









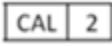




# BioCLIA<sup>®</sup> Autoimmune Calibrator Set

*sp100*

## sp100 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, sp100

## Intended Use

The BioCLIA Autoimmune Calibrator Set, sp100 is intended for the calibration of the BioCLIA sp100 performed on the BioCLIA® 1200 and BioCLIA® 6500.

## Catalog Numbers

MY00217 (2 X 1 mL)

MY00268 (4 X 1 mL)

## Summary and Principles of the Procedure

Autoimmune liver diseases (ALD) include autoimmune hepatitis (AIH),<sup>1, 2</sup> primary biliary cirrhosis (PBC)<sup>3</sup> and primary sclerosing cholangitis (PSC).<sup>4</sup> Determination of indicators such as AMA, CENP-B, LKM-1 and SLA/LP has significant correlation to ALD diagnosis.

By indirect immune-fluorescence method, a special fluorescence karyotype was detected (Anti-centromere antibodies positive) in Primary Biliary Cirrhosis (PBC) and chronic arthritis patients. 5 - 20 scattered point-like particles with different sizes distribute are visible in the cell nucleus in the cell split phase. It is specific to sp100 antigen (100 kDa) which is a soluble acidic phosphorylation nucleoprotein.

Anti-sp100 antibodies are closely related to primary biliary cirrhosis (PBC) that the specificity is about 97% and sensitivity is 10% ~ 30%. For PBC patients, sensitivity of anti-sp100 antibodies is 60% for antimitochondrial antibodies (AMA) negative ones and 20% for AMA positive ones, therefore anti-sp100 antibodies is of great significance for the diagnosis of AMA in PBC patients.<sup>5, 6</sup>

Other than PBC, anti-sp100 antibodies are also found in the rheumatism ones associated with PBC but in a lower sensitivity (about 5% for progressive scleroderma and 1.5% for SLE).

## Materials supplied

- **sp100 Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator 1 contains human antibodies to sp100 in stabilizers and preservatives.

sp100 CAL 1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **sp100 Calibrator 2** A tube contains 1mL, ready to use reagent. Calibrator 2 contains human antibodies to sp100 in stabilizers and preservatives.

sp100 CAL 2

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.<sup>7</sup> 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. sp100 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 sp100. 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. Nakamura M, Kondo H, Mori T, Komori A, Matsuyama M, Ito M, et al. Anti - gp210 and anti - centromere antibodies are different risk factors for the progression of primary biliary cirrhosis. Hepatology 2007;45:118-27.
4. T Tabibian JH, Lindor KD. Primary sclerosing cholangitis: a review and update on therapeutic developments. Expert review of gastroenterology & hepatology 2013;7:103-14.
5. Szostecki C, Guldner H, Netter H, Will H. Isolation and characterization of cDNA encoding a human nuclear antigen predominantly recognized by autoantibodies from patients with primary biliary cirrhosis. The Journal of Immunology 1990;145:4338-47.
6. Blüthner M, Schäfer C, Schneider C, Bautz FA. Identification of major linear epitopes on the sp100 nuclear PBC autoantigen by the gene-fragment phage-display technology. Autoimmunity 1999;29:33-42.
7. 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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