

BioCLIA Autoimmune Control Set, PCA

Cat.No.	Kit Size
MY00349	2 X 1 mL
MY00400	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, PCA is intended for the quality control purposes of the BioCLIA PCA performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

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 characterized by stomach atrophy and the presence of antibodies to parietal cells and intrinsic factor. ³ This autoimmune disorder is localized 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 Control N** Barcode labeled tubes with buffer containing human antibodies to PCA in stabilizers and preservatives. Ready to use, 1 mL.



Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **PCA Control P** Barcode labeled tubes with buffer containing human antibodies to PCA in stabilizers and preservatives. Ready to use, 1 mL.



Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Control Code contains controls' information is provided in each kit.

Target value and acceptance range for the controls are indicated on the card provided in each kit.

WARNINGS AND PRECAUTIONS

- For professional *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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established!

Precautions:



Human serum is added in the controls.

- 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. ⁷ Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.



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

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened controls could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 35 controls, after which the reagent must be discarded.
- Avoid repeated freezing and thawing.

ASSAY PROCEDURE

Detailed information about operating the BioCLIA instruments can be

taken from the Instrument User's Manual.

Note that, it is important to perform all routine maintenance procedures for optimal performance.

Control

The control procedure should be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.

Each Laboratory should establish its own reference ranges.

Programming and Running samples

1. Put the kit into the corresponding position of the reagent chamber of the fully automatic chemiluminescence analyzer. The information of the kit can be uploaded into the instrument system through the scanning of reagent barcode, and can also be set through the supporting software of the instrument.
2. The information of calibrator / quality control is identified by scanning the calibrator / control barcodes, and the position of calibrator / quality control is assigned in the instrument system.
3. The sample to be tested is placed on the instrument sample rack chamber, and the corresponding test information is edited through the instrument supporting software.
4. Start the operation procedure, and all calibrator / quality control / sample processing steps will be automatically executed.

TRACEABILITY

The reported values were determined over multiple runs on the BioCLIA 6500 and BioCLIA 500 using specific lots of reagents against an in-house standard. DGP IgA 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

- The controls are designed for control of the same lot of BioCLIA Autoimmune Reagent Kit.
- The controls can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 35 controls are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper results.

SYMBOLS

	Catalog Number		Use-by date
	In Vitro diagnostic medical device		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in the European Community
	CE Marking		Contains Sufficient for <n> Tests
	Biological Risk		GHS07 Warning

	Negative Control
	Positive Control

REFERENCE

1. Toh BH, van Driel IR, Gleeson PA. Pernicious anemia. New England Journal of Medicine 1997;337:1441-8.
2. Hsing AW, Hansson LE, McLaughlin JK, Nyren O, Blot WJ, Ekblom A, Jr FJ. Pernicious anemia and subsequent cancer. A population-based cohort study. Cancer 1993;71:745-50.
3. De Block CE, De Leeuw IH, Van Gaal LF. Autoimmune gastritis in type 1 diabetes: a clinically oriented review. Journal of Clinical Endocrinology & Metabolism 2008;93:363-71.
4. Banka S, Ryan K, Thomson W, Newman WG. Pernicious anemia - genetic insights. Autoimmunity Reviews 2011;10:455-9.
5. Lahner E, Annibale B. Pernicious anemia: New insights from a gastroenterological point of view. World Journal of Gastroenterology 2009;15:5121-28.
6. Snow CF. Laboratory diagnosis of vitamin B12 and folate deficiency: a guide for the primary care physician. Archives of Internal Medicine 1999;159:1289-98.
7. Gräsbeck R. Imerslund-Gräsbeck syndrome (selective vitamin B12 malabsorption with proteinuria). Orphanet Journal of Rare Diseases 2006;1:4677-87.
8. Butler CC, Vidal-Alaball J, Cannings-John R, McCaddon A, Hood K, Papaioannou A, et al. Oral vitamin B12 versus intramuscular vitamin B12 for vitamin B12 deficiency: a systematic review of randomized controlled trials. Family practice 2006;23:279-85.
9. Richmond JY, McKinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.



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The eIFU is available on Website:

<http://en.hob-biotech.com/usercenter/login.aspx>

TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

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