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Paper Poster Session
Respiratory virus diagnostics

Idylla respiratory (IFV-RSV) panel (CE) demonstrates rapid results and performance for the detection and differentiation of influenza A, influenza B and respiratory syncytial viruses

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Background: The Idylla™ RESPIRATORY (IFV-RSV) Panel is a rapid, real-time RT-PCR assay performed on the Idylla™ System which automates and integrates sample preparation, nucleic acid purification, and target amplification to qualitatively detect IFVA, IFVA subtype H1, IFVA subtype H3, IFVA subtype 2009 H1, H275Y mutation of IFVA subtype 2009 H1, IFVB and Respiratory Syncytial Virus (RSV) subtype A and RSV subtype B from nasopharyngeal swabs of adult and pediatric patients.

Material/methods: Clinical performance of the IFV-RSV panel was conducted using 326 archived, banked nasopharyngeal (NP) swab samples in VTM. An FDA cleared MDx assay or bidirectional DNA sequencing were used as the comparator. Concordance (Negative and Positive Agreement), Limit of Detection, Analytical Inclusivity, Exclusivity, Reproducibility and Precision were evaluated using cultured viral fluids.

Results: LoD for all IFVA subtypes were between $2.9x10^{-1}$ and 1.2×10^{0} $TCID_{50}$/mL, 1.0×10^{0} $TCID_{50}$/mL for H275Y genotype , 2.3×10^{-2} and 5.6×10^{-2} $TCID_{50}$/mL for IFVB, 1.3×10^{0} and 2.0×10^{0} $TCID_{50}$/mL for RSVA and 4.2×10^{-2} and 1.7×10^{-1} $TCID_{50}$/mL for RSVB. Analytical Inclusivity was assessed across 9 IFV AH1 (pre-2009), 7 IFVA 2009 H1, 10 IFVA H3N2 ,4 H3N2v, 7 avian IFVA (H5 and H7), 8 IFV B, 3 RSVA and 3 RSVB strains, with all reporting correct results. The analytical specificity of the IFV-RSV Panel demonstrated no cross reactivity to 51 individual virus(es) and bacterium. Clinical performance was assessed across a total of 326 retrospective patient samples. The IFV-RSV Panel demonstrated 97.6% positive agreement for IFVA universal detection and 100% negative agreement across all IFVA subtypes. IFVA subtyping demonstrated 100%, 96.3% and 96.7% for IFV AH1, AH3, and 2009 H1, respectively. IFVB clinical results were 94.6% positive and 99.7% negative agreement. Both RSVA and RSVB demonstrated 100% negative agreement and 97.0% and 97.3% positive agreement, respectively. Discrepant results were analyzed via bidirectional DNA sequencing using independent primer sets. Discrepant resolution of IFVA clinical samples indicated IFV-RSV correctly identified a false positive IFVA 2009 H1 sample as true negative. IFV-RSV was also found to have identified two samples as IFVB positive where the comparator assay called them negative, and correctly called 1 comparator RSVA/RSVB co-infection as negative based on DNA sequencing results. When assessed for precision, the IFV-RSV Panel showed 100% concordance across 3 lots of product, with a %CV between 1.3% - 2.7%for all targets and concentrations. Reproducibility of the IFV-RSV Panel was less than 1.0% - 2.5%CV for all targets.

Conclusions: The IFV-RSV Panel demonstrates the ability to correctly identify and rapidly detect clinical patient samples containing IFVA and its subtypes H1, H3 and 2009 H1, H275Y genotype of 2009 H1, IFVB, and RSVA and RSVB in a simple to use format.