

# ABOUT US

NewScen Coast Bio-Pharmaceutical

NewScen is professional IVD products manufacturer and POCT service provider, founded in 2003. Our factory is located in Tianjin, one of biggest port city in Northern China, which benefit us from convenient logistics, and enable us fulfill better order delivery to our customers. We have more than 16 years of industry experience and export experience. Products are sold throughout the country and in North America, South America, Southeast Asia, Europe, the Middle East, Africa and other international markets. And our HIV and HCV products have both got CE approval and passed WHO laboratory evaluation.

We dedicated provide our customers an extensive range of RDTs in satisfying performance with favorable price. Both finished products, semi-finished products, OEM products, Uncut sheets are available for our cooperation.

# NEW SCEN



**“Honesty, verity, authenticicy, and innovation”**  
is our persistent commitment.

**“Encouraging our employees growing with  
company”**

is the driving force beneath our surging growth.



# CERTIFICATION

NewScen Coast Bio-Pharmaceutical

国际体系认证



**Dakks**  
Deutsche  
Akreditierungsstelle  
D-2411323-01-00

**TUV SUD**  
Product Service

**Certificate**  
No. QS 095791 0008 Rev. 01

**Holder of Certificate:** **NewScen Coast Bio-Pharmaceutical Co., Ltd.**  
No. 65, 6th Street  
Tianjin TEDA  
300457 Tianjin  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** NewScen Coast Bio-Pharmaceutical Co., Ltd.  
No. 65, 6th Street, Tianjin TEDA, 300457 Tianjin, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 

**Scope of Certificate:** **Design and Development, Production and Distribution of Lateral-Flow Technique based In Vitro Diagnostic Medical Devices and Readers for Lateral-Flow Devices**

**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.:** SH19107304

**Valid from:** 2019-10-21  
**Valid until:** 2022-10-20

**Date,** 2019-09-19 *Stefan Preis*  
Stefan Preis  
Head of Certification/Notified Body

Page 1 of 1  
TUV SUD Product Service GmbH • Certification Body • Riderstraße 65 • 80339 Munich • Germany

ISO13485



**ISO 9001 Accredited**  
Certification Body

**TUV SUD**  
America

**CERTIFICATE**  
No. QS5 095791 0009 Rev. 01

**Certificate Holder:** **NewScen Coast Bio-Pharmaceutical Co., Ltd.**  
No. 65, 6th Street  
Tianjin TEDA  
300457 Tianjin  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 

**Scope of Certificate:** **Design and Development, Production and Distribution of Lateral-Flow Technique based In-Vitro Diagnostic Medical Devices and Readers for Lateral-Flow Devices**

**Standard(s):** **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:** SH19107304

**Effective Date:** 2020-03-09

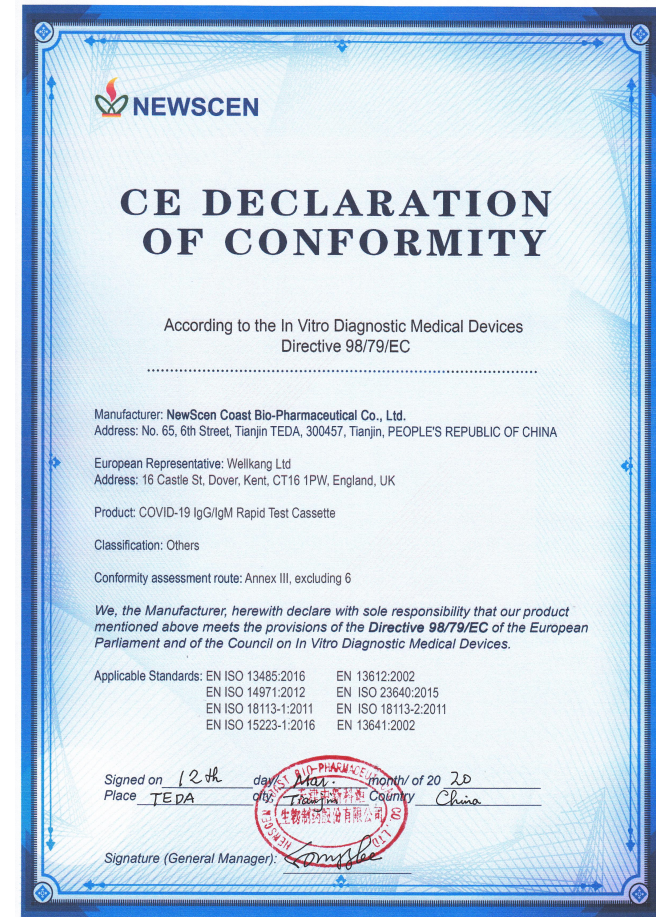
**Expiry Date:** 2022-11-24

Page 1 of 1  
Date of Issue: 2020-03-10

*Michael*  
(Tina Israel)  
Manager, US Certification Body,  
Medical and Health Services

TUV SUD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)

ISO9001



**NEWSZEN**

**CE DECLARATION OF CONFORMITY**

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: **NewScen Coast Bio-Pharmaceutical Co., Ltd.**  
Address: No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin, PEOPLE'S REPUBLIC OF CHINA

European Representative: **Wellkang Ltd**  
Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK

Product: **COVID-19 IgG/IgM Rapid Test Cassette**

Classification: **Others**

Conformity assessment route: **Annex III, excluding 6**

*We, the Manufacturer, herewith declare with sole responsibility that our product mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.*

Applicable Standards: EN ISO 13485:2016 EN 13612:2002  
EN ISO 14971:2012 EN ISO 23640:2015  
EN ISO 18113-1:2011 EN ISO 18113-2:2011  
EN ISO 15223-1:2016 EN 13641:2002

Signed on 12th day of May month of 2020  
Place TEDA City Tianjin County China

Signature (General Manager): *[Signature]*

Colloidal Gold

# CERTIFICATION

NewScen Coast Bio-Pharmaceutical

## 国内资质



营业执照  
Business license



医疗器械经营许可证  
Medical Device  
Manufacturing License

## 对外贸易经营者备案登记表

备案登记编号: 02578905 统一社会信用代码: 9112011674912841XT  
进出口企业代码: \_\_\_\_\_

经营者中文名称	天津中新科炬生物制药股份有限公司		
经营者英文名称	NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.		
组织机构代码	-----	经营者类型 (由备案登记机关填写)	外商投资股份有限公司
住所	天津经济技术开发区第六大街65号		
经营场所(中文)	天津经济技术开发区第六大街65号		
经营场所(英文)	NO.65,6TH STREET,TEDA,TIANJIN		
联系电话	022-25321648	联系传真	022-25328062
邮政编码	300457	电子邮箱	kejuchina@newscoast.com
工商登记注册日期	2003-5-27	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	孔德茂	有效证件号	120106196604085016
注册资金	贰仟陆佰陆拾万元		叁佰捌拾柒万叁千元(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/个体工商户负责人姓名		有效证件号	
企业资产/个人财产			(折美元)

备注

无进口商品分销业务
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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户负责人签字、盖章。

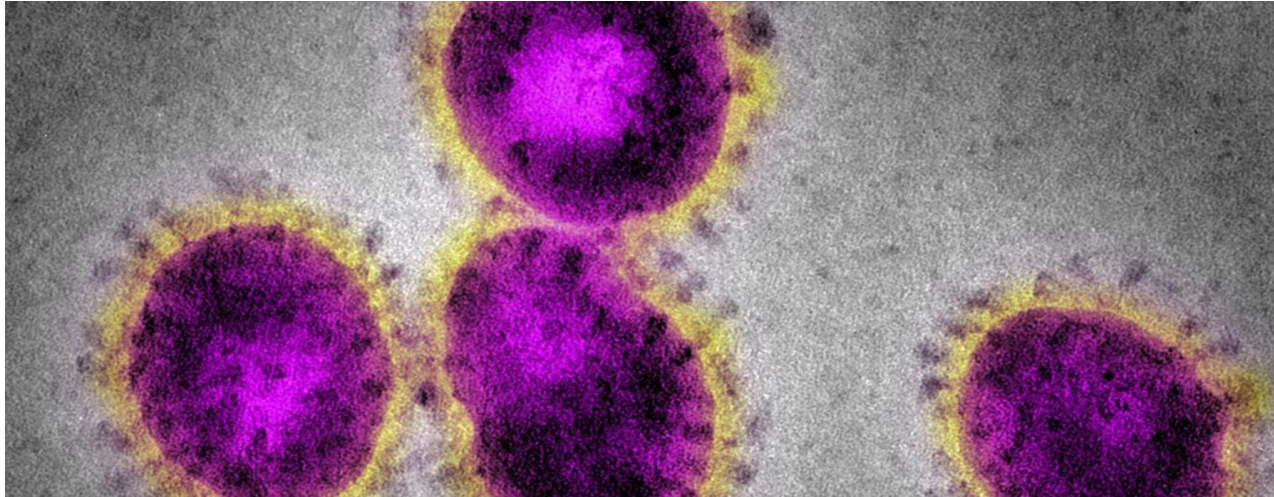


对外贸易经营备案登记表  
Registration Certificate For  
Foreign Trade Dealers



# WHAT IS CORONAVIRUS

NewScen Coast Bio-Pharmaceutical Co.,Ltd



Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

--- World Health Organization

## How is it spread?



Through the air  
by coughing and  
sneezing



Close personal  
contact, such  
as touching or  
shaking hands



Touching an  
object or surface  
with the virus on  
it, then touching  
your mouth,  
nose, or eyes

## What are the symptoms?

Illnesses can be mild, or in some cases be severe enough to require hospitalization. Symptoms of this respiratory illness primarily include:



Fever



Cough



Shortness of  
Breath

# COVID-19 RNA (RT-PCR)



NewScen Coast Bio-Pharmaceutical Co.,Ltd

A significant portion of patients who otherwise fit the diagnosis based on clinical and chest CT findings, including many hospitalized patients, have tested negative for viral RNA. Other common respiratory etiologies, such as influenza, were excluded. These remain “suspected” cases and may be reflective of false negativity in sampling. In some patients, the virus may be present in the lower respiratory secretion but absent in the upper respiratory tracts.

- “Evolving status of the 2019 novel coronavirus infection: Proposal of conventional serologic assays for disease diagnosis and infection monitoring” Journal of Medical Virology

**Nucleic Acid Test (PCR) False Negative Risk!**

# COVID-19 Serology Test

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For a new type of infection, it takes time for the body to make strong antibodies. The body can make several kinds of antibodies to fight infections. The two types that herpes blood tests look for are IgG and IgM.

**IgM:**

Herpes IgM antibodies usually are detectable by herpes blood tests within 7-10 days after initial infection. IgM levels stay high for approximately two weeks. After that, they usually decline. Therefore, IgM testing is primarily considered to be useful for detecting acute infection.

**IgG:**

Immunoglobulin G (IgG), the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections.

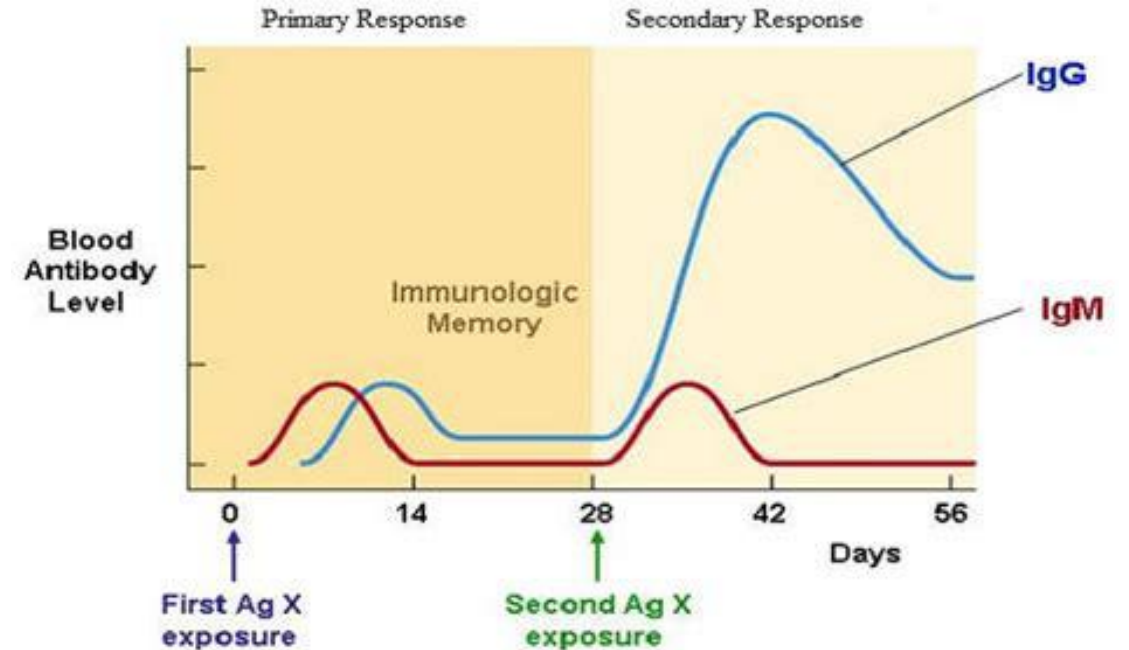


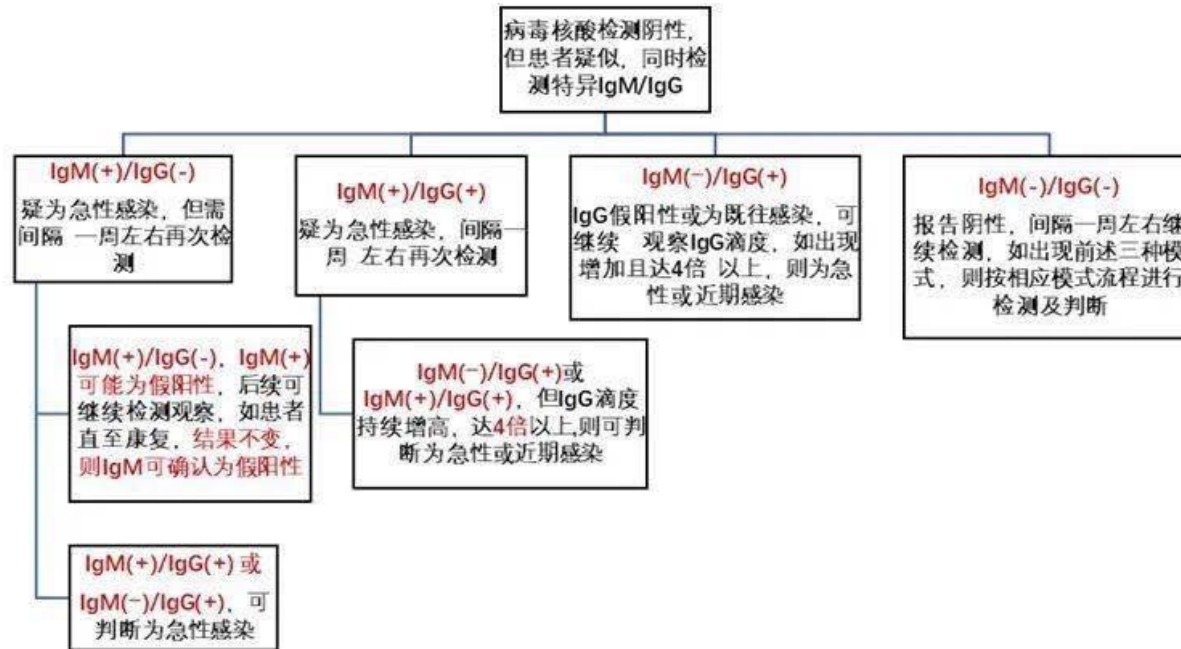
Fig. Immune Response and Secretion of antibodies

	Positive IgG	Negative IgG
Positive IgM	Infection date indeterminate	Acute/Recent infection
Negative IgM	Established Infection	No infection detected



# COVID-19 Serology Test

NewScen Coast Bio-Pharmaceutical Co., Ltd



Continuous Dynamic Detection

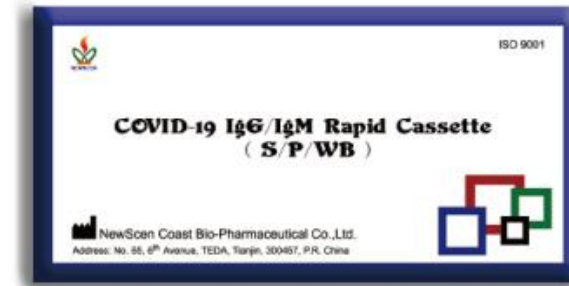
7th Edition COVID-19 Diagnosis & Treatment Guideline  
published by the National Health Commission of P.R.China

COVID-19 specific antibody IgM positive & IgG positive  
OR COVID-19 specific antibody IgG seroconverts or  
increase 4 times or more then acute phase  
→ INFECTION CONFIRMED

- ◆ Highly recommended to use with nucleic Acid (PCR) test in diagnosis of COVID-19
- ◆ Easy to sampling, effectively reduce the risk of infection in medical staffs
- ◆ Avoid misdiagnosis due to the incorrect sample collection when performing PCR test

# COVID-19 IgM/IgG TEST

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Colloidal Gold

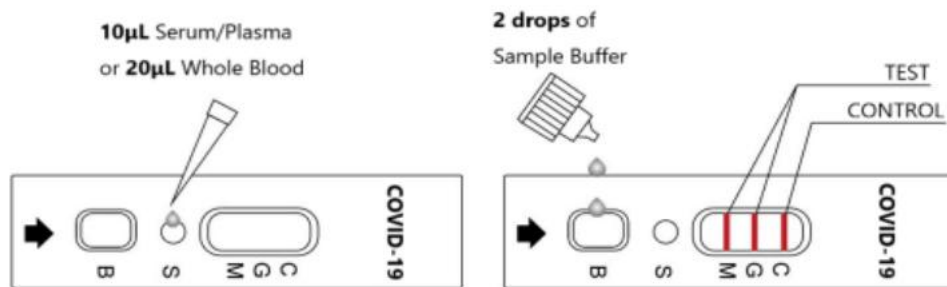


# COVID-19 IgM/IgG TEST

NewScen Coast Bio-Pharmaceutical Co.,Ltd

## OPERATION PROCESS

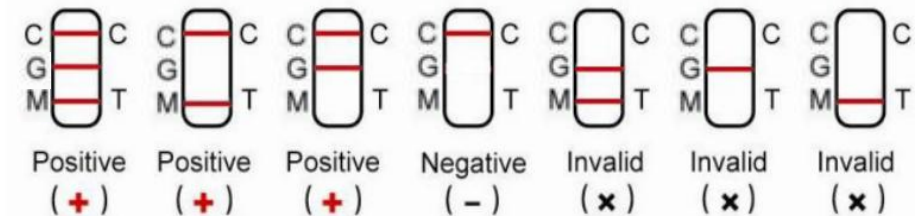
- Add the sample



10uL Serum/Plasma  
20uL Whole Blood

## INTERPRETATION OF RESULTS

- Observe the result in 15-20minutes



COVID-19 IgG/IgM Rapid Test Cassette

# COVID-19 IgM/IgG TEST

NewScen Coast Bio-Pharmaceutical Co.,Ltd

NewScen	Diagnosed Sample				Total	
	Positive		Negative			
Positive	A	86	B	9	A+B	95
Negative	C	8	D	258	C+D	266
<b>Total</b>	<b>A+C</b>	<b>94</b>	<b>B+D</b>	<b>267</b>	<b>ABCD</b>	<b>361</b>

**Sensitivity** =  $A/(A+C)\% = 91.49\%$

**Specificity** =  $D/(B+D)\% = 96.63\%$

**Total Accuracy** =  $(A+D)/(ABCD)\% = 95.29\%$

*The evaluation is carried out on the sample from COVID-19 nucleic acid test (PCR) confirmed cases from CDC and classIII hospitals*

Finger Tip Blood ✓

15 minute Result GET ✓

2-30°C Storage ✓

24M Shelf-life ✓

**FAST! EASY! ACCURATE!**