Validation of the Idaho Technology Inc. FilmArray® Respiratory Panel for Clinical Use at Primary Children’s Medical Center, Salt Lake City, UT

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Abstract

The FilmArray®, from Idaho Technology Inc. (Salt Lake City, UT) is a user-friendly multiplex PCR designed to detect respiratory pathogens in an automated, self-contained instrument. Respiratory panel cartridges have been validated in vitro by the manufacturer for detection of 12 respiratory pathogens, including 21 respiratory pathogens. The FilmArray® demonstrates high sensitivity and specificity, as well as the ability to detect respiratory pathogens in a rapid 45-minute turnaround time. The FilmArray® Respiratory Panel (FilmArray® Respiratory Panel) has been prospectively validated by clinical laboratories and has been in clinical use for over 2 years. This validation study evaluated detection of 12 respiratory pathogens in clinical samples collected at the Primary Children’s Medical Center (Salt Lake City, UT) or Luminex® Respiratory Virus Panel (Rhinovirus only, Intermountain Central Laboratory, Murray, UT) were analyzed for this validation study. In order to obtain 30 positive samples for each analyte, cultivated organisms (FluA (methicillin resistant), S. aureus, Streptococcus pneumoniae, Haemophilus influenzae, RSV, and Adeno) were used for each analyte. The remaining analytes were performed as singleplex PCR reactions using laboratory developed assays. Resolution was achieved by a one-time run of the sample, which was then run three times in a single day at the established LoD. Each analyte was tested four times on a single day in three concentrations defined as "medium-positive" (3X LoD), "low-positive" (LoD), and "negative" (less than LoD). Accuracy, sensitivity, and specificity values are included. All Medium- and Low-positive samples were detected for each analyte for both intra- and inter-run reproducibility testing. The LoD for all 12 analytes were variable, as would be expected with a multiplexed PCR reaction. The absolute LoD values were less than 95% Accuracy/Specificity/Sensitivity vs DFA. Of the 12 analytes tested in this validation study only Adeno was determined to have unacceptable performance (less than 95% Accuracy/Specificity/Sensitivity vs DFA). Other analytes were able to detect all samples, however, one sample was not detected for Adeno. Overall, accuracy, sensitivity, and specificity values were above 90% for each analyte. The FilmArray® Respiratory Panel is a user-friendly multiplex PCR designed to detect respiratory pathogens with rapid turnaround time and reproducible results.

Background

Respiratory infections are a leading cause of acute hospital admission and mortality in children. Culture for many organisms is notoriously insensitive due to fastidious growth rates, leading to delay in diagnosis using classical microbiological techniques. Historically, culture and detection by direct fluorescence antibody (DFA) staining have been the hallmark for diagnostics of respiratory infections. Culture techniques are slow and time-consuming, and are often unsuitable for the detection of fastidious pathogens such as respiratory syncytial virus (RSV). In addition, many respiratory pathogens are difficult to culture, and even when culture techniques are available, sensitivity and specificity are limited due to the large number of pathogens that must be cultured.

Methods

The FilmArray® Respiratory Panel was chosen for this validation study because it utilizes a self-contained extraction and amplification cartridge to detect 12 respiratory pathogens in a rapid 45-minute turnaround time. The FilmArray® Respiratory Panel is a multiplex PCR assay that detects 12 respiratory pathogens, including 21 respiratory pathogens, such as influenza A and B, parainfluenza 1, 2, and 3, adenovirus, rhinovirus, respiratory syncytial virus (RSV), and human metapneumovirus (hMPV). The FilmArray® Respiratory Panel has been validated by the manufacturer in vitro for detection of 12 respiratory pathogens. The FilmArray® Respiratory Panel has been prospectively validated by clinical laboratories and has been in clinical use for over 2 years. The objective of this validation study was to determine the accuracy, sensitivity, and specificity of the FilmArray® Respiratory Panel for detection of 12 respiratory pathogens in clinical samples collected at the Primary Children’s Medical Center (Salt Lake City, UT) or Luminex® Respiratory Virus Panel (Rhinovirus only, Intermountain Central Laboratory, Murray, UT) were analyzed for this validation study. In order to obtain 30 positive samples for each analyte, cultivated organisms (FluA (methicillin resistant), S. aureus, Streptococcus pneumoniae, Haemophilus influenzae, RSV, and Adeno) were used for each analyte. The remaining analytes were performed as singleplex PCR reactions using laboratory developed assays. Resolution was achieved by a one-time run of the sample, which was then run three times in a single day at the established LoD. Each analyte was tested four times on a single day in three concentrations defined as “medium-positive” (3X LoD), “low-positive” (LoD), and “negative” (less than LoD). Accuracy, sensitivity, and specificity values are included. All Medium- and Low-positive samples were detected for each analyte for both intra- and inter-run reproducibility testing. The LoD for all 12 analytes were variable, as would be expected with a multiplexed PCR reaction. The absolute LoD values were less than 95% Accuracy/Specificity/Sensitivity vs DFA. Of the 12 analytes tested in this validation study only Adeno was determined to have unacceptable performance (less than 95% Accuracy/Specificity/Sensitivity vs DFA). Other analytes were able to detect all samples, however, one sample was not detected for Adeno. Overall, accuracy, sensitivity, and specificity values were above 90% for each analyte. The FilmArray® Respiratory Panel is a user-friendly multiplex PCR designed to detect respiratory pathogens with rapid turnaround time and reproducible results.

Results

Accuracy, sensitivity, and specificity values were above 90% for each analyte. The calculated accuracy, sensitivity, and specificity values for each analyte were greater than 95% for each analyte except Adeno. The FilmArray® did not react with organisms that were not respiratory viruses or were not included in the 12 analytes.

Discussion

This study evaluated detection of 12 respiratory pathogens in clinical samples collected at the Primary Children’s Medical Center (Salt Lake City, UT) or Luminex® Respiratory Virus Panel (Rhinovirus only, Intermountain Central Laboratory, Murray, UT) were analyzed for this validation study. In order to obtain 30 positive samples for each analyte, cultivated organisms (FluA (methicillin resistant), S. aureus, Streptococcus pneumoniae, Haemophilus influenzae, RSV, and Adeno) were used for each analyte. The remaining analytes were performed as singleplex PCR reactions using laboratory developed assays. Resolution was achieved by a one-time run of the sample, which was then run three times in a single day at the established LoD. Each analyte was tested four times on a single day in three concentrations defined as “medium-positive” (3X LoD), “low-positive” (LoD), and “negative” (less than LoD). Accuracy, sensitivity, and specificity values are included. All Medium- and Low-positive samples were detected for each analyte for both intra- and inter-run reproducibility testing. The LoD for all 12 analytes were variable, as would be expected with a multiplexed PCR reaction. The absolute LoD values were less than 95% Accuracy/Specificity/Sensitivity vs DFA. Of the 12 analytes tested in this validation study only Adeno was determined to have unacceptable performance (less than 95% Accuracy/Specificity/Sensitivity vs DFA). Other analytes were able to detect all samples, however, one sample was not detected for Adeno. Overall, accuracy, sensitivity, and specificity values were above 90% for each analyte. The FilmArray® Respiratory Panel is a user-friendly multiplex PCR designed to detect respiratory pathogens with rapid turnaround time and reproducible results.

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