**INTRODUCTION**

Rapid and reliable detection of respiratory pathogens is critical in the diagnosis and treatment of respiratory infections. Idaho Technology, Inc. (ITI) has developed a lab-in-a-pouch system called FilmArray. The FilmArray is a self-contained and fully automated system that performs nucleic acid purification, reverse transcription, and real-time PCR in the same pouch. The FilmArray offers a comprehensive panel of assays for viral and bacterial respiratory pathogens. The FilmArray is being used in a clinical evaluation study to determine its ability to detect genetically diverse organisms within the panel (analytical reactivity).

**METHODS AND PROCEDURES**

The FilmArray pouches for testing were provided by ITI. For this study, 1000 nasopharyngeal swab specimens were collected and transported to ITI for testing. In total, 60 specimens were positive for at least one organism.

**CLINICAL EVALUATION**

The FilmArray pouches were tested in a multi-laboratory study. A panel of 21 common and emerging respiratory pathogens was used to evaluate the performance of the FilmArray. The FilmArray was able to detect all of the target organisms with high sensitivity and specificity.

**ANALYTICAL PERFORMANCE TESTING**

A FilmArray pouch was tested at the Medical University of South Carolina, Charleston, SC, Children's Medical Center and UT Southwestern Medical School, Dallas, TX, and Children's Medical Center and UT Southwestern Medical School, Dallas, TX. The FilmArray was able to detect all of the target organisms with high sensitivity and specificity.

**STUDIES IN PROGRESS**

Multi-laboratory studies are in progress to determine run-to-run and day-to-day variability (reproducibility) between different labs, operators, instruments and lots of FilmArray pouches. Positive and negative spike samples were tested in all labs and all samples were tested in triplicate. The FilmArray was able to detect all of the target organisms with high sensitivity and specificity.

**CONTACT INFORMATION**

For more information, please visit the Idaho Technology website at [www.idahotechnology.com](http://www.idahotechnology.com).