

Clinical performance of the second-generation GenomEra[®] SARS-CoV-2, Flu A/B, + RSV Assay Kit

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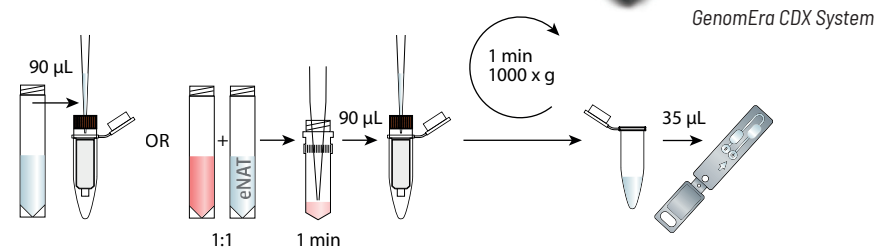
BACKGROUND AND MATERIALS

Background

- Rapid, easy-to-use, and accurate molecular testing of SARS-CoV-2, influenza A/B (Flu A/B) and respiratory syncytial virus (RSV) is essential for the control and treatment of respiratory diseases
- Here, the clinical performance of the GenomEra[®] SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit (Uniogen, Finland) is presented

Materials and methods

- A total of 751 clinical respiratory swab specimens collected in liquid transport medium (UTM, eSwab, or similar) were analysed
- The performance of the GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit was compared with well-characterized CE-IVD marked real-time RT-PCR tests:
 - QiaStat-Dx[®] Respiratory SARS-CoV-2 panel (Qiagen)
 - Xpert[®] Xpress SARS-CoV-2/Flu/RSV Assay (Cepheid)
 - BAG ViroQ Rapid SARS-CoV-2/FluA/B-RSV (BAG Diagnostics GmbH)
 - Allplex Respiratory Full Panel (Seegene)
 - cobas[®] SARS-CoV-2 assay (Roche)
 - GenomEra SARS-CoV-2, Flu A/B + RSV Assay Kit v1.0 (Uniogen).



Sample preparation protocol of the GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit

RESULTS

- The GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit demonstrated comparable performance with conventional real-time RT-PCR methods
 - The overall clinical sensitivity: **97.5%** (95% CI: 95.1-98.9%)
 - The overall clinical specificity: **100%** (95% CI: 99.9-100%)
- The analyte-specific sensitivities and specificities are presented in Table 1.

Table 1. Clinical performance of the GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit (n = 751).

Analytes	Agreement with the reference methods					PPA % (CI 95)	NPA % (CI 95)
	n	TP	FP	TN	FN		
SARS-CoV-2	751	121	0	628	2*	98.4% (94.3-99.8%)	100% (99.4-100%)
Influenza A	751	57	0	693	1*	98.3% (90.8-100%)	100% (99.5-100%)
Influenza B	751	44	0	707	0	100% (92.0-100%)	100% (99.5-100%)
RSV	751	85	0	661	5*	94.4% (87.5-98.2%)	100% (99.4-100%)

* Threshold cycle (C_t) values were ≥ 35 with the reference tests.

CONCLUSION

- The rapid turnaround time and simple hands-on steps make the GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit competitive and suitable for small and medium-sized laboratories.
 - Time-to-result: 55 minutes for 1-4 samples
 - Hands-on time: <5 min
 - Assay run time: 50 min

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