

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

# Materials supplied

•Ro52Calibrator 1 A tube contains1mL, ready to use reagent. Control contains human antibodies to Ro52 in stabilizers and preservatives.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

•Ro52Calibrator 2 A tube contains1mL, ready to use reagent. Control contains human antibodies to Ro52 in stabilizers and preservatives. Ro52 CAL 2

 $\label{eq:preservatives: 0.0015\% < Proclin 300 < 0.6\%.}$ 

Target value informationis 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. 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 fromdifferent 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.
- Calibratorscontain chemical and biological components. Avoidingestingor splashing onto skin and mucous membrane. If direct contact with calibrators happens, rinse immediately the contact surface with plenty of waterand 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 bediscarded. 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 forpreparation, 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

- Tan EM. Autoantibodies to nuclear antigens (ANA): their immunobiology and medicine. Advances in Immunology 1982;33:167-240.
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- 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.







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#### **Technical Assistance**

For technical assistance, contact your National Distributor.

17<sup>th</sup> April 2019

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