














BioCLIA[®] Autoimmune Calibrator Set

CCP

CCP 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, CCP

Intended Use

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

Catalog Numbers

MY00234 (2 X 1 mL)

MY00285 (4 X 1 mL)

Summary and Principles of the Procedure

Rheumatoid Arthritis (RA) is a chronic systemic disease mainly with inflammatory synovitis. About 1% of the world's people suffer from this disease in which 75% are women. ¹ At present, in patients with suspected of RA, the most commonly used detection includes conventional inflammatory parameters, or rheumatoid factors (RFs) detection with 60-80% sensitivity in RA. However, RFs are also detected in healthy people, Systemic Lupus Erythematosus (SLE) or Sjogren's Syndrome patients, so RF is a sensitive but not very specific indicators for RA diagnosis. ²

Antibodies to citrullinated protein antigens (ACPAs) are autoantibodies that are directed against peptides and proteins that are citrullinated. They are present in the majority of patients with RA. Clinically, cyclic citrullinated peptides (CCP) are frequently used to detect these antibodies with high sensitivity in patient serum or plasma. ^{3, 4, 5} Anti-CCP antibody is very useful in the early diagnosis of RA in high-risk groups, such as relatives of RA patients. ⁶ It is mainly in IgG types and having the same sensitivity but higher specificity at 95% for RA diagnosis. ⁷

Materials supplied

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

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

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

CCP	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. ⁸ 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. CCP 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 CCP. 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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Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019

Revision 9