



**INTRINSIC FACTOR &
PARIETAL CELL**

EliA™
Excellence in Autoimmunity

The ideal combination for automated **pernicious anemia testing**

EliA Intrinsic Factor and EliA Parietal Cell – safe and efficient antibody testing to aid in the diagnosis of pernicious anemia

Thermo
SCIENTIFIC

Identify pernicious anemia patients with high accuracy

Two autoantibodies help to explain the cause of anemia

Pernicious anemia (PA) is the late stage of autoimmune atrophic gastritis¹ and accounts for 20%-50% of the causes of vitamin B12 deficiency in adults³. The vitamin B12 deficiency is the result of two factors:

- A lack of intrinsic factor, caused by the destruction of parietal cells in the stomach that produce this glycoprotein.¹
- The blockage of intrinsic factor, caused by intrinsic factor antibodies preventing the absorption of the intrinsic factor-Vitamin B12-complex in the ileum.¹

The predominant patient symptoms relate more to anemic status than to gastric disorders. The prevalence of PA is 0.1 % in the general population and reaches 1.9 % in patients over 60.³

A definitive diagnosis of PA is important because affected patients need lifelong treatment with vitamin B12.^{4,5}

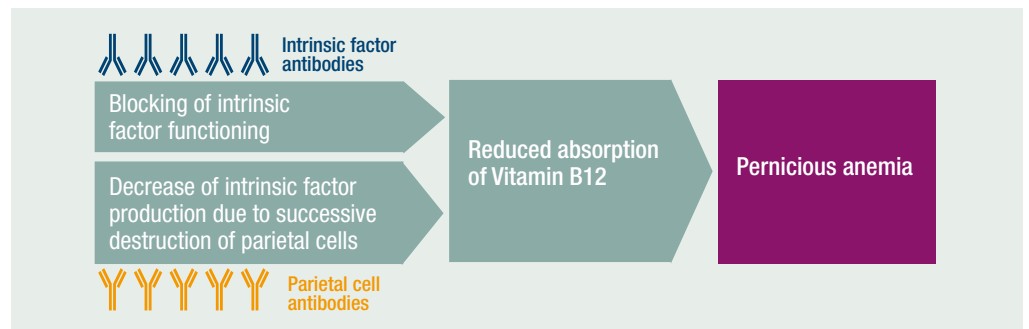


Figure 1: Schematic explanation: development of PA

Differentiate PA from other diseases with EliA Intrinsic Factor

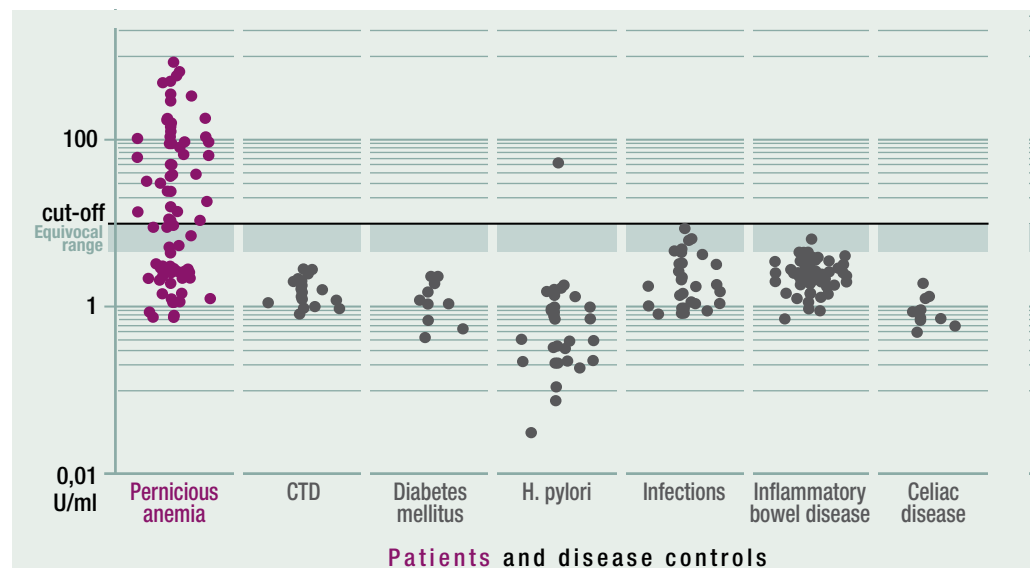


Figure 2: Performance of EliA Intrinsic Factor in 248 clinically defined serum samples: 79 PA patients and 169 disease controls (20 CTD, 10 Diabetes mellitus, 30 H. pylori, 30 Infectious disease, 69 Inflammatory bowel disease, 10 Celiac disease); internal study (data on file).

Combine two assays to gain more diagnostic information

Intrinsic factor antibodies show high diagnostic specificity³ whilst parietal cell antibodies are characterized by high sensitivity in pernicious anemia^{2,4}.

Designed for highest clinical relevance

| | EliA Intrinsic Factor (Phadia 250) | Supplier 1 (automated) | Supplier 2 (manual) |
|--|------------------------------------|------------------------|---------------------|
| Specificity | 99.4% | 81.1% | 100.0% |
| Sensitivity | 51.9% | 64.6% | 46.8% |
| Sensitivity at stratified specificity 97%* | 59.5% | 41.8% | 58.2% |
| Agreement with clinical diagnosis | 83.9% | 75.8% | 83.1% |

Table 1: Performance of EliA Intrinsic Factor in 248 clinically defined serum samples – see study cohort above (Figure 2); internal study (data on file).

| | EliA Parietal Cell (Phadia 250) | Supplier 1 (automated) | Supplier 2 (manual) |
|--|---------------------------------|------------------------|---------------------|
| Specificity | 89.9% | 84.6% | 88.8% |
| Sensitivity | 81.0% | 87.3% | 70.9% |
| Sensitivity at stratified specificity 90,5%* | 81.0% | 69.6% | 67.1% |
| Agreement with clinical diagnosis | 87.1% | 85.5% | 83.1% |

Table 2: Performance of EliA Parietal Cell in 248 clinically defined serum samples – see study cohort above (Figure 2); internal study (data on file).

EliA Intrinsic Factor and EliA Parietal Cell, with the optimal combinations of sensitivity and specificity, ensure good agreement with clinical diagnosis.

At stratified specificity, both assays show the highest sensitivity, illustrating their excellent performance.

The convincing clinical test performances of both assays provide early diagnostic guidance in the patient pathway.

| | EliA Intrinsic Factor & EliA Parietal Cell combined |
|-------------|---|
| Specificity | 89.3% |
| Sensitivity | 91.1% |

Combination of tests for high sensitivity

Table 3: Sensitivity and specificity of combined EliA Intrinsic Factor and EliA Parietal Cell testing in 248 clinically defined serum samples – see study cohort above (Figure 2); internal study (data on file)

Testing both EliA Intrinsic Factor and EliA Parietal Cell increases the sensitivity, therefore detecting even more patients suffering from PA.

* For ease of comparison of the different assays, the Receiver Operating Curves (ROC) data was used to compare sensitivities at a defined specificity at 97% (EliA Intrinsic Factor) and 90.5% (EliA Parietal Cell).

Simplify pernicious anemia diagnostics on an intuitive, automated, tailor-made platform

EliA Intrinsic Factor and EliA Parietal Cell on the Phadia® Laboratory Systems (Phadia 250/2500/5000) bring high quality and operational efficiency into your laboratory routine leading to an optimized workflow.

Your advantages with EliA Intrinsic Factor and EliA Parietal Cell:

- Benefit from clear diagnostic guidance: both assays derived from convincing test performances
- Detect more patients suffering from PA with the combination of a sensitive (EliA Parietal Cell) and a specific test (EliA Intrinsic Factor)
- Increase operational efficiency with the fully automated testing of both assays on Phadia Laboratory Systems
- Easy integration of the assays into laboratory routine – just add EliA Intrinsic Factor and EliA Parietal Cell and start testing

References:

- 1 Toh BH and Alderuccio F; *Autoimmunity* 37 2004: 357–361
- 2 Rusak E et al.; *Advances in Medical Sciences* 61 2016: 175–179
- 3 Andres E, Serraj K; Optimal management of pernicious anemia. *Journal of Blood Medicine* 2012: 3 97–103
- 4 Devalia V et al.; Guidelines for the diagnosis and treatment of cobalamin and folate disorders. *Br J Haematol.* 166 2014: 496–513
- 5 Varbanova M et al.; Chronic gastritis – an update. *Best Pract Res Clin Gastroenterol.* 28 2014: 1031–42

Technical data:

| Ordering information | Article No. | Package size | Cut-off | | | Short name |
|-----------------------|-------------|--------------|----------|-----------|-----------|------------|
| | | | negative | equivocal | positive | |
| EliA Intrinsic Factor | 14-5668-01 | 2 x 12 wells | < 7 U/ml | 7–10 U/ml | > 10 U/ml | inf |
| EliA Parietal Cell | 14-5669-01 | 2 x 12 wells | < 7 U/ml | 7–10 U/ml | > 10 U/ml | par |