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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**

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# COVID-19 In Vitro Diagnostic Medical Device - detail

## SARS-CoV-2 Antigen Test Kit

**Manufactured by Hubei Jinjian Biology Co., Ltd,  
China - [en.jinjianbio.com/](http://en.jinjianbio.com/) **

Device

identification

number

1759

CE Marking      ✓ Yes

HSC              ✓ Yes

common list

HSC mutual      ✓ Yes

recognition

Format            Automated

Physical            Cassette  
Support

Target             Antigen

Specimen           Nasopharyngeal swab, Oropharyngeal swab

Commercial        Commercialised

Status

Last Update 2021-08-25 09:42:56 CET

[Show HSC list status history](#) 

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Assay Type	Immuno-Antigen
Rapid Diagnostic	Yes
Reader Required	Yes
Method	Immunochromatography
Measurement	
Qualitative	
Time	15 minutes
Detection Principle	Colorimetry
LOD	115 U/ml
Calibration	Not Evaluated
Crossreactivity	
Evaluated	
Fp	1 % (1 out of 100)
Fn	1.35 % (2 out of 148)
Precision	Evaluated
Accuracy	98.8 %
Reproducibility	
Evaluated	
Robustness	Evaluated
Clinical Sensitivity	98.02 %
Type of antigen	Nucleoprotein

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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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