

BioCLIA[®] Autoimmune Calibrator Set

PCA

PCA 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, PCA

Intended Use

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

Catalog Numbers

MY00247 (2 X 1 mL)

My00298 (4 X 1 mL)

Summary and Explanation

Pernicious anemia (PA) is a disease in which there are not enough red blood cells partially due to autoimmune problems or lack of vitamin B₁₂. The most common initial symptom is feeling tired. Other symptoms may include shortness of breath, pale skin, chest pain, numbness in the hands and feet, poor balance, a smooth, red tongue, poor reflexes, and confusion. ¹ If treatment is not provided, some of these problems may become permanent. ²

PA may be considered as an end stage of immune gastritis, a disease characterised by stomach atrophy and the presence of antibodies to parietal cells and intrinsic factor. ³ This autoimmune disorder is localised to the body of the stomach, where parietal cells are located. ⁴ Antibodies to intrinsic factor and parietal cells cause the destruction of the oxyntic gastric mucosa, leading to the subsequent loss of intrinsic factor synthesis. Without intrinsic factor, the ileum can no longer absorb the B₁₂. ⁵

Parietal cell antibodies are found in other autoimmune disorders and also in up to 10% of healthy individuals, making the test nonspecific. However, around 85% of PA patients have parietal cell antibodies, which means they are a sensitive marker for the disease. ⁶ The combination of both tests of intrinsic factor antibodies and parietal cell antibodies may improve overall sensitivity and specificity of the diagnostic results. ⁷ About 90% of individuals with PA have antibodies for parietal cells; however, only 50% of all individuals in the general population with these antibodies have pernicious anemia. ⁸

Materials supplied

- **PCA Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator contains human antibodies to

| | | |
|-----|-----|---|
| PCA | CAL | 1 |
|-----|-----|---|

 in stabilizers and preservatives.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **PCA Calibrator 2** A tube contains 1mL, ready to use reagent. Calibrator contains human antibodies to

| | | |
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| PCA | CAL | 2 |
|-----|-----|---|

 in stabilizers and preservatives.

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. ⁹ 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. PCA 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 PCA. 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.

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Revision 9



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