Test Definition: BPRPV

Bordetella pertussis and Bordetella parapertussis, Molecular Detection, PCR, Varies

Overview

Useful For

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

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

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

Method Name

Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available

Yes

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

The high sensitivity of amplification by polymerase chain reaction (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:
Specimen Type: Nasopharyngeal swab
Supplies: Culture Swab - Liquid Stuarts/Single Swab (NP Swab) (T515)
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), or Stuart's media with charcoal, or Amies media 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

Nose, nasal, or throat swab	Reject
Calcium alginate or cotton-tipped swab	Reject
Swab sent in gel transport medium	Reject
Swab sent in viral/universal transport medium	Reject
Swab sent in Regan Lowe media	Reject
ESwab	Reject
Dry swab	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	
	Ambient	7 days	
	Frozen	7 days	

Clinical & 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, polymerase chain reaction [PCR]), serology, culture, and direct fluorescent antibody testing. Culture and direct fluorescent antibody testing are limited by low sensitivity, rendering nucleic acid amplification 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. After symptom onset *B pertussis* DNA can be detected up to 4 weeks or longer (up to 8 weeks in our experience).(1) 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 within 2 weeks following infection, and therefore, detection of IgG-class antibodies to pertussis toxin, 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 *Bordetella parapertussis*. In some cases, a patient may test positive for both *B pertussis* and *B parapertussis*. Cross-reactivity with *Bordetella holmesii* and *Bordetella 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 polymerase chain reaction, 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 (BORDG / *Bordetella pertussis* Antibody, IgG, Serum) may be considered.

Cautions

Cross-reactivity with *Bordetella holmesii* may occur with the *Bordetella pertussis* polymerase chain reaction (PCR) assay. The prevalence of *B holmesii* is relatively low, with positivity in less than 1% of nasopharyngeal swabs.(2) Note: *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, IS*481*, has been reported to be between 1% and 5% in *B bronchiseptica* isolates.

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, IS*481* and IS*1001*, 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 positive 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

1. Theofiles AG, Cunningham SA, Chia N, et al. Pertussis outbreak, southeastern Minnesota, 2012. Mayo Clin Proc. 2014;89(10):1378-1388
2. Guthrie JL, Robertson AV, Tang P, Drews SJ. Novel duplex real-time PCR assay detects *Bordetella holmesii* in specimens from patients with pertussis-like symptoms in Ontario, Canada. J Clin Microbiol. 2010;48(4):1435-1437
3. 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(1):96-100
4. Karalius VP, Rucinski SL, Mandrekar JN, Patel R. Bordetella parapertussis outbreak in Southeastern Minnesota and the United States, 2014. Medicine (Baltimore). 2017;96(20):e6730

Performance

Method Description

The LightCycler instrument platform amplifies and monitors the development of target nucleic acid sequences by fluorescence after each cycle of polymerase chain reaction (PCR). The automated detection of amplified products is based on the fluorescence resonance energy transfer principle. The assay uses the repetitive (50-100 copies) insertion sequence (IS*481*) found in *Bordetella pertussis* and the repetitive (35-50 copies) insertion sequence (IS*1001*) found in *Bordetella 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[1]:96-100; van der Zee A, Schellekens JF, Mooi FR. Laboratory diagnosis of pertussis. Clin Microbiol Rev. 2015;28[4]:1005-26. doi:10.1128/CMR.00031-15)

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PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
1 to 3 days

Specimen Retention Time
3 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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 account representative. 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. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87798 x 2
87798 (if appropriate for government payers)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BPRPV	Bordetella, PCR, Varies	90441-7

Result ID	Test Result Name	Result LOINC® Value
BPRS	Specimen source	31208-2
618312	Bordetella pertussis PCR	43913-3
618313	Bordetella parapertussis PCR	42588-4