

BioCLIA[®] Autoimmune Calibrator Set

Intrinsic Factor

Intrinsic Factor 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, Intrinsic Factor

Intended Use

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

Catalog Numbers

MY00248 (2 X 1 mL)

My00299 (4 X 1 mL)

Summary and Explanation

Pernicious anemia (PA) is a disease in which there are not enough red blood cells, that partially due to lack of vitamin B₁₂, not enough intrinsic factor, or autoimmune attack on the parietal cells. It can also occur following the surgical removal of part of the stomach or from an inherited disorder. 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 When suspected, diagnosis is often made by testing antibodies to intrinsic factor.²

Intrinsic factor is produced by parietal cells of the gastric mucosa (stomach lining) and the intrinsic factor-B₁₂ complex is absorbed by cubilin receptors on the ileum epithelial cells.^{3,4} PA is characterised by B₁₂ deficiency caused by the absence of intrinsic factor.⁵ Antibodies to intrinsic factor and parietal cells cause the destruction of the oxyntic gastric mucosa, in which the parietal cells are located, leading to the subsequent loss of intrinsic factor synthesis. Without intrinsic factor, the ileum can no longer absorb the B₁₂.⁶

The presence of antibodies to gastric parietal cells and intrinsic factor is common in PA. Intrinsic factor antibodies are much less sensitive than parietal cell antibodies, but they are much more specific. They are found in about half of PA patients and are very rarely found in other disorders. These antibody tests can distinguish between PA and food-B₁₂ malabsorption.⁷ The combination of both tests of intrinsic factor antibodies and parietal cell antibodies may improve overall sensitivity and specificity of the diagnostic results.⁸

Materials supplied

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

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

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

IF	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.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. IF 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 Intrinsic Factor. 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. 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. Wickramasinghe SN. Diagnosis of megaloblastic anaemias. Blood Reviews 2006;20:299-318.
4. Christensen EI, Birn H. Megalin and cubilin: multifunctional endocytic receptors. Nature Reviews Molecular Cell Biology 2002;3:256-66.
5. Banka S, Ryan K, Thomson W, Newman WG. Pernicious anemia - genetic insights. Autoimmunity Reviews 2011;10:455-9.
6. Lahner E, Annibale B. Pernicious anemia: New insights from a gastroenterological point of view. World Journal of Gastroenterology 2009;15:5121-28.
7. 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.
8. Gräsbeck R. Imerslund-Gräsbeck syndrome (selective vitamin B12 malabsorption with proteinuria). Orphanet Journal of Rare Diseases 2006;1:4677-87.
9. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

EUROPE REPRESENTATIVE: Emergo Europe

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Technical Assistance

For technical assistance, contact your National Distributor.

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Revision 9



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