COVID-19

THE NEW CORONA VIRUS

To Qualitatively Detection of
SARS-COV-2 Antibody IgG/IgM

By NewScen Coast

2020.03

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ABOUT US

16 YEARS DEDICATED IN IVD;
NMPA, FDA, CE, ISO13485

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, authenticiy, 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

国际认证

Certificate

No. Q5 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 Preiß

Head of Certification/Notified Body

Page 1 of 1

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

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

(Tina Israel)

Manager, US Certification Body, Medical and Health Services

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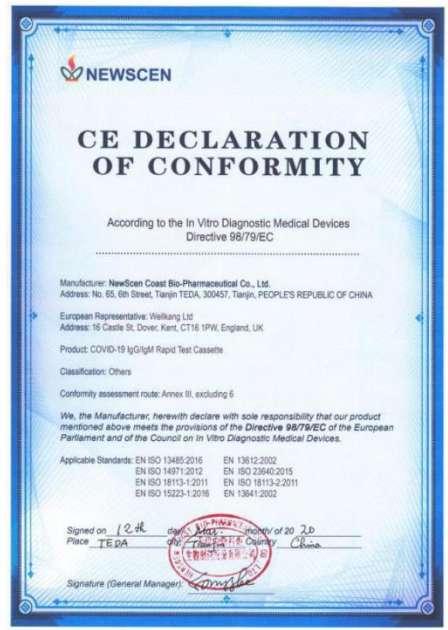


NEWSCEN

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

Signed on 12th day of May in the year of 20 20

Place TEDA city Tianjin Country China

Signature (General Manager)

ISO13485

ISO9001

EC DOC

CERTIFICATION

NewScen Coast Bio-Pharmaceutical

国内资质

统一社会信用代码 91120116749128413XT

营业执照

（副本）

名　称　天津中新科炬生物制药股份有限公司

类　型　股份有限公司(中外合资、未上市)

法定代表人　孔德茂

经营范围　生物医药类股票试剂的高科技产品的开发、咨询、转让、出、引进、6840 体外诊断试剂及分析判读仪器的生产销售。（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）

注册资本　贰仟陆佰陆拾万元人民币

成立日期　2003-05-27

营业期限　2003-05-27至长期

住　所　天津经济技术开发区第六大街65号

登记机关

2019 年 05 月 07 日

国家市场监督管理总局监制

营业执照

Business license

医疗器械生产许可证

许可证编号：津食药监械生产许20110189号

企业名称：天津中新科炬生物制药股份有限公司

法定代表人：孔德茂

企业负责人：李洲

住　所：天津经济技术开发区第六大街65号

生产地址：天津经济技术开发区第六大街65号

生产范围：III类:6840—体外诊断试剂及分析判读仪器
II类:6840—体外诊断试剂及分析判读仪器

发证部门：天津市药品监督管理局

有效期限：至　20年1　男　日　26　发证日期：　2019　年　07　月　0日

国家药品监督管理局制

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

备案登记表编号：02578905　　统一社会信用代码：91120116749128413XT　　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		联系传真	
邮政编码	300457	电子邮箱	
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	贰仟动佰陆拾万元	经营场所	叁佰捌拾柒万美元（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　无进口商品分销业务

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

2019 年 07 月 09 日

对外贸易经营备案登记表

Registration Certificate For Foreign Trade Dealers

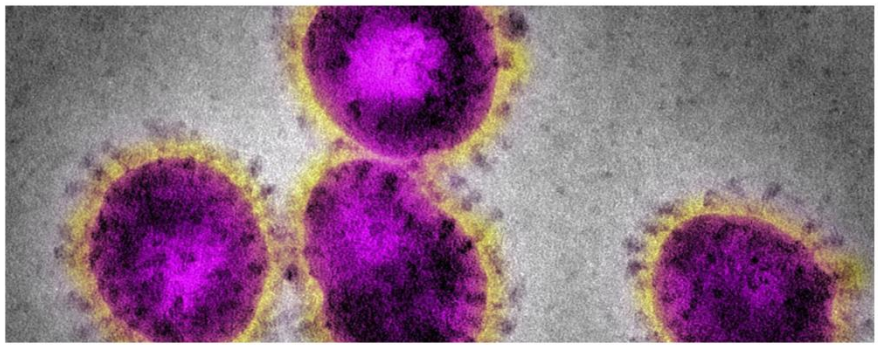
/02

WHAT IS COVID-19

THE NEW CORONAVIRUS OUTBREAK IN WUHAN 2019

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 Organztion

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 Medicl Virology

Nucleic Acid Test (PCR) False Negative Risk!

COVID-19 Serology Test

NewScen Coast Bio-Pharmaceutical Co.,Ltd

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.

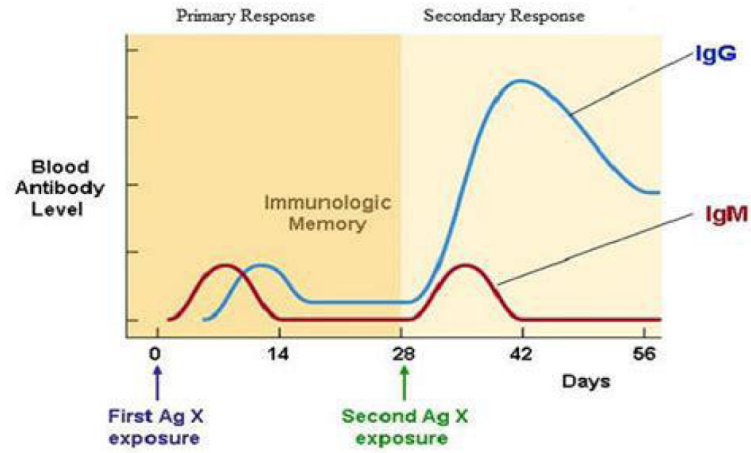
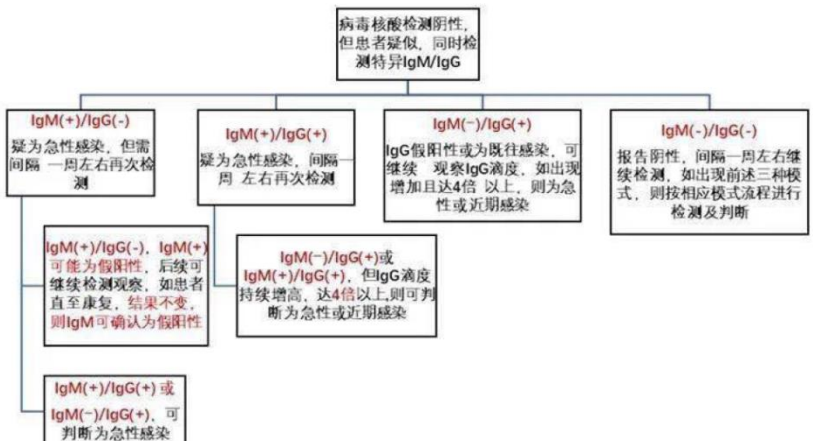


Fig. Immune Response and Secretion of antibodies

	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 positve
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 tot the incorrect sample collection when performing PCR test

/03

TEST RESULTS

SAFETY AND ACCURATELY

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
Total	A+C	94	B+D	267	ABCD	361

Sensitivity = A/(A+C)% = 91.49%
Specificity = D/(B+D)% = 96.63%
Total Accuracy = (A+D)/(ABCD)% = 95.29%

The evaluation is carried out in comparison with the blood sample from COVID-19 nucleic acid test (PCR) confirmed cases in CDC and classIII hospitals

Finger Tip Blood ✔

15 minute Result GET ✔

2-30℃ Storage ✔

12M Shelf-life ✔

FAST ! EASY ! ACCURATE!

Certificate of Analysis

NEWSCEN COAST
BIO-PHARMACEUTICAL CO.,LTD.

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TEL: 86-22-25321648
Web: www.newscen.com
E-mail: business.int@newscen.com

COVID-19 IgG/IgM Rapid Test Cassette

Certificate of Analysis

Document NO.: ZXKJ- COVID-001 User Department: QC Dept.

Product Name	COVID-19 IgG/IgM Rapid Test Cassette		
Lot No.	17C2006	Batch quantity	50,000 pcs
Specification	40 pcs/box	Manufacture Date	2020.03.17
Inspection Date	2020.03.18	Expire Date	02/2021
Report Date	2020.03.18		

Inspection Item	Inspection Standard	Result
Visual Inspection	Appearances complete no damage. Cassette smooth and flawless. Material firmly attached and Complete content.	pass
Negative Reference Product Coincidence Rate	Negative reference sample coincidence rate: 10 negative enterprise reference samples were tested and the results were all negative.	pass
Positive Reference Product Coincidence Rate	Positive reference sample coincidence rate 100%: 5 IgG positive enterprise reference samples were tested and the results were all positive. 5 IgM positive enterprise references samples were tested and the results were all positive.	pass
Lower Limit of Detectability	3 IgG enterprise reference samples of limited detection were used for testing, L1 should be negative, L2 was an uncertain result, and L3 should be positive.	pass
Sophisticated Detection	Test results are consistent, color intensity of test lines are the same.	pass

Conclusion	According to the Enterprise Internal Standards of COVID-19 IgG/IgM Rapid Test Cassette ☐ PASS ☐ NOT PASS				
Remark					
Checker		Reviewer		Person In Charge	

MSDS 1/2

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Email: business.int@newscen.com

Material Safety Data Sheet

Printing date:20130508 **Date Updated: 20130121**

Section 1- Product and Company Information

Product Name: Sample Diluent
Product Number: Not Applicable
Application of the Product: For research use only. Not for use in diagnostic procedures.
Manufacturer: NewScen Coast Bio-Pharmaceutical Co., Ltd
Telephone: +86-22-25321648 Ext: 822
Fax: +86-22-25328062
Emial: business.int@newscen.com

Section 2 –Composition/Information on Ingredient

Description of Components: Na_2HPO_4 0.29%; KH_2PO_4 0.02%; NaCl 0.85%; NaN_3 0.02%; H_2O_2 98.82%
Hazardous Ingredients: No hazardous substances or mixtures are contained

Section 3 – Hazards Identification

Potential Health Effects
Inhalation: None anticipated with normal use
Skin: None anticipated with normal use
Eyes: None anticipated with normal use
Ingestion: May be harmful if swallowed
Potential Effects of Chronic Exposure: None anticipated with normal use
Universal Precautions: All patient samples and contaminated components should be handled as potentially infectious. Wear personal protective equipment and wash hands after handling test.
Warning Properties: None related to the components within this kit.

Section 4 – First Aid Measure

If inhaled: Inhalation of any component is unlikely.
In case of Skin Contact: Wash off with soap and plenty of water.
In case of Eye contact: Flush eyes with water as a precaution.
If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water.

Section 5 – Fire Fighting Measures

Suitable Extinguishing Media: For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.
Special Fire Fighting Procedures: This material will not significantly contribute to the intensity of a fire. Trained emergency responders should wear self-contained breathing

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apparatus and appropriate personal protective gear to prevent contact with skin, eyes and respiratory system.
Unusual Fire and Explosion Hazards: When involved in a fire, this material may decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).
Additional Considerations: Not applicable

Section 6 – Accidental Release Measures

Personal Precautions: Follow Universal Precautions when cleaning-up patient samples.
Environmental Precautions: Not applicable
Spill and Leak Procedures: Not applicable

Section 7 – Handling and Storage

Precautions for Safe Handling:
As with all chemicals and biological substances, avoid getting components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when using this kit.
Conditions for Safe Storage: To maintain efficacy, store according to the package insert instructions.
Specific Use: For in vitro diagnostic use only – Not for use by general public!

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: Not available
Occupational Exposure Controls:
Engineering Controls: No special engineering controls are required when working with this kit.
Personal Protective Equipment (PPE): Safety glasses and disposable gloves are recommended.
Hygiene Measures: Wash hands and work surfaces after handling the components of this kit.
Environmental Controls: No special environmental controls are required.

Section 9 –Physical and Chemical properties

Characteristic	Liquid
Boiling Point, Melting Point, Flash Point, Ignition Temperature (C)	Not applicable
Specific Gravity / Evaporation Rate (Ether = 1)	Not applicable
Vapor Pressure (mm Hg) / Vapor Density (AIR = 1) / pH	Not applicable

MSDS 2/2

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Lower Explosion Limit (LEL) / Upper Explosion Limit (UEL)	Not applicable
Solubility in Water:	Not applicable
Appearance and Odor:	Not applicable

Section 10 – Stability and Reactivity

Characteristic	Liquid
Stability	Stable
Conditions to Avoid	None known
Materials to avoid (Incompatibilities)	None known
Hazardous Decomposition or Byproducts	None known
Hazardous Polymerization	None known

Section 11 – toxicological Information

Toxicity Data for Hazardous Ingredients: No toxicity data available
Primary Routes of Exposure: Overexposures to the components within this kit are unlikely.
Potential Health Effects (Chronic / Acute):
General irritation to skin, eyes and GI tract with repeated contact from the improper use of the test components.
Symptoms of Overexposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for this kit.
Medical Exposure Aggravated by Exposure: None known
Carcinogenicity:
To the best of our knowledge, this kit does not contain any substances that are listed by ACGIH, IARC, NTP or California Prop 65.
Specific target organ toxicity – single or repeated exposure (GHS): No data available

Section 12 – Ecological Information

Ecotoxicity, Mobility, Persistence and Degradability, Bio accumulative Potential and Other Adverse Effects: No data available

Section 13 – Disposal Considerations

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

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Section 14 – Transport information

DOT
Proper Shipping Name: None
Non-Hazardous for transport: This substance is considered for transport.
IATA
Non-hazardous for air Transport: Non-hazardous for air transport.

Section 15 – Regulatory information

U.S. Federal and State Regulations: Not applicable
Label Information – ANSI Z129.1: Not applicable
Canadian Regulations: Not applicable
EU Labeling Classification: Not applicable
Japan – Existing and New Chemical Substances (ENCS): Not applicable

Section 16 – Other information

This MSDS has been prepared in accordance with ANSI Z400.1 format and the guidance provided under the Globally Harmonized System (GHS). Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

/04

PRODUCT SPECIFICATION

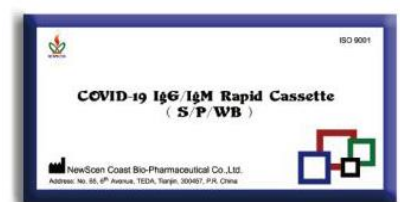
EASY TO USE

FAST TO GET RESULT

PRODUCT VIEW

COVID-19 IgM/IgG TEST

NewScen Coast Bio-Pharmaceutical Co.,Ltd



NewScen SARS-COV-2 Antibody IgM/IgG Rapid Test Kit (Colloidal Gold)

OPERATION MANUAL

CE IVD

COVID-19 IgG/IgM Rapid Test Cassette

For the qualitative detection of IgG/IgM antibodies in serum/ plasma and whole blood
(Single use test cassette)

The instruction must be read carefully and completely prior to the use of COVID-19 IgG/IgM Rapid Test Cassette. Instruction must be followed carefully. If directions are not followed exactly, inaccurate test result may occur. Before performing testing, all operators must read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and Other Blood-Borne Pathogens in Health-Care Settings.

INTENDED USE
COVID-19 IgG/IgM Rapid Test Cassette is for the detection of IgG/IgM in human serum, plasma or whole blood. It cannot be used as the basis for the diagnosis and exclusion of COVID-19.

PRINCIPLE
This kit uses colloidal gold immunochromatography and indirect immune capture principle of comprehensive detection technology to detect IgG/IgM of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum, plasma and whole blood. During detection, the colloidal gold labeled recombinant antigens bind to the SARS-CoV-2 antibodies in the sample to form immune complexes. The immune complexes move forward along the cassette by chromatography. The IgM in the immune complexes will be captured by the pre-coated anti-human IgM on the test zone, condense the color to form the reaction line M. The IgG in the immune complexes will be captured by the pre-coated anti-human IgG on the test zone, condense the color to form the reaction line G. The colloidal gold-labeled chicken IgY antibodies are combined with the pre-coated goat anti-chicken IgY antibodies on the quality control line to form the quality control line C.

REAGENTS AND MATERIALS PROVIDED
1. Test cassette (individually pouched)
2. Each pouch contains one cassette with one desiccant bag
3. Diluent buffer
4. Instruction for use
5. Plastic dropper (optional)

MATERIALS REQUIRED BUT NOT PROVIDED
1. Timer or stopwatch
2. Blood collection devices, for the testing of venipuncture whole blood, serum or plasma
3. Biohazard disposal container
4. Disposable gloves
5. Pipette and pipette tip.

For fingerstick samples, the following materials are required:
Alcohol pad
Sterile lancet
Sterile gauze or cotton

WARNING
For in vitro diagnostic use ONLY
Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false negative result (i.e. a missed positive).

PRECAUTIONS
1. This product is an in vitro diagnostic reagent to qualitatively detect the IgG/IgM of SARS-CoV-2 in human serum, plasma and whole blood.
2. Unqualified samples will lead to wrong results, such as the hemoglobin in the hemolysis sample > 8g/L, triglycerides in hyperlipidemia samples > 15g/L, bilirubin in jaundice samples > 0.2g/L, RF > 1200IU/mL in rheumatoid samples.
3. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
4. Make sure the test is not expired (EXP Date is indicated on the kit box).
5. Do not use the test if the pouch has been perforated.
6. If pipette is used, calibrate pipette frequently to assure the accuracy of dispensing. Use a different disposal pipette tip for each specimen in order to avoid cross-contaminations.
7. Do not modify the test procedure.
8. Each test is for single use only.
9. Blood that has been chemically treated, heated, diluted, or otherwise modified may result in inaccurate results.
10. Always interpret the results under good light conditions to avoid misreading of the results. 11. Different batch of product components cannot be mixed.
12. If desiccant bag is not present in the pouch, DO NOT USE the test.
13. Always add accurate volume of specimen by following the instruction.
14. The test cassette must be used directly after unsealing. It is not allowed to divide it for use.
15. Do not touch the reaction zone of the reagent.
16. If the samples are stored in refrigerator, they should be placed in room temperature before testing.
17. If the detection reagent is stored in refrigerator, it should be restored to room temperature before testing.
18. Read the result in 15~20 minutes. Interpret the test result after 20 minutes may cause false result.

STORAGE
COVID-19 IgG/IgM Rapid Test Cassette should be stored in dark place at 2-30°C for 12 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, use it immediately. Do not use the test beyond the indicated expiration date.

SAMPLE COLLECTION AND TEST PREPARATION
Fingerstick Specimens (Whole Blood)
1. Clean the area to be lanced with an alcohol pad.
2. Squeeze the end of the fingertip and pierce it with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton; collect the sample from the second drop.
4. Use dropper to draw the fresh blood to 1/2 of the tube wall and dispense into the sample well.
Fingerstick whole blood should be used immediately after collection.
Serum/ Plasma specimens: fresh serum or plasma specimen can be used.
Plasma
1. Collect whole blood into a collection tube (containing EDTA, Na-citrate or heparin) by venipuncture.
2. Separate the plasma by centrifugation.
Serum
1. Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. 2. Allow the blood to clot.
3. Separate the serum by centrifugation.
Avoid the use of hemolytic, turbid, microorganism contaminated specimens. Specimen should be stored at 2-8°C for up to 3 days or frozen at -20°C for up to 9 days. Avoid specimen deterioration by multiple freeze-thaw cycles.
Venipuncture Whole Blood
Venipuncture whole blood can be used immediately after collection or stored up to 3 days at 2-8°C.

ASSAY PROCEDURE

1. Sample preparation: Fresh serum, plasma or whole blood samples, no pretreatment is required. If the samples are stored in 2~8°C, the samples should be restored at room temperature for 15~30 minutes before use, returned to room temperature, and thoroughly mixed before testing.
2. Reagent preparation: Open the package, the pouch should be sealed well. If the test reagent stores in the refrigerator, it should be restored to room temperature. Then open the package pouch and take out the test reagent, place it on the platform.
3. Detection and interpretation: Add 10μL serum/plasma or 20μL whole blood sample into S well, after the sample has permeated completely, add 2 drops diluent buffer. Read the result in 15~20 minutes, interpret the test result after 20 minutes may cause false result.

INTERPRETATION OF RESULTS

1. Positive of IgG and IgM: One color line in the control zone (C), one color line in the test zone (G) and one color line in the test zone (M). Indicates IgG and IgM test result is positive.
2. Positive of IgG: One color line in the control zone (C) and one color line in the test zone (G), indicates IgG test result is positive.
3. Positive of IgM: One color line in the control zone (C) and one color line in the test zone (M), indicates IgM test result is positive.
4. Negative of IgG and IgM: Only one color line in the control zone (C) indicates IgG and IgM test result is negative.
5. Invalid: If no color line appears in the control zone (C), the test is invalid. Discard the test cassette and perform with new cassette.

Built-in Control
COVID-19 IgG/IgM Rapid Test Cassette has a built-in procedural control that demonstrates assay validity. A color line appeared on the control zone (C) indicates that the test runs correctly.

LIMITATION
1. The kit is only used to detect human serum, plasma and whole blood sample.
2. The accuracy of the test depends on the process of sample collection. Improper sample collection, improper sample storage or repeated freezing and thawing of samples will affect the test results.
3. The test results of this reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of the patient should be considered in combination with other laboratory tests of the patient's symptoms/signs history and treatment response.
4. Due to the limitation of antibody detection reagent methodology, nucleic acid detection or virus culture identification method is recommended to confirm the negative test results.
5. Too low levels of the virus in the sample can lead to false negative results.
6. The mutation of the virus gene may cause the change of the antibody determination cluster, resulting in false negative results.

PERFORMANCE CHARACTERISTICS
1. Negative reference sample coincidence rate: 10 negative enterprise reference samples were tested and the results were all negative.
2. Positive reference sample coincidence rate: 5 IgG positive enterprise reference samples were tested and the results were all positive. 5 IgM positive enterprise reference samples were tested and the results were all positive.
3. Minimum detectability: 3 IgG limited detection of enterprise reference samples were used for testing, L1 should be negative, L2 was an uncertain result, and L3 should be positive.
3 IgM limited detection of enterprise reference samples were used for testing, L4 should be negative, L5 was an uncertain result, and L6 should be positive.
4. Intra-lot repeatability: Parallel test IgG enterprise repeatability reference sample 10 times, the color development results of parallel determination should be consistent and uniform.
Parallel test IgM enterprise repeatability reference sample 10 times, the color development results of parallel determination should be consistent and uniform.
5. Inter-lot repeatability: Parallel determination of IgG enterprise repeatability reference sample with 3 batches of reagents, each batch repeated 10 times, the color development results of parallel determination between 3 batches should be consistent and uniform.
Parallel determination of IgM enterprise repeatability reference sample with 3 batches of reagents, each batch repeated 10 times, the color development results of parallel determination between 3 batches should be consistent and uniform.
6. Interfering substance: Unqualified samples will lead to wrong results, such as the hemoglobin in the hemolysis sample > 8g/L, triglycerides in hyperlipidemia samples > 15g/L, bilirubin in jaundice samples > 0.2g/L, RF > 1200IU/mL in rheumatoid samples.
7. Cross reaction: The kit has no cross reaction against human immunodeficiency virus antibody, hepatitis B surface antibody, hepatitis C virus antibody, treponema pallidum antibody, mycoplasma pneumoniae antibody, helicobacter pylori antibody positive samples.
8. Clinical sample compliance: A total of 523 clinical samples were tested for validation, of which 142 were positive and 381 were negative. The test results are as follows:

NewGcen	Clinical sample information				Total	
	Positive		Negative			
Positive	A	129	B	0	A+B	129
Negative	C	13	D	381	C+D	391
Total	A+C	142	B+D	381	A+B+C+D	523

Positive coincidence rate:
A/(A+C)% = 90.85% (95% credibility interval: 84.85%～95.04%)
Negative coincidence rate:
D/(B+D)% = 100.00% (95%credibility interval: 99.04%～100.00%)
Total coincidence rate:
(A+D)/ A+B+C+D)% = 97.51% (95%credibility interval: 95.79%～98.67%)

INDEX OF SYMBOLS

2	Do not re-use
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
2°C 30°C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
n	Contains sufficient for < n > tests
CE	CE Mark
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulation to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.
Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin, PEOPLE'S REPUBLIC OF CHINA

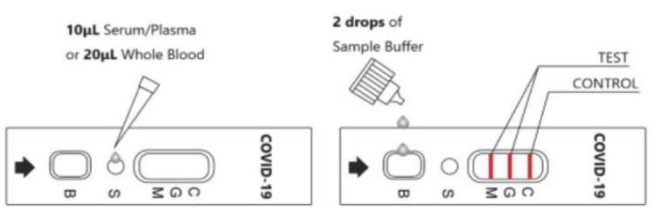
EC REP
Wellkang Ltd
16 Castle St, Dover, Kent, CT16 1PW, England, UK

COVID-19 IgM/IgG TEST

NewScen Coast Bio-Pharmaceutical Co.,Ltd

OPERATION PROCESS

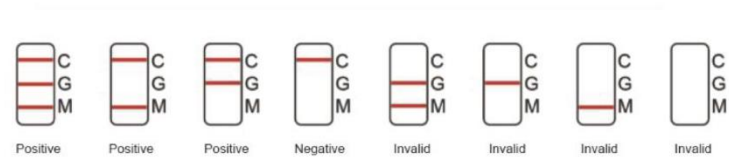
- Add the sample



10uL Serum/Plasma
20uL Whole Blood

INTERPRETATION OF RESULTS

- Observe the result in 15-20minutes



NewScen SARS-COV-2 Antibody IgM/IgG Rapid Test Kit (Colloidal Gold)

PACKAGE SPEC.

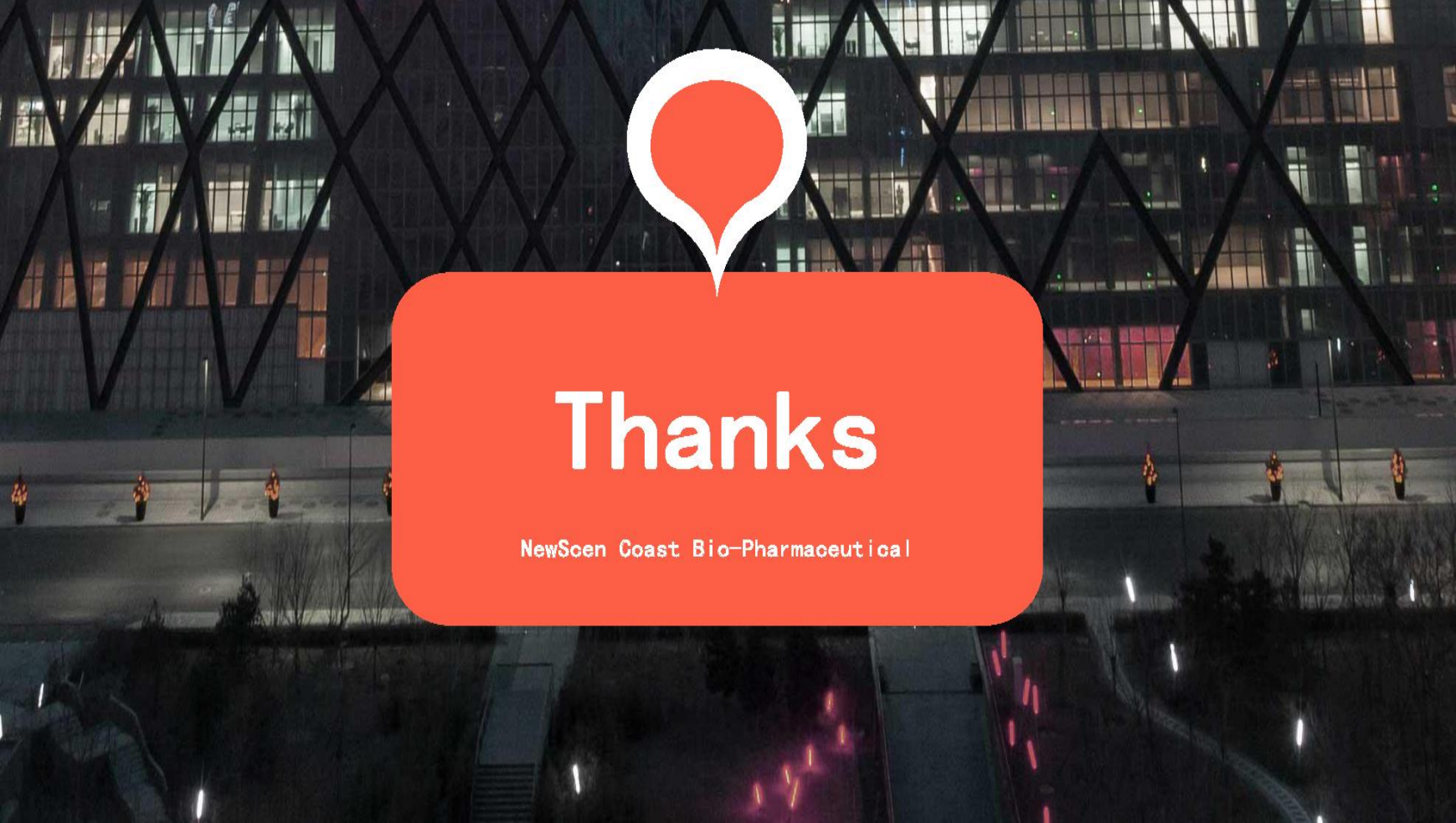
Box size: 250*125*65 mm

Carton size: 65*51*33 cm

Weight/each carton: 18KG

Package: 40pcs/box, and 50 boxes/carton

Totally: 100,000 pcs for 50 cartons


Thanks
NewScen Coast Bio-Pharmaceutical