COVID-19(SARS-CoV-2)Antigen Test Kit(Colloidal Gold):(With Saliva Assay)

Compilation of foreign trade product introduction materials

Anhui Deepblue Medical Technology Co.,Ltd.
Website:www.dbluemedical.com
Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei, Anhui, China

Anhui Deepblue Medical Technology Co.,Ltd.
Website:http://www.dbluemedical.com/
Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei,Anhui,China

COVID-19(SARS-CoV-2)Antigen Test Kit(Colloidal Gold): (With Saliva Assay)

Material catalog

1. Introduction
2. Enterprise-led products
3. Number of employees, scientific research strength and facilities, production capacity
4. Various relevant licenses and export approvals of the enterprise
5. Photograph of the new coronavirus detection kit; packaging (internal and external packaging photos)
6. Photos of the company's factory location, workshop, main laboratory photos, photos of high-precision equipment);
7. Detailed description of the new coronavirus detection kit (English product manual)

Customs declaration code of Deepblue COVID-19(SARS-CoV-2)Antigen Test Kit(Colloidal Gold):(With Saliva Assay)

1. Introduction

Anhui DeepBlue Medical Technology Co., Ltd. (hereinafter referred to as "DeepBlue Medical") is a new type of biotech enterprise specializing in the rapid diagnosis of infectious diseases, diagnostic reagents for pregnancy and family planning and the development, production and sales of biological raw materials. The main scope includes a Class II, Class III and Class III medical devices and in vitro diagnostic reagents production and sales; self-operated and agent import and export business of various commodities and technologies (except those prohibited or limited by national laws and regulations); production and sales of disinfection products; research and development of biomedical products ; Biomedical technology consulting, technology transfer, technology promotion services; pharmaceutical consulting services; pharmaceutical investment.

DeepBlue Medical has an advanced rapid diagnostic reagent production line, applies the latest clinical testing technology, has the advantages of simple operation, accurate and reliable, timely and convenient, and its technical performance has reached the international advanced level. The enterprise has passed the quality management system audit of the Food and Drug Administration and the European Union, and the quality management system established in accordance with YY / T0287-2017 idt ISO13485: 2016 standard has obtained EN ISO 13485: 2016 quality system certification and CE product certification; enterprise products have There are three categories of tumors, infectious diseases, and pregnancy and family planning. The core technology has multiple patents, including the patent numbers of authorized certificates: ZL201010115778.9, ZL201120082202.7, ZL201120537680.2, ZL201120537660.5, ZL 201410109117.3, ZL 201610207306.3 . At the same time, four clinical indicators of CRP \ PCT \ SAA \ IL-6 infection were used to monitor clinically infected patients and guide clinical use of antibiotics. Carry out industry-university-research cooperation with Hefei University of Technology, Wenzhou University, Anhui Medical University, etc., and develop a series of clinical drug monitoring kits with Anhui Medical University. Reagent testing supporting intelligent system has been applied to

enterprise products.

2. Enterprise-led products

After ten years of technological innovation and experience accumulation, Deep Blue Medical has deeply cultivated the field of POCT rapid diagnosis, product marketing from domestic to foreign countries, and accumulated a large number of customer resources. The company has 15 medical device product registration certificates, 28 record certificates, and 58 products exclusively for export; 7 overseas product international registration certificates: CoVID-19 antibody detection reagent and dengue virus antibody detection reagent German registration Certificate; Kyrgyzstan and Tajikistan registration certificate of epithelial tissue staining solution (under review in Russia and Uzbekistan); early pregnancy test paper registration certificate in the Philippines, Indonesia, Singapore, etc .; enterprise quality management system obtained EU CE certification; early pregnancy, ovulation, hemoglobin, Five CE (announcement) registration certificates for transferrin and fecal occult blood.

The leading products are infectious disease series: mainly including new crown virus, dengue fever, AIDS, hepatitis B, hepatitis C, malaria, syphilis, etc .; tumor early detection and early diagnosis series: mainly including special staining diagnostic solution series, fecal occult blood series, etc .; pregnancy and family planning series: Mainly include premature rupture of membranes, early pregnancy, ovulation, BV detection series, etc .; anti-killing gel and biological dressing series: mainly include cavity coupling agent, no-clean hand disinfection gel, wound dressing, etc. The core products all have intellectual property rights such as independently developed invention patents and computer software copyrights.

3. Number of employees, scientific research strength and facilities, production capacity

The company has a total of 100 employees, including 35 scientific and technical personnel, accounting for 35% of the total number of employees, and 24 personnel engaged in research and development, accounting for 24% of the total number of employees. The company has high-skilled and continuous innovation in scientific research

and development capabilities. The main engineering and technical personnel have university degrees and above, and the research and development personnel are from medicine, testing and other related majors. They have won many scientific and technological achievement awards. Developed more than ten types of products, and obtained a number of independent intellectual property rights. The company's reagent production capacity is 150,000 copies per day.

4. Various relevant licenses and export approvals of the enterprise:

医疗器械生产许可证

许可证编号：皖食药监械生产许20150023号

企业名称：安徽深蓝医疗科技股份有限公司　　生产地址：合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层

法定代表人：张超　　生产范围：Ⅱ类:6840 体外诊断试剂

企业负责人：陈奉玲　　Ⅱ类:06-08 超声影像诊断附属设备

住　　所：合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层　　发证部门：安徽省药品监督管理局

有效期限：至 2024 年 10 月 21 日　　发证日期：2019 年 10 月 22 日

国家药品监督管理局制

DeepBlue Medical Device Production License

营业执照

(副本)

统一社会信用代码 91340100550190371 4(1—1)

名称	安徽深蓝医疗科技股份有限公司
类型	股份有限公司(非上市)
住所	安徽省合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层
法定代表人	张超
注册资本	壹仟万圆整
成立日期	2010年02月04日
营业期限	2010年02月04日至2030年02月03日
经营范围	一类、二类、三类医疗器械和体外诊断试剂生产和销售；自营和代理各类商品和技术的进出口业务（国家法律法规禁止或限定的除外）；消毒产品生产销售；生物医药产品研发；生物医药技术咨询、技术转让、技术推广服务；医药咨询服务；医药投资。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

登记机关 合肥市工商行政管理局 3401030138021

2017年 05月 08日

每年1月1日至6月30日填报年度报告

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

Deepblue business license

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS CRT2 / A4 07.17 ZM

TÜV SÜD Product Service

CERTIFICATE

No. Q5 18 03 03706 001

Holder of Certificate: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
4th Floor, D-1# Zone
Pearl Industrial Park
106 Innovation Avenue, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

Certification Mark: TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents by Colloidal Gold and Enzyme Chemical Reaction Method, Medical Ultrasonic Couplant, Acetowhite Solution, Epithelial Tissue Staining Solution, Rapid Test for Vaginitis (Polyamines) and Cell Preservation Solution**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH18130301
Valid from: 2018-06-22
Valid until: 2021-06-21

Date, 2018-06-22

Stefan Preiß

TÜV SÜD 0405276858184

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Page 1 of 1

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany TÜV®

CE EN ISO 13485 2016 Quality System Certificate

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

安徽深蓝医疗科技股份有限公司 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
安徽深蓝医疗科技股份有限公司	Anhui Deepblue Medical Technology Co., Ltd.	新型冠状病毒检测试剂	COVID-19(SARS-CoV-2) Antibody Test Kit(Colloidal Gold) COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) Influenza A+B & COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) COVID-19 (SARS-CoV-2) Antibody & Antigen Combo Test Kit (Colloidal Gold)	91340100550190371 4	欧盟CE

友情链接

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157154

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **02.09.2020**		Registriernummer / Registration number **DE/CA20/01-IVD-Luxuslebenswelt-207/20**
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

German product registration form 1

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157154

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047791**		
	Bezeichnung / Name **Luxus Lebenswelt GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Hersteller / Manufacturer			
	Bezeichnung / Name **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.**		
	Staat / State **CN**		
	Ort / City **Hefei**		Postleitzahl / Postal code **230088**
	Straße, Haus-Nr. / Street, house no. **4th Floor, D-1# Zone, Pearl Industrial Park,106 Innovation Avenue, High-Tech Development Zone**		
	Telefon / Phone **0086-551-65326797**		Telefax / Fax **0086-551-65326758**
	E-Mail / E-mail **284423655@qq.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Lin Sun**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

German product registration form 2

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157154

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification £ Produkt der Liste A, Anhang II / Device of List A, Annex II £ Produkt der Liste B, Anhang II / Device of List B, Annex II £ Produkt zur Eigenanwendung / Device for self-testing S Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG £ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)**
	Produktbezeichnung / Name of device **COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)**
	Angabe der benutzten Nomenklatur / Nomenclature used S EDMS-Klassifikation / EDMS Classification £ GMDN
	Nomenklaturcode / Nomenclature code **15-70-90-90-00**
	Nomenklaturbezeichnung / Nomenclature term **OTHER OTHER VIROLOGY RAPID TESTS**
	Kurzbeschreibung / Short description In Deutsch / In German **Dieses Produkt wird zum qualitativen In-vitro-Nachweis des Antigens des neuartigen Coronavirus in menschlichen Rachen- oder Nasentupfern verwendet.**
	In Englisch / In English **This product is used for in vitro qualitative detection of the antigen of novel coronavirus in human throat swabs or nasal swabs.**

German product registration form 3

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157154

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	£ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Willich**

Datum
Date **2020-07-31**

Name **Lin Sun**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

German product registration form 4

CE CE

DECLARATION OF CONFORMITY

MANUFACTURER:	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD. 4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone , 230088 Hefei, Anhui, People's Republic of China
EUROPEAN REPRESENTATIVE:	Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany
PRODUCT:	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)
Models:	Strip;cassette
CLASSIFICATION:	**OTHER**
EDMA CODE:	15 70 90 90 00

CONFORMITY ASSESSMENT ROUTE: Following the procedure relating to the EC Declaration of Conformity set out in Annex III of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:	EN ISO 13485:2016 EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO 14971:2012.
START OF CE-MARKING:	2020-07-31
PLACE, DATE OF ISSUE:	HEFEI, 2020-07-31

CE

SIGNATURE: **CHEN FENGLING** chenfengling
GENERAL MANAGER

EC Declaration of Conformity
DOC-COVID-19 Ag- (A/0) Page 1/1

CE IVD Certificate（Influenza A+B& COVID-19(SARS-CoV-2) Antigen Test Kit (Colloidal Gold)）

QG07

中华人民共和国海关
报关单位注册登记证书

重要提示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

海关注册编码：3401360741
组织机构代码：55019037-1
企业名称：安徽深蓝医疗科技股份有限公司
企业住所：安徽省合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层
企业经营类别：进出口货物收发货人
注册登记日期：2017年6月26日
法定代表人：张望
有效期：长期

注册海关：合肥海关
核发日期：2017年6月26日

中华人民共和国海关总署监制

Deep Blue Customs Registration Certificate

对外贸易经营者备案登记表

统一社会信用代码：913401005501903714

备案登记表编号：02360120　　进出口企业代码：----------

经营者中文名称	安徽深蓝医疗科技股份有限公司		
经营者英文名称	Anhui Deep Blue Medical Technology Co.,Ltd.		
组织机构代码	---------	经营者类型（由备案登记机关填写）	私营企业
住　所	安徽省合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层		
经营场所（中文）	安徽省合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层		
经营场所（英文）	1#,D Zone,Four Floor,Pearl Industrial Park,106 Innovation Avenue,Hefei Hi-tech Development Zone,Anhui		
联系电话	0551-65326768	联系传真	0551-65326758
邮政编码	230088	电子邮箱	284423655@qq.com
工商登记注册日期	2017-5-8	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	张超	有效证件号	342501196903020338
注册资金	壹仟万元	（折美元）	

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产		（折美元）	

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2017　年　06　月　05　日

DeepBlue Foreign Trade Operator Registration Form

出入境检验检疫报检企业备案表

编号： 170629093646000000069
备案类别： 自理企业　　**备案号码：** 3411601143

企业名称	中文	安徽深蓝医疗科技股份有限公司	
	英文	Anhui Deepblue Medical Technology Co.,Ltd	
住　　所	安徽省合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层		
经营场所	安徽省合肥市高新区创新大道106号明珠产业园一期1#厂房D区四层		
企业性质	私营企业	企业类别	
营业执照号	913401005501903714	统一社会信用代码（组织机构代码）	913401005501903714
开户银行	交通银行合肥长江西路支行	银行账号	341309000018010094302
法定代表人/负责人	张超	有效证件号	
联 系 人		联系电话	
传　　真		电子邮箱	

快件运营企业备案还须填写以下内容

快递业务经营许可证号		经营范围	

报检专用章印模：（使用报检专用章的需提供。另附页）
填表前请认真阅读背面的条款，并由企业法定代表人/负责人签字、盖章。

备案机构（签章）

2017 年 7 月 11 日

Entry-Exit Inspection and Quarantine Application Enterprise Record Form

5. Photograph of the new coronavirus detection kit; packaging (internal and external packaging photos);

COVID 19 TESTING – LFT STATUS

8 January 2021
Fengling Chen
Anhui Deepblue Medical Technology Co. Ltd

TC/HF/20

Dear Fengling

In light of the public holidays around Christmas and New Year and associated short pause in validation activities during this period, we thought it would be useful to provide a summary of the validation level which your LFDs have reached.

Name of Product	Sample Method	Validation Level passed
Anhui Deepblue COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Nasopharyngeal or Oropharyngeal	All phases up to and including Phase 3B

CONFIDENTIALITY

We remind you of your ongoing obligations of confidentiality as set out in the non-disclosure agreement recently signed by you dated 8 January 2021.

We thank you for your continued interest in supporting our COVID-19 response.

Yours sincerely,

th
England

SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/053/v1
Report date	30 October 2020
Undertaken by High Containment Microbiology, NIS Laboratories, National Infection Service, Public Health England N.B. This is an interim report and may be updated as further results are obtained	

Product/treatment details	
Product/treatment	COVID-19 (SARS-CoV-2) Antigen Test Kit Extraction Reagent
Manufacturer	Anhui Deepblue Medical Technology Co.
Product code	Not known
Manufacturer's recommended ratio of sample to product	Swab to be added directly to tube containing approximately 300µl extraction buffer

Sample details	
Sample type tested	Tissue culture fluid containing 5% (v/v) foetal calf serum
Virus strain tested	SARS-CoV-2 England 2
Ratio of spiked virus stock to sample matrix	Not applicable; tissue culture fluid used undiluted

Interim report: Experiments ongoing

Experimental conditions	
Ratio of sample to product tested	1 volume sample to 3 volumes product
Contact time/s	1 minute; 5 minutes; 10 minutes
Temperature of incubation	Room temperature
Brief description of tests performed	Triplicate samples were treated with test buffer for indicated contact time/s or mock-treated in triplicate with an equivalent volume of PBS. Samples were immediately titrated on Vero E6 cells to establish virus titre. This test is quantitative and reports the titre of virus in each treatment condition in TCID50 per ml. Reduction in virus titre following treatment is given as the difference between the mean log_{10} TCID50/ml for treated conditions and the PBS control.

Table of results

	Mean virus titre in log_{10} TCID50/ml [95% confidence interval]	Titre reduction in log_{10} TCID50/ml [95% confidence interval]
PBS-treated	6.1 [5.8-6.3]	-
Test buffer-treated (1 minute)	6.1 [5.8-6.4]	0.0 [-0.4-0.3]
Test buffer-treated (5 minutes)	6.2 [5.9-6.6]	0.0 [-0.6-0.3]
Test buffer-treated (10 minutes)	6.0 [5.7-6.3]	0.1 [-0.3-0.5]

Interim report: Experiments Ongoing

Interpretation
Treatment with Deepblue COVID-19 Antigen Test Kit Extraction Reagent had no effect on SARS-CoV-2 titre following a 1, 5 or 10 minute treatment time. This buffer should not be relied upon to inactivate infectious samples. This test has been performed using tissue culture fluid. The effectiveness of this treatment against SARS-CoV-2 may vary when used to inactivate clinical samples or other types of sample matrix. Any results of inactivation testing using other sample matrices will be released as they become available. **Inactivation reagents should not be assumed to be 100% effective against SARS-CoV-2.** **Suitability of products and treatments for inactivation of other pathogens has not been evaluated in this study.** **All COVID-19 laboratory testing workflows must be subjected to suitable and sufficient risk assessment, with consideration given to any inactivation step. Risk assessments should be reviewed regularly as new information on the inactivation of SARS-CoV-2 becomes available.** **The impact of chosen inactivation method on the sensitivity of subsequent SARS-CoV-2 detection should also be assessed locally.**

Interim report. Experiments ongoing

Disclaimer
PHE's evaluations of commercial products and treatments for inactivating SARS-CoV-2 have been carried out primarily for PHE's own internal use and the reports of such evaluations are shared solely for readers information; PHE does not in any way recommend any particular product for virus inactivation; and PHE shall not be responsible for the choice of product or treatment for virus inactivation, and it is the responsibility of the testing laboratory to ensure that any such product or treatment implemented has undergone the necessary verification and validation; and PHE shall not be liable, to the greatest extent possible under any applicable law, for any claim, loss or damage arising out of or connected with use of this and related reports and choice of virus inactivation products or treatments. PHE is an Executive Agency of the Department of Health and Social Care. Unauthorised use of the PHE name and/or logo is prohibited.

Summary of revisions
Version 1: New document

Queries regarding this report or HCM inactivation testing should be directed to HCMgroup@phe.gov.uk

Interim report: Experiments ongoing

NINIEJSZYM POŚWIADCZAM ZGODNOŚĆ TEGO TŁUMACZENIA Z TEKSTEM ŹRÓDŁOWYM
HEREBY CERTIFY THAT THIS IS A FAITHFUL TRANSLATION OF THE ORIGINAL TEXT
Nr rejestrowy/Repertory No: 007/01/2021 data/date: 08.01.2021
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Warsaw, December 30, 2020

Test verification report: COVID-19 (SARS-CoV-2) Antigen Test Kit (COLLOIDAL Gold) ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD. conducted by Laboratorium Analiz Lekarskich ALAB Sp. z o. o. in Warsaw

Verification of the immunochromatographic test: COVID-19 (SARS-CoV-2) Antigen Test Kit (COLLOIDAL Gold) detecting the SARS-CoV-2 virus antigen was conducted in the Microbiology room at Laboratorium Analiz Lekarskich ALAB sp. z o.o. ul. Stępińska 22/30 in Warsaw in the period: 12.12.2020 - 21.12.2020 The test was verified by a qualified personnel: laboratory diagnosticians and medical microbiology specialists based on clinical samples taken from patients. The test sensitivity and specificity was calculated. The reference method was the commercial molecular test: TaqPath™ detecting the genes of ORF1ab, S and N of the SARS-CoV-2 virus with the real-time PCR method (the test has the CE-IVD certificate).

The fast antigen test examination and the PCR test examination were made at the same time and independently one from the other, with the use of samples taken from the same patient in the same time span.

The Laboratory received 192 swabs taken for the purpose of the verification of the test: COVID-19 (SARS-CoV-2) Antigen Test Kit (COLLOIDAL Gold). The testing material was collected on 2 transport mediums:

- sterile swab medium, without the transport gel, provided by the test producer (LOT 20200608) destined for detecting the SARS-CoV-2 antigen,
- transport liquid medium dedicated for viruses (Cepheid) (REF: SWAB/F-100) destined to detect the genetic material of SARS-CoV-2 with the PCR method.

29 swabs were excluded from the evaluation, but 11 were eliminated because of lack, or inconclusive PCR result and 18 because the sample transport time was exceeded > 24 hours from the collection. 163 swab results were qualified for the test evaluation. In case of 56 swabs the SARS-CoV-2 antigen was detected, whereas in case of 104 the antigen marking result was negative. There were no invalid results The results appear in table 1.

Antigen SARS-CoV-2 detection was conducted in accordance with the test producer's instruction:

- the extraction tube was prepared and 8 drops of extraction solution was added to it,
- the swab was put into the tube and the tube was rotated for 10 seconds, whereas its walls were being squeezed,
- the swab was removed, as the extraction tube walls were squeezed,
- the dropper was put in the extraction tube,
- the pack containing the test was opened,
- 2 drops of the extraction solution was added to the test window,
- the result was read after 20 minutes.

The result qualification was be made as follows:

- positive result of SARS-CoV-2 antigen and PCR positive result – truly positive (TP)
- negative result of SARS-CoV-2 antigen and PCR negative result – truly negative (TN)
- positive result of SARS-CoV-2 antigen and PCR negative result – falsely positive (FP)
- negative result of SARS-CoV-2 antigen and PCR positive result – falsely negative (FN)

175	+	+	19	TP
176	-	-	18	TN
177	+	+	19	TP
178	-	-	19	TN
179	-	-	18	TN
180	-	-	18	TN
181	-	-	20	TN
182	+	+	19	TP
183	-	-	18	TN
184	-	-	20	TN
185	-	-	20	TN
186	-	-	20	TN
187	+	inconclusive	19	excluded
188	-	-	20	TN
189	-	inconclusive	20	excluded
190	-	-	18	TN
191	-	none	23	excluded
192	-	-	48	excluded

The following results were obtained:

Test result	PCR(+)	PCR(-)
Ag(+)	56 (TP)	3 (FP)*
Ag(-)	0 (FN)	104 (TN)

* in Table 1 position:18; 38; 58

The sensitivity and specificity of the COVID-19 (SARS-CoV-2) test was calculated - Antigen Test Kit (COLLOIDAL Gold) ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.:

Test sensitivity - 100%

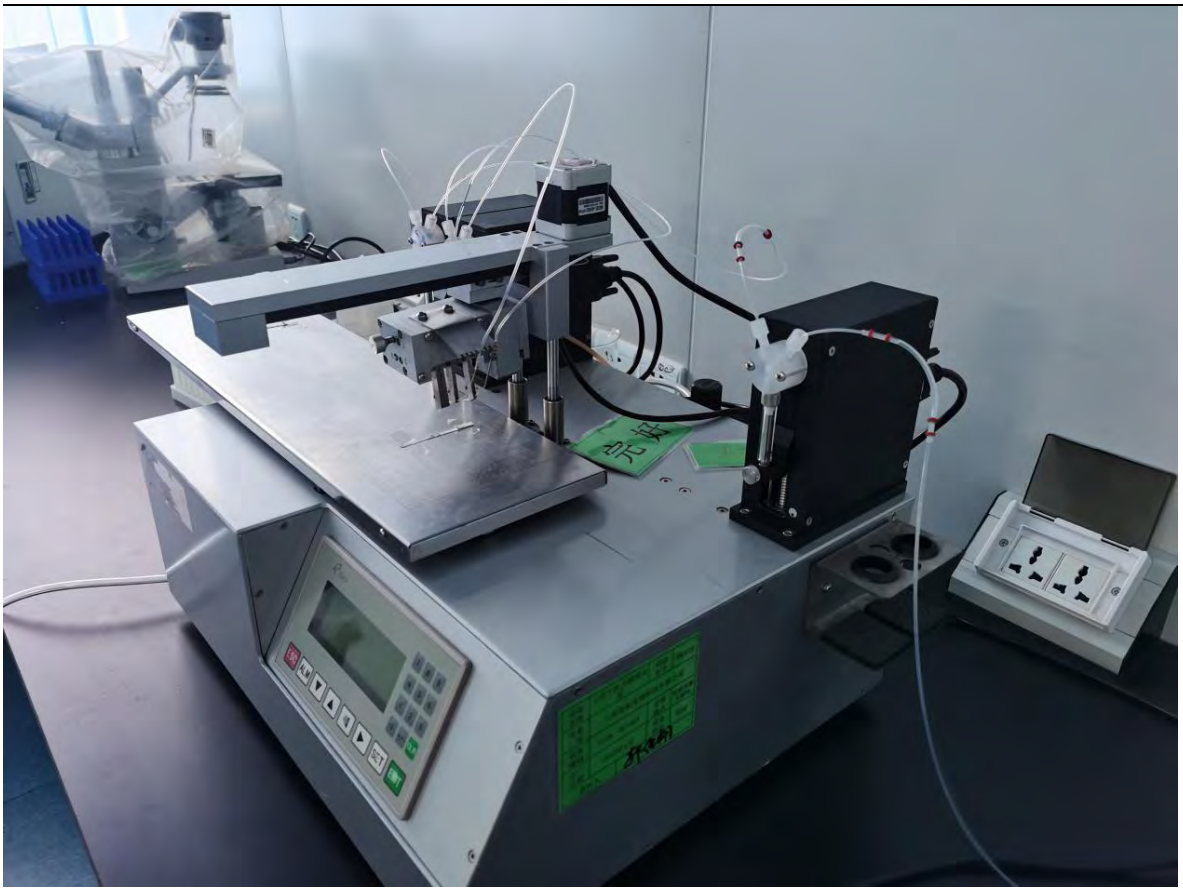
Test specificity - 97,2%

Report prepared by:

Microbiology Team at Laboratorium Analiz Lekarskich ALAB in Warsaw

6. Photos of the company's factory location, workshop, main laboratory photos, photos of high-precision equipment);

Main laboratory:




检验中心
微生物
JY-10
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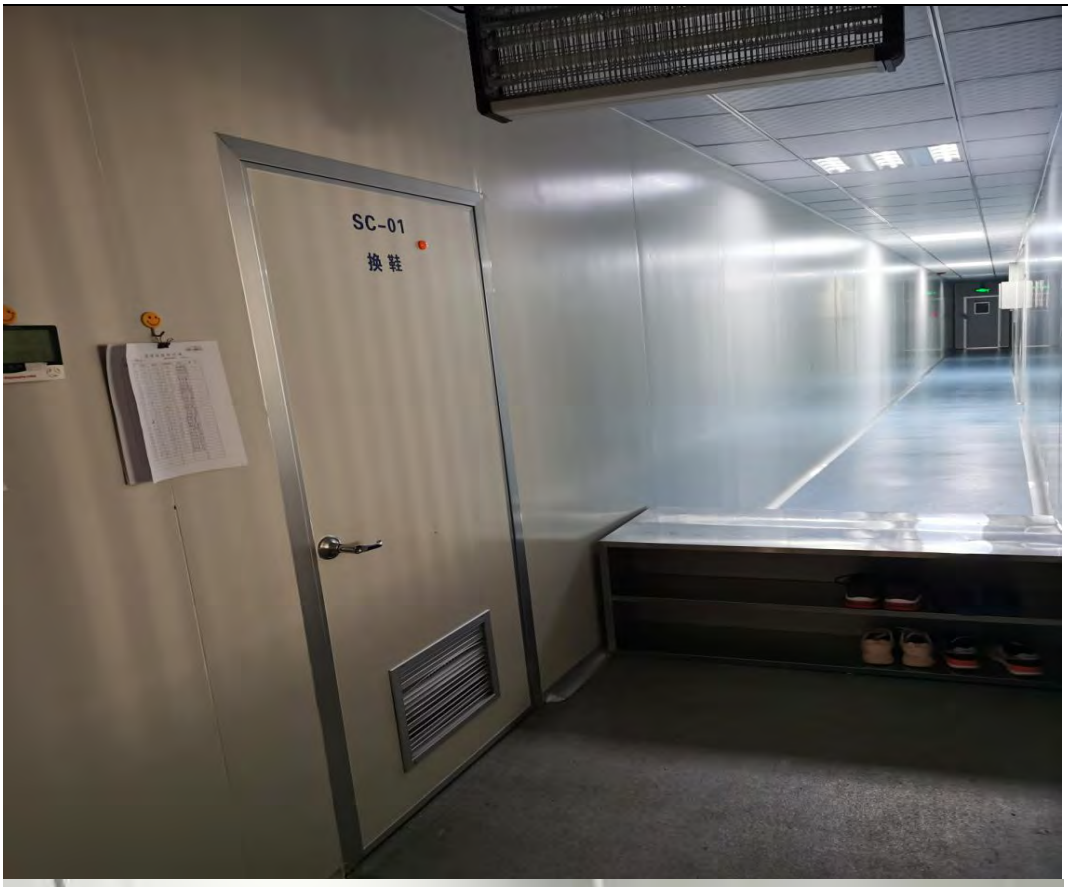
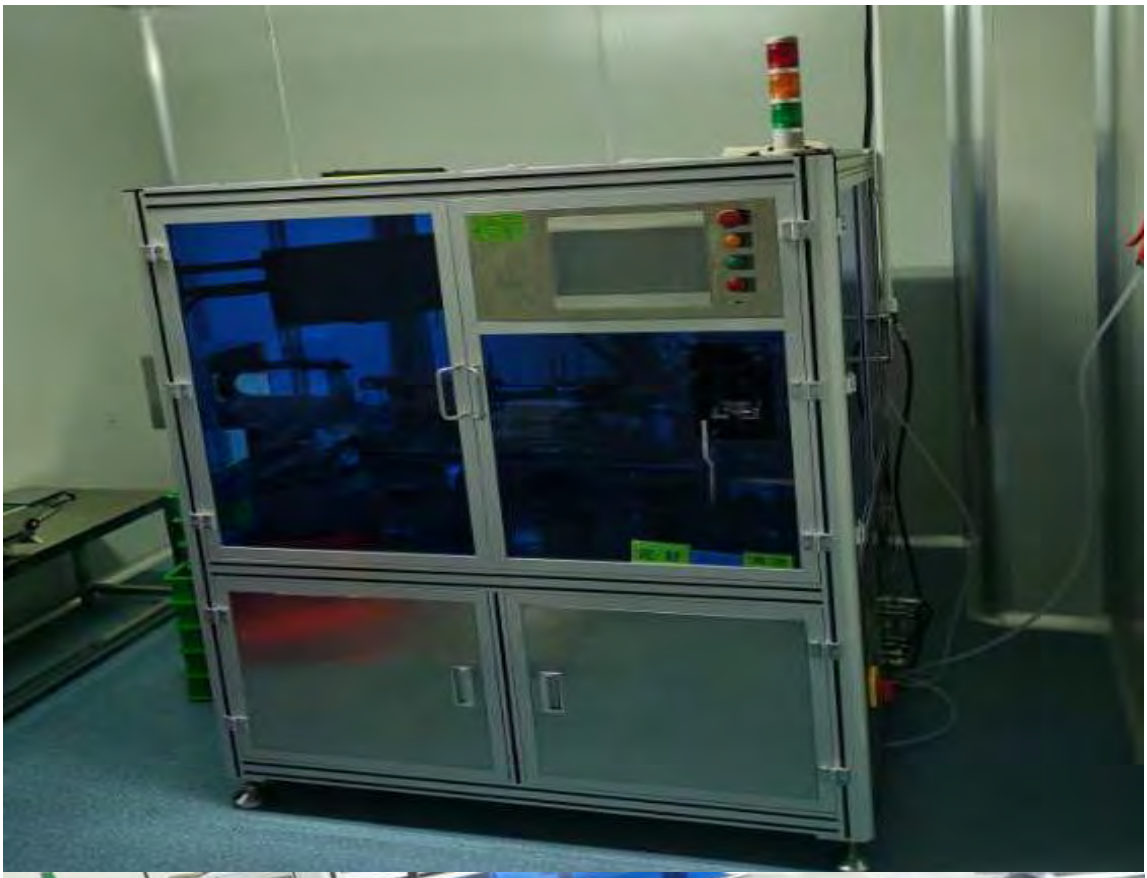
研发中心

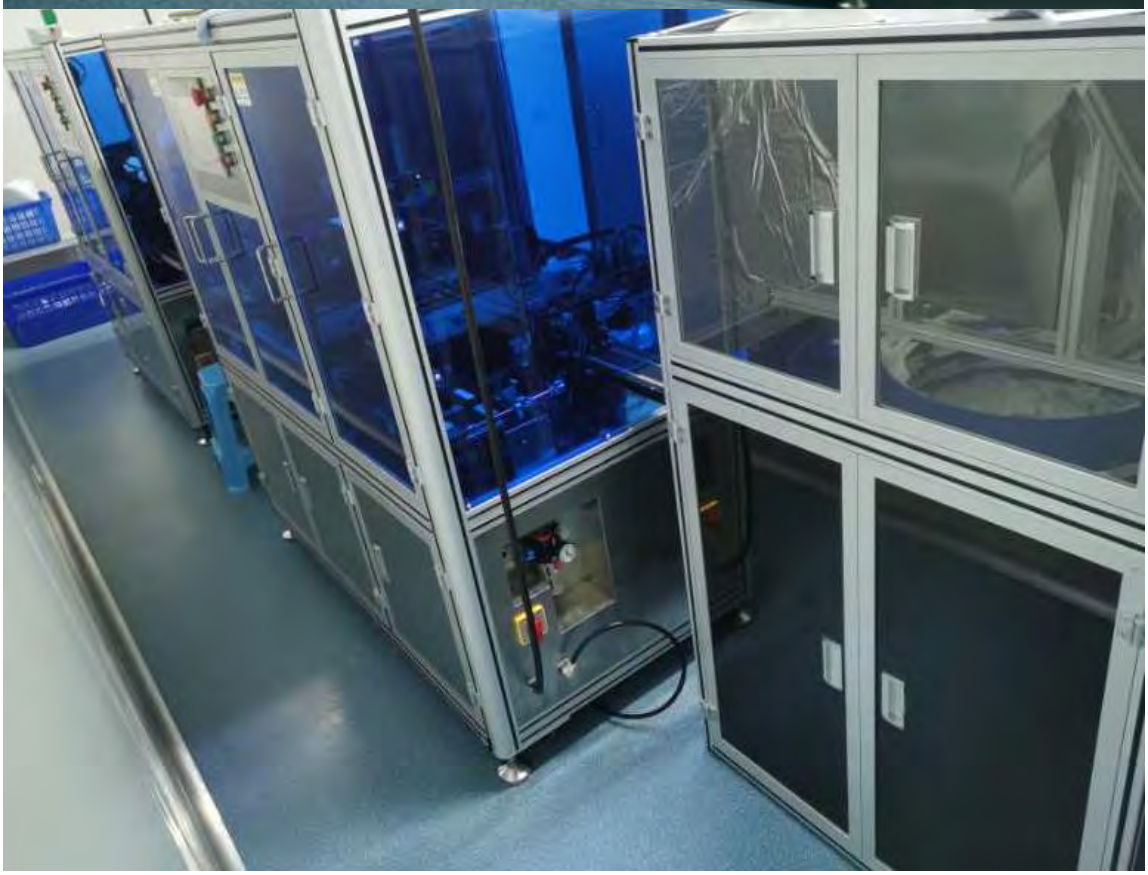
Anhui Deepblue Medical Technology Co.,Ltd.

Website:http://www.dbluemedical.com/

Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei,Anhui,China



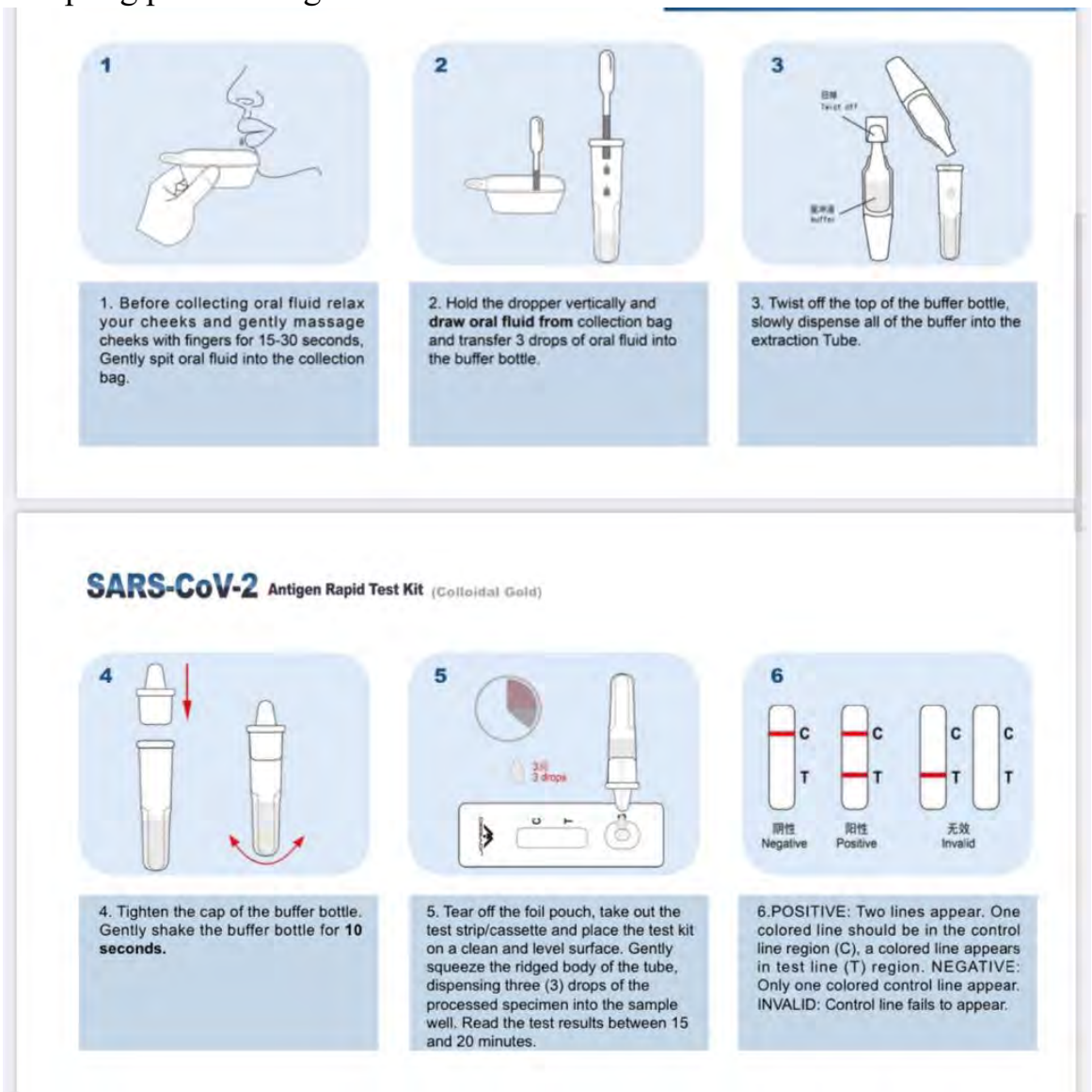




7. Detailed description of the new coronavirus detection kit (English product manual)

product warehouse

Sampling process diagram：



Detailed description of enterprise products (English product manual);

No.IFU-COVIDAg-S-01,Ver.A/0

CE

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

REF SL030101

Saliva

Spec:1pc/box,10pcs/box,25pcs/box.
For professional use only
[Intended use]
This product is used for in vitro qualitative detection of the antigen of SARS-CoV-2 in human saliva specimen.
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main Manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[Test principle]
This kit uses the double antibody-sandwich method to detect SARS-CoV-2 antigens. When an appropriate amount of specimen is added to the specimen well(s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to mouse anti-SARS-CoV-2 N protein monoclonal antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated mouse anti- SARS-CoV-2 N protein monoclonal antibody which was coated on the test line, a visible colored line will show up, which indicates that the SARS-CoV-2 antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and need to do the test again.

[Warnings and Precautions]
1. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
2. Do Not eat, drink, chew gum, smoke or vape for at least 30 minutes before collecting saliva.
3. Guard against moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use it if the aluminum foil bag is damaged or the test device is damp.
4. Please use it within the validity period.
5. Balance all reagents and specimens to room temperature (15 ~ 30 °C) before use.
6. Do not replace the components in this kit with components in other kits.
7. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
8. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
9. The test methods and results must be interpreted in strict accordance with this specification.
10. Negative results may occur if the SARS-CoV-2 antigen titer in the specimen falls below the minimum detection limit of this kit.
11.If the extraction reagent is individual packing and one piece per test device, the batch number, expiration date and other information cannot be marked separately due to the space is limited, but those information will be consistent with the corresponding test kit.

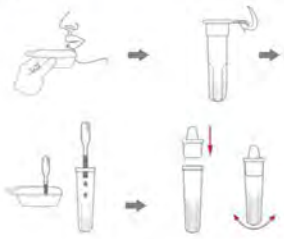
[Materials and Components]
Materials provided
1) Saliva Collection Container
2) Antigen Extraction Tube (Contains Extraction Reagent)
3) Dropper
4) Test Device
5) Instruction
6) Tube Rack (Except for individual package)

Materials required but not provided
Timer.

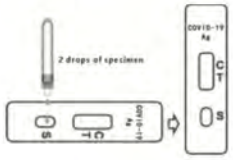
[Storage conditions & period of validity]
1. Store at 4°C~30°C, and it is valid for 24 months.
2. After the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour.

[Sample Transport and Storage]
After specimens were collected, specimens can be stored in extraction reagent provided with the kit.
Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8°C for no more than 24 hours; Store at -70 °C for a long time, but avoid repeated freeze-thaw cycles.

[Specimen Collection and Preparation]
1.Before collecting oral fluid relax your cheeks and gently massage cheeks with fingers for15-30s.
2.Gently spit oral fluid into collection container, try to collect oral fluid without bubbles.
3.Tear off the sealing film on the antigen extraction tube.
4.Use a dropper to draw the oral fluid and transfer 2-3 drops of oral fluid to the antigen extraction tube.
5.Insert a dropper tip into the extraction tube tightly.
6.Gently shake the extraction bottle for 10 seconds, to make sure the sample is well mixed.



[Test Procedure]
Read the instructions carefully before use and allow test device, extraction reagent and specimens to equilibrate to room temperature prior to testing.
1. Open the package and take out the test device.
2. Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer.
3. Interpret the results within 20 minutes. Strong positive results can be reported within 20 minutes, however, negative results must be read after 20 minutes, and the results after 30 minutes are no longer valid.



[Interpretation of test results]
Negative result: if there is only a quality control line C, the detection line T is colorless, indicating that SARS-CoV-2 antigen has not been detected and the result is negative.
Positive result: if both the quality control line C and the detection line T appear, indicating that SARS-CoV-2 antigen has been detected and the result is positive.
Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line T (as shown in the figure below), and the test shall be conducted again.

Positive Negative Invalid

[Quality Control]
Program control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume. The kit does not provide control standards.

[Limitations of inspection methods]
1.This test kit is only used for in vitro diagnosis.
2.This test kit is only used to detect human saliva. The results of other specimens may be wrong.
3.This test kit is only used for qualitative detection and cannot indicate the level of SARS-CoV-2 antigen in the specimen.
4.This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

[Performance index]
1. Physical characters

1.1 Appearance: The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without waggle. The extraction reagent should be clear and free of foreign matter.
1.2 Size: the size of the inner strip should not be less than 2.5mm.
1.3 Liquid migration speed should not be less than 10mm/min.
2. **Minimum detection limit:** The minimum test limit reference products S1 should be negative, S2 and S3 should be positive.
NOTE:S1:Extraction Reagent for Antigen;S2:0.1ng/ml of recombinant antigen
S3:1ng/ml of recombinant antigen
3. **Negative compliance rate:** 5 pieces of negative reference products of the test company shall be all negative, with a negative compliance rate of 100%.
4. **Positive compliance rate:** 5 pieces of positive reference products, each reference test one times and shall be all positive, with a positive compliance rate of 100%.
5. **Repeatability:** Test 1 piece of the enterprise positive reference, test it 10 times, the color should be consistent and all positive.

[Limit of detection, LOD]
Using the 320 $TCID_{50}$/mL concentration, the LOD was further refined using a 2-fold dilution series (four dilutions in total) of the gamma-irradiated SARS-CoV-2 virus made in pooled negative human nasal matrix. These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3 replicates) were positive was treated as the tentative LOD for the DeepBlue SARS-CoV-2 Ag Test. This $TCID_{50}$/mL was still 320.

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test Result
320	3/3 positive
160	0/3 positive
80	1/3 positive
40	0/3 positive

[Cross-reactivity (Analytical Specificity)]

The cross-reactivity of the DeepBlue SARS-CoV-2 Ag Test is evaluated by testing a group of related pathogens, high-prevalence disease pathogens, and normal or pathogenic flora. The results prove that the product has no cross-reactivity.

Microorganism	Concentration	Cross-Reactivity (Yes/No)
Adenovirus 3	1 x 10^5 PFU/mL	No (3/3 negative)
Parainfluenza virus Type 2	1 x 10^5 PFU/mL	No (3/3 negative)
Human coronavirus NL63	9.87 x 10^3 PFU/mL	No (3/3 negative)
MERS coronavirus(Pseudovirus, part of ORFlab+N gene)	7930 PFU/mL	No (2/2 negative)
Human coronavirus 229E	1 x 10^5 PFU/mL	No (3/3 negative)
Human coronavirus OC43	1 x 10^5 PFU/mL	No (3/3 negative)
Human Coronavirus HKU1	1 x 10^5 PFU/mL	No (3/3 negative)
SARS-COV-2Pseudovirus (N full-length gene)	1 x 10^5 PFU/mL	No (3/3 negative)
Enterovirus	1 x 10^5 PFU/mL	No (3/3 negative)
Respiratory syncytial virus(A)	1 x 10^5 PFU/mL	No (3/3 negative)
Parainfluenza virus Type 3	1 x 10^5 PFU/mL	No (3/3 negative)
Paramfluenza virus Type 4a	1 x 10^5 PFU/mL	No (3/3 negative)
Influenza A H3N2 (Wisconsin/67/05)	8.82 x 10^4PFU/mL	No (3/3 negative)
Influenza A H1N1	1 x 10^5 PFU/mL	No (3/3 negative)
Influenza B (VICRTORIA)	2.92 x 10^4 PFU/mL	No (3/3 negative)
Rhinovirus(HRVA30)	4.17 x 10^5 PFU/mL	No (3/3 negative)
Haemophilus influenzae	1 x 10^6 CFU/mL	No (3/3 negative)
Streptococcus pneumoniae	1 x 10^6 CFU/mL	No (3/3 negative)
Streptococcus pyogenes	1 x 10^6 CFU/mL	No (3/3 negative)
Candida albicans	1 x 10^6 CFU/mL	No (3/3 negative)
Bordetella pertussis	1 x 10^6 CFU/mL	No (3/3 negative)
Mycoplasma pneumoniae	1 x 10^6 CFU/mL	No (3/3 negative)
Chlamydia pneumoniae	1 x 10^6 CFU/mL	No (3/3 negative)
Legionella pneumophila	1 x 10^6 CFU/mL	No (3/3 negative)
Mycobacterium tuberculosis	1 x 10^6 CFU/mL	No (3/3 negative)
Pneumocystis jirovecii	1 x 10^6 CFU/mL	No (3/3 negative)
Pseudomonas Aeruginosa	1 x 10^6 CFU/mL	No (3/3 negative)
Human Metapneumovirus (hMPV)	1 x 10^5 PFU/mL	No (3/3 negative)
Parainfluenza virus Type 1	1 x 10^5 PFU/mL	No (3/3 negative)
Staphylococcus Epidermidis	1 x 10^6 CFU/mL	No (3/3 negative)
Streptococcus Salivarius	1 x 10^6 CFU/mL	No (3/3 negative)

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. For Human Coronavirus HKU1, homology exists between the SARS- CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results showed 30 sequence IDs, all nucleocapsid protein, showing homology. Sequence ID AGW27840.1 had the highest alignment score and was found to be 39.1% homologous across 76% of the sequences, this is relatively low but cross-reactivity cannot be fully ruled out. For SARS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1, had the highest alignment score isolated from a human patient and was found to be 90.76% homologous across 100% of the sequence. This is high and cross-reactivity is likely.
For MERS-Coronavirus, high homology exists between the SARS- CoV-2 nucleocapsid protein and MERS-Coronavirus. BLAST results showed at least 114 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence IDs AHY61344.1 and AWH65950.1, had the highest alignment scores isolated from a human patient and were found to be 49.4% and 50.3% homologous across 88% of the sequence. Whilst this potentially represents moderate cross-reactivity testing of the MERS virus at 7930 PFU/mL showed no reactivity (see table above).

[Microbial Interference Studies]

Microbial interference in the DeepBlue SARS-CoV-2 Ag Test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora to demonstrate that false negatives do not occur when SARS-CoV-2 is present in a specimen with other microorganisms.

Microorganism	Concentration	Interference (Yes/No)
Parainfluenza virus Type 1	1 x 10^5 PFU/mL	No (3/3 positive)
Parainfluenza virus Type 2	1 x 10^5 PFU/mL	No (3/3 positive)
Parainfluenza virus Type 3	1 x 10^5 PFU/mL	No (3/3 positive)
Parainfluenza virus Type 4a	1 x 10^5 PFU/mL	No (3/3 positive)
Adenovirus (e.g. C1 Ad. 71)	1 x 10^5 PFU/mL	No (3/3 positive)
Human Metapneumovirus (hMPV)	1 x 10^5 PFU/mL	No (3/3 positive)

Influenza A H3N2(Wisconsin/67/05)	8.82 x 10^4 PFU/mL	No (3/3 positive)
Influenza A H1N1	1 x 10^5 PFU/mL	No (3/3 positive)
Haemophilus influenzae	1 x 10^6 CFU/mL	No(3/3 positive)
Streptococcus pneumoniae	1 x 10^6 CFU/mL	No (3/3 positive)
Streptococcus pyogenes	1 x 10^6 CFU/mL	No (3/3 positive)
Influenza B (Malaysia/2506/04)	2.92 x 10^4 PFU/mL	No (19/20 positive)
Enterovirus	1 x 10^5 PFU/mL	No (3/3 positive)
Respiratory syncytial virus	1 x 10^5 PFU/mL	No (3/3 positive)
Rhinovirus	4.17 x 10^5 PFU/mL	No (3/3 positive)
Chlamydia pneumoniae	1 x 10^6 CFU/mL	No (3/3 positive)
Legionella pneumophila	1 x 10^6 CFU/mL	No (3/3 positive)
Mycobacterium tuberculosis	1 x 10^6 CFU/mL	No (3/3 positive)
Pneumocystis jirovecii	1 x 10^6 CFU/mL	No (3/3 positive)
Pseudomonas Aeruginosa	1 x 10^6 CFU/mL	No (3/3 positive)
Candida albicans	1 x 10^6 CFU/mL	No (3/3 positive)
Pooled human nasal wash	14% v/v	No (3/3 positive)
Bordetella pertussis	1 x 10^6 CFU/mL	No (3/3 positive)
Mycoplasma pneumoniae	1 x 10^6 CFU/mL	No (3/3 positive)
Staphylococcus Epidermidis	1 x 10^6 CFU/mL	No (3/3 positive)
Streptococcus Salivarius	1 x 10^6 CFU/mL	No (3/3 positive)
Human coronavirus 229E	1 x 10^5 PFU/mL	No(3/3 positive)
Human coronavirus OC43	1 x 10^5 PFU/mL	No (19/20 positive)
Human coronavirus NL63	9.87 x 10^5 PFU/mL	No(3/3 positive)
MERS coronavirus	7930 PFU/mL	No (3/3 positive)

[Endogenous Interference Studies]

A study was performed to demonstrate that potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications) do not cross-react or interfere with the detection of SARS-CoV-2 in the DeepBlue SARS-CoV-2 Ag Test.

Interfering Substance	Concentration	Interference (Yes/No)
Zicam Cold Remedy	5% v/v	No (3/3 Negative, 3/3 Positive)
Homeopathic (Alkalol)	10 % v/v	No (3/3 Negative, 3/3 Positive)
Sore Throat Phenol Spray	15% v/v	No (3/3 Negative, 3/3 Positive)
Blood (human)	5%	No (3/3 Negative, 3/3 Positive)
Mucin	5 mg/mL	No (3/3 Negative, 3/3 Positive)
Naso GEL (NeilMed)	5% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Drops (phenylephrine)	15% v/v	No (3/3 Negative, 3/3 Positive)
Afrin (Oxymetazoline)	15% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Spray (Cromolyn)	15% v/v	No (3/3 Negative, 3/3 Positive)
Tamiflu (Oseltamivir phosphate)	500 mg/dL	No (3/3 Negative, 3/3 Positive)
Budenoside	0.00063 mg/dL	No (3/3 Negative, 3/3 Positive)
Biotin	0.35 mg/dL	No (3/3 Negative, 3/3 Positive)
Tobramycin	3.3 mg/dL	No (3/3 Negative, 3/3 Positive)
Mupirocin	0.15 mg/dL	No (3/3 Negative, 3/3 Positive)
Fluticasone	0.000126 mg/dL	No (5/5 Negative, 4/4 Positive)
Dextromethorphan	0.00156 mg/dL	No (19/20 Negative, 3/3 Positive)
Dexamethasone	1.2 mg/dL	No (3/3 Negative, 3/3 Positive)
Mucinex	5%	No (3/3 Negative, 3/3 Positive)
Methanol	150 mg/dL	No (19/20 Negative, 3/3 Positive)
Acetylsalicylic Acid	3 mg/dL	No (3/3 Negative, 3/3 Positive)
Diphenhydramine	0.0774 mg/dL	No (3/3 Negative, 3/3 Positive)
Benzocaine	150 mg/dL	No (3/3 Negative, 3/3 Positive)

[High Dose Hook Effect]

The serial increased concentrations of SARS-CoV-2 samples were tested with the COVID-19 (Sars-CoV-2) Antigen Test Kit (Colloidal gold) manufactured by the DeepBlue. No impact on test performance or hook effect at high concentrations was observed up to 1.4 x 10^5 $TCID_{50}$/mL of SARS-CoV-2 with the DeepBlue SARS- CoV-2 Ag Test.

Test Dilution	Concentration ($TCID_{50}$/mL)	Mean Signal (ADC Units)
1	0	495
2	62.5	26100.6
3	250	63013.8
4	1000	83451.8
5	1.4 x 10^5	86220

[Clinical Performance]

The overall study scale was 520 cases, 110 positive samples and 410 negative samples.

Statistics of test results of saliva samples:

Reference RT-PCR Assay							95% Wilson Score CI	
							LCI	UCI
DEEP BLUE SARS-CoV-2 Ag Test		POS	NEG	Total	PPA	96.4%	90.8%	98.2%
	POS	106	1	107	NPA	99.8%	94.4%	99.9%
	NEG	4	409	413	PPV	99.1%	93.7%	99.8%
	TOTAL	110	410	520	NPV	99.0%	93.5%	99.7%

PPA - Positive Percent Agreement (Sensitivity)
NPA - Negative Percent Agreement (Specificity)
PPV - Positive Predictive Value
NPV - Negative Predictive Value
CI - Confidence Interval
LCI - Lower Confidence Interval
UCI - Upper Confidence Interval

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[Index of CE Symbols]

IVD	The product is used in vitro		Please don't reuse it
	Expire date		Please read the instruction book carefully before using
	Warning, please refer to the instruction in the package		Manufacturer
	Temperature scope within which the product is reserved	LOT	Batch number
	European union authorization representative		Keep dry
	Avoid over exposure to the sun		Don't use the product when the package is damaged
	Date of manufacture		Biological risks
CE	CE Mark		Contains sufficient for <n> tests