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** 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

Advisory Information
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 a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
<tr>
<td>Heat inactivated</td>
<td>Reject</td>
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</tbody>
</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
<td></td>
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</tbody>
</table>

Clinical and 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

- **> or =100 IU/mL** (positive)
- **> or = 40-<100 IU/mL** (borderline)
- **<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

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.
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 CDC recommends 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 Euroimmun antipertussis toxin (PT) IgG EIA and the results are indicated below.

<table>
<thead>
<tr>
<th>Comparison of the Euroimmun and Focus Diagnostics <em>Bordetella</em> pertussis PT EIAs</th>
<th>Focus Diagnostics PT EIA</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Euroimmun PT EIA</strong></td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Borderline(a)</td>
</tr>
</tbody>
</table>

(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 Euroimmun ELISA.

Positive Agreement: 100% (18/18); 95% Confidence Interval (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**


3. Andre P, Caro V, Njamkepo E, et al: Comparison of serological and real-time PCR assays to diagnose Bordetella

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, Mountain Lakes, New Jersey 03/05/2019)

PDF Report
No

Day(s) and Time(s) Test Performed
Thursday; 9 a.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
7 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
86615

LOINC® Information
### Test Definition: BORDG

**B. pertussis Ab, IgG, S**

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<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>BORDG</td>
<td>B. pertussis Ab, IgG, S</td>
<td>42330-1</td>
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<table>
<thead>
<tr>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
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<td>B. pertussis IgG</td>
<td>29659-0</td>
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<tr>
<td>DEXBG</td>
<td>B.pertussis Value</td>
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