普迈德（北京）科技有限公司

Pro-med (Beijing) Technology Co.,Ltd

www.pmdt.com.cn

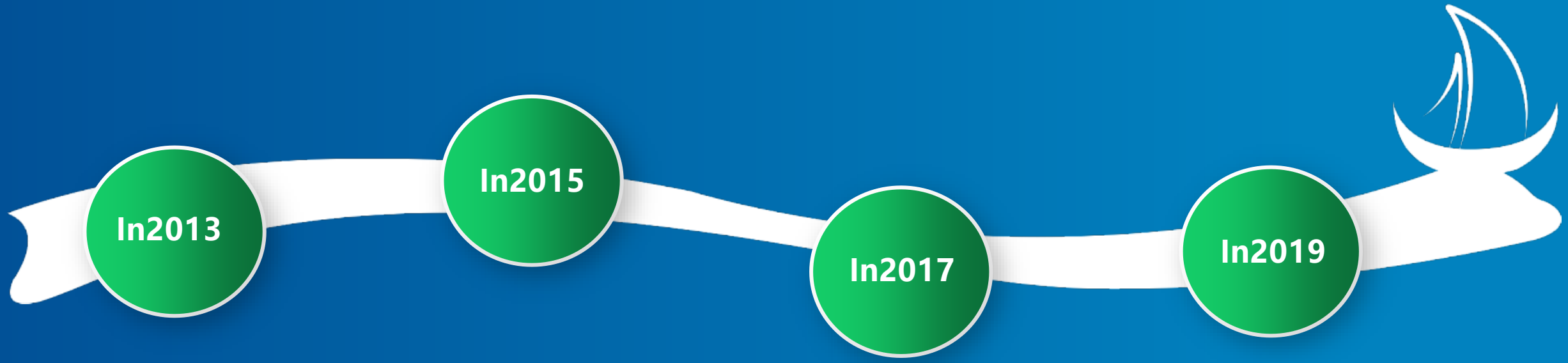
Pro-med technology 普迈德

- Company Overview
- Enterprise Qualification & honor
- Production Capacity
- COVID-19 Antigen Rapid Test

Company Overview

- Pro-med established in 2013 which has two production, R&D bases in Beijing’ s Zhongguancun Science and Technology Park and Jiangsu China Medical City, 30 independent intellectual property rights, and 80 conventional product lines.
- More than 10,000 m^2 production area, 300 employees, the daily production capacity exceeds 3 million.
- self-produced core IVD raw materials.
- Pro-med have obtained CE certificates and China whitelists, Germany BfArM, Italian approval and Austrian BASG.
- The self-test list of France, Netherlands, Denmark, Austria and other countries are in application.

Milestone



pro-med was founded, focusing on rapid diagnosis

Entered into the POCT market,
At present, the business has covered 8000+ medical institutions

Set up a wholly owned subsidiary, Jiangsu Aoya Biotechnology Co., Ltd

Entered into the international market. Business coverage of Germany, France, the Netherlands, Denmark, Austria....

Service

- Include 80+ Clinical Test Items
- Serve 8,000+ Medical Institutions
- Safeguard Health of 100,000,000 People

7 Technology Platforms

- Immune Colloidal Gold Platform
- Immunofluorescence Platform
- Diagnostic platform for bleeding/coagulation
- Chemiluminescence Platform
- Molecular Diagnostics Platform
- Instrument Platform
- Biological Raw Material Platform

Enterprise Qualification & honor

Chinese Certificates

Business license | Produce license | ISO 13485:2016

编号：I 03516612

营 业 执 照

(副 本) (1-1)

统一社会信用代码 91110114078587382R

名　　称	普迈德（北京）科技有限公司
类　　型	有限责任公司(自然人投资或控股)
住　　所	北京市昌平区马池口镇昌流路738号8#楼三层C区
法定代表人	余占江
注册资本	1176.4706万元
成立日期	2013年08月29日
营业期限	2013年08月29日 至 2063年08月28日
经营范围	技术推广；生物制品技术开发、技术服务；货物进出口、技术进出口；生产临床检验分析仪器以及临床诊断器械；生产第二类、第三类医疗器械。（企业依法自主选择经营项目，开展经营活动；生产临床检验分析仪器以及临床诊断器械、生产第二类、第三类医疗器械以及依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

在线扫码获取详细信息

登记机关　北京市工商行政管理局昌平分局

2017年 10月 12日

提示：每年1月1日至6月30日通过企业信用信息公示系统报送上一年度年度报告并公示。

企业信用信息公示系统网址：qyxy.baic.gov.cn　　中华人民共和国国家工商行政管理总局监制

医疗器械生产许可证

许可证编号：京食药监械生产许20140008号

企业名称：普迈德（北京）科技有限公司

生产地址：北京市昌平区马池口镇昌流路738号8#楼一层C区、三层C区和C1区

法定代表人：余占江

生产范围：2002版分类目录：Ⅱ类：Ⅱ-6840 体外诊断试剂，Ⅱ-6840-3免疫分析仪***

企业负责人：余占江

住　　所：北京市昌平区马池口镇昌流路738号8#楼三层C区

发证部门：

有效期限：至 2023 年 05 月 01 日　　发证日期：2019 年 05 月 13 日

国家药品监督管理局制　　印刷质水号NO 0003754

Chinese Certificates

Chinese Whitelist

中国医药保健品进出口商会
服 务 产 业 链 | 助 力 国 际 化

English 登陆 | 注册

请输入关键词进行搜索

开具不可抗力相关事实性证明

取得国外认证和注册企业查询

首页 关于商会 新闻中心 行业服务 权威发布 商会会刊 企业风采 会员之家 加入商会

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

普迈德 检索

企业名称（中文）	企业名称（英文）	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况
普迈德（北京）科技有限公司 P	ro-med （Beijing） Technology Co., Ltd.	新型冠状病毒检测试剂	COVID-19 and COVID-19 Mutant Strain (B.1.1.7 Strain)Antigen Rapid Detection Kit (Colloidal Gold) COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) Influenza A+B and COVID-19 Antigen Combo Rapid Detection Kit (Colloidal Gold) COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold) COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)	91110114078587382R	欧盟CE

Global Certificates

European CE

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec
Bezoekadres:
Hofloven
Rijnstraat 50
2515 XP Den Haag
T 070 340 8161
http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-2021-5327

Bijlagen
-

Uw aanvraag
22 januari 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 29 januari 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 22 januari 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Pro-med（Beijing）Technology Co., Ltd. met Europese gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

COVID-19 Antigen Rapid Detection Kit(Colloidal Gold),
COVID-19 Neutralizing Antibody Rapid Detection Kit(Colloidal Gold),
COVID-19 IgM/IgG Antibody Rapid Detection Kit(Colloidal Gold)
(geen merknaam) (NL-CA002-2021-S5692)
Influenza A+B and COVID-19 Antigen Combo Rapid Detection Kit(Colloidal Gold),
COVID-19 and COVID-19 Mutant Strain(B.1.1.7 Strain)Antigen Rapid Detection Kit(Colloidal Gold)
(geen merknaam) (NL-CA002-2021-S5693)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke reviseren van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Pagina 1 van 2

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Pro-med（Beijing）Technology Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage 1 bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit).

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Pagina 2 van 2

EC Declaration of Conformity

Manufacturer:
Name: Pro-med （Beijing） Technology Co., Ltd.
Address: C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China
Tel:+86-10-57277459 **Website:**www.pmdt.com.cn

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We,Pro-med（Beijing）Technology Co., Ltd.,here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them.The declaration of conformity is exclusively under the responsibility of Pro-med（Beijing）Technology Co., Ltd.

Product Name	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 antigen in human nasopharyngeal or pharyngeal swab specimens.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016 / ISO 14971:2019 / EN ISO 18113-1:2011 / EN ISO 18113-2:2011 / EN ISO 18113-3:2011 / EN 13641:2002 / ISO 15223-1:2016 / EN 13612:2002 / ISO 23640:2015 / EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

EC Declaration of Conformity

Manufacturer:
Name: Pro-med （Beijing） Technology Co., Ltd.
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Product Name	COVID-19 IgM/IgG Antibody Rapid Detection Kit(Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 IgM/IgG antibodies in human serum, plasma or whole blood samples.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016 / ISO 14971:2019 / EN ISO 18113-1:2011 / EN ISO 18113-2:2011 / EN ISO 18113-3:2011 / EN 13641:2002 / ISO 15223-1:2016 / EN 13612:2002 / ISO 23640:2015 / EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

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Product Name	COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 neutralizing antibodies in human serum, plasma or whole blood samples.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016 / ISO 14971:2019 / EN ISO 18113-1:2011 / EN ISO 18113-2:2011 / EN ISO 18113-3:2011 / EN 13641:2002 / ISO 15223-1:2016 / EN 13612:2002 / ISO 23640:2015 / EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

EC Declaration of Conformity

Manufacturer:
Name: Pro-med （Beijing） Technology Co., Ltd.
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Tel:+86-10-57277459 **Website:**www.pmdt.com.cn

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E-mail: peter@lotusnl.com

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Product Name	Influenza A+B and COVID-19 Antigen Combo Rapid Detection Kit(Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the Influenza A+B and COVID-19 antigen in human nasopharyngeal or pharyngeal swab specimens.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016 / ISO 14971:2019 / EN ISO 18113-1:2011 / EN ISO 18113-2:2011 / EN ISO 18113-3:2011 / EN 13641:2002 / ISO 15223-1:2016 / EN 13612:2002 / ISO 23640:2015 / EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

EC Declaration of Conformity

Manufacturer:
Name: Pro-med （Beijing） Technology Co., Ltd.
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Product Name	COVID-19 and COVID-19 Mutant Strain (B.1.1.7 Strain) Antigen Rapid Detection Kit (Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 and COVID-19 Mutant Strain (B.1.1.7 Strain) antigen in human nasopharyngeal or pharyngeal swab specimens.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016 / ISO 14971:2019 / EN ISO 18113-1:2011 / EN ISO 18113-2:2011 / EN ISO 18113-3:2011 / EN 13641:2002 / ISO 15223-1:2016 / EN 13612:2002 / ISO 23640:2015 / EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

Global Certificates

Germany BfArM

Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluierung PEI	Hersteller: Name	Hersteller: Stadt	Hersteller: Land	Europäischer Bevollmächtigter: Name	Europäischer Bevollmächtigter: Stadt	Europäischer Bevollmächtigter: Land	Deutsche(r) Vertreiber	Testort*	Sensitivität: %	Sensitivität: 95%iges Vertrauens-intervall	Spezifität: %	Spezifität: 95%iges Vertrauens-intervall
AT863/21	COVID-19 Antigen-Schnellnachweis-Kit (Kolloidales Gold)	Nein	Pro-med (Beijing) Technology Co., Ltd.	Beijing	CN	Lotus NL B. V.	Hague	NL	Details	POC (ohne Gerät)	93,98	88,58 - 96,92	99,44	96,90 - 99,90
AT864/21	COVID-19 Antigen-Schnellnachweis-Kit (Kolloidales Gold)	Nein	Pro-med (Beijing) Technology Co., Ltd.	Beijing	CN	Lotus NL B. V.	Hague	NL	Details	POC (ohne Gerät)	94,74	89,53 - 97,43	99,44	96,90 - 99,90

全球认证
Global Certificates

意大利专业版 Italian Salute

Elenco dispositivi individuati

Dati aggiornati al:16/05/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2105362	S	10 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105364	S	20 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105365	S	25 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105366	S	30 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105367	S	40 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105357	S	5 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105368	S	50 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105355	S	ONE TEST/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105349	S	One test/package	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL

Global Certificates

Austrian BASG

			Wuxi, Jiangsu, CN 214174.	
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) - Nasal swab	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) - Saliva sample	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam

全球认证
Global Certificates

自由销售证明 | CFS

中国医药保健品进出口商会
China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010
Tel：0086 10 58036272/75/78/71/70 Fax：0086 10 58036274 Website：www.cccmhpie.org.cn
E-mail：110982739@qq.com 82579517@qq.com md@cccmhpie.org.cn

自 由 销 售 证 书

CERTIFICATE OF FREE SALE

2021YB1414

产品名称：COVID-19 新冠抗原快速检测试剂盒（胶体金法）
Product(s)：COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)
规格型号：1 人份/袋、1 人份/盒、5 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒
Model ： 1 test/package;1 test/kit;5 tests/kit;10 tests/kit;20 tests/kit;25 tests/kit;30 tests/kit;40 tests/kit;50 tests/kit.

产品名称：COVID-19 新冠抗体 IgM/IgG 快速检测试剂盒（胶体金法）
Product(s)：COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold)
规格型号：1 人份/袋、1 人份/盒、5 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒
Model ： 1 test/package;1 test/kit;5 tests/kit;10 tests/kit;20 tests/kit;25 tests/kit;30 tests/kit;40 tests/kit;50 tests/kit.

产品名称：COVID-19 新冠中和抗体快速检测试剂盒（胶体金法）
Product(s)：COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)
规格型号：1 人份/袋、1 人份/盒、5 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒
Model ： 1 test/package;1 test/kit;5 tests/kit;10 tests/kit;20 tests/kit;25 tests/kit;30 tests/kit;40 tests/kit;50 tests/kit.

销往国家： 泰国
Export to: Thailand

买家：
Buyer: AD NANO CO., LTD.
地址：
Address: 36/1-6, Soi Ramkhamhaeng 24 Yaek 4 (Thawon Tawat 2), Hua Mak, Bang Kapi, Bangkok, 10240, Thailand.

制造商：普迈德（北京）科技有限公司
Manufacturer：Pro-med (Beijing) Technology Co., Ltd.
地址： 北京市昌平区马池口镇昌流路 738 号 8 号楼三层 C 区，邮编 102202
Address: C-3F, 8#,738 Changliu Road, Machikou Town, Chang ping, 102202, Beijng, China.

兹证明上述产品符合相关标准，未在中国注册，出口不受限制。
THIS IS TO CERTIFY THAT THE ABOVE PRODUCTS COMPLY WITH THE RELEVANT STANDARD HAVE NOT BEEN REGISTERED IN CHINA THE EXPORTATION OF THE PRODUCTS ARE NOT RESTRICTED.

此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 7 月 8 日
DATE OF ISSUE: July 8, 2021

全球认证
Global Certificates

PEI

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

Paul-Ehrlich-Institut

Pro-med COVID-19 Antigen Rapid Detection Kit	Pro-med (Beijing) Technology Co.,Ltd.

Search link:
https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=49

全球认证
Global Certificates

法国 | French Pro.

Dear Sir/Madam

We acknowledge receipt of the EC certification and the documents provided for your antigen test for professional use for nasal swabs.
The information provided is in accordance with national requirements. We will forward this information to the Ministry.

Kindly note that rapid antigen diagnostic tests on nasal swabs are subject to very restricted conditions of use, which must be organized by a regional health agency or an educational institution, and have not yet been deployed as part of the national strategy. As a result, and in order to avoid misuses or unregulated and unauthorized uses, the list of these products is not published on the ministerial platform.

Persons interested in the methods of marketing and use of these tests are invited to refer to the provisions of the amended Order of June 1, 2021 prescribing the general measures necessary for the management of the end of the health crisis.

Best regards,

Madame, Monsieur,

Awards & Honors

Pro-med technology 普迈德

International Quality Management System &Authoritative Certification

Pro-med has established an international quality management system, strictly complying with international standards and regulations, including ISO 13485:2016, ISO 9001:2015, WHO, etc.

证书编号：04720Q10000330

医疗器械

质量管理体系认证证书

兹证明

（副本）

普迈德（北京）科技有限公司

（统一社会信用代码：91110114078587382R）

住　所：北京市昌平区马池口镇昌流路 738 号 8#楼三层 C 区

生产地址：北京市昌平区马池口镇昌流路 738 号 8#楼一层 C 区、三层 C 区和 C1 区

质量管理体系符合：

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖：

胶体金免疫层析分析仪、荧光免疫层析分析仪和血栓弹力图仪的设计开发、生产和服务。

颁证日期：2020 年 08 月 15 日

有效期至：2023 年 08 月 14 日

总经理：

北京国医械华光认证有限公司

REGISTRATION NO. 04720Q10000330

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Beijing Pro-med Technology Co., Ltd.

Registered Address: C-3F, 8#, 738 Changliu Rd., Machikou Town, Changping District, Beijing

Manufacturing Address: C1, C-3F,C-1F, 8#, 738 Changliu Rd., Machikou Town, Changping District, Beijing

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of Quantitative Immunoassay Analyzer, Fluorescence Immunochromatorgphi Analyzer and Thrombelastograph Instrument.

Date of issue: August 15,2020

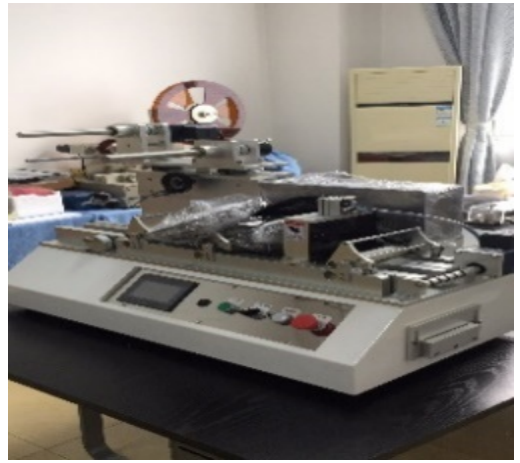
Date of expiry: August 14,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Production Capacity

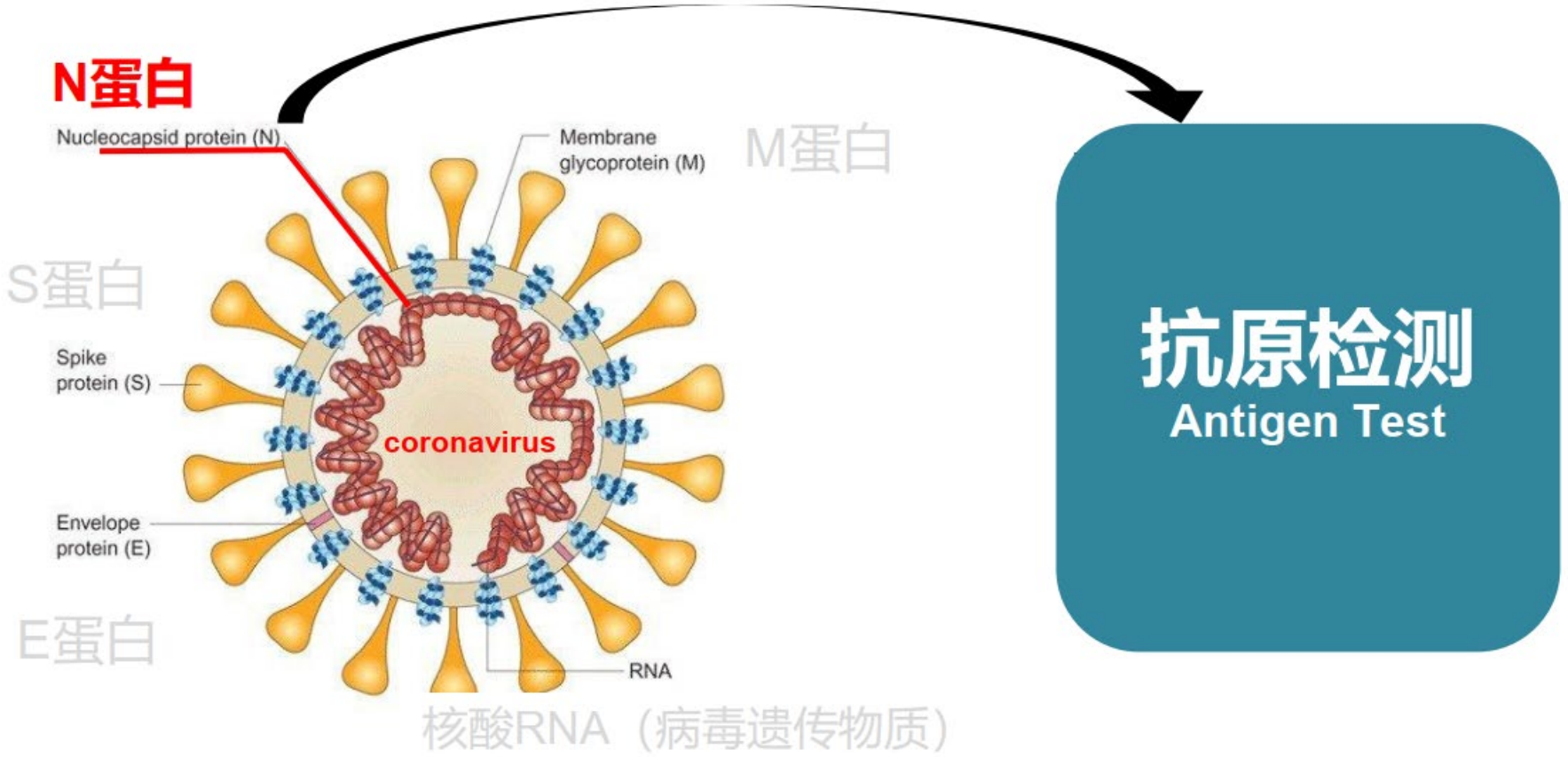
Mature production system and automated production line, Production capacity 3 million tests/day



COVID-19 Product Solution——

Antigen Test

Coronavirus Detection Method-Antigen Test



Pro-med COVID-19 Antigen Rapid Test Intended Use

Professional Scenarios

CDC

Screening Scenarios

School

Professional Scenarios

Hospital

Screening Scenarios

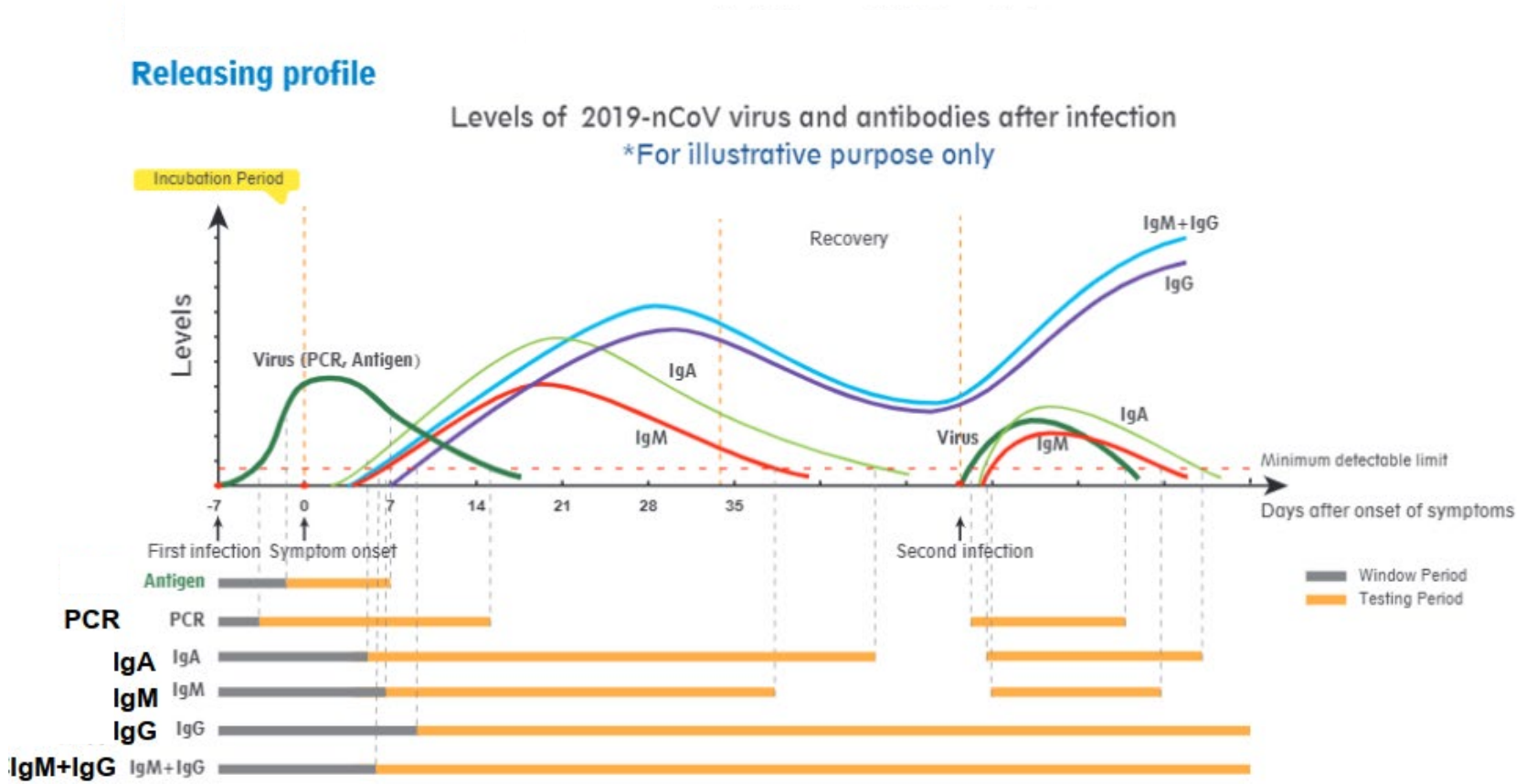
Border

Screening Scenarios

Factory

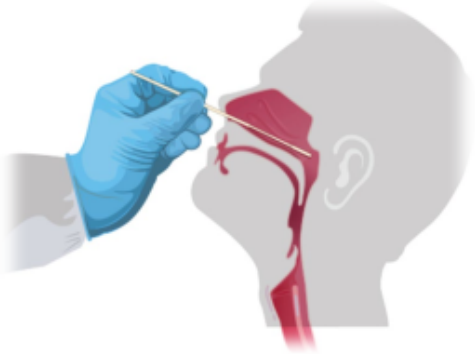
Similar to RT-PCR, the detection of antigen indicates the active infection. Under the circumstance that the area is still undergoing widespread community transmission and/or the area with limited RT-PCR resources, antigen can be used for aiding in the diagnosis of COVID-19 suspect patients.

Detection window of antigen test

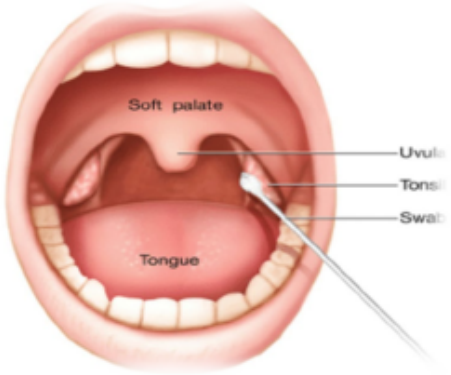


- The best detection window for antigen test is 3 days prior to symptoms onset and 7 days after symptoms onset.
- Along with the disease progress, the viral load will decrease and the detection rate for antigen will go down.

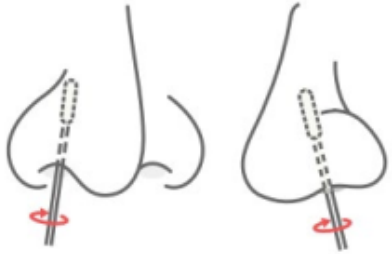
Applicabe sample types



Nasopharyngeal Swab



Oropharyngeal Swab



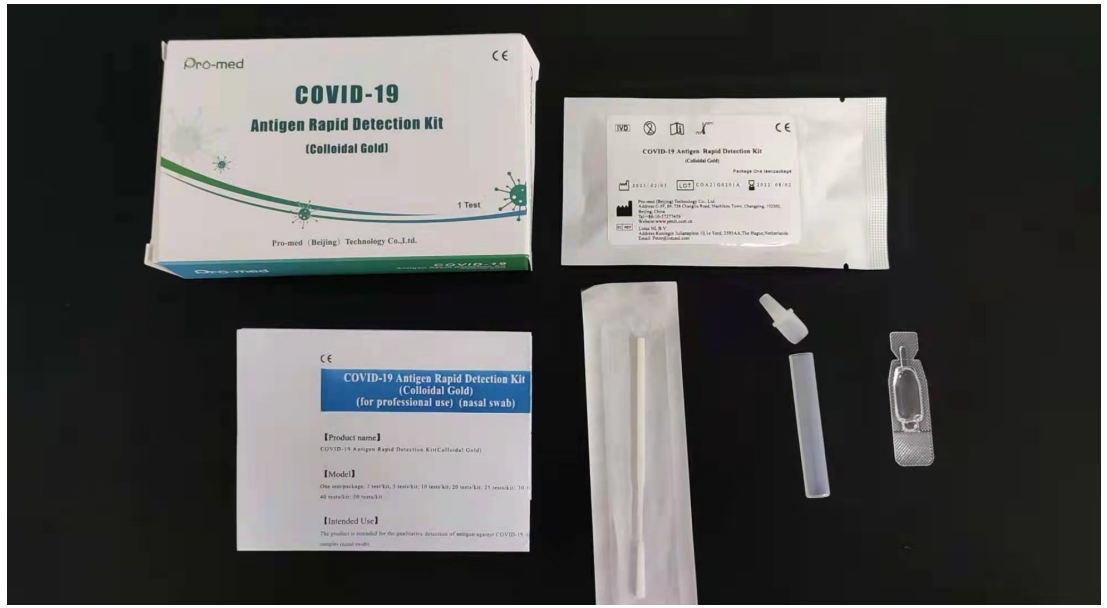
Nasal Swab

Saliva

COVID-19 Antigen Rapid Test

(Nasal swab)

Pro-med Covid-19 Antigen Rapid Test



- Nasal Antigen Test (1Test/Box) cassette

Box Size:

Length: 12.5cm

Width: 8cm

Height: 2.5cm

400 tests in box

Outside box:
60cm*45.5cm*46cm

Components:

1. Individual sealed pouches, each pouch contains:
   - 1×Test cassette
   - 1×Desiccant pouch
2. Single-use extraction buffer
3. Nasal swab
4. Dripper
5. Sample extraction tube
6. Instruction for use

Pro-med Covid-19 Antigen Rapid Test

- Nasal Antigen Test (20 Tests/Box)

Box Size:

Length: 17cm

Width: 12.5cm

Height: 7cm

1000 tests in box

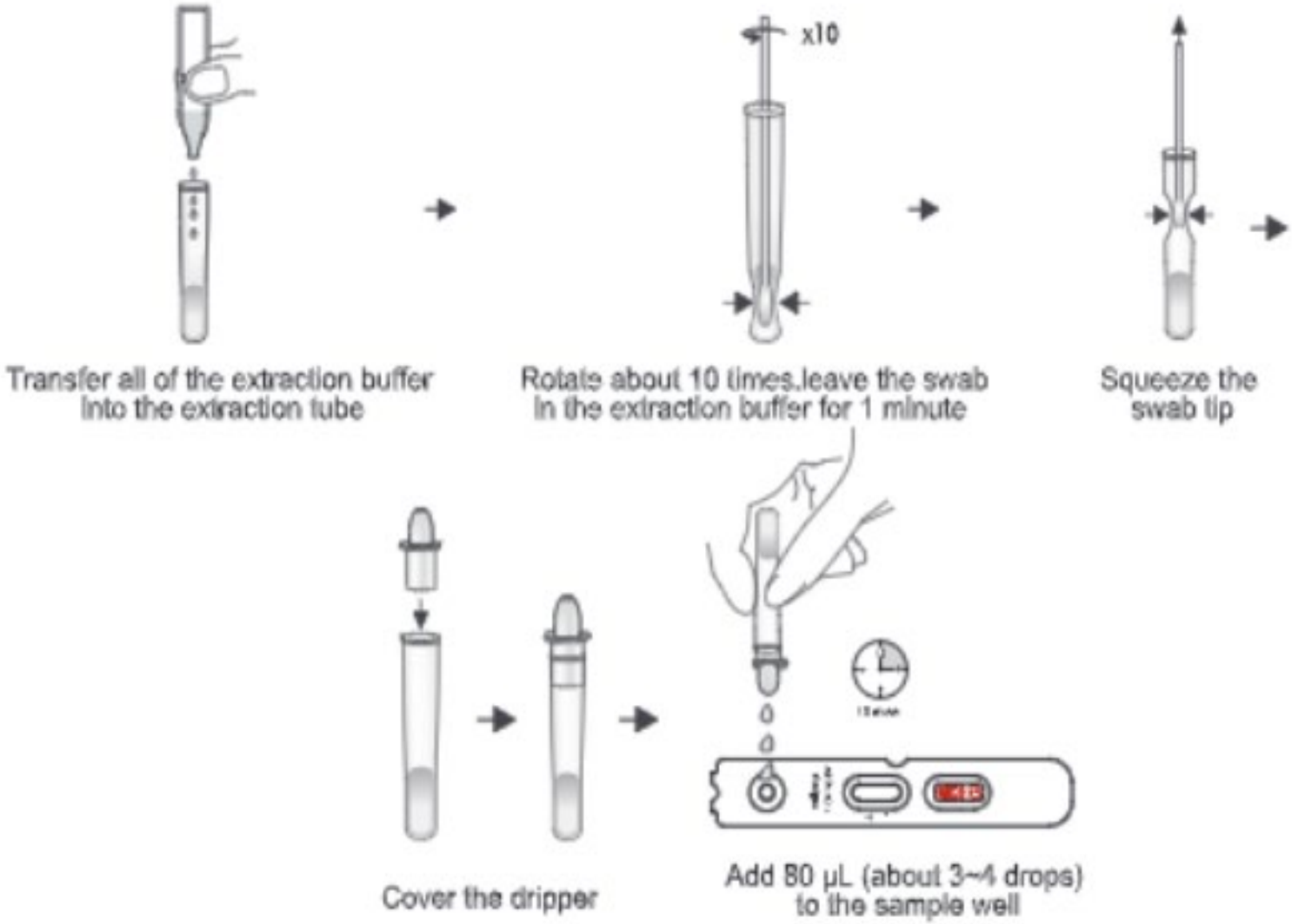
Outside box:
38.5cm*38.5cm*67cm

Components:

1. 20 Individual sealed pouches, each pouch contains:
   - 1×Test cassette
   - 1×Desiccant pouch
2. Extraction buffer(2*6ml)
3. 20 nasal swabs
4. 20 sample extraction tubs
5. 20 Drippers
6. Instruction for use

* *Single-use extraction buffer can also be provided for 20 tests/box antigen test*

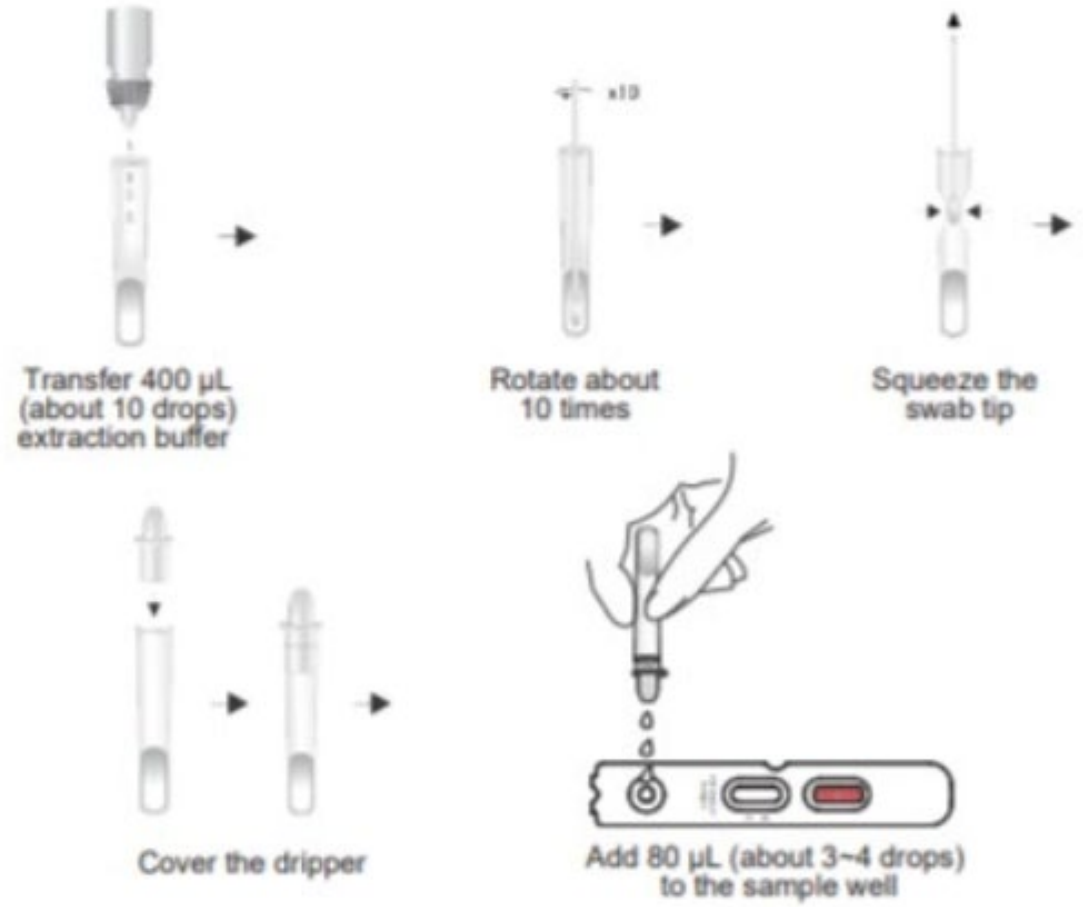
Operation Procedure (After Sample Collection)



操作步骤（采样后）
Operation Procedure (After Sample Collection)

Pro-med technology 普迈德

For with bottle buffer



普迈德新冠抗原试剂盒（胶体金法）
Pro-med Covid-19 Antigen Rapid Test

- Nasal Antigen Test (1Test/Box) card

Box Size：

Length：19cm

Width： 1.5cm

Height：14cm

250 tests in box
Outside box:
60cm*45.5cm*46cm

420 tests in box(small card)
Outside box:
50.5*55.5*49.5

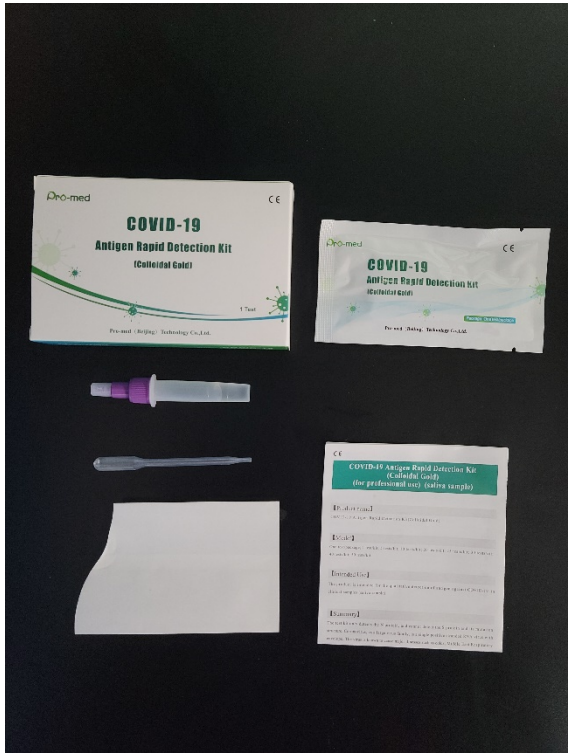
Components:

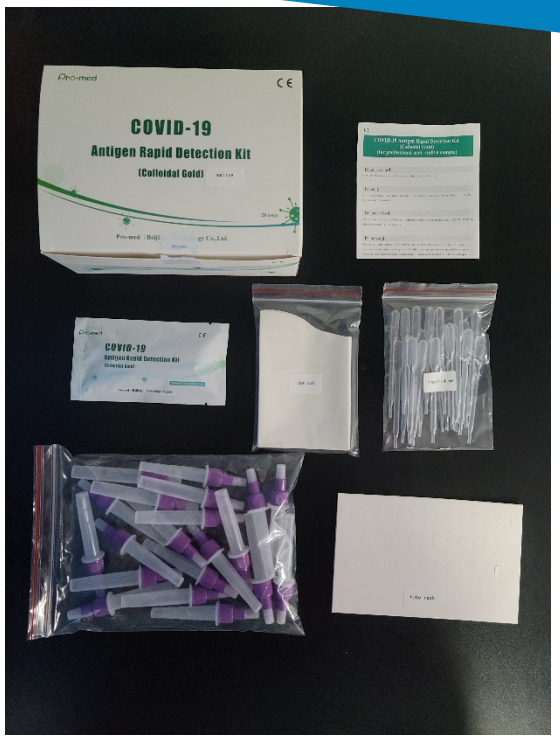
1. Individual sealed pouches, each pouch contains:
   - 1×Test Card
   - 1×Desiccant pouch
2. Single-use extraction buffer
3. Nasal swab
4. Instruction for use

* *Card can also be provided for 25 tests/box antigen test*

COVID-19 Antigen Rapid Test (Saliva)

普迈德新冠抗原试剂盒（胶体金法）
Pro-med Covid-19 Antigen Rapid Test





- Saliva Antigen Test (1/20 Test/Box) cassette

Box Size：

Length：12.5cm

Width： 2.5cm

Height： 8cm

400 tests in box

Outside box:
60cm*45.5cm*46cm

1000 tests in box

20 tests/kit Box Size:
17cm*12.5cm*7cm

Outside box:
38.5cm*38.5cm*67cm

Components:

1. Individual sealed pouches, each pouch contains:
   - 1×Test Card
   - 1×Desiccant pouch
2. Single-use extraction buffer
3. Saliva collection
4. Dripper
5. Sample extraction tube
6. Instruction for use

www.pmdt.com.cn

Clinical Data(Sample: NP/OP)

Reagent		PCR		Total
		Positive	Negativ	
Pro-med Covid-19 Antigen Rapid Test (Colloidal Gold)	Positive	125	1	126
	Negative	8	178	186
Total		133	179	312

Sensitivity：93.98%
(95%CI:88.58%~96.92%)
Specificity：99.44%
(95%CI:96.90%~99.90%)
Total agreement：97.12%
(95%CI:94.61%~98.48%)

普迈德新冠抗原产品优势
Pro-med Covid-19 Antigen Rapid Test Kit Advantages

- Simple operation, no lab equipment requied
- Rapid test, instant results within 15mins
- Affordable price, reliable results
- high sensitivity and good specificity

Thanks for you watching

More details please further contact