Bordetella pertussis Advisory Notice

ADVISORY
::: NOTICE

Purpose

Bordetella pertussis (*B. pertussis*) is among the 20 organisms detected by the FilmArray® Respiratory Panel (RP). The purpose of this advisory notice is to describe the FilmArray RP *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 IS*481* target, while the FilmArray RP *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 IS*481,* 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 IS*481* 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, CDC 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 *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 IS*481* 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 RP *B. pertussis* assay is designed to detect only *B. pertussis*, crossreactivity has been observed when testing very high levels (culture suspension containing >10^6 cfu/mL) of *B.*

parapertussis during validation testing. Crossreactivity has not been observed at concentrations below 10^6 cfu/mL.

Support

BioFire Diagnostics is dedicated to providing you with the best customer support available. If you have any questions or concerns, please contact the FilmArray Technical Support team at 801-736-6354, option 5 or by email at support@biofiredx.com

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References

1. CDC. Pertussis – United State, 2001-2003. *MMWR* 2005; 54 (50): 1283-6.
2. CDC. Preventing Tetanus, Diptheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diptheria 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-pcr-bestpractices.html