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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

Green Spring SARS-CoV-2 Antigen-Rapid test-Set

Manufactured by Shenzhen Lvshiyuan Biotechnology Co. Ltd., China - https://www.lsybt.com/ *(https://www.lsybt.com/)*

Device identification number
2109

CE Marking
✓ Yes

HSC common list (RAT)
✓ Yes

Format
Near POC / POC

Physical Support
Cassette

Target type
Antigen

Targets
nucleocapsid protein

Specimen
Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab

Cross-reactivity (pathogens tested)

Coronaviruses (HCoV), SARS-CoV

Lineages detected
B.1.1.7 (Alpha), B.1.351 (Beta), B.1.617.1 (Kappa), B.1.617.2 (Delta), B.1.617.3, P.1 (Gamma)

Commercial Status
Commercialised

Last Update
2022-08-24 09:08:01 CET

Comments
Dear colleagues, we have removed the saliva sample method from our test and the data of the sensitivity and specificity are from the newest performance evaluation. Thank you very much for the update! Best regards, Anna Zhu

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Assay Type
Immuno-Antigen

Rapid Diagnostic
Yes

Reader Required
No

Subcategory
Other ()

Method
Immunochromatography

Measurement
Qualitative

Time
15 minutes

Subclass
Capture

LOD
400 AU

Calibration
Evaluated

Analysis of cross reactivity
Evaluated

False positives
0 % 0 of 210 (100% specificity)

False negatives
3.23 % (5 of 155 (96.77% sensitivity))

Precision
Evaluated

Accuracy

98.63 % (Antigen)

Reproducibility
Evaluated

Robustness
Evaluated

Clinical Sensitivity
96.77 % (Antigen)

Clinical Specificity
100 % (Antigen)

Type of antigen
Nucleoprotein

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)*