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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

Covid-19 Antigen Rapid Test Kit

Manufactured by Hangzhou Clongene Biotech Co., Ltd, China - en.clongene.com/ 

Device

identification

number

1363

CE Marking ✓ Yes

HSC ✓ Yes

common list

HSC mutual recognition ✓ Yes

Format Near POC / POC

Physical Support Cassette

Target Antigen

Specimen Nasal swab

Commercial Status	Commercialised
Last Update	2021-05-10 01:04:00 CET

[Show HSC list status history](#) 

Assay Type	Immuno-Antigen
Rapid Diagnostic	Yes
Reader Required	No
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
LOD	2300 AU
Fp	0 %
Fn	1.5 % (Ct<33)
Accuracy	99.6 % (Ct<33)
Clinical Sensitivity	98.5 % (Ct <33)
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](#)

COVID-19 Test Methods and Devices

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