Comparative Evaluation of the 3M™ Rapid Flu A & B test with the Remel Xpect Assay and R-Mix Culture for Detecting Influenza A/B Viruses in Nasopharyngeal Specimens

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Introduction

The conventional laboratory approach for the direct detection of influenza A and B viruses in nasopharyneal specimens typically involves the use of either an immunochromatographic assay ((ICA) or a direct fluorescent antibody (DFA) test. The commercially available ICAs are convenient and easy to perform but lack sensitivity while the DFA tests offer increased sensitivity but are labor intensive and require the use of experienced technologists and specialized equipment. Both methods are prone to human error due to subjective visual interpretation of test results.

The 3M Rapid Detection Flu A & B Test (3M Medical Diagnostics, St. Paul, MN) is a qualitative immunochromatographic, fluorescent-based test that can detect and differentiate influenza A and B viruses directly in nasal washes, aspirates, or nasopharyngeal swab samples. Test results are read on an automated instrument, called the 3M Rapid Detection Reader, which eliminates human error associated with test interpretation.

The purpose of this study was to evaluate the ability of the 3M Rapid Flu Test to detect the presence of influenza A and/or B virus in 65 archived nasopharyngeal specimens that tested negative for influenza A/B viruses using the Remel Xpect ICA (Remel, Lenexa, KS) but were culture positive using the R-Mix cell hybrid system (Diagnostic Hybrids, Athens, OH).

Methods

During the 2007 to 2008 viral respiratory season, nasopharyngeal swab samples for influenza A/B testing were transported to the Microbiology laboratory using Universal Transport Medium (Diagnostic Hybrids, Athens, OH). The Remel Xpect ICA was performed on these samples according to the manufacturer's instructions. Samples that tested "negative" for influenza A/B viruses using the Remel ICA were subsequently cultured using the R-Mix system. A total of 65 specimens that were negative by the ICA but were culture positive for influenza A or B virus were stored at -70oC for subsequent testing using the 3M Rapid Flu Test.

The 3M Rapid Flu Test was performed according to the manufacturer's instructions. Basically, the test sample is mixed with the sample buffer using an Assay Tip. The Assay Tip contains fluorescent-dyed particles coated with anti-influenza A and anti-influenza B antibodies to bind with the influenza A or B nucleoprotein antigens, if present in the sample. An aliquot of this sample is then transferred into the well of the Test Cartridge. The Test Cartridge is then inserted into the Rapid Detection Reader (Figure 1). As the sample migrates along the Test Cartridge strip, influenza-bound particles are captured by either anti-influenza A or anti-influenza B nucleoprotein monoclonal antibodies at their respective detection zones. Excess fluorescent-dyed particles are captured at the internal standard zone.

The Reader then measures the amount of fluorescence emitted by the complexes at the two detection zones (Influenza A and Influenza B) and at the internal standard zone. The instrument calculates a ratio (RAMP® Ratio) of the Influenza A fluorescence reading detection zone reading and the Influenza B detection zone fluorescence reading to the internal standard zone fluorescence reading. The Reader then compares these ratios to pre-defined threshold limits to determine a positive or negative result for Influenza A and Influenza B in the tested sample. Assay throughput time is approximately 15 minutes.

Figure 1: Rapid Detection Reader

Results

Of the 65 R-Mix culture positive specimens that were negative by the Remel ICA, influenza B virus was cultured from 28 samples of which 13 (46.4%) were detected by the 3M Rapid Flu Test. Influenza A virus was cultured from the remaining 37 specimens of which 8 (21.6%) were detected as positive using the 3M Rapid Flu Test. One nasopharyngeal sample that was culture positive for only influenza B virus gave repeatedly positive test results for both influenza A and B viruses using the 3M system. Overall, the 3M Rapid Flu Test had a 35.4% increased sensitivity for the 65 archived nasopharyngeal samples compared to the Remel Xpect assay.

Conclusions

The 3M Rapid Detection Flu A and B Test provided significantly improved overall detection rates and sensitivity (35.4%) for influenza A and B viruses in archived nasopharyngeal samples compared to the Remel Xpect ICA.

The 3M Rapid Flu Test is completed within 15 minutes and its increased test sensitivity eliminates the need and costs associated with performing unnecessary cultures when using less sensitive direct specimen ICA methods.

The use of the automated, fluorescent Rapid Detection Reader eliminates the human error associated with subjective visual test interpretation that can lead to false positive and false negative results. This automated feature also allows the test to be performed by less highly skilled individuals.