

## Overview

### Useful For

Diagnosis of recent infection with *Bordetella pertussis* in patients with symptoms consistent with whooping cough for 2 or more weeks

This test should **not be used** in neonates, young infants or in children between the ages of 4 to 7 years as the routine childhood vaccine schedule may interfere with result interpretation.

This test should **not be used** as a test of cure, to monitor response to treatment, or to determine vaccine status.

### Highlights

This test may be used to diagnose recent infection with *Bordetella pertussis* in patients who have **not** had the acellular pertussis vaccine or booster in the last 6 months.

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

This test should be ordered in patients with 2 or more weeks of symptoms consistent with whooping cough. Nucleic acid amplification testing for *Bordetella pertussis* should be used in patients who have been symptomatic less than 2 weeks; order BPRP / *Bordetella pertussis* and *Bordetella parapertussis*, Molecular Detection, PCR, Varies.

### Specimen Required

#### Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 1 mL

### Forms

If not ordering electronically, complete, print, and send [Infectious Disease Serology Test Request](#) (T916) with the specimen.

**Specimen Minimum Volume**

0.5 mL

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat inactivated	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	30 days	
	Frozen	30 days	

**Clinical & Interpretive****Clinical Information**

*Bordetella pertussis*, the causative agent of whooping cough, is highly contagious and remains endemic in the United States despite the high rate of vaccination. Acute *B pertussis* infections are typically diagnosed by culture or nucleic acid amplification testing (NAAT). However, symptomatic adults and adolescents often seek medical attention later in the course of infection, at which time the sensitivity of these 2 methods to detect the infectious agent decreases. A serologic response to *B pertussis* is typically mounted 2 weeks following infection, and therefore, detection of IgG-class antibodies to pertussis toxin (PT), which is only produced by *B pertussis*, can be a useful adjunct for diagnosis at later stages of illness.

Prior to testing, providers should review whether the patient was recently vaccinated using the Tdap (Tetanus-Diphtheria-acellular Pertussis) or DTap vaccines. The acellular pertussis vaccine contains 1 to 5 *B pertussis* antigens, including filamentous hemagglutinin, pertactin, 2 fimbrial agglutinogens, and significant levels of PT. Therefore, recent vaccination for *B pertussis*, specifically within the last 2 to 6 months, may lead to a positive result by the anti-PT IgG assay, and knowledge of the patient's vaccination history is important for accurate result interpretation.

**Reference Values**

&gt; or =100 IU/mL (positive)

&gt; or = 40-&lt;100 IU/mL (borderline)

&lt;40 IU/mL (negative)

Reference values apply to all ages.

**Interpretation**

Negative (<40 IU/mL): No IgG antibodies to pertussis toxin (PT) detected. Results may be falsely negative in patients with less than 2 weeks of symptoms.

Borderline (40-<100 IU/mL): Recommend follow-up testing in 10 to 14 days if clinically indicated.

Positive (> or =100 IU/mL): IgG antibodies to pertussis toxin (PT) detected. Results suggest recent infection with or recent vaccination against *Bordetella pertussis*.

### Cautions

Immune response following vaccination cannot be distinguished from recent infection.

For diagnosis, clinical symptoms, the patient's age and vaccination history should always be taken into account along with the serological results.

Whooping cough caused by *Bordetella parapertussis* will not be detected by this assay.

The Centers for Disease Control and Prevention recommend nucleic acid amplification tests (NAAT) or culture as first-line tests for *B pertussis* infection. However, serologic testing may be useful in patients who are symptomatic for more than 2 weeks.

### Supportive Data

Accuracy:

A total of 108 previously characterized serum samples (originally tested by Focus Diagnostics Inc.) were evaluated by the EuroImmuno antipertussis toxin (PT) IgG EIA and the results are indicated below.

Comparison of the EuroImmuno and Focus Diagnostics <i>Bordetella pertussis</i> PT EIAs			
		Focus Diagnostics PT EIA	
		Positive	Negative
EuroImmuno PT EIA	Positive	18	0
	Negative	0	77
	Borderline(a)	8(b)	5(c)

(a) Testing of a convalescent sample is recommended. Samples not included in positive and negative agreement calculations below.

(b) All 8 samples had low positive values by the Focus assay.

(c) All 5 samples were near the lower end of the borderline range for the EuroImmuno ELISA.

Positive Agreement: 100% (18/18); 95% CI: 79.3%-100%

Negative Agreement: 100% (77/77); 95% CI: 94.3%-100%

Overall Agreement: 95.4% (95/108); 95% CI: 80.4%-93.0%

### Clinical Reference

1. Leber AL: Pertussis: relevant species and diagnostic update. Clin Lab Med. 2014;34:237-255
2. Guiso N, Berbers G, Fry NK, et al: What to do and what not to do in serological diagnosis of pertussis: recommendation from EU reference laboratories. Eur J Clin Microbiol Infect Dis. 2011;30(3):307-312
3. Andre P, Caro V, Njamkepo E, et al: Comparison of serological and real-time PCR assays to diagnose Bordetella pertussis infection in 2007. J Clin Microbiol. 2008;46(5):1672-1677

## Performance

### Method Description

The antipertussis toxin (PT) IgG enzyme-linked immunosorbent assay (ELISA) test is a quantitative assay. Microtiter wells are coated with PT from *Bordetella pertussis* and diluted patient samples, calibrators, and controls are incubated in the wells. If present, antibodies to *Bordetella pertussis* will bind to the antigen. After wells are washed, enzyme-labeled antihuman IgG is added, and wells are incubated a second time. After incubation, wells are washed and a tetramethylbenzidine (TMB) chromogen/substrate solution is added and wells are incubated. Stop solution is added to stop the reaction. Wells are read using a microplate reader with 450/620 nm wavelength. Calibrator values are plotted to make a point-to-point standard curve. Sample antibody concentrations are determined using the standard curve. (Package insert: Anti-Bordetella pertussis toxin ELISA (IgG) Test Instructions. EUROIMMUN US; 03/05/2019)

### PDF Report

No

### Day(s) Performed

Thursday

### Report Available

Same day/1 to 7 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Rochester

## Fees & 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 was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with

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CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

**CPT Code Information**

86615

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
BORDG	B. pertussis Ab, IgG, S	42330-1

Result ID	Test Result Name	Result LOINC® Value
BIGG	B. pertussis IgG	29659-0
DEXBG	B.pertussis Value	42330-1