

Overview
Useful For

Evaluating patients suspected of having pernicious anemia or immune-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

Specimen Minimum Volume

0.45 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK
Other	Heat-treated specimen

Specimen Stability Information

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

Clinical and Interpretive
Clinical Information

Pernicious anemia (PA) is characterized by atrophic body gastritis (ABG) and is the end state of a progressive disease known as autoimmune chronic atrophic gastritis.(1) In this disease, immune-mediated inflammation leads to destruction of gastric parietal cells with the resultant loss of intrinsic factor production and the inability to absorb dietary vitamin B12. Diagnosis of PA involves demonstrating the presence of a macrocytic anemia in the context of vitamin B12 deficiency, as well as documenting positive autoantibody serology, specifically anti-parietal cell antibody (PCA) and intrinsic factor antibody (IFA).(2) PCAs bind to the alpha- and beta-subunits of the membrane-bound H(+)/K(+)-ATPase. In contrast, IFAs bind directly to intrinsic factor, blocking its ability to bind vitamin B12.(1,2) Both PCAs and IFAs are useful diagnostic markers for PA. In a recently published study, PCAs were 81% sensitive and 90% specific for ABG, while IFAs were 27% sensitive and 100% specific. The study concluded that a combination of PCA and IFA testing was the optimal strategy for the evaluation of patients with suspected PA.(4)

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 suggests the possibility 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 indeterminate.

Cautions

The presence of immune complexes or other immunoglobulin aggregates in the patient specimen may cause an increased non-specific 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. Lahner E, Annibale B: Pernicious anemia: new insights from a gastroenterological point of view. *World J Gastroenterol* 2009;15(41):5121-5128
3. Lahner E, Normal GL, Severi C, et al: Reassessment of intrinsic factor and parietal cell autoantibodies in atrophic gastritis with respect to cobalamin deficiency. *Am J Gastroenterol* 2009;104(8):2071-2079

4. Product Insert: QUANTA Lite GPA, INOVA Diagnostics, Inc., San Diego, CA

Performance

Method Description

Purified H(+)/K(+) ATPase antigen, isolated from pig gastric mucosa, is bound to the wells of a polystyrene microwell 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., December 2002, Revision 1)

PDF Report

No

Day(s) and Time(s) Test Performed

Tuesday, Friday; 3 p.m.

Analytic Time

1 day

Maximum Laboratory Time

4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared or approved by the U.S. 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

LOINC® Information



Test ID	Test Order Name	Order LOINC Value
PCAB	Parietal Cell Ab, IgG, S	40960-7

Result ID	Test Result Name	Result LOINC Value
PCAB	Parietal Cell Ab, IgG, S	40960-7