Overview

Useful For
Preferred diagnostic test for the detection of *Bordetella pertussis* or *Bordetella parapertussis*

Method Name
Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

Includes DNA preparation from specimen, PCR amplification, and hybridization

NY State Available
Yes

Specimen

Specimen Type
Varies

Necessary Information
Specimen source is required.

Specimen Required
The high sensitivity of amplification by PCR requires the specimen to be processed in an environment in which contamination of the specimen by *Bordetella pertussis* or *Bordetella parapertussis* DNA is unlikely.

Submit only 1 of the following specimens:

Preferred:

Supplies:

Nasopharyngeal Swab (Rayon Mini-Tip Swab) (T515)

Specimen Type: Nasopharyngeal swab

Container/Tube: Rayon swab with an aluminum shaft placed in transport medium such as a green-top nasopharyngeal swab (rayon mini-tip) with Stuart's media (no charcoal) (T515), or Stuart's with charcoal, or Amies with or without charcoal (Transwab Nasopharyngeal with Charcoal System).

Additional Information:

1. Swab transport containers without charcoal must contain a pledget saturated with either Stuart's or Amies liquid media. Clear semi-solid/solid media is gel and will be rejected.

2. Other swab or media types may be inhibitory to PCR testing and will be rejected.

Acceptable:

Specimen Type: Nasopharyngeal (not throat) aspirate/wash or nasal aspirate/wash
Container/Tube: Sterile container with a screw top cap (no transport media)

Specimen Volume: Entire collection

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

| Other | Nose, nasal, or throat swab; calcium alginate or cotton-tipped swab; swab sent in gel transport medium, viral/universal transport medium, or Regan Lowe media; ESwab; swabs with solid plastic shaft; dry swab |

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
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Clinical and Interpretive

Clinical Information

*Bordetella pertussis* is the highly contagious etiological agent of pertussis or whooping cough. *Bordetella parapertussis* causes a similar, but generally less severe illness. Despite vaccination efforts, *B pertussis* remains common in the United States, underscoring the need for effective diagnostic tests. In the United States, pertussis is most common in the late summer months. Pertussis vaccination does not prevent *B parapertussis* infection, which generally occurs in a younger age group than disease caused by *B pertussis*. Diagnosis of pertussis is based on having a high clinical index of suspicion for the infection, along with confirmation by laboratory testing. Laboratory testing methods include nucleic acid amplification tests (eg, PCR), serology, culture and direct fluorescent antibody testing. Culture and direct fluorescent antibody testing are limited by low sensitivity, rendering nucleic acid amplification tests and serology the tests of choice.

The Centers for Disease Control and Prevention recommends PCR testing for patients suspected of having acute pertussis. *B pertussis* PCR detects roughly twice as many cases as culture. *B pertussis* DNA can be detected up to 4 weeks, or longer (up to 8 weeks in our experience),(1) after symptom onset. However, over time, the amount of *B pertussis* and *B parapertussis* DNA will diminish, rendering the assay less sensitive. A serologic response to *B pertussis* is typically mounted by 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 at a time when the amount of *B pertussis* may be below the limit of detection of the PCR assay.

Reference Values

Not applicable
Interpretation

A positive result indicates the presence of DNA from *Bordetella pertussis* or *B parapertussis*. In some cases, a patient may test positive for both *B pertussis* and *B parapertussis*. Cross-reactivity with *B holmesii* and *B bronchiseptica* may occur with the *B pertussis* assay (see Cautions).

A negative result indicates the absence of detectable *B pertussis* and *B parapertussis* DNA in the specimen but does not negate the presence of organism or active or recent disease (known inhibition rate of <1%) and may occur due to inhibition of PCR, sequence variability underlying primers and/or probes, or the presence of *B pertussis* or *B parapertussis* in quantities less than the limit of detection of the assay. Additionally, patients presenting late after symptom onset may test negative; in such cases, testing for *B pertussis* antibody, IgG, in serum may be considered.

**Cautions**

Cross-reactivity with *Bordetella holmesii* may occur with the *B pertussis* PCR assay. The prevalence of *B holmesii* is relatively low, with positivity in <1% of nasopharyngeal swabs.(2) Please note that *B holmesii* has been associated with pertussis-like symptoms.(2)

Cross-reactivity of the *B pertussis* assay has been demonstrated with a limited number of *Bordetella bronchiseptica* isolates. The prevalence of the insertion sequence target, IS481, has been reported to be between 1% and 5% in *B bronchiseptica* isolates.

This assay is not recommended for screening asymptomatic individuals who may carry *B pertussis* or *parapertussis*.

This assay is not recommended for follow up of patients previously diagnosed with pertussis (ie, as a test of cure).

Some *B pertussis* acellular vaccines (ie, Pentacel, Daptacel, Adacel) contain PCR detectable DNA. Contamination of specimens with vaccine can cause false-positive *B pertussis* PCR results. Specimens should not be collected or processed in areas that are exposed to *B pertussis* vaccine material.

**Supportive Data**

The assay targets the multicopy insertion gene sequences, IS481 and IS1001, of *Bordetella pertussis* and *Bordetella parapertussis*, respectively. This assay was previously performed using analyte specific reagents from Roche Diagnostics(3); these reagents are no longer available. The assay was revalidated using probes and primers with the same sequence, but provided by an alternate vendor. Performance of the new assay was then compared to the previous assay, which used the Roche analyte specific reagents, using 374 nasopharyngeal swabs and washings submitted for *Bordetella* testing. Fifty-four specimens were positive (48 *Bordetella pertussis* and 6 *Bordetella parapertussis*) and 314 specimens were negative by both assays. Five nasopharyngeal specimens were negative for *Bordetella pertussis* or *Bordetella parapertussis* by the new assay and negative by the old assay. One nasopharyngeal specimen was positive for *Bordetella pertussis* by the old assay but negative by the new assay. Overall, there was 98% (368/374) agreement between the 2 assays. *Bordetella holmesii* cannot be distinguished from *Bordetella pertussis* by the assay. The analytical sensitivity of the assay is 1 target/mcL for nasopharyngeal swabs and 10 targets/mcL for nasopharyngeal wash/aspirates.

**Clinical Reference**


Performance

Method Description
The LightCycler instrument platform amplifies and monitors the development of target nucleic acid sequences by fluorescence after each cycle of PCR. The automated detection of amplified products is based on the fluorescence resonance energy transfer (FRET) principle. The assay uses the repetitive (50-100 copies) insertion sequence (IS481) found in Bordetella pertussis and the repetitive (35-50 copies) insertion sequence (IS1001) found in B parapertussis as targets. Detection and differentiation of Bordetella targets is performed through melting curve analysis. The probes were designed to obtain a 10 degree C temperature shift between B pertussis and B parapertussis that is seen in the melting curve analysis. Analysis of the PCR amplification and probe melting curves is accomplished through the use of the LightCycler software. (Sloan LM, Hopkins MK, Mitchell PS, et al: Multiplex LightCycler PCR assay for detection and differentiation of Bordetella pertussis and Bordetella parapertussis in nasopharyngeal specimens. J Clin Microbiol 2002;40:96-100)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday, Sunday

Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
3 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
87798 x 2

LOINC® Information
### Test Definition: BPRP

**Bordetella PCR**

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