# BioCLIA® Autoimmune Control Set

## *PCA*

**PCA Assay Controls**

### Key to Symbols Used

| | | | |
|---|---|---|---|
| REF | Catalog Number | | Expiration Date |
| IVD | For *In Vitro* Diagnostic Use | LOT | Lot Number |
| | Store between +2°C and +8°C | | Consult Instruction for Use |
| | Manufacturer | EC REP | Authorized Representative in European Union |
| | | Σ | Contains Sufficient for < *n* > Tests |
| Control L | Control 1 | | |
| Control H | Control 2 | | Chemical Risk Warning |
| | | | Biological Risk Warning |

# BioCLIA® Autoimmune Control Set, PCA

**Intended Use**

The BioCLIA Autoimmune Control Set, PCA is intended for the quality control purposes of the BioCLIA PCA performed on the BioCLIA® 1200 and BioCLIA® 6500.

**Catalog Numbers**

MY00349 (2 X 1 mL)

My00400 (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 $B_{12}$. 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 $B_{12}$. [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 Control 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to PCA in stabilizers and preservatives (Low).

| PCA | Control | L |
|---|---|---|

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **PCA Control 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to PCA in stabilizers and preservatives (High).

| PCA | Control | H |
|---|---|---|

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value and acceptable range for the controls are indicated on control information sheet 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 controls.

 Proclin 300 is added in the controls at concentration between 0.0015% - 0.6%.

- The product is for *in vitro* diagnostic use only.
- Do not use any controls beyond their expiration dates. Do not mix controls from different lots unless specified.
- Instructions must be carefully followed for using and storing of controls. Any modification in procedure may interfere with the results. Controls and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Controls contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with controls happens, rinse the contact surface with plenty of water immediately and see a doctor if necessary.

**Storage Conditions**

The kit is stable until the expiration date, if it is stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a control 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.

The control procedure can be done before running the specimens each day. Users also can adjust the

control procedure period according to their own lab frequency.

**Limitations**

This product is designed as controls for monitoring the performance of the BioCLIA PCA. These controls are subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

**References**


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EC REP

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**Technical Assistance**

For technical assistance, contact your National Distributor.

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