G-COVID-19 lgM/lgG
Antibody rapid detection kit

G-COVID-19 lgM/lgG Antibody rapid detection kit

(Colloidal gold method)

Rapid screening in 5 to 8 minutes,
no equipment required

Product information

Designation	**G-COVID-19** lgM/lgG Antibody rapid detection kit
Specifications	**10** persons / **25** persons / **50** persons
Sample type and sample size	Serum/plasma /whole blood of **20 μL**,Peripheral blood of **40 μL**
Storage conditions	Sealed and stored at **4-30**℃

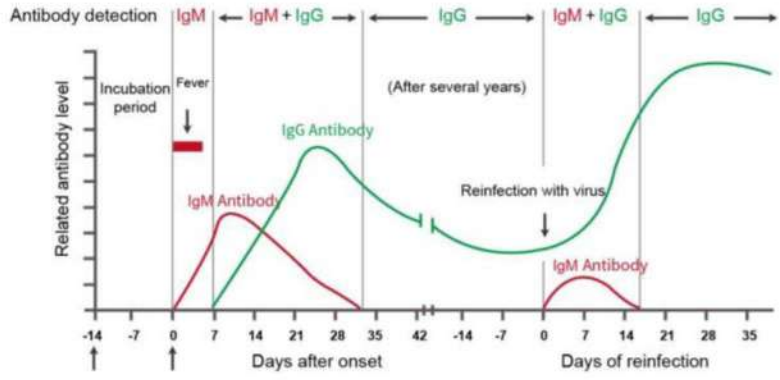
Product advantage

01	It can not only screen in the window period of infection onset, but also indicate the previous infection and reduce the rate of missed diagnosis
02	Blood sample detection, simple sampling, simple operation
03	Combined with nucleic acid kit to improve the screening rate of suspected patients
04	Rapid screening within 5 to 8 minutes, results effective for 15 minutes
05	Single detection, visual interpretation, no equipment, to adapt to the community
06	Easy operation, compatible with different samples
07	Room temperature storage

Application scenarios

Significance of IgM/IgG antibody detection

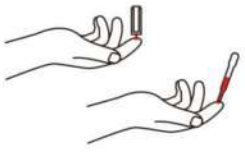
IgG antibody detection is suitable for screening suspected patients, tracking the treatment effect of patients, and determining whether the cured patients have the risk of secondary infection; Compared with IgG, IgM has a tendency of increasing and decreasing earlier, and the content of early stage is high, which is convenient for early screening, and the judgment of treatment effect, and is used with IgG type.



Instructions for use

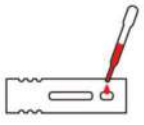
TEST PROCEDURE - Using Capillary whole blood

1 Collecting of Specimen



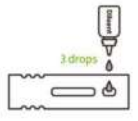
Using a disposable peripheral blood collection needle and capillary tube, collect blood.

2 Adding of Specimen



Squeeze the blood beads the size of mung beans into the sample hole

3 Dropping of Diluent



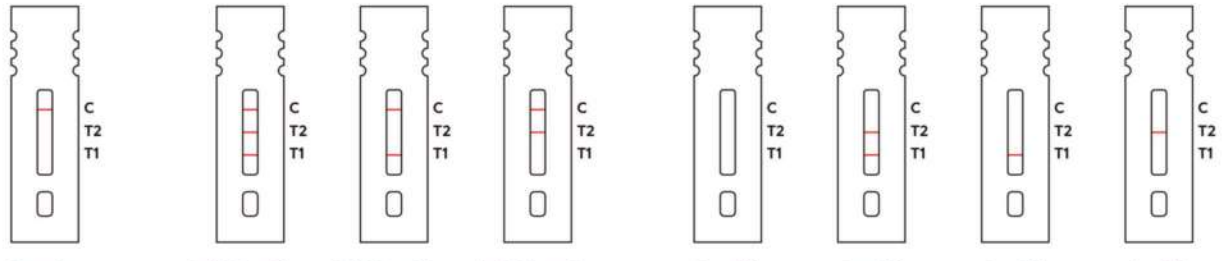
Add 3 drops of diluent vertically into the test device.

4 Reading Tine

10 - 15 mins

Read test result at 10~5 minutes. Do not read after 15 mins. It may five false results.

INTERPRETATION OF TEST RESULT



Negative	IgM:Positive IgG:Positive Positive	IgM:Positive IgG:Negative Positive	IgM:Negative IgG:Positive Positive	Invalid	Invalid	Invalid	Invalid

* Positive: Lind C shows the red ribbon, line T also shows the red ribbon, regardless of the color depth are judged as positive.
* Negative: Lind C shows the red ribbon, line T does not show the red ribbon, is judged as negative.
* Invalid: Lind C does not show the red ribbon, regardless of whether the T line shows the red ribbon, the test paper is invalid.

1. A colored band will appear in the top of the result window to show that the test is working properly. This band is control line(C).
2. A colored band will appear in the lower section of the result window. These bands are test line of IgM/IgG(T1, T2)
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

Gillbio,Inc.
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EC Declaration of Conformity

Manufacturer:

42, Seocho-daero 78-gil, Seocho-gu,
Seoul, Republic of Korea
Republic of Korea
GillBiO inc.

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
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E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

COVID-19 IgM/IgG antibody detection kit (colloidal gold method)

Product Type: **In vitro diagnostic reagent**

Product Classification: **Class I**

We hereby state that:

Those above products with CE marking which are manufactured by our company all comply with In vitro diagnostic medical devices directive(Directive 98/79/EC)and realize their expected uses.

CE

Directive we are following:

European Union Committee In vitro diagnostic medical devices directive (Directive 98/79/EC)

Standards we are implementing:

EN ISO 14971:2012; EN ISO 15223-1:2016; EN ISO 13485:2016/AC:2016;
EN ISO 18113-3:2011; EN ISO 18113-1:2011

42, Seocho-daero 78-gil, Seocho-gu, Seoul, Republic of Korea
Republic of Korea GillBiO inc.

March 12, 2020

Place, date

Legally binding signature, Function

G-COVID-19 lgM/lgG Antibody rapid detection kit usage manual

【Product Name】

Generic name: G-COVID-19 lgM/lgG Antibody rapid detection kit

【Packaging specification】

1 person / 1 pack

【Intended use】

This product does not require any instruments. It is used for the qualitative detection of COVID-19 IgM / IgG antibodies in humans. The entire detection process takes only 5-8 minutes, and the operation is simple and sensitive.

IgG antibody detection is suitable for screening suspected patients, follow-up treatment of patients, and determine whether the cured patients have a risk of secondary infection. IgM has an earlier change trend than IgG, and the content is higher in the early stage, which is convenient for early screening and treatment effect judgment.

【Testing principle】

COVID-19 IgG / IgM antibody detection uses the principle of indirect method and colloidal gold immunochromatography to qualitatively detect new coronavirus antibodies in human serum plasma. COVID-19 recombinant antigen and rabbit anti-IgG labeled on colloidal gold are used as indicator markers. The anti-human IgM antibody, anti-human IgG antibody, and goat anti-rabbit IgG were coated on detection line 1, detection line 2 and control line on the nitrocellulose membrane, respectively. During the detection, the samples were chromatographed under the capillary effect. If the tested sample contains anti-COVID-19 IgG antibody, COVID-19 recombinant antigen combines with the COVID-19 IgG antibody to form a complex. During the chromatography process, it combines with the anti-human IgG antibody fixed at the detection line 2 to form "Au-COVID-19 recombinant antigen-COVID-19 IgG antibody - anti human IgG antibody "sandwich, thus a purple red strip appears in the detection area (T2); if the tested sample contains anti-COVID-19 IgM antibody, the gold standard COVID-19 recombinant antigen combines with the COVID-19 IgM antibody to form a complex, and in the process of chromatography, it combines with the anti-human IgM antibody fixed at the detection line 1 to form" Au-COVID-19 recombinant antigen-COVID-19 " IgM antibody - anti human IgM antibody "sandwich, so there is a purple red band in the detection area (T1); otherwise, there is no purple red band in the detection area (T1) (T2). Whether the novel coronavirus antibody was detected in the samples, the complexes would continue move upward to the control area (C), and a purple red band appeared in the reaction with Sheep anti rabbit IgG. The purple red band in the control region (C) is the standard to judge whether the chromatographic process is normal or not, and it is also the internal control of the reagent.

【Main components】

1. COVID-19 IgM/IgG antibody test kit (1person): each person's aluminum foil bag is individually packed. The kit consists of gold labeled COVID-19 recombinant antigen, anti-human IgM antibody, anti-human IgG antibody, Goat anti COVID-19 polyclonal antibody, and Goat anti mouse NC membrane, plastic backing and plastic template.

2. Diluent: 5ml / tube, composed of phosphate buffer, pH = 7.4 ±0.2.

3. Disposable plastic straw (1 pieces / 1 pack)

4. Operation manual (1 copy / box)

Note: the components in different batches of kits are not interchangeable.

【Storage conditions and validity】

Storage conditions: the original package shall be stored in a dry place away from light at 4-30 ℃, and shall not be frozen.

Validity: 6 months.

The reagent shall be used as soon as possible within 1 hour after the unpacking of the aluminum foil bag; it is recommended to use the reagent as soon as possible when the ambient temperature is higher than 30 ℃ or high humidity.

【Applicable instrument】

Timer, specimen collector, centrifuge

【Sample requirements】

1. The reagent is applicable to whole blood (venous blood or fingertip blood), serum or plasma. The whole blood / plasma / serum samples have no requirements for commonly used clinical anticoagulants (such as EDTA, heparin sodium, sodium citrate, etc.).

2. Hemolysis should be avoided in the whole blood sample.

3. If the serum or plasma samples are tested within 7 days after collection, the samples shall be stored at 2-8 ℃ and frozen (- 20 ℃) if it is more than 7 days; the whole blood samples are recommended to be tested within 3 days, and the samples shall be stored at 2-8 ℃ and shall not be frozen.

4. Before testing, the refrigerated samples must be restored to room temperature, and the frozen samples must be completely melted, re heated and mixed evenly before use. Do not freeze and thaw repeatedly.

【Test method】

1. Before testing, unsealed reagents shall be placed in room temperature to make the temperature of reagents reach balance.

2. Use the matching disposable blood sampling needle to take fingertip blood.

3. Tear the aluminum foil bag along the incision, take out the kit and place it on a clean table. Drop 1 drop of serum, plasma or whole blood sample (about 20 μL) vertically into the sample hole of IgG / IgM test item of the kit, then add 2 drops of diluent, and start timing.

4. Read the result in 8 minutes. The results are valid within 15 minutes.

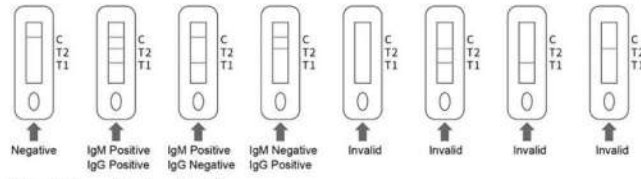
【Interpretation of test results】

IgG / IgM positive: there were purple red bands in the detection area (T1) (T2) and control area (c). The results showed that the samples contained COVID-19 IgG antibody and COVID-19 IgM antibody.

If only two purple red bands appear. One is in the detection area (T1) or (T2) and the other is in the control area (c). The results showed that there were only covid-19 IgM antibody or COVID-19 IgG antibody in the samples.

IgG / IgM negative: there was no purplish red strip in the detection area (T1) (T2), and there was no purplish red strip in the control area (c). The results showed that there was no COVID-19 IgG antibody and covid-19 IgM antibody in the samples.

Invalid: there is no purplish red strip in control area (c), no matter whether there is a purplish red strip in detection area (T1) (T2), the strip is invalid.



【Limitations of test methods】

1. The test results of this product are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with their symptoms, physical signs, medical history, other laboratory tests, treatment reactions and epidemics and other information. It is recommended to retest suspected samples at intervals.

2. this novel coronavirus IgG/IgM antibody is only qualitative test and can not be used for quantitative analysis. If you need to test the specific content of a certain index, please use the relevant professional instruments.

3. The accuracy of the test is affected by the sample collection process. Improper sample collection and storage process will affect the test results and avoid high temperature and direct sunlight.

4. novel coronavirus is limited to the initial screening. The negative results can not exclude the possibility of new coronavirus infection. It is necessary to combine other test results and clinical comprehensive judgement so as to make accurate diagnosis.

【Product performance index】

1. Use the enterprise quality control products for verification, and the results meet the following requirements:

Negative reference conformity rate: 20 negative references were tested, the results were all negative, the conformity rate was 100%.

The coincidence rate of positive references: 10 positive references were tested, the results were all positive, the coincidence rate was 100%.

The lowest detection quantity: four reference samples with the lowest detection quantity were tested, and the results were all positive.

Repeatability: 10 times of parallel test with 2 copies of repeatability reference materials, the results were all positive, and the color was uniform.

Difference between batches: the test results of the three batches of the kits are all positive and the color is uniform.

【Note】

1. Please read the instruction manual carefully before use. The inspector who needs professional training shall operate it, and the test operation shall be carried out in strict accordance with the instructions of the kit.

2. This product is a disposable in vitro diagnostic product, please use it within the validity period.

3. Do not use the aluminum foil bag if it is found damaged. Please use it as soon as possible after unpacking the aluminum foil bag.

4. If the test result is negative and there are clinical symptoms, it is suggested to use other clinical methods for testing. The novel coronavirus infection could not be ruled out by negative results.

5. Temperature has a great influence on the test results.

6. Samples with high concentrations of rheumatic factors or heterophilic antibodies may lead to false positive results.

7. Keep it clean and treat the pollutants as wastes. The waste treatment shall be carried out in accordance with the waste safety treatment, infectious waste safety treatment and infectious waste safety treatment regulations in WS / t249-2005 "principles for waste treatment in clinical laboratories". Please handle with caution.

【Reference】

1. Hui, D. S., I Azhar, E., et al. (2020). The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health-The latest 2019 novel coronavirus outbreak in Wuhan, China [J]. International Journal of Infectious Diseases, 91, 264–266.

2. Templeton, K.E., Scheltinga, S.A., et al. (2004). Rapid and sensitive method using multiplex real-time PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4 [J]. Journal of clinical microbiology 42(4): 1564-1569.

3. Smith, A.B., Mock, V., et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR [J]. Journal of Clinical Virology 28(1): 51-58.

【Approval and modification date of the specification】

March 4, 2020

【Production date and expiration date】

See the sealing part of the package

The test report

Sample type	Sample No.	Age	Gender	Blood type	necleic and tests	C Line	T_2 Line	T_1 Line	Detection Date	Clinical Diagnosis	Admission Date
COVID-19 negative patients	1	54	Male	Whole Blood	Negative	✓			2020.02.21	CHB	outpatient
	2	53	Female	Whole Blood	Negative	✓			2020.02.21	CHB	outpatient
	3	31	Male	Whole Blood	Negative	✓			2020.02.21	HIV	outpatient
	4	25	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	5	27	Male	Whole Blood	Negative	✓			2020.02.21	Hydrothorax	2020.02.21
	6	52	Male	Whole Blood	Negative	✓			2020.02.21	CHB	outpatient
	7	42	Male	Whole Blood	Negative	✓			2020.02.21	CHB	outpatient
	8	18	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	9	44	Male	Whole Blood	Negative	✓			2020.02.21	HIV	outpatient
	10	47	Male	Whole Blood	Negative	✓			2020.02.21	CHB	outpatient
	11	46	Male	Whole Blood	Negative	✓			2020.02.21	CHB	outpatient
	12	37	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	13	50	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	14	30	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	15	71	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	16	45	Female	Whole Blood	Negative	✓			2020.02.21	Physical examination	outpatient
	17	32	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	18	30	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	19	68	Male	Whole Blood	Negative	✓			2020.02.21	TB	outpatient
	20	31	Female	Whole Blood	Negative	✓	✓	✓	2020.02.21	TB	outpatient
COVID-19 positive patients	21	56	Female	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.03
	22	49	Female	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.06
	23	25	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.01.31
	24	74	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.05
	25	53	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.10
	26	72	Male	Whole Blood	Positive	✓	✓		2020.02.22	COVID-19	2020.02.02
	27	53	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.10
	28	72	Male	Whole Blood	Positive	✓	✓		2020.02.22	COVID-19	2020.02.02
	29	74	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.05
	30	61	Male	Whole Blood	Positive	✓	✓		2020.02.22	COVID-19	2020.01.31
	31	46	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.08
	32	56	Female	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.06
	33	56	Female	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.03
	34	49	Female	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.06
	35	25	Female	Whole Blood	Positive	✓			2020.02.22	COVID-19	2020.02.21
	36	25	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.01.31
	37	74	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.05
	38	53	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.10
	39	72	Male	Whole Blood	Positive	✓	✓		2020.02.22	COVID-19	2020.02.02
	40	53	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.10
	41	72	Male	Whole Blood	Positive	✓	✓		2020.02.22	COVID-19	2020.02.02
	42	74	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.05
	43	61	Male	Whole Blood	Positive	✓	✓		2020.02.22	COVID-19	2020.01.31
	44	46	Male	Whole Blood	Positive	✓	✓	✓	2020.02.22	COVID-19	2020.02.08

The test report

Sample type	Sample No.	Age	Gender	Blood type	necleic and tests	C Line	T2 Line	T1 Line	Detection Date	Clinical Diagnosis	Admission Date
COVID-19 positive patients	45	42	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	46	46	Female	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	47	37	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	48	36	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	49	55	Male	Whole Blood	Negative	√			2020.04.20	TB	Outpatient
	50	57	Male	Whole Blood	Negative	√			2020.04.20	CHB	2020.04.09
	51	52	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	52	35	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	53	34	Female	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	54	58	Female	Whole Blood	Negative	√			2020.04.20	TB	Outpatient
	55	42	Female	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	56	31	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	57	33	Male	Whole Blood	Negative	√			2020.04.20	CHB	Outpatient
	58	62	Male	Whole Blood	Negative	√			2020.04.20	TB	Outpatient
	59	54	Male	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.03
	60	58	Male	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.03
	61	60	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.08
	62	55	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.10
	63	30	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.08
	64	32	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.10
	65	47	Male	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.03
	66	44	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.06
	67	33	Female	Whole Blood	Positive	√	√		2020.04.20	COVID-19	2020.03.31
	68	54	Male	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.10
	69	58	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.07
	70	60	Female	Whole Blood	Positive	√	√	√	2020.04.20	COVID-19	2020.04.02
	71	55	Female	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.06
	72	30	Female	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.06
	73	66	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.08
	74	33	Male	Whole Blood	Positive	√	√		2020.04.21	COVID-19	2020.04.08
	75	46	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.07
	76	32	Male	Whole Blood	Positive	√	√		2020.04.21	COVID-19	2020.04.06
	77	44	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.10
	78	41	Male	Whole Blood	Positive	√	√		2020.04.21	COVID-19	2020.04.02
	79	50	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.07
	80	55	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.06
	81	38	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.08
	82	42	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.08
	83	49	Female	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.09
	84	60	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.02
	85	31	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.07
	86	46	Male	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.04.03
	87	33	Female	Whole Blood	Positive	√	√		2020.04.21	COVID-19	2020.04.01
	88	36	Female	Whole Blood	Positive	√	√	√	2020.04.21	COVID-19	2020.03.31

The test report

Sample type	Sample No.	Age	Gender	Blood type	necleic and tests	C Line	T2 Line	T1 Line	Detection Date	Clinical Diagnosis	Admission Date
COVID-19 positive patients	89	41	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.07
	90	31	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.09
	91	34	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.03.31
	92	42	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.03
	93	67	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.02
	94	54	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.07
	95	60	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.06
	96	32	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.10
	97	34	Female	Whole Blood	Positive	✓	✓		2020.04.21	COVID-19	2020.03.30
	98	42	Female	Whole Blood	Positive	✓	✓		2020.04.21	COVID-19	2020.04.03
	99	44	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.08
	100	34	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.09
	101	51	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.10
	102	44	Female	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.07
	103	60	Male	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.08
	104	51	Male	Whole Blood	Positive	✓	✓		2020.04.21	COVID-19	2020.04.03
	105	45	Female	Whole Blood	Positive	✓	✓		2020.04.21	COVID-19	2020.04.02
	106	42	Male	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.06
	107	50	Male	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.10
	108	34	Male	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.09
	109	42	Male	Whole Blood	Positive	✓	✓	✓	2020.04.21	COVID-19	2020.04.07
	110	67	Male	Whole Blood	Positive	✓	✓		2020.04.21	COVID-19	2020.04.02
COVID-19 suspected patients	111	67	Male	Whole Blood	Negative	✓		✓	2020.02.21	PTPI	2020.01.27
	112	64	Male	Whole Blood	Negative	✓		✓	2020.02.21	PTPI	2020.02.15

G-COVID-19 IgM/IgG Antibody rapid detection kit	Sensitivity	94%
	Specificity	97%

Main Raw Research Data

Main raw materials:

Material	
Tetrachloroauric acid hydrate	
COVID-19 Ag	
Anti-human IgG	
Anti-human IgM	
Chicken IgY	
Rabbit anti chicken IgY	
IgM Positive reference	
IgM Positive reference	
Negative reference	

Key protocol

1. colloidal gold preparation:

According to the operation of preparing SOP file of colloidal gold, chloroauric acid was reduced by using the reducing agent trisodium citrate to obtain colloidal gold with a suitable particle size.

Visual observation requires clear and transparent particles without suspended particles or precipitation; observation by transmission electron microscopy requires uniform particle size and particle size of about 40nm.

2. Preparation of gold label conjugate:

According to the colloidal gold-labeled new coronavirus antigen SOP file and colloidal gold-labeled chicken IgY SOP file, the stable coupling between colloidal gold and COVID-19 Ag, colloidal gold and chicken IgY was mainly formed by electrostatic force.

The gold standard conjugate is required to be visually inspected for no suspended particles or precipitation. The BCA method was used to measure the free COVID-19 Ag content and chicken IgY content, and the coating amount was calculated according to the subtraction method.

3. Preparation of gold label bonding pad:

According to the operation of the new coronavirus colloidal gold detection card spraying gold SOP file, the gold label COVID-19 Ag conjugate and the gold label chicken IgY conjugate were mixed in a certain proportion and sprayed on the binding pad.

The bonding pad sprayed with gold label conjugate is required, and the lines are uniform to the naked eye without breakpoints.

4. Preparation of film for quality control line and inspection line:

According to the SOP file of the NC membrane of the new coronavirus colloidal gold test card, the diluted IgG, IgM, and rabbit anti-chicken IgY were respectively coated on the corresponding positions on the NC membrane, and then placed in a 37 ° C oven overnight.

It is required that the lines on the NC film after scribing are uniform without breakpoints.

5. Assembly of new coronavirus colloidal gold detection card:

Assemble the SOP file according to the colloidal gold test card, and complete the corresponding assembly, cutting, and packaging work. The assembled new coronavirus colloidal gold test card needs to meet the requirements of enterprise reference product testing.

6. Preparation of reference products for new coronavirus IgM / IgG detection reagents:

According to the SOP file of the new coronavirus IgM detection reagent enterprise reference product configuration and the new coronavirus IgG detection reagent enterprise reference product configuration SOP file, the purchased IgM and IgG positive reference materials were configured to the corresponding

concentrations using fetal bovine serum, respectively. (Refer to the reference product concentration in Appendix 1: New Coronavirus IgM / IgG Detection Reagent Enterprise Reference Product Manual)

Stability Research Data

After testing at least three different batches of the COVID-19 IgM/IgG antibody rapid detection kit at 37 °C for 20 days, the performance of the product should meet at least the positive reference rate, negative reference rate, repeatability, minimum detection limit, Technical requirements for precision between batches.

1. Positive reference rate

Take 20 copies from the same batch of the COVID-19 IgM / IgG rapid antibody detection kit (batch number: 20021801, which has been placed at 37 ° C for 20 days) to detect the reagents, and follow the instructions to use 10 copies of the enterprise IgM positive reference at different concentrations. Products (P1-P10) for IgM positive detection and 10 different concentrations of enterprise IgG positive reference products (P11-P20) for IgG positive detection, the results should meet the corresponding technical requirements.

Reference type	No.	Result
IgM positive reference	P1	+
	P2	+
	P3	+
	P4	+
	P5	+
	P6	+
	P7	+
	P8	+
	P9	+
	P10	+
IgG positive reference	P11	+
	P12	+
	P13	+
	P14	+
	P15	+
	P16	+
	P17	+
	P18	+
	P19	+
	P20	+

"+" Means positive test result, "-" means negative test result

The test results of 10 IgM antibody positive reference products were all positive, and the positive reference product compliance rate (+/+) was

10/10; the test results of 10 companies' IgG antibody positive reference products should be all positive, and the positive reference product compliance rate (+/+) is 10/10, which meets the corresponding technical requirements.

2、Negative reference rate

Take 10 copies of the new batch of COVID-19 IgM / IgG antibody rapid detection kit (batch number: 20021801, which has been placed at 37 ° C for 20 days) to detect the reagents, and follow the instructions to use 10 copies of the company negative reference product (N1-N10) Test, the results should meet the corresponding technical requirements.

Reference type	No.	Result
Negative reference	N1	-
	N2	-
	N3	-
	N4	-
	N5	-
	N6	-
	N7	-
	N8	-
	N9	-
	N10	-

"+" Means positive test result, "-" means negative test result

The test results of the 10 negative reference materials were all negative, and the compliance rate (-/-) of the negative reference materials was 10/10, which met the corresponding technical requirements.

3、Repeatability

Take 40 copies of the same batch of the COVID-19 IgM / IgG antibody rapid detection kit (batch number: 20021801, which has been placed at 37 °C for 20 days) to detect the reagents. Follow the instructions and use the enterprise IgM repeatable reference products (Q1, Q2). Repeat the test 10 times and the company IgG repeatability reference product (Q3, Q4) respectively repeat the test 10 times, the results should meet the corresponding technical requirements.

Reference type	No.	Result
IgM Repeatable reference	Q1	+
	Q1	+
	Q1	+

	Q1	+
	Q1	+
	Q1	+
	Q1	+
	Q1	+
	Q1	+
	Q1	+
IgM Repeatable reference	Q2	+
	Q2	+
	Q2	+
	Q2	+
	Q2	+
	Q2	+
	Q2	+
	Q2	+
	Q2	+
	Q2	+
IgG Repeatable reference	Q3	+
	Q3	+
	Q3	+
	Q3	+
	Q3	+
	Q3	+
	Q3	+
	Q3	+
	Q3	+
	Q3	+
IgG Repeatable reference	Q4	+
	Q4	+
	Q4	+
	Q4	+
	Q4	+
	Q4	+
	Q4	+
	Q4	+
	Q4	+
	Q4	+

"+" Means positive test result, "-" means negative test result

IgM repeatable reference Q1 was used for 10 repeated tests, and the results were all positive, and there was no significant difference in color development, which was consistent with the corresponding technical

requirements; IgM repeatable reference Q2 was used for 10 repeated tests, and the results were all positive There is no obvious difference in color consistency, which meets the corresponding technical requirements; 10 repeated tests of IgG repeatability reference Q3, all of which are positive, and there is no significant difference in color consistency, which meets the corresponding technical requirements; 10 repeats of IgG repeatability reference Repeated tests, all the results were positive, and there was no significant difference in color consistency, which met the corresponding technical requirements.

4、Minimum detection limit

Take 18 copies of COVID-19 IgM / IgG antibody rapid detection kit (batch number: 20021801, which has been placed at 37 °C for 20 days) to detect reagents, and follow the instructions to use the IgM minimum detection limit reference product (L1, L2, L3). Detection, each IgM minimum detection limit reference is repeated 3 times; using enterprise IgG minimum detection limit reference (L4, L5, L6) detection, each IgG minimum detection limit reference is repeated 3 times, the result should meet the corresponding technical requirements.

Reference type	No.	Result
IgM Minimun detection limit reference	L1	+
	L1	+
	L1	+
	L2	+
	L2	+
	L2	+
	L3	+
	L3	-
	L3	-
IgG Minimun detection limit reference	L4	+
	L4	+
	L4	+
	L5	+
	L5	+
	L5	+
	L6	+
	L6	-
	L6	+

"+" Means positive test result, "-" means negative test result

IgM's lowest detection limit reference was used to test. The results were positive for L1 and L2 three times, and three times for L3, one

positive and two negative. The minimum detection limit of IgG was tested with reference products. The results were positive for L4 and L5 three times, three times for L6, two times positive, and one time negative.

5、Inter-assay precision

Take three batches of 20 copies of COVID-19 IgM / IgG antibody rapid detection kit (batch number: 20021801, which has been stored at 37 ° C for 20 days; batch number: 20021601, which has been stored at 37 ° C for 20 days. (Stored at 37 ℃ for 20 days) detection reagents, operate according to the instructions, use the company IgM precision reference product (PC1) for IgM repeatability test and the company IgG precision reference product (PC2) for IgG repeatability test, the results should meet the corresponding skills requirement.

Lot number: 20021601 COVID-19 IgM / IgG antibody rapid detection kit

Reference type	No.	Result
IgM Precision reference	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
IgG Precision reference	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+

"+" Means positive test result, "-" means negative test result

Lot number: 20021701 COVID-19 IgM / IgG antibody rapid detection kit

Reference type	No.	Result

IgM Precision reference	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
IgG Precision reference	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+

"+" Means positive test result, "-" means negative test result

Lot number: 20021801 COVID-19 IgM / IgG antibody rapid detection kit

Reference type	No.	Result
IgM Precision reference	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
	PC1	+
IgG Precision reference	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+
	PC2	+

	PC2	+
	PC2	+
	PC2	+
	PC2	+

"+" Means positive test result, "-" means negative test result

IgM precision reference products were used for repeatability testing of three batches of test cards, and the results were all positive, and there was no significant difference in color consistency, which met the corresponding technical requirements; IgG precision reference products were used for repeatable detection of three batches of test cards. Results All were positive, and there was no significant difference in color development, which met the corresponding technical requirements.