



GENEME

Intended Use	Qualitative isothermal amplification test for detection of SARS-CoV-2 S gene from individuals suspected by their healthcare provider of having COVID-19
Sample Type	Upper respiratory tract fluids - nasopharyngeal and oropharyngeal swabs
User	Trained personnel instructed and trained in steril work conditions
COVID-19	
Limit of Detection* (copies / 1 ul)	1 x 10 ⁻⁶ ng SARS-CoV-2 RNA which corresponds to around 10 viral copies
Sensitivity**	96.67% (95% CI 88.47% - 99.59%)
Specificity**	100.00% (95% CI 94.04% - 100.00%)
Clinical Matrix Used for verification	Upper respiratory tract fluid (nasopharyngeal and oropharyngeal swabs)
Analytical Specificity (in silico analysis, in vitro analysis)	<p>No microorganism in the in silico studies has revealed > 80% homology between the cross reactivity microorganisms, including the ones of relevance listed below.</p> <p>In vitro analysis: Human coronavirus HCoV-NL63, Human coronavirus HCoV-283E, Human coronavirus HCoV-OC43, Human coronavirus HCoV-229E, Human coronavirus HCoV-223E, RSV, Rhinovirus, Influenza A, Epstein-Barr virus, Haemophilus influenzae, Streptococcus pyogenes, Streptococcus aureus, Pseudomonas aeruginosa, Klebsiella pneumoniae, and Bordetella pertussis.</p> <p>In silico analysis: Human coronavirus HKU1, SARS-coronavirus, MERS-coronavirus, Adenovirus (e.g. C1, Ad. 71), Human Metapneumovirus (hMPV), Parainfluenza virus 1-4, Influenza B, Enterovirus (e.g. EV68), Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Mycoplasma</p>

	pneumoniae, Pneumocystis jirovecii (PJP), Candida albicans, Staphylococcus epidermis, Streptococcus salivarius.
Time to Detection	30 minutes
Extraction System	No need to use - No extraction step
Thermocycler compatibility	MyGo Pro BioRad CFX Connect

* Calculations are based on 400 replications of extracted RNA from SARS-CoV-2.

** Calculations are based on 120 clinical residual samples (60 positive and 60 negative) from patients directed for testing by Polish Sanitary and Epidemiological Stations.