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6499 7555

Whatsapp Enquiry

地址：香港新界粉嶺安全街10及12號堅達中心

Address : Smile Centre, 10 & 12 On Chuen Street, Fanling,
New Territories, Hong Kong

查詢電郵 Email :

enquiry@medfort.com.hk

銷售熱線 Enquiry :

(852) 3955 8592

服務時間 Opening Hours :

星期一至五 Mon - Fri : 0900 – 1300 / 1400 – 1800

星期六 Sat : 0900 – 1300

星期日及公眾假期休息 Closed on Sundays and Public Holidays



Instagram



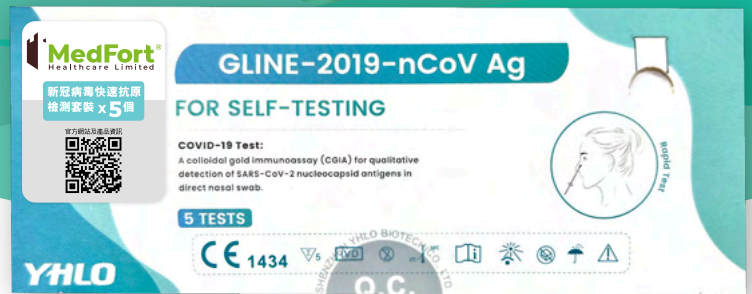
Facebook



medfort.com.hk



1個檢測套裝
1 Test kit package



5個檢測套裝
5 Tests kit package

YHLO GLINE 新冠病毒快速抗原檢測套裝

YHLO GLINE-2019-nCov Ag Rapid Test Kit

COVID-19

自我檢測 Self Testing

歐盟CE驗證 CE Certificate

檢測結果快速：只需15分鐘就可以取得檢測結果
Quick test result : 15 mins

操作簡單：無需使用特殊專業設備和儀器

Easy operation : No special professional equipment and instruments required



高準確度 High Accuracy

靈敏度 (檢測真陽性率) - 96.38% *

Sensitivity (True Positive Rate) - 96.38% *

特異度 (檢測真陰性率) - 99.56% #

Specificity (True Negative Rate) - 99.56% #

* 是指實際為陽性的樣本中，判斷為陽性的比例

* Refers to the probability of a positive test, conditioned on truly having the condition

是指實際為陰性的樣本中，判斷為陰性的比例

Refers to the probability of a negative test, provided one does not have the condition

測試配件 / Contains

無菌棉籤 / Sterile Swab

測試溶液瓶 / Extraction Buffer Tube

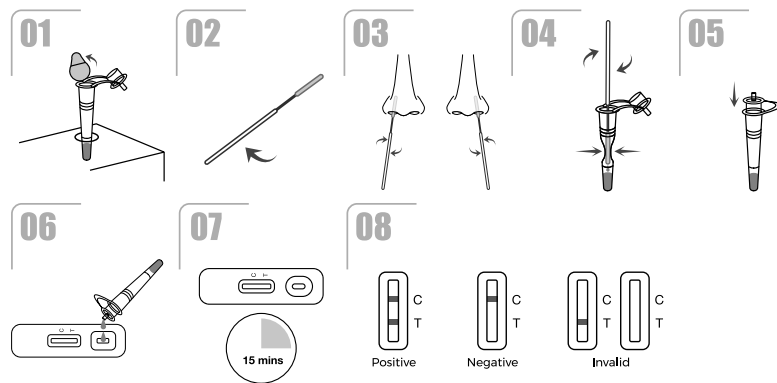
測試棒 / Test Cassette

棄置組件用垃圾袋 / Biohazard Sample Bag

使用說明 / Instruction Guide



使用說明 / Instruction Guide



操作視頻
Operation Video



YHLO GLINE 新冠病毒快速抗原檢測套裝 YHLO GLINE-2019-nCoV Ag Rapid Test Kit

<p>產品選擇 Test Kit Package</p>	<p>1個檢測套裝 1 Test kit package</p> 	<p>5個檢測套裝 5 Tests kit package</p> 
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生產商：亞輝龍生物科技股份有限公司
Manufacturer: YHLO (EST. 2008)



CERTIFICATE

EC Certificate No. 1434-IVDD-519/2021

EC Design-examination

Directive 98/79/EC concerning

***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

SHENZHEN YHLO BIOTECH CO., LTD.

**Building 1, YHLO Biopark, Baolong 2nd Road, Baolong
Subdistrict, Longgang District, 518116 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA**

in vitro diagnostic medical devices
for self-testing

The list of medical devices covered by this certificate is provided in the annex I

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 16.12.2021 to 27.05.2024

The date of issue of the Certificate: 16.12.2021

The date of the first issue of the Certificate: 16.12.2021



Issued under the Contract No. MD-146/2021
Application No: 556/2021
Certificate bears the qualified signature.
Warsaw, 16.12.2021
Module A1
FBM-30-E_10

Director
Medical Device Certification
Department

ANNEX 1 TO THE CERTIFICATE VALID ONLY WITH CERTIFICATE

No 1434-IVDD-519/2021

List of medical devices covered by the certificate:

Product	REF number	variant
GLINE-2019-nCoV Ag	G86256	1 test/kit
GLINE-2019-nCoV Ag	G86257	5 tests/kit
GLINE-2019-nCoV Ag	G86278	7 tests/kit
GLINE-2019-nCoV Ag	G86279	10 tests/kit
GLINE-2019-nCoV Ag	G86280	15 tests/kit
GLINE-2019-nCoV Ag	G86273	20 tests/kit
GLINE-2019-nCoV Ag	G86281	25 tests/kit



Issued under the Contract No. [MD-146/2021](#)
Application No: [556/2021](#)
Certificate bears the qualified signature.
Warsaw, [16.12.2021](#)

Director

Medical Device Certification Department



European Commission 歐盟委員會





EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

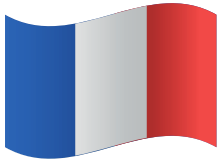
**A common list of COVID-19 rapid antigen tests;
A common standardised set of data to be included in COVID-19 test result certificates; and
A common list of COVID-19 laboratory based antigenic assays**

Agreed by the Health Security Committee 

			<i>Retrospective in vitro study</i>					
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	1347	DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.85%	Nasal: Sensitivity: 97.37% (95%CI: 92.50% - 99.45%) Specificity: 99.25% (95%CI: 97.82% - 99.85%) NP: Sensitivity: 96.49% (95%CI: 91.26% - 99.04%) Specificity: 99.25% (95%CI: 97.82% - 99.85%)	DE ^{II}	Nucleo-capsid protein	Nasal swab; Nasopharyngeal	8 December 2021 

通過測試並列入歐盟健康安全委員會(HSC)常用新型冠狀病毒快速抗原檢測劑清單

Registered in Common List of COVID-19 rapid antigen tests in European Commission



France ANSM 法國國家藥品和健康產品安全局



通過測試並列入法國 French ANSM 認可的新型冠狀病毒快速抗原檢測劑清單

Registered in France ANSM (National Agency for the Safety of Medicines and Health Products)



Germany Bfarm 德國聯邦藥品和醫療器械研究所

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen tests for SARS-CoV-2 for self-testing
which are the subject of the claim according to §1 sentence 1 Coronavirus Test Ordinance (TestV) ("self-tests")

Search: All text columns | Lot | Actions | Reset

Test ID	Name of the test	Evaluation f. Name	Manufacturer		European Plenipotentiary		Sampling	Sensitivity		Specificity		Directions
			Land	Name	Land	Name		%	95% confidence interval	%	95% confidence interval	
AT1401/21	GLINE-2019-nCoV Ag	Nein	Shenzhen YHLO Biotech Co., L.	CN	Lotus NL B.V.	NL		96,38	91,75 - 98,81	99,56	97,57 - 99,99	Lin...

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen tests for SARS-CoV-2 for professional use
which are the subject of the claim according to §1 sentence 1 Coronavirus Test Ordinance (TestV) ("rapid tests")

Search: All text columns | Lot | Actions | Reset

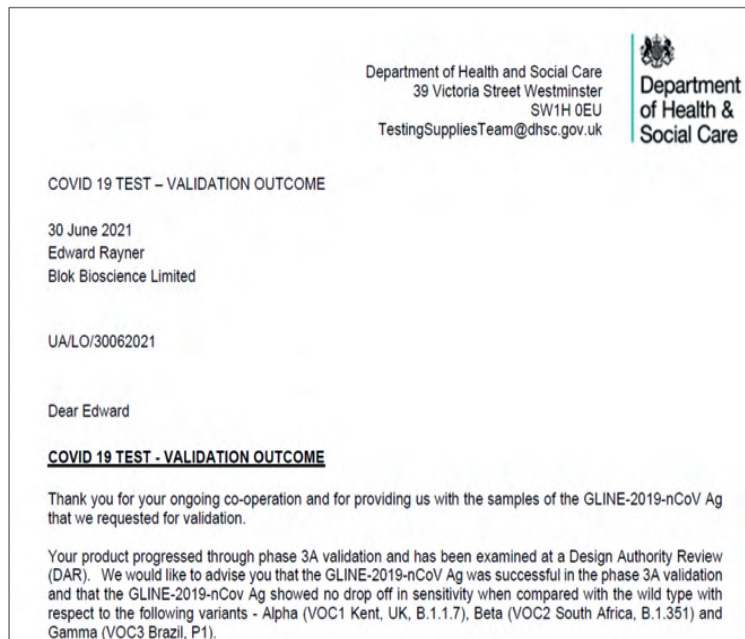
Test ID	Trade name	Evaluation PEI	Manufacturer			European Plenipotentiary			Test location	Sensitivity		Specificity		Directions for use
			Name T.	City	Land	Name	City	Land		%	95% confidence interval	%	95% confidence interval	
AT1105/...	GLINE-2019-nCoV Ag Saliva	No	Shenzhen YHLO Biotech Co., Ltd.	Shenzhen	CN	Lotus NL B.V.	The Hague	NL	POC (with device)	95,27	93,15 - 96,89	100,00	97,05 - 100,00	Op...
AT409/21	GLINE-2019-nCoV Ag	Yes	Shenzhen YHLO Biotech Co., Ltd.	Shenzhen	CN	Lotus NL B.V.	The Hague	NL	POC (with device)	96,49	91,26 - 99,04	99,25	97,82 - 99,85	Op...

通過測試並列入德國 Germany BfArM 認可的新型冠狀病毒快速抗原檢測劑清單

YHLO GLINE-2019-nCoV Ag assay had 2 versions (professional and self-testing), both of them were listed in Bfarm (Germany Federal Institute for Drugs and Medical Devices)

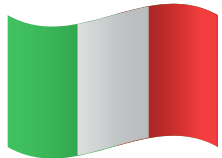


DHSC of UK 英國衛生與社會關懷部



通過英國UK DHSC的Phase 3A評估認證

Evaluated by DHSC (Department of Health and Social Care) of UK, and passed Phase 3A evaluation



Italy Ministry of Health 意大利衛生部

21/12/2020 Elenco dei dispositivi medici Area tematica Dispositivi medici | Archivio banche dati

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario: 12111591009
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, implantabili attivi e IVD):

Elenco dispositivi individuati
Dati aggiornati al:20/12/2020

Dispositivo	2044443	N	G86247	GLINE-2019- NCOV AG
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通過測試並列入意大利 Italy Ministry of Health認可的新型冠狀病毒快速抗原檢測劑清單

Listed in Italy Ministry of Health



Belgium FAMHP 比利時聯邦藥品和健康產品局

List of recommended SARS-CoV-2 antibody and antigen tests


Latest update: 18/01/2022

Manufacturer	Test	Sensitivity	Specificity	Specimen type
Shenzhen YHLO Biotech Co	GLINE-2019-nCoV Ag	96.5/97.4	99.3/99.3	NP swab/Nasal swab

通過測試並列入比利時 Belgium FAMHP認可的新型冠狀病毒快速抗原檢測劑清單
Listed in Belgium FAMHP (Federal Agency for Medicines and Health Products)



Bulgaria Ministry of Health 保加利亞衛生部

 REPUBLIC OF BULGARIA Ministry of Health Minister of Health	
ORDER X _____	
<p>Pursuant to Art. 61, para. 2, Art. 63, para. 4, 5 and 11 and Art. 63c of the Health Act, Art. 73 of the Code of Administrative Procedure, and in conjunction with Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a Framework for the Issuance, Verification and Adoption of Interoperable Vaccination Certificates against a examination for and recovery from COVID-19 (EU Digital COVID Certificate), in order to facilitate free movement during the pandemic of COVID-19, and Decision No. 826 of the Council of Ministers of November 25, 2021 for the extension of the term of the emergency epidemic situation announced by Decision no. 325 of the Council of Ministers of 14 May 2020, extended by Decision No. 378 of the Council of Ministers of 12 June 2020, Decision No. 418 of the Council of Ministers of 25 June 2020, Decision No. 482 of the Council of Ministers of 15 July 2020, Decision No. 525 of the Council of Ministers of 30 July 2020, Decision No. 609 of the Council of Ministers of 23 August 2020, Decision No. 673 of the Council of Ministers of 25 September 2020, Decision No. 855 of the Council of Ministers of 25 November 2020, Decision No. 72 of the Council of Ministers of 26 January 2021, Decision No. 395 of the</p>	
GLINE-2019-nCoV Ag	Shenzhen YHLO Biotech Co., Ltd.

通過測試並列入保加利亞 Bulgaria Ministry of Health認可的新型冠狀病毒快速抗原檢測劑清單
Listed in Bulgaria Ministry of Health



Malaysia MDA 馬來西亞醫療器械管理局

Official Portal
Medical Device Authority
 Ministry of Health Malaysia

Our Hotline ☎ +603 - 8230 0300

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Home / Announcement / SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)

SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)

SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)

List of RTK ANTIGEN (Self-Test) that is approved for Conditional Approval based on the decision on the consensus of the Covid-19 Test Kit Expert committee is as follows.

GLINE-2019-nCoV Antigen Saliva Sample type: Saliva	Shenzhen YHLO Biotech Co., Ltd.P.R.China	G86259 (1T)	20211001
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通過測試並列入馬來西亞 Malaysia MDA認可的新型冠狀病毒快速抗原自我檢測劑清單
 Listed in Malaysia Medical Device Authority (MDA)



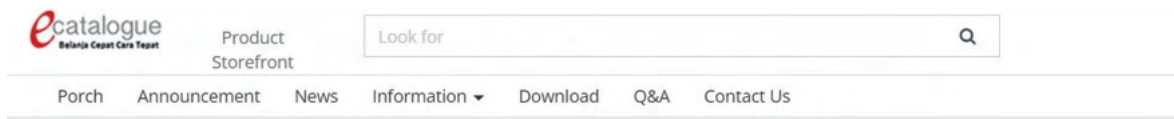
Slovenia MOH 斯洛文尼亞衛生部

Šifra za CRPP	Ustreza kriterijem strokovne skupine	Naziv za prikaz v šifrantu	Proizvajalec	Komerčno ime	Tip vzorca	Podatki proizvajalca		Podatki proizvajalca	
						občutljivost %	95 % interval zaupanja	specifičnost %	95 % interval zaupanja
8081	DA	GLINE-2019-nCoV Ag/Shenzhen YHLO Biotech Co., Ltd.	Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	bNF, bN	95,5	91,3 - 99	99,2	97,8 - 99,8

通過測試並列入斯洛文尼亞 Slovenia MOH認可的新型冠狀病毒快速抗原檢測劑清單
 Listed in Slovenia MOH official list



Indonesia government 印尼政府



Home ▶ Medical Devices ▶ Immunology and Microbiology Equipment ▶ Serological reagent ▶ YHLO GLINE-2019-nCoV Ag



YHLO YHLO GLINE-2019-NCOV AG

4815000150-AK1-001038973

PT. Setia Anugrah Medika

National Catalog

Health Facilities

Rp 500.000.00

通過測試並列入印尼政府認可的新型冠狀病毒快速抗原檢測劑清單
Listed in Indonesia government eCatalogue