














# BioCLIA<sup>®</sup> Autoimmune Control Set

## *Intrinsic Factor*

### Intrinsic Factor Assay Controls

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
	Control 1		Contains Sufficient for $< n >$ Tests
	Control 2		Chemical Risk Warning
			Biological Risk Warning

# BioCLIA® Autoimmune Control Set, Intrinsic Factor

## Intended Use

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

## Catalog Numbers

MY00350 (2 X 1 mL)

My00401 (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 B<sub>12</sub>, 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.<sup>1</sup> When suspected, diagnosis is often made by testing antibodies to intrinsic factor.<sup>2</sup>

Intrinsic factor is produced by parietal cells of the gastric mucosa (stomach lining) and the intrinsic factor-B<sub>12</sub> complex is absorbed by cubilin receptors on the ileum epithelial cells.<sup>3,4</sup> PA is characterised by B<sub>12</sub> deficiency caused by the absence of intrinsic factor.<sup>5</sup> 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 B<sub>12</sub>.<sup>6</sup>

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-B<sub>12</sub> malabsorption.<sup>7</sup> The combination of both tests of intrinsic factor antibodies and parietal cell antibodies may improve overall sensitivity and specificity of the diagnostic results.<sup>8</sup>

## Materials supplied

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

IF	Control	L
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

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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 Intrinsic Factor. 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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5. Banka S, Ryan K, Thomson W, Newman WG. Pernicious anemia - genetic insights. Autoimmunity Reviews 2011;10:455-9.
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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.



HOB Biotech Group Co., Ltd



C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park,  
Suzhou, Jiangsu, 215123, China

**REGISTRANT/MANUFACTURE:** HOB Biotech Group Co., Ltd

#### ADDRESS/LOCATION:

C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215123 China

**CONTACT INFORMATION:** TEL (+86)512-69561996  
Fax (+86)512-62956652

**WEBSITE:** [www.hob-biotech.com](http://www.hob-biotech.com)

**CUSTOMER SERVICE:** HOB Biotech Group Co., Ltd

**CUSTOMER SERVICE CONTACT:** TEL (+86)4008601202

**EUROPE REPRESENTATIVE:** Emergo Europe

#### ADDRESS/LOCATION:

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

#### Technical Assistance

For technical assistance, contact your National Distributor.

17<sup>th</sup> April 2019

Revision 9

