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)	The study showed a sensitivity of 1 x 10-6 ng RNA virus, which corresponds to about 10 copies of the SARS-CoV-2 virus per reaction. Reaction size was set at 50 (50/µl) micro liters, equal to 200 copies of SARS-Cov-2 per milliliter (200/ml).
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)	No microorganism in the in silico studies has revealed > 80% homology between the cross reactivity microorganisms, including the ones of relevance listed below. 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.

	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 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.