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

Purpose

Bordetella pertussis (B. pertussis) is among the many organisms detected by the FilmArray® Respiratory Panels (RP, RP2, RP2plus, RP EZ). The purpose of this technical note is to describe the 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.

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 FilmArray 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

Potential for Assay Discrepancies

The FilmArray 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 FilmArray 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 FilmArray 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).
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.

**BioFire Technical Support**
Email: support@biofiredx.com
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For FilmArray technical assistance and support outside of the US, please contact your local BioMérieux representative or authorized distributor.