32nd European Congress of Clinical Microbiology &
Infectious Diseases, 23–26 April 2022, Lisbon Portugal

Evaluation of analytical and clinical performances of the second generation GenomEra® SARS-CoV-2 Assay Kit

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BACKGROUND AND MATERIALS

Background

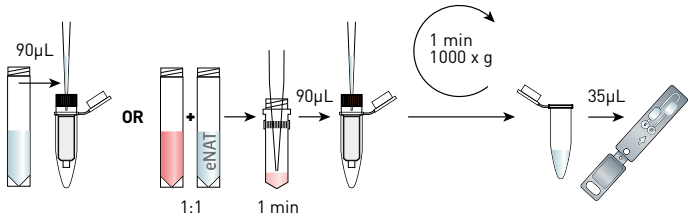
- Reliable, robust, and easy-to-use molecular testing for SARS-CoV-2 remains a critical element in the global strategy to control COVID-19.
- Aim of the study was to evaluate the analytical and clinical performance of the GenomEra SARS-CoV-2 2.0 Assay Kit.

Materials and methods

- Analytical sensitivity was assessed using two inactivated SARS-CoV-2 standards.
- Analytical specificity was determined by *in vitro* testing using a panel of potentially cross-reactive microbes at high concentration supplemented with *in silico* analysis.
- Clinical performance was evaluated in a clinical microbiology laboratory and a SARS-CoV-2 testing center based in Norway.
  - A total of 102 clinical specimens (20 saliva and 82 naso-/oropharyngeal swabs) collected in Oslo, Norway during October–December 2021.
  - Reference assays:
    RIDA®GENE SARS-CoV-2 (R-Biopharm AG, Germany)
    DirectDetect™ SARS-CoV-2 Detection Kit (Coyote Bioscience, China)

GenomEra Test Chip

GenomEra CDX Instrument



Sample preparation protocol of the GenomEra SARS-CoV-2 2.0 Assay Kit.

RESULTS

Analytical sensitivity – Limit of Detection (LoD)

- First WHO International Standard for SARS-CoV-2 RNA: **250 IU/mL**
- NATtrol™ SARS-Related Coronavirus 2 (SARS-CoV-2) Stock: **500 copies/mL**

Analytical specificity

- No cross-reactivity was detected *in vitro* or *in silico*

Clinical performance

- Clinical sensitivity: **100%** (CI95: 93.2–100%)
- Clinical specificity: **100%** (CI95: 92.9–100%)
- Technical successful rate: **97.1%** (99/102)

Organism	Result
Human coronavirus 229E	Negative
Human coronavirus OC43	Negative
Human coronavirus HKU1	Negative
Human coronavirus NL63	Negative
SARS-CoV-1	Potentially positive for E gene target[1]
MERS-CoV	Negative
Influenza A	Negative
Influenza B	Negative
Respiratory syncytial virus A	Negative
Respiratory syncytial virus B	Negative
Legionella pneumophila	Negative

[1] *The primers and the probe for E gene are not exclusively specific for SARS-CoV-2 and may also detect SARS coronavirus (SARS-CoV-1) especially when present in high copy numbers.*

GenomEra SARS-CoV-2 2.0 Assay Kit	Reference assays		PPA % (CI 95)	NPA % (CI 95)
	Positive	Negative		
Positive	52	0	100 (93.2–100)	100 (92.9–100)
Negative	0	50		

CONCLUSION

- The GenomEra SARS-CoV-2 2.0 Assay Kit provides a rapid and accurate method for COVID-19 testing
- Comparable performance with conventional real-time RT-PCR methods
- Short turnaround time
  - Time-to-result: 55 minutes for 1–4 samples
  - <5 min hands-on time
  - 50 min assay run time
- Suitable for small and medium-sized laboratories not necessarily having a specialist in molecular biology

INNO4COV-19

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016203.