

## Overview

### Useful For

[Evaluating patients suspected of having pernicious anemia or autoimmune-mediated deficiency of vitamin B12 with or without megaloblastic anemia](#)

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

#### Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 0.5 mL

### Reject Due To

Gross hemolysis            Reject

Gross lipemia             Reject

Gross icterus              OK

Heat-treated specimen    Reject

### Specimen Minimum Volume

0.45 mL

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	21 days	
	Frozen	21 days	

## Clinical & Interpretive

### Clinical Information

[Pernicious anemia \(PA\) is a common form of cobalamin \(vitamin B12\) deficiency anemia.\(1\) The disorder is characterized](#)

[by abnormally large \(megaloblastic\) red blood cells and atrophic body gastritis \(ABG\) resulting from autoimmune-mediated destruction of parietal cells that line the stomach wall. The destruction of parietal cells leads to impaired production of intrinsic factor \(IF\) required for the absorption of vitamin B12. PA is frequently associated with other autoimmune conditions such as autoimmune thyroid disease, type 1 diabetes mellitus, and vitiligo.\(2-5\) Diagnosis of PA relies on histologically proven ABG, peripheral blood examination showing megaloblastic anemia, vitamin B12 deficiency, parietal cell antibodies \(PCA\) with or without intrinsic factor antibodies \(IFA\), and elevated serum gastrin from loss of acid secretion.\(2-4\) PCA bind to the alpha- and beta-subunits of the membrane-bound H\(+\)/K\(+\)-ATPase while IFA bind directly to intrinsic factor, blocking its ability to bind vitamin B12.\(1,4\) Both PCA and IFA are useful diagnostic tests for PA, however, compared to PCA, IFA are more specific and lack diagnostic sensitivity.\(2,4,5\)](#)

### Reference Values

Negative: < or =20.0 Units

Equivocal: 20.1-24.9 Units

Positive: > or =25.0 Units

Reference values apply to all ages.

### Interpretation

[A positive result indicates the presence of IgG antibodies to H\(+\)/K\(+\) ATPase and maybe suggestive of pernicious anemia \(PA\) or a related autoimmune disease.](#)

[A negative result indicates no detectable IgG antibodies to H\(+\)/K\(+\) ATPase; it does not rule out PA.](#)

[An equivocal result is inconclusive for the presence of IgG antibodies to H\(+\)/K\(+\)ATPase. Consider re-testing in 4-6 weeks if clinical suspicion for PA is high.](#)

### Cautions

[The presence of immune complexes or other immunoglobulin aggregates in the patient specimen may cause an increased nonspecific binding and produce false-positive results in this assay.](#)

A negative result does not rule out the presence of parietal cell antibodies; the concentration of antibody may be below the detection limit of the assay.

A positive result only indicates the presence of antibody to H(+)/K(+) ATPase and does not necessarily indicate the presence of autoimmune disease or other diseases.

The assay performance has not been established for pediatric patients.

Results of this assay should be used in conjunction with clinical findings and other serological tests.

The assay performance characteristics have not been established for matrices other than serum.

### Clinical Reference

1. Toh BH, Van Driel IR, Gleeson PA: Pernicious anemia. N Eng J Med. 1997;337(20):1441-1448
2. Bizzaro N, Antico A: Diagnosis and classification of pernicious anemia. Autoimmun Rev. 2014;13(4-5):565-568
3. Toh BH: Pathophysiology and laboratory diagnosis of pernicious anemia. Immunol Res. 2017;65(1):326-330
4. Lenti MV, Rugge M, Lahner E, et al: Autoimmune gastritis. Nat Rev Dis Primers. 2020 Jul 9;6(1):56
6. Oo TH: Diagnostic difficulties in pernicious anemia. Discov Med. 2019;28(155):247-253

### Performance

### Method Description

[Purified H\(+\)/K\(+\) ATPase antigen, isolated from pig gastric mucosa, is bound to the wells of a polystyrene microwell](#)

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[plate under conditions that will preserve the antigen in its native state. Prediluted controls and diluted patient sera are added to separate wells, allowing any H\(+\)/K\(+\) ATPase antibodies present to bind to the immobilized antigen. Unbound sample is washed away, and an enzyme-labeled antihuman IgG conjugate is added to each well. A second incubation allows the enzyme-labeled antihuman IgG to bind to any patient antibodies, which have become attached to the microwells. After washing away any unbound enzyme-labeled antihuman IgG, the remaining enzyme activity is measured by adding a chromogenic substrate and measuring the intensity of the color that develops. The assay is evaluated spectrophotometrically by measuring and comparing the color intensity that develops in the patient wells with the color in the control wells.](#)(Package insert: QUANTA Lite GPA. INOVA Diagnostics, Inc; Revision 6, 09/2019)

**PDF Report**

No

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees & Codes****Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

83516