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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

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COVID-19 In Vitro Diagnostic Medical Device - detail

Rapid SARS-CoV-2 Antigen Test Card

Manufactured by MP Biomedicals Germany GmbH

Manufacturer website <u>https://www.mpbio.com/eu/</u>

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
Fp Fn	414 PCR negative samples = 99.03%
	414 PCR negative samples = 99.03% specificity Clinical study result: 3 false negatives out of
Fn	414 PCR negative samples = 99.03%specificityClinical study result: 3 false negatives out of83 PCR positive samples = 96.39% sensitivity
Fn Lod Analysis of Cross	 414 PCR negative samples = 99.03% specificity Clinical study result: 3 false negatives out of 83 PCR positive samples = 96.39% sensitivity 1
Fn Lod Analysis of Cross Reactivity	 414 PCR negative samples = 99.03% specificity Clinical study result: 3 false negatives out of 83 PCR positive samples = 96.39% sensitivity 1 evaluated
Fn Lod Analysis of Cross Reactivity Robustness	 414 PCR negative samples = 99.03% specificity Clinical study result: 3 false negatives out of 83 PCR positive samples = 96.39% sensitivity 1 evaluated evaluated
Fn Lod Analysis of Cross Reactivity Robustness Precision	414 PCR negative samples = 99.03% specificity Clinical study result: 3 false negatives out of 83 PCR positive samples = 96.39% sensitivity 1 evaluated evaluated evaluated

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Accuracy 98.59% Percent Reproducibility evaluated Type of nucleoprotein Antigen

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. <u>Acknowledgements</u>

COVID-19 Test Methods and Devices This site is managed by the Joint Research Centre

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