TRIPLEX INTERNATIONAL
BIOSCIENCES(CHINA) CO., LTD.
泰普生物科学(中国)有限公司

新型冠状病毒抗原检测试剂盒(胶体金法)资料

SARS-CoV-2 Antigen Rapid Test Kit (Collodial Gold) Data

泰普生物科学(中国)有限公司
TRIPLEX INTERNATIONAL BIOSCIENCES(CHINA) CO., LTD

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资 料 目 录

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TIB
TRIPLEX INTERNATIONAL
BIOSCIENCES(CHINA) CO., LTD.

About us

Founded in 2004 with a registered capital of US$ 130 million, Triplex International Biosciences (TIB) has become a leading molecular bioscience enterprise which integrates R&D, production and sales of molecular diagnosis and the supporting instruments as well as high-end medical diagnosis services covering the diagnosis of tumors, infectious diseases, genetic diseases and heart diseases.

统一社会信用代码
91350200751630628A

营业执照
（副 本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、许可、备案、监管信息。

名　　称　泰普生物科学（中国）有限公司

类　　型　法人商事主体【有限责任公司（港澳台投资、非独资）】

法定代表人　李劲

经营范围　商事主体的经营范围、经营场所、投资人信息、年报信息和监管信息等请至厦门市商事主体登记及信用信息公示平台查询。经营范围中涉及许可审批经营项目的，应在取得有关部门的许可后方可经营。

注册资本　美元　壹亿叁仟万元整

成立日期　2004年04月07日

营业期限　自2004年04月07日至2054年04月06日

住　　所　厦门市思明区前埔工业园55号409单元

登记机关　厦门市市场监督管理局　350200117800

2020 年 07月 30 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

商事主体应当于每年1月1日至6月30日通过厦门市商事主体登记及信用信息公示平台公示年度报告

国家市场监督管理总局监制

医疗器械经营许可证

许可证编号：闽厦食药监械经营许 20150093 号

企业名称：泰普生物科学（中国）有限公司

法定代表人：姚铭锋

经营方式：批发

企业负责人：李劲

住　　所：厦门市思明区前埔工业园 55 号 409 单元

经营范围：《医疗器械分类目录》（旧版）III类：6801、6802、6803、6804、6805、6806、6807、6808、6809、6810、6812、6813、6815、6816、6820、6821、6823、6824、6825、6826、6827、6828、6830、6831、6832、6833、6834、6840、6841、6845、6854、6855、6856、6857、6858、6863、6864、6865、6866、6870。

经营场所：厦门市思明区前埔工业园 55 号 409 单元

库房地址：厦门市同安区西柯镇西洲路 2041 号 101 单元；委托福建梧合冷链仓储管理有限公司仓储（福州分仓：福建省福州市仓山区盖山投资区高南路 2 号 5 栋 2 层）

发证部门：厦门市市场监督管理局

有效期限：至 2025 年 03 月 05 日

发证日期：2020 年 03 月 06 日

国家药品监督管理局制

医疗器械生产许可证

许可证编号：闽药监械生产许20110184号

企业名称：泰普生物科学（中国）有限公司

法定代表人：姚铭锋

企业负责人：姚铭锋

住　　所：厦门市思明区前埔工业园55号409单元

生产地址：厦门市同安区西洲路2041号101、201、301单元；2045号101、201、501单元

生产范围：二类6822医用光学器具、仪器及内窥镜设备；三类、二类6840临床检验分析仪器、6840体外诊断试剂**

发证部门：福建省药品监督管理局

有效期限：至 2025 年 03 月 17 日

发证日期：2020 年 03 月 18 日

国家食品药品监督管理总局制

对外贸易经营者备案登记表

统一社会信用代码：　91350200751630628A

备案登记表编号：03520886　　进出口企业代码：----------

经营者中文名称	泰普生物科学（中国）有限公司		
经营者英文名称	Triplex International Biosciences (China) Co.,Ltd.		
组织机构代码	---------	经营者类型（由备案登记机关填写）	港、澳、台商投资
住　所	厦门市思明区前埔工业园55号409单元		
经营场所（中文）	厦门市思明区前埔工业园55号409单元		
经营场所（英文）	Unit 409, No.55 Qianpu Industrial Park, SiMing District, Xiamen		
联系电话	13860465489	联系传真	0592-3788599
邮政编码	361000	电子邮箱	xzjl@tibchina.com
工商登记注册日期	2004-4-7	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	李劲	有效证件号	620102196709265411
注册资金	捌亿陆仟壹佰捌拾肆万捌仟元	壹亿叁仟万美元（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　原备案登记表编号02906124已失效；	

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

2020　年　12　月　30　日

本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

泰普生物科学（中国）有限公司

年　月　日

注：1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。

海关进出口货物收发货人备案回执

企业名称	泰普生物科学（中国）有限公司
统一社会信用代码	91350200751630628A
海关备案日期	2004-05-13
海关注册编码	3502141674
检验检疫备案号	3995602783
有效期	长期

高崎海关

2021年1月4日

自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台”（http://credit.customs.gov.cn）或者“互联网+海关”（http://online.customs.gov.cn）查询海关公示的企业信息。

TRIPLEX INTERNATIONAL BIOSCIENCES(CHINA) CO., LTD.
泰普生物科学(中国)有限公司

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

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

TÜV SÜD Product Service

Certificate

No. Q5 104849 0001 Rev. 00

Holder of Certificate: **TRIPLEX INTERNATIONAL BIOSCIENCES CO.,LTD**
Unit 101, 201, and 301, No. 2041
Unit 101, 201, and 501, No. 2045, Xizhou Road
Tongan District
361100 Xiamen
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 Kit for Fertility Diagnosis, In-vitro Diagnostic Kit for Tumor marker, In-vitro Diagnostic Kit for Infectious Diseases, Nucleic Acid Extraction Reagent, Staining Solution and Supporting Instruments**

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.: GZ1941401

Valid from: 2020-04-02
Valid until: 2023-04-01

Date, 2020-04-02

Christoph Dicks
Head of Certification/Notified Body

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

TIB
TRIPLEX INTERNATIONAL BIOSCIENCES(CHINA) CO., LTD.
泰普生物科学(中国)有限公司

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 104849 0001 Rev. 00

Applied Standard(s):

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

Facility(ies):

TRIPLEX INTERNATIONAL BIOSCIENCES CO.,LTD
Unit 101, 201, and 301, No. 2041, Unit 101, 201, and 501, No. 2045, Xizhou Road, Tongan District, 361100 Xiamen, PEOPLE'S REPUBLIC OF CHINA

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC Declaration of Conformity

Manufacturer:

Name: Triplex International Biosciences (China) Co., LTD.

Address: Unit 101,201,and 301,No.2041,Unit 101,201,and 501,No.2045, Xizhou Road, Tongan District, 361100 Xiamen, PEOPLE' S REPUBLIC OF CHINA.

Tel: +86-592-3737666

Web: http://www.tibchina.com

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We,Triplex International Biosciences (China) Co., LTD.(Manufacturer), 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 Triplex International Biosciences (China) Co., LTD.(Manufacturer).

Product Name	SARS-CoV-2 Antigen Rapid Test Kit					
Intended Purpose	This SARS-CoV-2 Antigen Rapid Test Kit is only used for rapid in vitro qualitative detection of nucleocapsid protein (N protein) from SARS-CoV-2 antigen in human nasopharyngeal swabs, anterior nasal swab or posterior oropharyngeal saliva within 5 days after clinical symptoms. This test is intended for clinical laboratories, medical institutions, or real-time inspection by professional medical staff only.					
PackSize/REF/ Barcodes	***PackSize:*** 1 test/kit	2 tests/kit	5 tests/kit	10 tests/kit	25 tests/ kit	50 tests/ kit
	REF: C011907	C011908	C011909	C011910	C011906	C011905
	Barcodes: 6950917930065	6950917930072	6950917930089	6950917930096	6950917930102	6950917930119
Classification	Others					

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

Applicable Standards:

QMS:

EN ISO 13485:2016

Risk Management:

ISO 14971:2019

Product Standards:

EN ISO 18113-1:2011 *EN ISO 18113-2:2011*

EN 13612:2002 *EN 13641:2002* *EN 62366-1:2015*

ISO 15223-1:2016 *ISO 23640:2015* *ISO 10993*

CE

Valid until: May 24, 2022

Name Of Authorized Signatory	Jin Li（李劲）
Position Held In The Company	General Manager
Signature	
Date	January 12, 2021
Place	Xiamen, China.
Seal (Manufacturer)	

TRIPLEX INTERNATIONAL BIOSCIENCES (CHINA) CO., LTD. 泰普生物科学（中国）有限公司

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:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20205563

Bijlagen
-

Uw aanvraag
18 november 2020

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

Datum: 4 december 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 18 november 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Triplex International Biosciences (China) Co., LTD. met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 Antigen Rapid Test Kit
(geen merknaam) (NL-CA002-2020-54367)

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

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient 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 revisies 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).

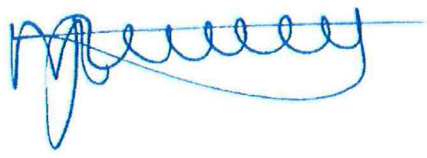
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Triplex International Biosciences (China) Co., LTD. de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I 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

TRIPLEX INTERNATIONAL BIOSCIENCES(CHINA) CO., LTD.

泰普生物科学(中国)有限公司

Clinical Evaluation Report of SARS-CoV-2 Antigen Rapid Test Kit

Product name: SARS-CoV-2 Antigen Rapid Test Kit

Manufacturer: Triplex International Biosciences (China) Co., Ltd.

1. Introduction

This product is limited to clinical use and emergency storage during the pneumonia epidemic caused by SARS-CoV-2 since December 2019, and cannot be used as a routine in vitro diagnostic reagent for clinical use. The test results of this Kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the patient's condition in combination with clinical manifestations and other laboratory tests.

To carry out laboratory test of SARS-CoV-2, biosafety work shall be ensured in accordance with the requirements of "technical guidelines for laboratory test of pneumonia infected by SARS-CoV-2 ".

This product is suitable for the qualitative detection of SARS-CoV-2's antigen in human posterior oropharyngeal saliva and nasopharyngeal swab samples. The Kit is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease (COVID-19). This product is only used by medical institutions. The Kit uses colloidal gold labeled immunochromatography as the technical platform to achieve its advantages of high specificity, high sensitivity and rapid detection. On this background, Xiamen Disease Control and Prevention Center and Putian Disease Control and Prevention Center have conducted clinical verification work of SARS-CoV-2 Antigen Rapid Test Kit developed by Triplex International Biosciences (China) in August, 2020.

2. Purpose of research

The purpose of this research is to evaluate the clinical performance of the kit, including sensitivity, specificity and accuracy by statistically analyzing test results through comparative experimental research.

3. Clinical trial institutions

The clinical trial was conducted in two centers for disease control and prevention, Xiamen Disease Control and Prevention Center and Putian Disease Control and Prevention Center.

4. Experiment design

4.1 Description of the overall design and program

A total of 1016 clinical samples were tested in this clinical study. The clear diagnosis and

exclusion criteria from "SARS-CoV-2 diagnosis and treatment protocol" were taken as reference to verify the clinical application performance of the SARS-CoV-2 Antigen Rapid Test Kit produced by Triplex International Biosciences (China).

4.2 Selection of samples and experiment design

4.2.1 Clinical trial sample quantity

In this clinical trial, 135 cases of clinically positive human secreta specimens, including 67 cases of SARS-CoV-2 human nasopharyngeal swab sample, 32 cases of anterior nasal swab sample and 36 cases of posterior oropharyngeal saliva were collected respectively; 881 cases of SARS-CoV-2 clinically negative human secreta specimens including 603 cases of nasopharyngeal swab sample, 90 cases of anterior nasal swab sample and 188 cases of posterior oropharyngeal saliva were collected respectively.

4.2.2 Sample inclusion and exclusion criteria

1) Positive sample inclusion: Meets the following 3 criteria, it is included into positive sample group:

Patients with symptoms within 5 days after onset;

PCR test is positive;

CT test results and symptoms are clinically positive.

2) Positive sample exclusion: Samples only meet 1 or 2 of the 3 inclusion criteria; it is excluded out of positive sample group.

3) Negative sample inclusion: Meets 2 of the following 3 criteria, it is included into negative sample group:

PCR test is negative;

CT test results and symptoms are clinically negative;

No history of novel coronavirus exposure within 14 day.

4) Negative sample exclusion: Samples only meet 1 of the 3 criteria of inclusion; it is excluded out of negative sample group.

4.2.3 Sample collection and storage

Sample collection and transportation shall be conducted in strict accordance with the pretest

flow of samples.

Experiment operation: The experiment operation is carried out in strict accordance with the IFU of the Kit.

Sample storage: The human nasopharyngeal swab samples and posterior oropharyngeal saliva should be stored at 2℃ ~ 8℃ within 12 hours. Over 12 hours storage, samples should be placed in -20℃ cryopreservation. Avoid repeatedly freeze-thaw.

4.2.4 Test reagents

Name: SARS-CoV-2 Antigen Rapid Test Kit

Specification: 25 tests/Kit

LOT: 012005

Expiry: May 20, 2022

Storage Conditions: Store at 2°C ~30°C in a cool, dark, and dry place.

Source: Triplex International Biosciences (China) Co., LTD.

4.2.5 Reference products

Name: Detection Kit for 2019-nCoV (PCR-Fluorescence);

Manufacturer: Da An Gene Co., Ltd. of Sun Yat-sen University;

Storage Conditions: Store at 2°C ~8°C in a dry place, protected from light.

4.2.6 Test method

The clinical samples were tested by double-blind method and the operation steps were carried out according to the requirements of the product manual. This clinical study was conducted in P2 laboratory. The equipment and personnel fully meet the requirements of this clinical study.

4.2.7 Statistics and data management

Test results should be recorded on the original record sheet. After the end of the experiment, the original data were analyzed statistically.

5. Statistical analysis of clinical data

The statistical analysis of test results selects the data in accordance with the protocol, that is, the sample data of all the subjects in accordance with the requirements of the test protocol for statistical analysis. The fourfold table is mainly used for the calculation of indicators such as

sensitivity, specificity and accuracy.

reference method / Test kits	Positive	Negative	Total
Positve	a	b	a+b
Negative	c	d	c+d
Total	a+c	b+d	a+b+c+d

Use the following formula to calculate:

Sensitivity (true positive rate) =a/(a+c) ×100%

Specificity (true negative rate) =d/(b+d) ×100%

Accuracy (overall concordance rate)=（a+d）/(a+b+c+d)× 100 %

6. Clinical research results and analysis

6.1 Clinical test results

The SARS-CoV-2 Antigen Rapid Test Kit has tested 135 cases of human nasopharyngeal swab sample, anterior nasal swab sample and posterior oropharyngeal saliva that were RT-PCR positive (the median Ct value of the RT-PCR is 26.10) for SARS-CoV-2 infection and 881 cases of human nasopharyngeal swab sample, anterior nasal swab sample and posterior oropharyngeal saliva that were RT-PCR negative. The test results are shown in the table below:

Nucleic acid detection / SARS-CoV-2 antigen detection	Positive	Negative	Total
Positive	133	0	133
Negative	2	881	883
Total	135	881	1016

6.2 Statistic analysis

Statistical analysis of clinical test results of SARS-CoV-2 antigen is as follows:

Sensitivity = 133/ (133+2) ×100%=98.52% (95%CI: 94.21%～99.74%)

Specificity=881/ 881 ×100%=100% (95%CI: 99.46%～100%)

Overall coincidence rate= (133+881)/1016×100%=99.80%

6.3 Analysis on inconsistency in test results

The Ct values of RT-PCR tests of two samples with inconsistent detection results were lower than 35, and these two cases were both posterior oropharyngeal saliva.

Sample number	Sample type	real time RT-PCR(DAAN GENE)		SARS-CoV-2 Antigen Rapid Test Kit（TIB）
		Ct(ORF lab)	Ct(N Gene)	
42#	Posterior oropharyngeal saliva	36.04	35.43	Negative
97#	Posterior oropharyngeal saliva	37.92	37.15	Negative

7. Discussion and Conclusions

The SARS-CoV-2 Antigen Rapid Test Kit produced by Triplex International Biosciences (China) has a high concordance rate of clinical diagnosis of SARS-CoV-2 and its clinical performance can meet the emergency needs of epidemic. It can be used for for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease (COVID-19).

8. References

1. World Health Organization (WHO). Coronovirus. https://www.who.int/health-topics/coronavirus.

2. “Pneumonitis Diagnosis and Treatment Program for New Coronavirus Infection (Trial Version 7)” issued by the National Health Committee on February 19, 2020.