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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

COVID-19 Antigen Detection Kit

Manufactured by New Gene (Hangzhou) Bioengineering Co., Ltd., China - www.new-gene.net/ (//www.new-gene.net/)

Device identification number
1501

CE Marking
✓ Yes

HSC common list (RAT)
✓ Yes

Format
Lab-based, Manual, Near POC / POC

Physical Support
Card, Cassette, Lateral flow, Strip

Target type
Antigen

Antibody type
Monoclonal

Targets
nucleocapsid protein,

Specimen
Nasal swab, Nasopharyngeal swab, Oropharyngeal swab

Cross-reactivity (pathogens tested)
Adenovirus, Adenovirus 3, Alpha Coronavirus 229E (HCoV-229E), Alpha Coronavirus NI63 (HCoV-NI63), Beta Coronavirus HKU1 (HCoV-HKU1), Beta Coronavirus OC43 (HCoV-OC43), Influenza A H1N1, Influenza A H3N2, Influenza A H5N1, Influenza B Victoria, Influenza B Yamagata, MERS-CoV, Mumps Virus (MuV), Mycobacterium Tuberculosis, Mycoplasma Pneumoniae, Parainfluenza Virus Type, Parainfluenza Virus Type 2, Respiratory Syncytial V (RSV), Rhinovirus, SARS-CoV

Lineages detected
A.23.1 AT.1 B.1.1.7 (Alpha), B.1.351 (Beta), B.1.427 (Epsilon), B.1.429 (Epsilon), B.1.525 (Eta), B.1.526 (Iota), B.1.616 B.1.617.1 (Kappa), B.1.617.2 (Delta), B.1.617.3 B.1.621 (Mu), C.36 C.37 (Lambda), P.1 (Gamma), P.2 (Zeta), P.3 (Theta), B.1.526.1 B.1.526.2 B.1.1.529 (Omicron),

Commercial Status
Commercialised

Last Update
2022-05-16 09:36:46 CET

Comments
The COVID-19 Antigen Detection Kit by New Gene (Hangzhou) Bioengineering Co., Ltd. has been widely used in practice in many EU member countries. Please visit the following links, and search search “New Gene” in their whitelists for more information. (Germany) https://antigentest.bfarm.de /ords/f?p=110:100:17097377707548 (France) https://covid-19.sante.gouv.fr/tests (Belgium)https://www.famhp.be/en/human_use/health_products/medical_devices_accessories/covid_19/tests (Italy) https://www.salute.gov.it/interrogazioneDispositivi /RicercaDispositiviServlet?action=ACTION_MASCHERA (Portugal) https://www.infarmed.pt/web/Infarmed /pesquisa-dispositivos

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Assay Type
Immuno-Antigen

Rapid Diagnostic
Yes

Self Test
Yes

Reader Required
No

Subcategory
Sample collection device

Method
Immunoassay

Measurement
Qualitative

Time

30 minutes

Subclass
Sandwich, Double

LOD
0.05 ng/mL

Calibration
Evaluated

Calibration
Evaluated

Crossreactivity
Evaluated

Crossreactivity
Evaluated

Fp
0.87 % (1 out of 114)

Fn
2.02 % (5 out of 247)

Precision
Evaluated

Accuracy
98.3 % (Antigen)

Reproducibility
Evaluated

Robustness
Evaluated

Clinical Sensitivity
98 % (Antigen)

Clinical Specificity
99.1 % (Antigen)

Type of antigen
Nucleocapsid protein

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark. Acknowledgements *(/acknowledgements)*