DIRUI 迪瑞

Together with **DIRUI**

Fight against COVID-19

COVID-19 IgG/IgM Antibody Assay Kit

(Colloidal Gold Method)

Prepared by International Marketing Department

Established in 1992 in Changchun, China, DIRUI is a listed company at the Shenzhen Stock Exchange. The company focuses on the research, development, production, marketing and service of high-quality medical diagnosis products (diagnostic instruments, diagnostic reagents, test strips, etc.), and is committed to becoming a global service provider of overall laboratory solutions. Has been rated as "National Enterprise Technology Center", "National Technology Innovation Demonstration Enterprise", "National Advanced Implementation of Intellectual Property Strategy", won "National Well-known Trademark", "Jilin Province Quality Award", undertook a number of national and provincial Ministerial science and technology projects, including "863 Projects", "National Science and Technology Cooperation Projects", "National Torch Projects“ and so on.

The annual R&D accounts for 10% -15% of the total sales revenue. DIRUI is building an international-level medical devices R&D platform. The current products cover the series of "biochemical analysis, chemiluminescence immunoassay, urine analysis, gynecological secretion analysis, blood cell analysis, coagulation analysis, integrated laboratory" series, covering more than 80% of the routine tests of laboratory. All products have obtained CE marks, and some products have obtained USA FDA approval.

DIRUI has 5 overseas branches and more than 100 distributors all around the world. DIRUI achieve global product distribution, after service, reagent supply and maintenance by professional cooperation with all distributors. DIRUI is a well-known brand in global IVD market. Maintenance and distribution of reagents and supplies in overseas markets.

Together with DIRUI Fight against COVID-19

At the beginning of 2020, a sudden outbreak of a novel coronavirus gripped the hearts of people all around the world.

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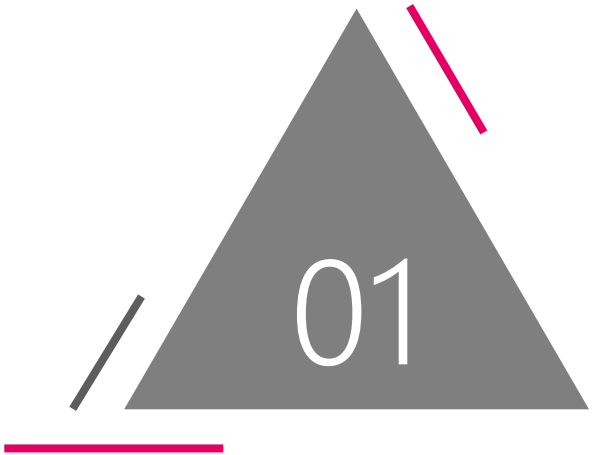
The global campaign against the new coronavirus is under way. Up to now, DIRUI's biochemical analysis, urinalysis, hematology analysis (including CRP detection) and other kinds of products have been successively supplied to centers for disease control and prevention, medical and health institutions all over the world. At the same time, in order to fully cooperate with the pandemic prevention and control work, DIRUI and its five overseas branches urgently set up emergency teams covering production, after-sales, technical support, and clinical application departments, being fully-prepared to provide 24-hour uninterrupted service to more than 100 countries and regions, coordinate emergency delivery at any time, and ensure the normal operation of the installed equipment.

In this battle, DIRUI persisted in the struggle and helped thousands of medical staff to move forward to build a line of life, united against the epidemic!



Brief Introduction

COVID-19 IgG/IgM Antibody Assay Kit

(Colloidal Gold Method)

COVID-19 IgG/IgM Antibody Assay Kit

(Colloidal Gold Method)

COVID-19 IgG/IgM Antibody Assay Kit is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM anti–novel coronavirus nucleoprotein in human serum, plasma or whole blood.

EFFICIENT
Instant result in 15 minutes

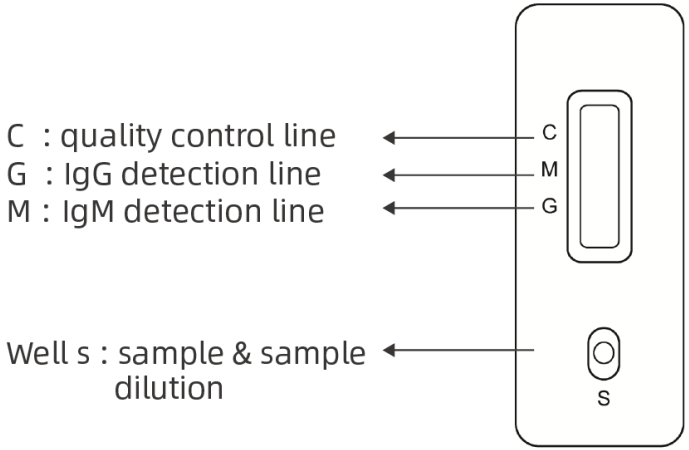
ACCURATE
High-purity antibody
with high accuracy

CONVENIENT
Suitable for finger blood

COVID-19 IgG/IgM Antibody Assay Kit

(Colloidal Gold Method)

- Sample Type: Whole blood / Plasma / Serum
- Sample Volume: 10μL
- Reaction Time: 15 mins
- Packing Size: 20 tests per box
- Storage Condition: 2℃~ 30℃
- Shelf Life: 18 months



Specification

- Packing Size: 20 tests per box, L*W*H=140mm*120mm*7mm
- Carton Size：45 kits per carton (900 tests per carton),

  L*W*H=430mm*370mm*350mm
- Carton Weight：9Kg
- Note：about 0.056m³/ Carton

CE

CE EC DECLARATION OF CONFORMITY CE

PRODUCT IDENTIFICATION			
Product Family Name	Product Name	Model	Registration Number
COVID-19 Detection Kit	COVID-19 IgG/IgM Antibody Assay Kit(Colloidal Gold Method)	20T/Kit	DE/CA20/01-IVD-Luxuslebenswelt-99/20

MANUFACTURER		
Name of Company	Address	Representative
Surge Medical Inc.	No.2，Factory Building 999-999/551-072, Zi' an Countryside, Tong hua Development District. Tonghua City, Jilin Province 134001 P.R. China	Xingjie Li

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/E-mail
Luxus Lebenswelt GmbH	Kochstr. 1, 47877, Willich, Germany	Tel: +0049-1715605732 Fax: +0049-1715605732 Info.m@luxuslw.de

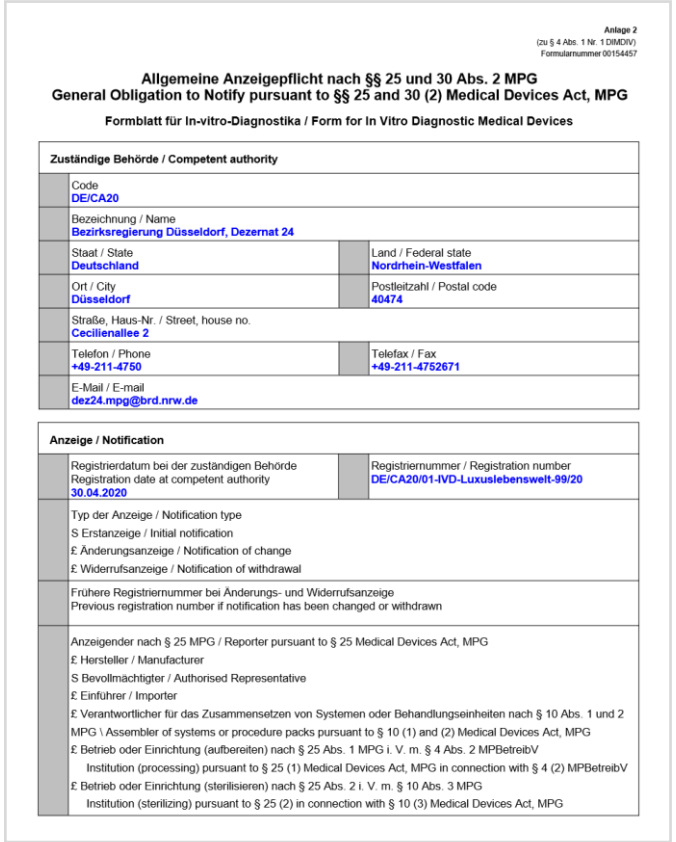
CONFORMITY ASSESSMENT	
Device Classification	Route to Compliance
Class: Others of ANNEX II of IVDD	Annex III of IVDD 98/79/EC Council Directive

Surge Medical Inc. hereby declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Xingjie Li

TITLE: Quality Manager SIGNATURE: Xingjie Li

DATE: May 9th, 2020



Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00154457

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

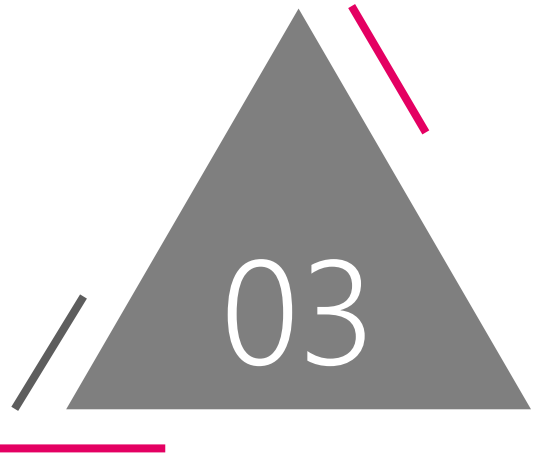
Registrierdatum bei der zuständigen Behörde
Registration date at competent authority
30.04.2020

Registriernummer / Registration number
DE/CA20/01-IVD-Luxuslebenswelt-99/20

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



Operation Steps

COVID-19 IgG/IgM Antibody Assay Kit

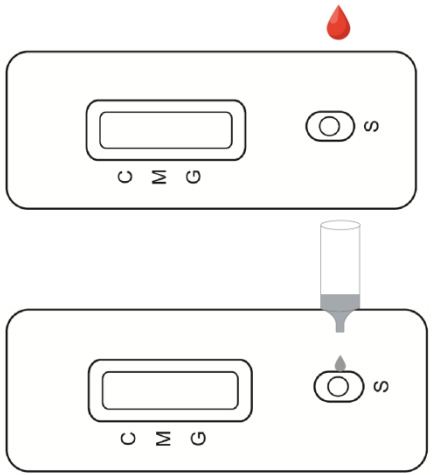
(Colloidal Gold Method)

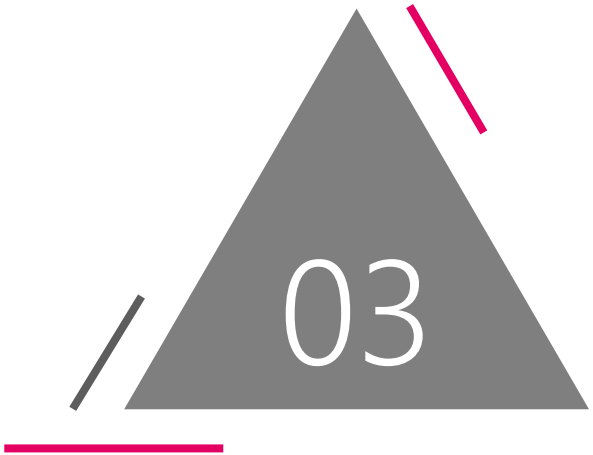
Operation Steps

Step 1 Add 10μL of whole blood, serum or plasma sample to well S.

Step 2 Add two drops (about 60-80μL) of sample dilution to well S, and start timing.

Step 3 The result will be indicated within 15 minutes, after 15 minutes the result is invalid.





Result Interpretation

COVID-19 IgG/IgM Antibody Assay Kit

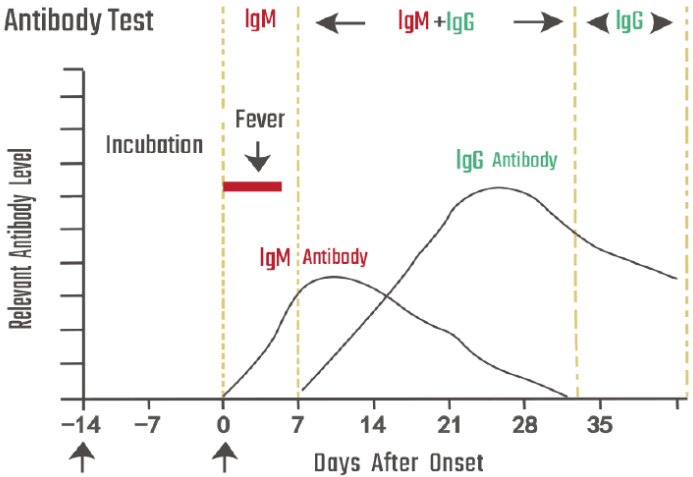
(Colloidal Gold Method)

IgM & IgG Test of SARS-CoV-2 (Colloidal gold)

Immunoglobulin M (**IgM**) comes out first, acting as the **early** sign of infection**.**

Immunoglobulin G (**IgG**) comes out **later**, arising a more specific and stronger reaction against the virus.

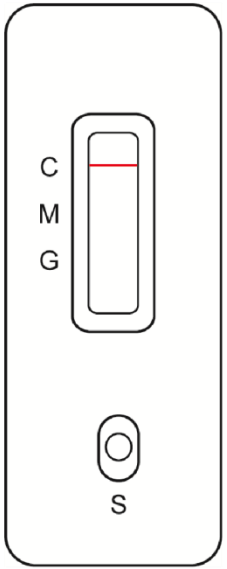
Most of the SARS-CoV-2 IgM antibodies begin to show positive after **3-5** days of onset, and the IgG antibodies are 4 times or higher in the recovery phase than in the acute phase.[1]



Result Interpretation

Negative：

A pink colored band appears only at the control region (C), indicating a negative result for COVID-19 infection or infection at a very early stage (within first few days).



Result Interpretation

Positive:

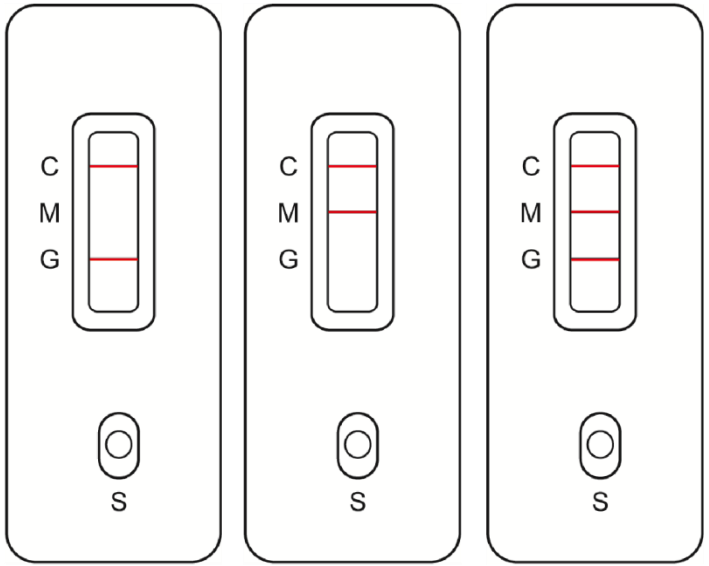
Pink colored bands appear at the control region (C) and M and/ or G region.

1) IgG positive, a visible band at G region, indicating positive result for a possible COVID-19 infection.

2) IgM positive, a visible band at M region, indicating positive result for a possible COVID-19 infection.

3)IgM and IgG positive, visible bands at M and G, indicating positive result for a possible COVID-19 infection.

*IgM can be detected as early as one week after infection, with slightly difference between individuals.

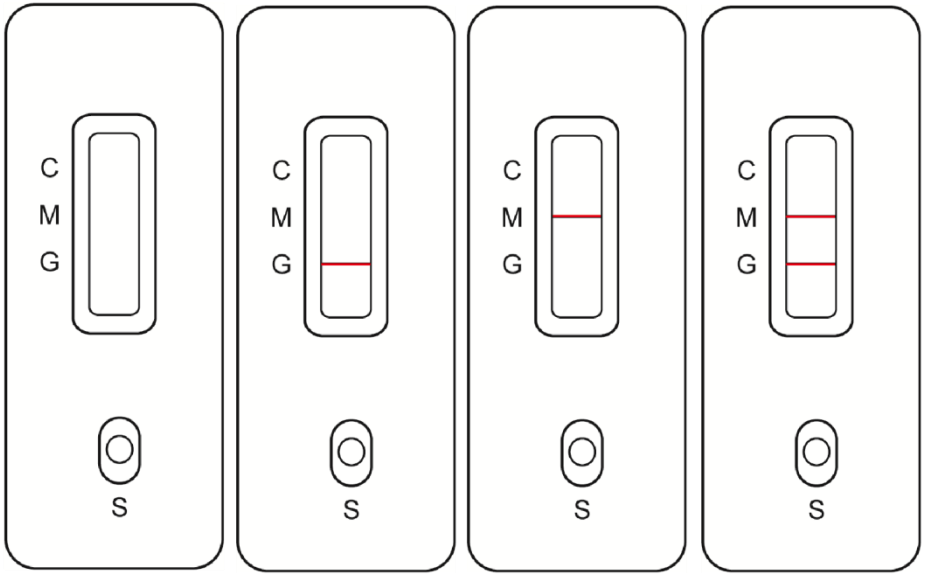


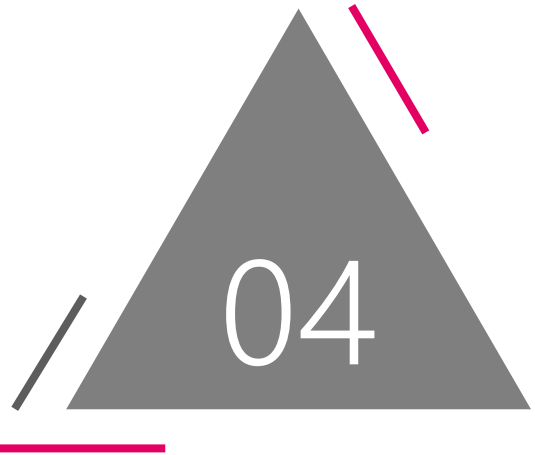
Result Interpretation

Invalid：

No visible band at the control region (C). Repeat with a new test device.

If the test still fails, please contact the distributor with the lot number.





The necessity of joint detection

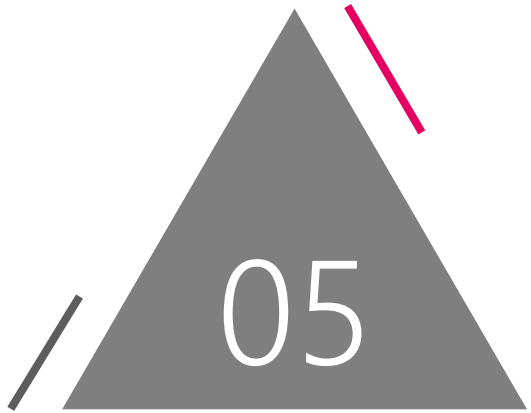
COVID-19 IgG/ IgM & PCR

The necessity of joint detection

PCR	IgM	IgG	Significance	Note	Possibility of infecting others
+	—	—	Incubation Period	At the very beginning, antibody had not been generated by the body.	Possible
+	+	—	Early Stage of Infection	**IgM** is usually the first specific antibody type generated by the body in response to infection while **IgG** had not been generated yet.	Possible
+	+	+	Active Stage of Infection	Antibody had been generated by the body, however the virus load in the body is relatively **high**.	Possible
+	—	+	Middle and late stage of infection	**IgG** quantity could grow **4** times more in recovery period than in the acute infection period.	Possible

The necessity of joint detection

PCR	IgM	IgG	Significance	Note	Possibility of infecting others
—	+	—	Acute Stage of Infection / Mal-operation of sample collection or PCR operation/test kit issue / Patient with rheumatoid	a. IgG is yet generated during the stage of acute infection b. Improper test of samples or PCR c. Interference of other disease for instance the IgM positive caused by RF.	Uncertain
—	—	+	Previous infection	IgG could remain for a long period of time, indicating the infection has passed and had developed immunity without being contagious.	None
—	±	—	Early Stage of Infection / Patient with rheumatoid	**a. IgG** is yet generated b. Interference by **RF**	Uncertain
—	+	+	Acute stage of infection / Patient with rheumatoid	PCR test result could be negative due to low quantity of virus load, continuous monitoring is required.	Uncertain



Application Scenarios

COVID-19 IgG/IgM Antibody Assay Kit

(Colloidal Gold Method)

Public transportation junctions(trains, planes, etc.)

Resumption of companies and schools

Inpatient and caretakers

Who need PCR & IgM/IgG test?

- **The widespread screening of COVID-19 infection risk groups**:

Screening for high-risk groups with suspected epidemiological history

Screening for the public transportation junctions (trains, planes, etc.)

Screening for the resumption of companies

Screening for the resumption of schools

Screening for inpatients and caretakers
etc..

- **Supplementary or joint of nucleic acid testing in designated hospitals:**

Supplementary detection for suspected cases with negative nucleic acid detection

Joint test with nucleic acid detection for the diagnosis of suspected cases

Prognosis monitoring for confirmed cases

It can be **widely used in different case scenarios** such as hospitals, communities, outpatients and other **medical and health institutions**, as well as **other special situations for instance**.

THANKS

A Partner for Life

To be the world class supplier of total laboratory solutions