

***Bordetella pertussis* Detection by the BioFire® FilmArray® Respiratory Panels (RP, RP2, RP2plus, RP EZ)**

TECHNICAL ::: NOTE

1. Purpose

Bordetella pertussis (*B. pertussis*) is among the many organisms detected by the BioFire Respiratory Panels (RP, RP2, RP2plus, RP EZ). The purpose of this technical note is to describe the BioFire® FilmArray® *B. pertussis* assay and how it compares to other PCR assays commonly used to test patient samples. In most cases, the test results are expected to be concordant between these different assays. However, discordant results can occur due to differences in assay sensitivity and specificity.

2. *Bordetella pertussis* Assays

Many PCR assays for detection of *B. pertussis* are designed to target multi-copy insertion sequences such as the IS481 target, while the BioFire RP, RP2, RP2plus, and RP EZ *B. pertussis* assay targets the single-copy toxin promoter region. Studies comparing the relative sensitivities of different PCR assays to culture indicate that single-copy target assays appear to be at least as sensitive as culture, while assays for multi-copy targets, such as IS481, are more sensitive than culture (approximately 2.5 to 4-fold greater detection of *B. pertussis*).^{1,2} Though high sensitivity is an important feature of a clinical diagnostic test, the IS481 assay will also detect other non-*pertussis Bordetella* species, such as *B. holmesii* and *B. bronchiseptica*. In addition, false positive test results due to contamination with pertussis vaccine material have been reported.³ To reduce the likelihood of false positive PCR test results, the Centers for Disease Control and Prevention provides specific recommendations for sample collection and suggests caution in the interpretation of test results, especially for assays to multi-copy targets with high cycle threshold values (Ct).⁴

3. Potential for Assay Discrepancies

The BioFire RP, RP2, RP2plus, and RP EZ *B. pertussis* assay targets a single-copy sequence and is designed to detect only *B. pertussis*. The differences between the BioFire *B. pertussis* assay and assays that target IS481 can result in discordant test results when the sample contains low levels of target DNA or when the sample contains a non-*pertussis Bordetella* species, such as *B. holmesii* and *B. bronchiseptica*. While the BioFire *B. pertussis* assay is designed to detect only *B. pertussis*, crossreactivity has been observed when testing very high levels or

sequence variants of other *Bordetella* species (*B. parapertussis* and *B. bronchiseptica*).

4. References

1. CDC. Pertussis – United State, 2001-2003. MMWR 2005; 54 (50): 1283-6.
2. CDC. Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine. MMWR Dec 15, 2006. 55(RR17); 1-33.
3. Vaccines shown to contain PCR-detectable DNA include Pentacel[®] Daptacel[®] and Adacel[®]. Leber A Et al. Detection of *Bordetella pertussis* DNA in Acellular Vaccines and in Environmental Samples from Pediatric Physician Offices, in 2010 Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC): Boston, USA.
4. <http://www.cdc.gov/pertussis/clinical/diagnostic-testing/diagnosis-pcrbestpractices.html>

Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the FilmArray Technical Support team for assistance.

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