Introduction / Background

Pertussis is a contagious respiratory disease caused by Bordetella pertussis which can lead to life-threatening complications in young children. Bordetella parapertussis also causes respiratory disease with similar symptoms, although usually milder than B. pertussis. Early and accurate diagnosis of Bordetella infection is critical for positive patient outcomes as guided treatment is most effective within the first two weeks of infection. Previously vaccinated individuals may present with less severe disease and have an atypical clinical presentation. The Luminex ARIES® Bordetella Assay is a qualitative real-time PCR assay for detection and identification of B. pertussis and B. parapertussis in nasopharyngeal swab specimens. The ARIES® Bordetella Assay targets the pertussis toxin (ptxA) promoter and IS1001 repeat sequence in the genomes of B. pertussis and B. parapertussis, respectively. The assay is used with ARIES® Systems, multiplex sample to answer test systems capable of automated nucleic acid extraction and purification and real-time PCR detection and data analysis in less than two hours. In this study, we assessed the clinical performance of the ARIES® Bordetella Assay in prospectively collected, de-identified, nasopharyngeal swab specimens collected from patients with clinical signs and symptoms of B. pertussis or B. parapertussis infection.

Materials and Methods

Specimen Collection and Preparation

The performance of the ARIES® Bordetella Assay was evaluated on 1,052 nasopharyngeal swab specimens prospectively collected at five U.S. clinical sites from July through November 2016. Due to low prevalence, the prospective sample set was supplemented with banked (pre-selected) B. pertussis (N=37) and B. parapertussis (N=20) positive specimens as well as confirmed B. parapertussis specimens (N=50). Pre-selected specimens were collected at multiple clinical sites in the United States. Contrived specimens were prepared by spiking well-characterized bacterial strains into negative clinical samples at titers spanning clinically low to high ranges. Low titer specimens were prepared at 3X LOD while the remaining specimens were prepared at 10X and 100X LOD concentrations. All pre-selected and contrived specimens were tested along with negative clinical specimens in a randomized, blinded fashion at three testing sites.

Reference Method Testing

The performance of the ARIES® Bordetella Assay for B. pertussis and B. parapertussis was compared to a composite comparator consisting of two well-characterized real-time PCR assays, followed by confirmation of positive PCR amplification product with bidirectional sequencing. Comparator PCR assays for B. pertussis and B. parapertussis targeted unique sequences within the promoter region of the ptxA gene and IS1001 insertion region (respectively) that were different than those targeted by the ARIES® Bordetella Assay. Comparator real-time PCR and bidirectional sequencing assays were performed at a centralized testing facility. Specimens were characterized as positive for B. pertussis or B. parapertussis if one or two of comparator PCR assays was positive and confirmed by bidirectional sequencing or if both comparator PCR assays were positive.

ARIES® Bordetella Assay Testing

The ARIES® Bordetella Assay testing was performed at the clinical sites according to the manufacturer’s instructions on nasopharyngeal swab specimens that were either kept refrigerated (2°C) for up to 72 hours prior to testing (N=667; 63.4%) or stored frozen (−70°C) for up to 12 days prior to testing (N=385; 36.6%). ARIES® workflow is shown in Figure 1.

Discussion and Conclusion

• The overall prevalence of B. pertussis and B. parapertussis, as reported by the ARIES® Bordetella Assay, in prospectively collected symptomatic clinical specimens during the enrollment period was 3.9% (41/1052) and 0.4% (4/1052) respectively.
• The breakdown, by age groups, of B. pertussis ARIES® positive prospective specimens was as follows: 0-1 years: 9/41 (22.0%); >1-5 years: 2/41 (4.9%); >18 years: 23/41 (56.1%); >18 years: 7/41 (17.1%).
• 3/4 (75%) of B. parapertussis ARIES® positive prospective specimens were from pediatric patients 0-1 years old. The remaining B. parapertussis ARIES® positive prospective specimen was from a patient 5 years of age.
• In the prospective evaluation, Positive Percent Agreement (PPA) of the ARIES® Bordetella Assay for B. pertussis was 93.8% (30/32; 95% confidence interval (CI), 79.2%-99.2%).
• In the prospective evaluation, Positive Percent Agreement (PPA) of the ARIES® Bordetella Assay for B. parapertussis was 100% (2/2; 95% CI, 15.8%-100%).
• Negative Percent Agreement (NPA) of the ARIES® Bordetella Assay for B. pertussis and B. parapertussis were 98.9% (100/102; 95% CI, 98.1%-99.5%) and 99.8% (1048/1050; 95% CI, 99.9%-100%), respectively.
• The ARIES® Bordetella Assay accurately detected all 37 B. pertussis (100% PPA; 95% CI, 90.5%-100%) and all 20 B. parapertussis positive pre-selected specimens tested (100% PPA; 95% CI, 83.2%-100%).
• One pre-selected B. parapertussis specimen generated a false positive result using the ARIES® Bordetella Assay when compared to the composite comparator method (02-179 and 06-267).

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