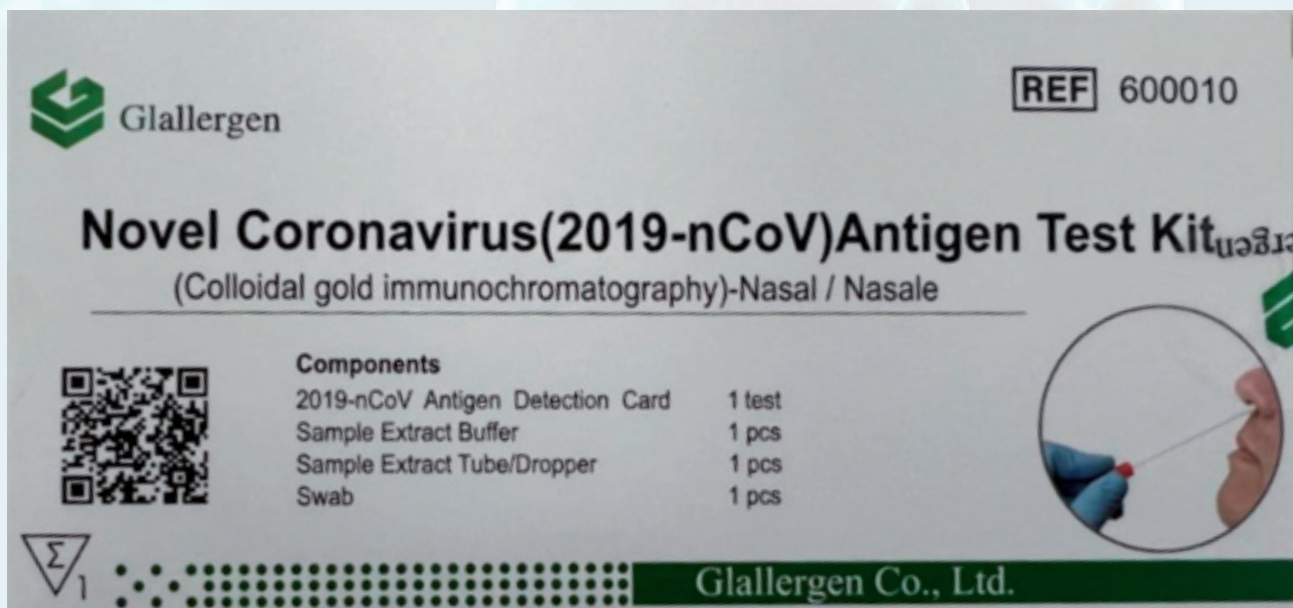


GLALLERGEN

Novel Coronavirus (2019-nCoV) Antigen Test Kit

新冠狀病毒檢測套裝



「Glallergen 格林新型冠狀病毒 (2019 nCoV) 抗原快速檢測試劑盒套裝」產品質量穩定，準確度達到 97%，臨床特異性(真陰性比率)達 99%，能在最大程度上降低出現假陽性的機率，亦可檢測出 Omicron 及 Delta 等已知品種變種病毒。產品已獲多種國際測試及認證，比較市場上現有產品相對安全可靠。產品有效期兩年。

產品名稱：Glallergen 格林新型冠狀病毒 (2019-nCoV) 抗原快速檢測試劑盒

使用方式：只需以鼻咽拭子樣本檢測，約15分鐘即有測試結果，適用於新型冠狀病毒感染及其變種病毒，可檢測 99% 已知的新冠病毒毒株，包括 Omicron 及 Delta 等變種病毒。

臨床特異性 (Clinical Specificity): 99%

準確度 (Accuracy): 97%

靈敏度 (Sensitivity):

Cq ≤ 25: 100%,

Cq 25-30: 100%,

Cq ≥ 30: 60%

總數: 92%

(參考資料及數據來源: 德國疫苗和生物製藥局)

- 歐盟CE認證
- 具ISO認證
- 獲德國, 法國, 奧地利等國家認證
- 出口歐洲市場, 具ISO及歐盟RAT表列認證
- 獲德國 Whitelist: PEI 權威認證
- 通過德國藥品和醫療器械研究所 BfArM 檢測
- 通過法國 Whitelist of French
- 通過意大利 Whitelist of Italy: Professional and Self-testing
- 通過奧地利 Whitelist of Austria



Whitelist of German

Antigen-Tests auf SARS-CoV-2 zur professionellen Anwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Schnelltests“)

Test-ID	Handelsname	Evaluierung PEI	Name ↑	Hersteller			Europäischer Bevollmächtigter			Sensitivität		Spezifität		Gebrauchsa...
				Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertrauensintervall	%	95%iges Vertrauensintervall	
AT756/21	Neuartiges Coronavirus (2019-nCoV) –Antigen-Testkit (Kolloidale Goldimmunochromatographie) –oropharyngealen Tupfern	Ja	Glallergen CO., LTD.	Tianjin	CN	Osmunda Medical Technology Service GmbH	Potsdam	DE	POC (ohne Gerät)	95,37	91,41 - 99,33	99,02	97,11 - 100,00	Link...



Whitelist of Italy

DISPOSITIVO MEDICO/ASSEMBLATO										FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA	IDENTIFICATIVO	ISCRITTO AL	CODICE ATTRIBUITO DAL	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE											
Dispositivo	2155677	N	600009	NOVEL CORONAVIRUS (2019-NCOV) ANTIGEN TEST KIT (COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY) - TEST SALIVARE	W0105099099 - VROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	IVD - Altro tipo di IVD	22/09/2021		FABBRICANTE	GLALLERGEN CO., LTD			CN
										MANDATARIO	OSMUNDA MEDICAL TECHNOLOGY SERVICE GMBH		DE333736296	DE



Whitelist of France

Tableau de bord des tests Cliquez pour déplier et visualiser les graphes du tableau de bord ▼

1 test affiché

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLÈVEMENT
Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal Gold Immunochromatography)	Glallergen Co., Ltd.		✔	✔	✔	Antigénique non automatisé (dont TROD)	N	Nasopharyngé, Nasal



Whitelist of Austria

SARS-CoV-2-Antigenschnelltestregister

Das SARS-CoV-2-Antigenschnelltestregister listet alle SARS-CoV-2-Antigenschnelltests, welche bis zum gegenwärtigen Zeitpunkt gemäß § 81 Absatz 4 Medizinproduktegesetz 2021 beim Bundesamt für Sicherheit im Gesundheitswesen eingemeldet wurden. Durch Eingabe des Produktnamens, Herstellers, Inverkehrbringers oder Bevollmächtigten in das Suchfeld kann erhoben werden, ob der SARS-CoV-2-Antigenschnelltest eingemeldet wurde.

Inverkehrbringer	Hersteller	Bevollmächtigter	REF-Nummer	PEI-Bewertung
Glallergen CO., LTD. North side of the third floor of No. 6 factory building, Wuqing Development Zone, 301799 Tianjin, P.R. China	Glallergen CO., LTD. North side of the third floor of No. 6 factory building, No. 1 Xinxing Road, Wuqing Development Zone, Tianjin, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam	600009 600010	Information liegt nicht vor.

Whitelist of EU

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 232903-1

Organization: Glallergen CO., LTD.
North side of the third floor of No. 6 factory building, No. 1 Xinxing Road, Wuqing Development Zone, 301799 Tianjin, P.R. China

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Test Kits used in the Detection of Infectious Diseases

TUV Rheinland Products GmbH
Tillystraße 2, 30627 Nürnberg, Germany

1 / 1

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices > COVID-19 In Vitro Diagnostic Medical Devices - detail

COVID-19 In Vitro Diagnostic Medical Device - detail

Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal gold immunochromatography)

Manufactured by **Glallergen CO., LTD.**

Device identification number	2050
CE Marking	Yes
MSC commercial	Yes
Formal	Manual
Physical support	Card, Cassette, Lateral flow
Target type	Antigen
Specimen	Nasal wash
Consistency	COVID-19
Pathogens tested	
Lineages detected	
Commercial Status	Commercialised
Last update	2020-04-10 09:35 CET
Comments	The product is listed by BMWi with AT75521 and has positive results by PEI.

Show MSC list status history

Assay type	Immuno-antigen
Rapid Diagnostic	Yes
Reader Required	No
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
Detection Principle	Colloidal gold
Calibration	Evaled
Consistency	Evaled
CP	0,0%
PPV	0,0%
Precision	Evaled
Accuracy	0,0%
Reproducibility	Evaled
Robustness	Evaled
Clinical Sensitivity	0,0%
Clinical Specificity	0,0%
Type of antigen	Recombinant protein

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and is being updated periodically. Please note that additional performance data retrieved from manufacturers web pages is provided only for devices commercially available with CE-IVD mark.

Paul Ehrlich -Institut Test

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	BioteC Corporation (Wuxi) Co., Ltd.
COVID-19 Antigen Test	Artron Laboratories Inc.
Accu-Biotech Rapid In-vitro Diagnostic Test	Accu-Biotech Co., Ltd.
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	Hubei Jianxin Biology Co., Ltd.
Corona Schnelltest-19	Abbot
Jimwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	Beijing Jimwofu Bioengineering Technology Co., Ltd.
STANDARD I-Q COVID-19 Ag Home Test	SD Biosensor, Inc.
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) SPOKTEST	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SARS-CoV-2 Antigen Test Kit (Colloidal Gold) WANTAI SPOKTEST	Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.
COVID-19 Antigen Rapid Test (Colloidal Gold)	Beijing Q&D Biotech Co., Ltd.
OnSite COVID-19 Ag Rapid Test	CIT Biotech, Inc.
COVID 19 Antigen Test Kit (Colloidal Gold Method)	Nuo-nostics (Suzhou) Bioengineering Co., Ltd.
Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	Hoyotek Biomedical Co., Ltd.
SARS-CoV-2 Antigen test Kit (Colloidal Gold Method)	Changsha Sinocare Inc.
FUJIFILM COVID-19 Ag Test	FUJIFILM Corporation
Greenlight SARS-CoV-2 Antigen-Test	Senova Gesellschaft für Biowissenschaft und Technik mbH
SARS-CoV-2 Antigen RFD kit SWAB	Shenzhen Redagent Technology Co., Ltd.
Novel Coronavirus (SARS-CoV-2) Ag Rapid Test Kit	Jiangsu Bioerfectus Technologies Co., Ltd.
Rapid SARS-CoV-2 Antigen Test Colloidal Gold (Nasopharyngeal specimen)	InTec Products, Inc.
INNOVA SARS-CoV-2 Selbsttest (Qualitative-Antigen-Schnelltest)	Innova Medical Group, Inc.
Goldsite COVID-19 SARS-CoV-2 Antigen Kit (Colloidal Gold)	GoldSite Diagnostics Inc.
Novel Corona Virus (2019-nCoV) Ag Rapid Test Kit	Glallergen CO., LTD.