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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

Rapid SARS-CoV-2 Antigen Test Card

Manufactured by MP Biomedicals Germany GmbH

Manufacturer website
https://www.mpbio.com/eu/

CE Marking	yes
Detection Principle	immunoAssay-Antigen
Format	Rapid diagnostic test
Target	Antigen
Commercial Status	Commercialised
Last Update	07/01/2021

Additional Information	https://www.mpbio.com/eu/covid-19-antigen-rapid-test-20-tests-per-kit

Test Type	Point-Of-Care test
Test Type Result	Qualitative
Format	card
Detection Principle Antibody	lateral flow chromatography
Specimen	nasal swab
Antigen IgG	no
Antigen IgM	no
Antigen IgA	no
Guidance Available	yes
Reader	not required
Time (Min)	15
Fp	Clinical study result: 4 false positives out of 414 PCR negative samples = 99.03% specificity
Fn	Clinical study result: 3 false negatives out of 83 PCR positive samples = 96.39% sensitivity
Lod	1
Analysis of Cross Reactivity	evaluated
Robustness	evaluated
Precision	evaluated
Calibration	evaluated
Sensitivity Percent	96.39%
Specificity Percent	99.03%

Accuracy Percent	98.59%
Reproducibility evaluated	
Type of Antigen	nucleoprotein

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