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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 In Vitro Diagnostic Medical Device - detail**

SARS-CoV-2 Antigen Kit (Colloidal Gold)

Manufactured by Goldsite Diagnostics Inc, China - en.goldsite.com.cn/ □

Device

identification

number

1197

CE Marking √ Yes

HSC √ Yes

common list

HSC mutual √ Yes

recognition

Format Near POC / POC

Target Antigen

Specimen Nasal swab, Other

Commercial Commercialised

Status

Last Update 2021-07-13 06:05:32 CET

#### Comments

# **Show HSC list status history** \

Assay Type Immuno-Antigen

Rapid Yes

Diagnostic

Reader No

Required

Method Immunoassay

Measurement Qualitative

Time 12 minutes

Detection

Colloidal gold

Principle

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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