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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

Previous

SC2Flu Triplex Fast Test (Colloidal Gold) For SARS-CoV-2 & influenza A/B antigens

Manufactured by AMPER INC, United States - http://www.amperbio.com

Device identification number	2872
CE Marking	✓ Yes
HSC common list	× No

HSC mutual recognition	× No
Format	Manual, Near POC / POC
Physical Support	Lateral flow
Target	Antigen
Specimen	Nasal swab, Nasopharyngeal swab
Pathogens detected	Influenza A, Influenza A H1N1, Influenza A H3N2, Influenza B, Influenza B Victoria, Influenza B Yamagata, SARS-CoV
Lineages detected	B.1.1.7 (United Kingdom), B.1.351 (South Africa), B.1.427 (USA), B.1.429 (USA), B.1.525 (Nigeria), B.1.617.2 (India), P.1 (Japan/Brazil), C.37 (Peru), ,
Commercial Status	Commercialised
Last Update	2021-12-17 11:55:59 CET
Comments	See IFU

Assay Type	Immuno-Antigen
Reader Required	No
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
Subclass	Sandwich, Double
Detection Principle	Colloidal gold
LOD	78 TCID50/ml
Calibration	Evaluated
Crossreactivity	Evaluated
Fp	0 %
Fn	3 %

Precision	Evaluated
Accuracy	100 %
Reproducibility	Evaluated
Robustness	Evaluated
Clinical Sensitivity	94.12 % (SARS-CoV-2 antigen)
Clinical Sensitivity	96.88 % (influenza A antigen)
Clinical Sensitivity	97.5 % (Influenza B antigen)
Clinical Specificity	100 % (SARS-CoV-2 antigen)
Clinical Specificity	100 % (influenza A antigen)
Clinical Specificity	100 % (Influenza B 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