

EVALUATION OF THE ERAGEN MULTICODE[®]-PLx RESPIRATORY VIRUS PANEL USING BARCODED MAGNETIC BEADS DESIGNED TO DETECT SEVENTEEN RESPIRATORY VIRUSES

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Objective: To evaluate the performance characteristics and workflow of EraGen Bioscience's MultiCode[®]-PLx Respiratory Virus Panel (RVP) using Applied BioCode's Barcoded Magnetic Beads (BMB) and the BioCode analyzer.

Methods: A total of 164 retrospective clinical samples (134 positive, 30 negative) were tested using MultiCode[®]-PLx Respiratory Virus Panel (RVP) on the Applied BioCode platform. All the retrospective specimens, except for Influenza A/B positive specimens, were previously tested with MultiCode[®]-PLx RVP on the Luminex system. The thirty Influenza A/B specimens were tested with the CDC IVD influenza RT-PCR assay. Nucleic acid (NA) was extracted without concentration using the Roche MagNA Pure Total Nucleic Acid isolation kit. Testing was performed in triplicate by two laboratory scientists to determine reproducibility. A Median Fluorescence Intensity (MFI) value of 1000 was used as the cutoff threshold and samples wherein the MFI was greater than the threshold for at least 2 of the 3 replicates were scored as positives. Discordant specimens were resolved by re-extracting the original specimen and testing the NAs with appropriate methods.

Results: MultiCode[®]-PLx RVP on BioCode analyzer was 100% sensitive for eleven respiratory viruses and 92.9% sensitive for Adenovirus B (n=13). Sensitivity varied for influenza isolates; Influenza A H1 (2009) was 62.5% sensitive (n=10), Influenza A H3 was 100% sensitive (n=10) and Influenza B was 100% sensitive (n=10) when compared to the CDC assay. Due to lack of positive specimens, no data were available for Coronaviruses 229E and NL63 or Parainfluenza virus 4a and 4b. Specificity for all 17 respiratory viruses included in the MultiCode[®]-PLx RVP assay was 100% (n=30). For 18 of the 134 specimens (4.5%) tested in triplicate, the results were not interpretable due to high background. Overall, the MultiCode[®]-PLx RVP assay on the Applied BioCode system was 95.2% sensitive for all viruses tested. Excluding influenza, there was a >99% agreement between the Applied BioCode and the Luminex platforms.

Conclusion: The multiplex respiratory virus panel format is useful for virus surveillance activities and for outbreak response because the test is sensitive, specific, reproducible and the results are available in <8 hours. The sensitivity of the MultiCode[®]-PLx RVP on Applied BioCode platform was comparable to the sensitivity of the MultiCode[®]-PLx RVP on the Luminex platform. Decreased sensitivity observed for Adenovirus B may have been due to low virus titer or degradation of viral NA from freeze-thaw cycles. Lower sensitivity for 2009 H1N1 may be due to the fact that the Influenza design pre-dates the 2009 H1N1 pandemic. Preliminary data suggest that the high background seen in a few specimens may be remedied with the use of an automated plate washer. The MultiCode[®]-PLx RVP assay on the Applied BioCode analyzer has significant workflow advantages over the Luminex1000 IS[™] system and provides a viable alternative for detecting multiple respiratory viruses from clinical specimens with a high degree of specificity and sensitivity.