Clinical Evaluation of the FilmArray® Respiratory Panel

INTRODUCTION
Pneumonia and lower respiratory tract infections are a significant burden of morbidity and mortality in children and adults in the United States. Each year, viral and bacterial pathogens cause millions of infections, and are responsible for more than 250,000 deaths in the United States alone. The accurate and timely diagnosis of respiratory infections is essential for appropriate therapy, containment of disease spread, and cost-effective treatment. FilmArray RP is a rapid, multiplexed PCR in vitro diagnostic system comprised of an instrument and reagent pouch that simultaneously detects any of 21 respiratory pathogens in a single nasopharyngeal swab sample. The FilmArray® RP system provides results within 45 minutes, and is insensitive to over-the-counter and prescribed topical and systemic medications (Table 8). The FilmArray correctly identified 99% of aspergillomas, including 100% of those with ductus arteriosus, which is important for early diagnosis and treatment of this rare condition.

RESULTS
Sixty-four percent (64%) of all specimens were positive for at least one FilmArray RP analyte. Of the 720 positive results, the most prevalent analytes were influenza A (319/335, 95%), influenza B (118/125, 94%), and adenovirus (51/597, 8%). The prevalence of specific analytes also differed between age groups (Table 3). Most analytes had higher prevalence in young children (6-9 years of age) and older adults (≥60 years of age), with the highest rate of FilmArray RP analyte detection observed in young children (78% of subjects). Following this initial assessment, analyses were performed to determine the positive and negative percent agreement between the FilmArray and reference methods for the seven cultured viruses (adenovirus, coronavirus, metapneumovirus, parainfluenza virus, influenza A, influenza B, and respiratory syncytial virus).

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CONCLUSIONS
FilmArray RP is a rapid, cost-effective, and highly sensitive tool for the diagnosis of respiratory infections, and is particularly useful for the diagnosis of respiratory infections in young children and older adults. The FilmArray RP system is currently available for use in the United States and in Europe, and has been approved by the FDA for the diagnosis of respiratory infections in children and adults. The FilmArray RP system is a valuable tool for the rapid diagnosis of respiratory infections, and is currently being used in clinical settings worldwide.