














BioCLIA[®] Autoimmune Calibrator Set

PM-Scl

PM-Scl 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, PM-Scl

Intended Use

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

Catalog Numbers

MY00209 (2 X 1 mL)

My00260 (4 X 1 mL)

Summary and Explanation

PM/Scl overlap syndrome or scleromyositis is a complex autoimmune disease (a disease in which the immune system attacks the body). Patients with scleromyositis have symptoms of both systemic scleroderma and either polymyositis or dermatomyositis, and is therefore considered an overlap syndrome. Although it is a rare disease, it is one of the most common overlap syndromes seen in scleroderma patients, together with MCTD and Antisynthetase syndrome. Autoantibodies often found in these patients are the anti-PM/Scl (anti-exosome) antibodies.¹

The symptoms that are seen most often are typical symptoms of the individual autoimmune diseases and include Raynaud's phenomenon, arthritis, myositis and scleroderma.² Treatment of these patients is therefore strongly dependent on the exact symptoms with which a patient reports to a physician and is similar to treatment for the individual autoimmune disease, often involving either immunosuppressive or immunomodulating drugs.^{3,4}

Materials supplied

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

PM-Scl	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

PM-Scl	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, 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. PM-Scl 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 PM-Scl. 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. Jablonska S, Blaszczyk M. Scleroderma Overlap Syndromes. Advances in Experimental Medicine & Biology 1999;455:85-92.
2. Mahler M, Raijmakers R. Novel aspects of autoantibodies to the PM/Scl complex: clinical, genetic and diagnostic insights. Autoimmunity Reviews 2007;6:432-7.
3. Jablonska S, Blaszczyk M. Scleromyositis: a scleroderma/polymyositis overlap syndrome. Clinical Rheumatology 1998;17:90-91.
4. Vandergheynst F, Ocmant A, Sordet C, Humbel RL, Goetz J, Roufosse F, et al. Anti-pm/scl antibodies in connective tissue disease: Clinical and biological assessment of 14 patients. Clinical & Experimental Rheumatology 2006;24:129-33.
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.

17th April 2019

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