COVID-19 IgM/IgG Antibody Test

For *In Vitro* Diagnostic Use Only

Made in the USA

Easy, Efficient & Accurate Screening Device for COVID-19

- COVID-19 Positive/Negative Results in 15 Minutes
- Works with Fingerstick, Whole Blood, Serum or Plasma
- Increased Screening with IgM and IgG Antibody Detection
- Ideal High-Volume Screening Device to Complement Nucleic Acid Tests

MYMsupply Lab, Inc. USA

W+H®

MYM Laboratory & Medical Supply, Inc | 8684 Ave de la Fuente Ste 14, San Diego, CA 92154 | +1 (619) 710.0126 | ryumymlab@gmail.com

Testing for Antibodies

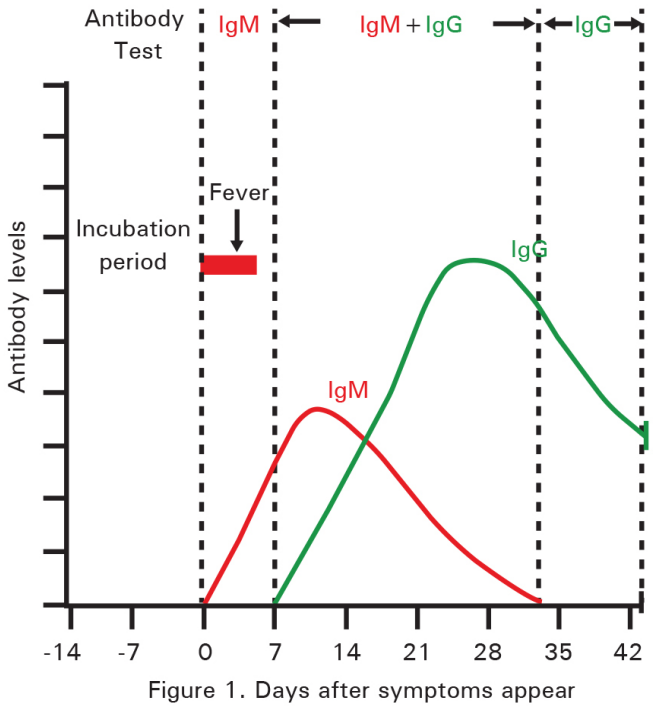

Figure 1. Days after symptoms appear

The human immune system is an incredibly effective defense mechanism in fighting and protecting the body against disease. When a patient is infected by the SARSCoV-2 virus, the immune system will begin to form IgM antibodies as the first line of defense. While IgM antibodies are effective in the fight against infection, as the immune system mounts a more direct defense against the infection the body will begin to form specialized IgG antibodies. IgG antibodies are highly specific to the disease in question, they will appear in a later
stage of the infection and remain in the body for some time after the infection has been defeated.

The COVID-19 IgM/IgG Antibody Test is designed to quickly detect and differentiate both the IgM and IgG antibodies produced by the immune system during a COVID-19 infection.

- The IgM antibody can be detected in patient specimen 3-6 days after infection
- Positive result indicate a presumptive infection
- Negative results are a presumptive indication of no infection

COVID-19 IgM/IgG Antibody Test	
Clinical Sensitivity	93.5%
Clinical Specificity	100%
Relative Accuracy	97.9%

Test Results	Colloidal Gold	Fluorescence-PCR
Test Time	15 Minutes	3-4 Hours
Operation Method	Simple without supporting equipment required	Complex with supporting equipment required
Portability	Highly portable and stable test device at room temperature. Testing can be conducted at point of care including certified small labs, clinics or patient.	Requires highly complex equipment only available in large hospitals

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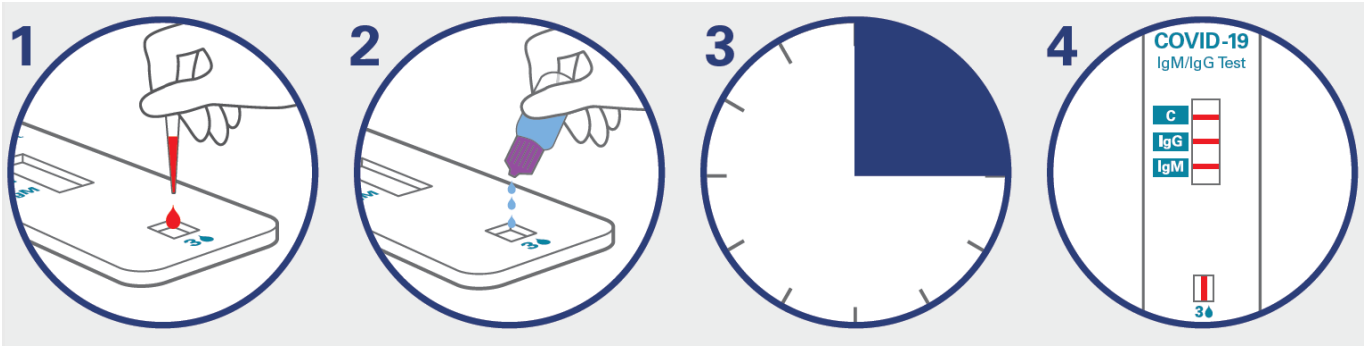
Finger Stick/Whole Blood Testing Procedure



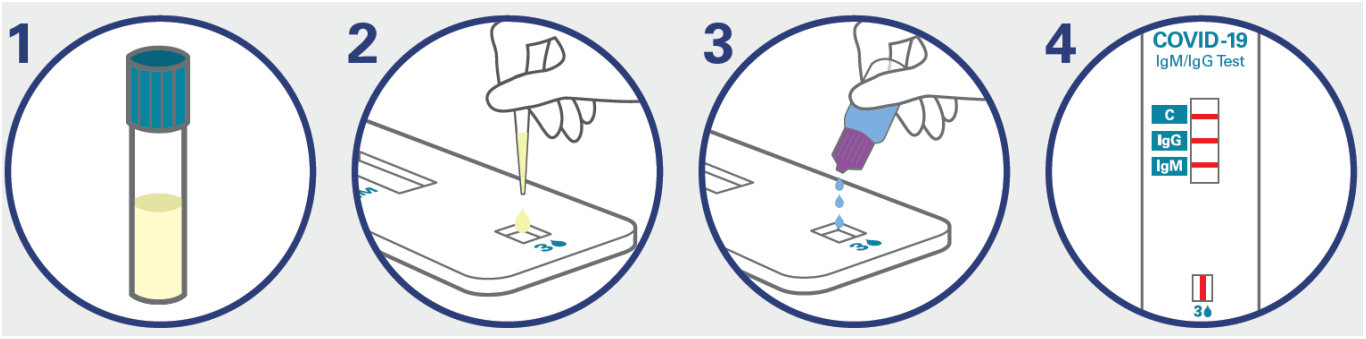
Collect 20ul whole blood and add sample to the sample well on the test.

Place 2-3 drops of buffer into the sample well.

Wait 15 minutes.

Read results.

Serum/Plasma Testing Procedure



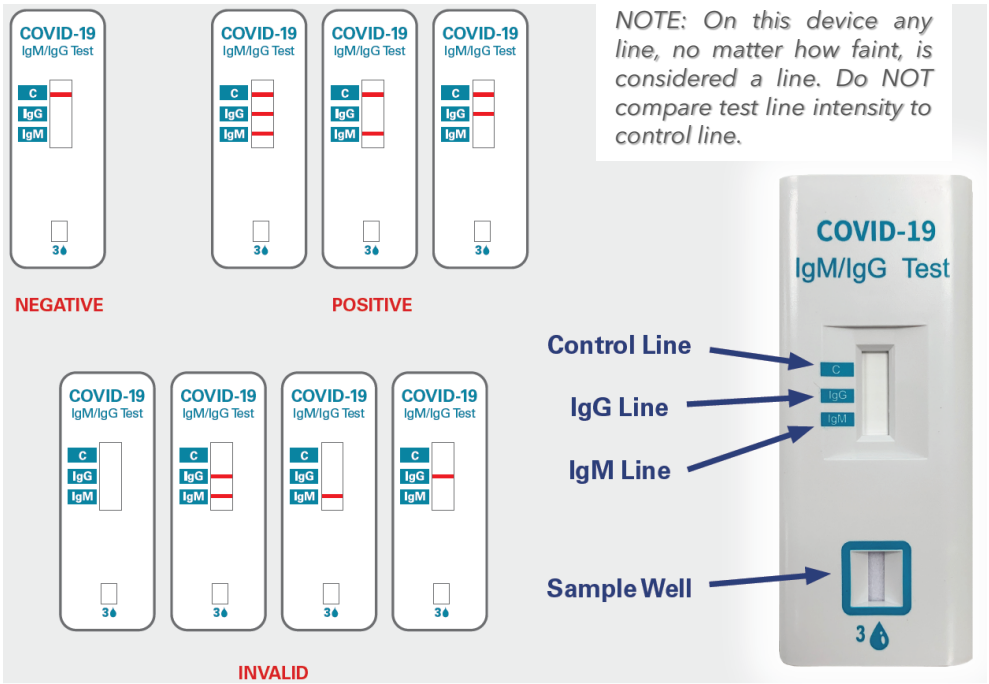
Collect 10ul of serum/plasma.

Add serum/plasma sample to sample well.

Place 2-3 drops of buffer in sample well.

Read results after 15 minutes.

Results Interpretation



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Serum/Plasma Testing Procedure

PCR (Ag test)	IgM Ab	IgG Ab	Clinical Implications
+	-	-	Patients may be in the "window period" of SARS-COV-2 infection.
+	+	-	Patient may be in the early stage of infection, and the body's immune response first produced the antibody IgM, but no IgG was produced, or the IgG content did not reach the detection limit of the diagnostic reagent.
+	-	+	Patients may be in late or recurrent stage of infection.
+	+	+	Patient is in the active phase of infection, but the human body has developed some immunity to SARS-COV-2 (the persistent antibody IgG has been produced).
-	+	-	Patient may be in the acute phase of SARS-COV-2 infection. At this time, nucleic acid test result need to be considered (PCR may be false negative).
-	-	+	Patient may be have been infected with SARS-COV-2 in the past, but the patient has been recovered or the virus in body has been cleared.
-	+	+	Patient has recently been infected with SARS-COV-2 and is in the recovery stage. Or the nucleic acid test result is false negative and the patient is in the active infection stage.

COVID-19 IgM/IgG Rapid Test		Know Healthy Individuals		
		Positive	Negative	Total
IgM	Positive	0	0	0
	Negative	0	100	100
IgG	Positive	0	0	0
	Negative	0	100	100
Total		0	200	200

Seroconversion Timeline Evaluation		Confirmed COVID-19 Positive Specimens		
		4-10 Days	11-24 Days	Total
Confirme Positives		10	36	46
COVID-19 IgM/IgG Rapid Test	IgM Positive	7	34	41
	IgG Positive	2	36	38

COVID-19 IgM/IgG Rapid Test		Confirmed COVID-19 Patient Specimens & Healthy Individuals Specimens		
		Positive	Negative	Total
IgM/IgG	Positive	43	0	43
	Negative	3	100	103
Total		46	100	146

PROFESSIONAL LAB KIT INCLUDES:

25 Cassettes • 1 Buffer Tube (5mL) • 25 Pipettes (20µL)

MYMsupply Lab, Inc. USA

Manufacturer by: W+H

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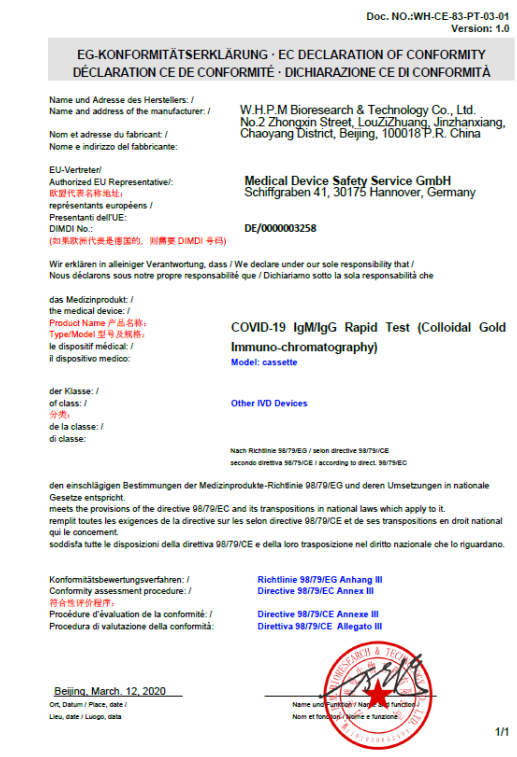
Certificates



Doc. NO.:WH-CE-83-PT-03-01
Version: 1.0

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

W.H.P.M Bioresearch & Technology Co., Ltd.
No.2 Zhongxin Street, LouZiZhuang, Jinzhanxiang,
Chaoyang District, Beijing, 100018 P.R. China

EU-Vertreter/
Authorized EU Representative/:
欧盟代表名称地址：
représentants européens /
Presentanti dell'UE:
DIMDI No.:
(如果欧洲代表是德国的，则需要 DIMDI 号码)

Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

DE/0000003258

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
Product Name 产品名称：
Type/Model 型号及规格：
le dispositif médical: /
il dispositivo medico:

COVID-19 IgM/IgG Rapid Test (Colloidal Gold Immuno-chromatography)
Model: cassette

der Klasse: /
of class: /
分类：
de la classe: /
di classe:

Other IVD Devices

Nach Richtlinie 98/79/EG / selon directive 98/79/CE
secondo direttiva 98/79/CE / according to direct. 98/79/EC

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht.
meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.
remplit toutes les exigences de la directive sur les selon directive 98/79/CE et de ses transpositions en droit national qui le concernent.
soddisfa tutte le disposizioni della direttiva 98/79/CE e della loro trasposizione nel diritto nazionale che lo riguardano.

Konformitätsbewertungsverfahren: / **Richtlinie 98/79/EG Anhang III**
Conformity assessment procedure: / **Directive 98/79/EC Annex III**
符合性评价程序：
Procédure d'évaluation de la conformité: / **Directive 98/79/CE Annexe III**
Procedura di valutazione della conformità: **Direttiva 98/79/CE Allegato III**

Beijing, March. 12, 2020
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione:

1/1

TÜVRheinland

CE Technical Documentation Review Report

Applicant:	**W.H.P.M. Bioresearch & Technology Co., Ltd.** No. 2 Zhongxin Street, LouZiZhuang, Jinzhanxiang, Chaoyang District, Beijing 100018, China
Report Number:	**60354884-001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	COVID-19 IgM/IgG Rapid Test (Colloidal Gold Immuno-chromatography)
Type(s)/Model(s):	Cassette
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.24.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (WH-CE-83, Revision 1.0, Dated 2020-Mar-16) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

Yuhong CHEN
Vice General Manager | Medical Greater China
TÜV Rheinland (China) Ltd.

To verify the report validity, please send email to: service-gc@tuv.com
or please visit our official website: http://www.tuv.com

Unit 707, AVIC Bldg., No. 108, Central Road, East 3rd Ring Road,
Chaoyang District, Beijing, 100022, P.R.China

(Rev.02, 2020-03-24)

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

W.H.P.M., Inc.
5358 Irwindale Avenue
Irwindale CA 91706
USA

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-12-18
Certificate Registration No.:	SX 60132864 0001
An audit was performed. Report No.:	16804804 004
This Certificate is valid until:	2021-09-22

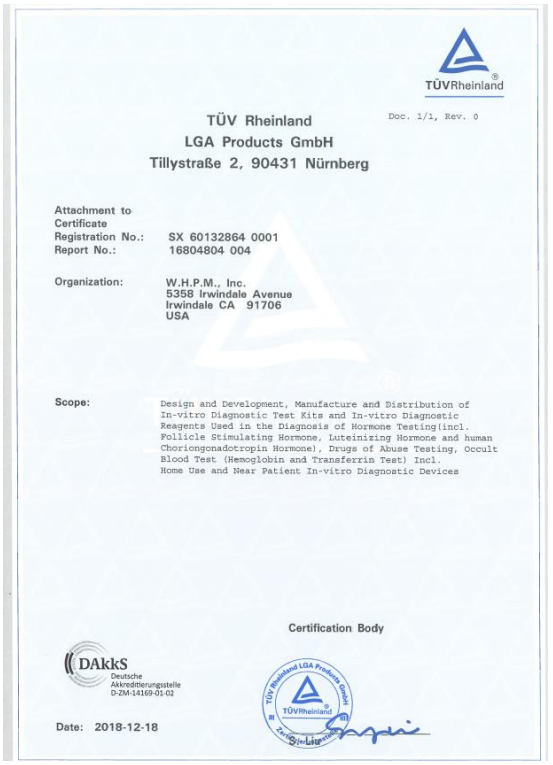
Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2018-12-18

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety



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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60132864 0001
Report No.: 16804804 004

Organization: W.H.P.M., Inc.
5358 Irwindale Avenue
Irwindale CA 91706
USA

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Test Kits and In-vitro Diagnostic Reagents Used in the Diagnosis of Hormone Testing(incl. Follicle Stimulating Hormone, Luteinizing Hormone and human Choriongonadotropin Hormone), Drugs of Abuse Testing, Occult Blood Test (Hemoglobin and Transferrin Test) Incl. Home Use and Near Patient In-vitro Diagnostic Devices

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date: 2018-12-18

S. Liu