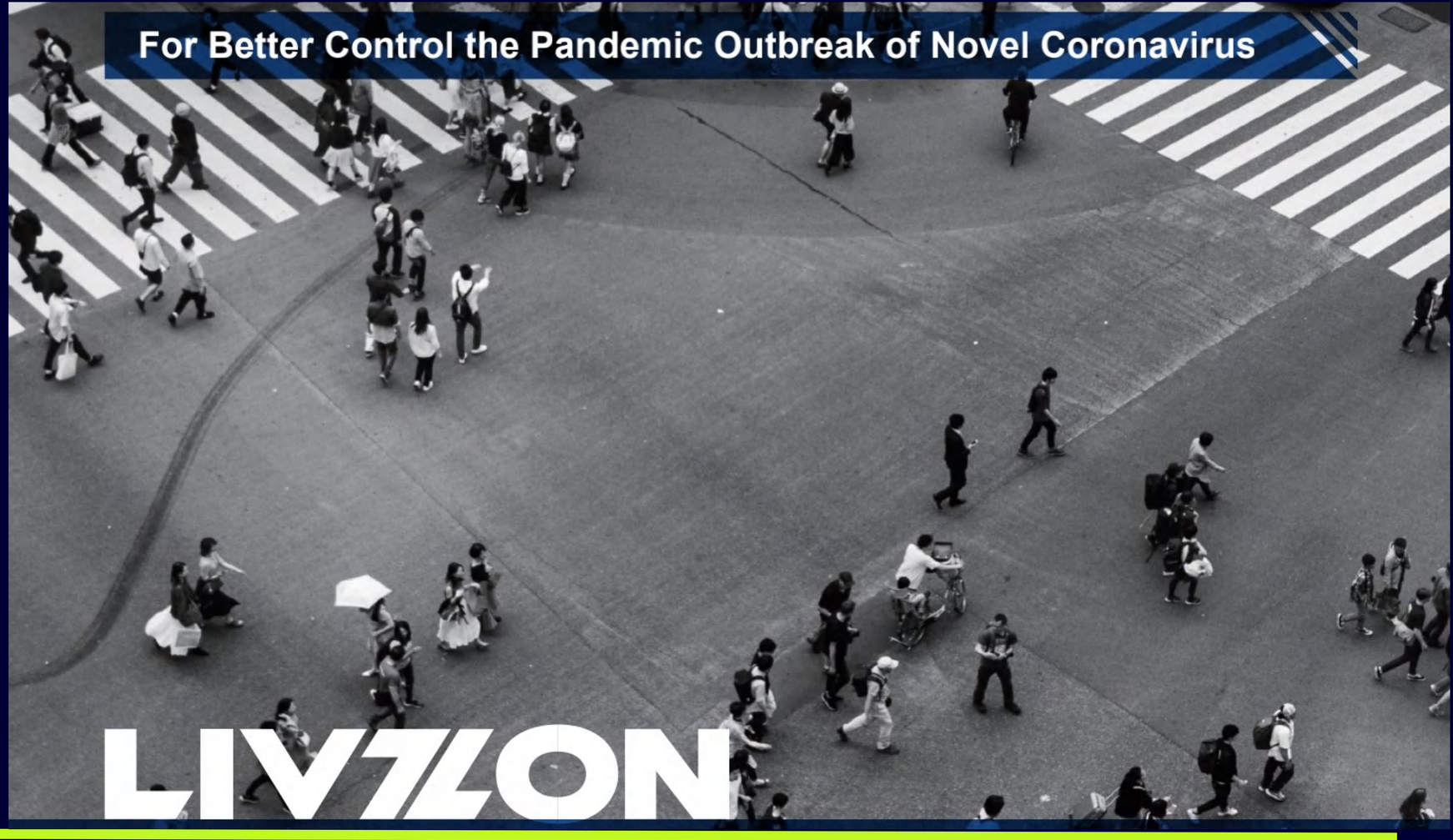
DIAGNOSTIC KIT
IgM/IgG



GMMIT GmbH
Wiesenstr.5 , 63225 Langen, Geramany
info@gmmit.com

GMMIT GmbH

Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)

CE IVD CFDA(NMPA) FSC TÜV WHO FIND Because diagnosis matters Program Listing

- *Whole Blood, Serum and Plasma Sample Types*
- *Result in 1-15min visually*
- *Independent IgM and IgG results*
- *Validated by Hundreds of Clinical Samples*
- *CFDA/NMPA approved, CE labeled*

ZHUHAI LIVZON DIAGNOSTICS INC.

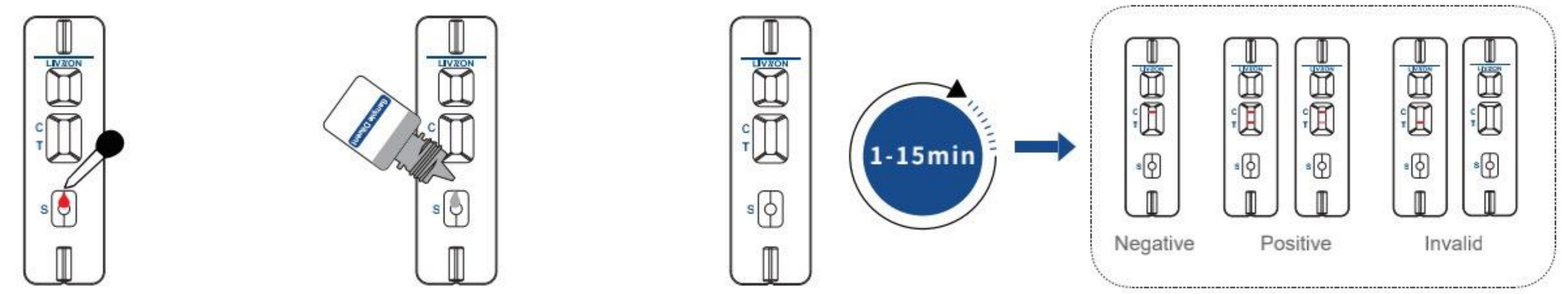
GMMIT GmbH

Rapid and Easy to Use, Auxiliary test for the diagnosis of COVID-19

- Ideal complement to coronavirus nucleic acid tests (RT-PCR etc.) to avoid misdiagnosis
- Independent IgM and IgG results in one kit, capable for confirmation of COVID-19
  (according to the *Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia 7th Edition* by the National Health Commission of P.R.China)
- Much easier and faster way to test people on site
- Possible to find asymptomatic carriers and to confirm hospital discharge

GMMIT GmbH

One-Step Rapid Test for Diagnosing COVID-19



Add Sample | 2 Drops of Diluent Buffer | Wait and View Result

Abundant Clinical Validation Shows Excellent Diagnostic Performance

Tests		Clinical Diagnosis Criteria		Total
		Diagnosed	Excluded	
IgM/IgG	Positive	259	3	262
	Negative	27	355	382
Total		286	358	644

IgM and IgG combined sensitivity and specificity is 90.6% and 99.2% respectively.

Total accordance rate equals 95.3%.

Product Name	Packing Size	Storage Temperature	Sample Type and Volume Needed
Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2)(Lateral Flow)	10 Test Sets/Kit, 20 Test Sets/Kit,	2-30°C	Plasma/Serum: 10μL Whole Blood: 20μL

GMMIT GmbH

珠海丽珠试剂股份有限公司
ZHUHAI LIVZON DIAGNOSTICS INC.

Declaration of Conformity

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

Manufacturer:			Zhuhai Livzon Diagnostics Inc.
Address:			No.266,Tongchang Road, Xiangzhou District, 519060 Zhuhai, P.R.China
EU Representative:			Shanghai International Holding Corp. GmbH (Europe)
Address:			Eiffestrasse 80, 20537 Hamburg，Germany

We declare under our sole responsibility that

the IVD Medical Device	Product Name	:	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)
	Type/model, batch/serial number, possibly sources and number of items (Where applicable)	:	Model: 10 Test Sets/Kit 20 Test Sets/Kit
of class	according to directive 98/79/EC	:	Other device ,not in Annex Ⅱ, not for self-testing ,not for performance evaluation

meets all the provisions of the directive 98/79/EC which apply to it.

Applied harmonised standards, national standards or other normative documents	EN ISO15223-1:2016	EN ISO 13485:2016
	EN 13612:2002	EN 23640:2015
	EN 13641:2002	EN 13975:2003
	EN ISO 14971:2012	EN ISO 18113-1:2011
	EN ISO 18113-2:2011	1272/2008 EC

Conformity assessment procedure: Annex Ⅲ: EC Declaration of Conformity

Zhuhai

2020.3.13

CE

Director of Quality & Regulation

DaiJunYing

珠海丽珠试剂股份有限公司
ZHUHAI LIVZON DIAGNOSTICS INC.

符合性声明

按体外诊断医疗器械指令 98/79/EC

制造者名称：	珠海丽珠试剂股份有限公司
地　　址：	珠海市香洲区同昌路266号　邮政编码：519060
欧盟代表：	Shanghai International Holding Corp. GmbH (Europe)
地　　址：	Eiffestrasse 80, 20537 Hamburg，Germany

我方完全以自己的责任声明

体外诊断医疗器械	名称	：	新型冠状病毒IgM/IgG抗体检测试剂（胶体金法）
	型号，批号、系列号，可能的来源和货号(如适用)	：	规格：10人份/盒，20人份/盒
分类	按体外诊断医疗器械指令	：	非附录Ⅱ中的其他医疗器械，不用于自测和性能评估

满足医疗器械指令98/79/EC中所有适用的条款。

适用的协调化标准，国家标准和其它标准化文件	EN ISO15223-1:2016	EN ISO 13485:2016
	EN 13612:2002	EN 23640:2015
	EN 13641:2002	EN 13975:2003
	EN ISO 14971:2012	EN ISO 18113-1:2011
	EN ISO 18113-2:2011	1272/2008 EC

符合性评审程序　附录Ⅱ：EC合格声明

珠海

2020.3.13

CE

质量法规总监

戴俊英

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

Q5 098773 0003 Rev. 00

Holder of Certificate: **Zhuhai Livzon Diagnostics Inc.**
No.266,Tongchang Road, Xiangzhou District
519060 Zhuhai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Zhuhai Livzon Diagnostics Inc.
No.266,Tongchang Road, Xiangzhou District, 519060 Zhuhai,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:
Design and Development,
Production and Distribution of
ELISA Diagnostic Kit,
Colloidal Gold Diagnostic Kit,
Clinical Chemistry Diagnostic Kit,
Microbiology Identification Kit and Media,
Instruments for Clinical Laboratory and Accessories

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.: SH1829511

Valid from: 2018-09-14
Valid until: 2020-04-30

Date, 2018-09-14

Stefan Preiß

TÜV®

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A4 / 07.17

GMMIT GmbH

Diagnostic Performance Evaluation and Clinical Validation Data Summary

Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)

Livzon Diagnostics Inc. March 2020

IgM Antibody to Coronavirus (SARS-CoV-2)	
Test description	*The product is intended for qualitative detection of Coronavirus (SARS-CoV-2) IgM antibody in human serum, plasma or whole blood samples in vitro, which is an auxiliary diagnosis method for early infection of Coronavirus (SARS-CoV-2)* *Sample type：serum, plasma or whole blood samples* *Pack Size: 20T&40T* *Storage Condition: 2C°~ 30 C°* *Material Provided:* *20T:* *1.20 Individual sealed pouches, each pouch contains:* *-1 Tests cassette* *-1 Desiccant pouch* *2.Pipette：20pcs* *Sample diluent：1*3 mL* *40T:* *1.40 Individual sealed pouches, each pouch contains:* *-1 Tests cassette* *-1 Desiccant pouch* *2.Pipette：40pcs* *Sample diluent：2*3 mL*
Analytical performance	*1. Sensitivity and Specificity* *Sensitivity: 78.7% (95%CI: 73.6% ~ 83.0%)* *Specificity: 99.7% (95%CI: 98.4% ~ 100.0%)* *Total agreement: 90.4% (95%CI: 87.8% ~ 92.4%)* *2. limit of detection (LOD)* *We used the dilution matrix to dilute a specific titer positive serum samples in different series. The results show that when the antibody concentration of 2019-ncov novel coronavirus in the samples was ⩾1:256, the positive detection rate of the reagent was ⩾95%. So the lowest limit of detection of the kit is determined as no less than 1:256.* *3. Cross-reactivity* *Specimens which tested positive with following various agents from patients were investigated with the kit. The results showed no cross reactivity.* *Endemic human coronaviruses (HKU1, OC43, NL63 and 229E), Influenza A, Influenza B, Nasal virus, EB virus, Mumps virus, Measles virus, Cytomegalovirus, Mycoplasma pneumoniae, Chlamydia pneumonia, Adenovirus,*

	Enterovirus ,Respiratory syncytial virus and Varicella-zoster virus IgM antibodies positive sample. *4. Interferences* *The test result of the kit do not be interfered with the substance at the following concentration:* *Substance — Concentration* *Bilirubin — 50mg/dL* *Hemoglobin — 50mg/mL* *Triglyceride — 500mg/dL* *Cholesterol — 500mg/dL* *Rheumatoid factors — 920 IU/mL* *Antinuclear antibody (ANA) titer — 1:1600* *Total IgM — 80mg/mL* *Total IgG — 55mg/mL* *5. Precision* *1). Within run precision: The negative agreement rate and the positive agreement rate should be 100% all the time.* *2). Between run precision: The negative agreement rate and the positive agreement rate should be 100% all the time.* *6. Reference assay* *The reference method used during our clinical study is based on the clinical diagnosed positive patient that a combination of clinical symptoms with PCR test was given.*
Clinical performance	*1. A total of 648 serum/plasma samples from 644 patients suspected of novel coronavirus pneumonia were tested, including homologous comparison and continuous monitoring samples. After removing 4 duplicate samples, A total of 644 samples were included for statistics, The results are as follows:* *Compared with the clinical reference standard, the clinical sensitivity was 78.7% (95% CI:73.6% ~ 83.0%). The clinical specificity was 99.7% (95% CI:98.4% ~ 100.0%), and the total coincidence rate was 90.4% (95% CI:87.8% ~ 92.4%).* 2. *The combined statistical analysis of the combined detection results of this kit and IgG gold standard kit showed that the combined sensitivity was 90.2%, (95% CI:86.2% ~ 93.1%). The combined specificity was 99.2%, (95% CI: 97.6% ~ 99.7%), and the overall coincidence rate was 95.2%, (95% CI:93.2% ~ 96.6%).*

IgG Antibody to Coronavirus (SARS-CoV-2)	
Test description	*The product is intended for qualitative detection of Coronavirus (SARS-CoV-2) IgG antibody in human serum, plasma or whole blood samples in vitro, which is an auxiliary diagnosis method for early infection of Coronavirus (SARS-CoV-2)* *Sample type：serum, plasma or whole blood samples.* *Pack Size: 20T&40T* *Storage Condition: 2C°~ 30 C°* *Material Provided:* *20T:* *1.20 Individual sealed pouches, each pouch contains:* *-1 Tests cassette* *-1 Desiccant pouch* *2.Pipette：20pcs* *Sample diluent：1*3 mL* *40T:* *1.40 Individual sealed pouches, each pouch contains:* *-1 Tests cassette* *-1 Desiccant pouch* *2.Pipette：40pcs* *Sample diluent：2*3 mL*
Analytical performance	*1. Sensitivity and Specificity* *Sensitivity: 83.6% (95% CI: 78.8% ~ 87.4%)* *Specificity: 99.4% (95% CI: 98.0% ~ 99.8%)* *Total agreement: 92.4% (95% CI:90.1% ~ 94.2%)* *2. limit of detection (LOD)* *We used the dilution matrix to dilute a specific titer positive serum samples in different series. The results show that when the antibody concentration of 2019-ncov novel coronavirus in the samples was ⩾1:128, the positive detection rate of the reagent was ⩾95%. So the lowest limit of detection of the kit is determined as no less than 1:128.* *3. Cross-reactivity* *Specimens which tested positive with following various agents from patients were investigated with the kit. The results showed no cross reactivity.* *Endemic human coronaviruses (HKU1, OC43, NL63 and 229E), Influenza A, Influenza B, Nasal virus, EB virus, Mumps virus, Measles virus, Cytomegalovirus, Mycoplasma pneumoniae, Chlamydia pneumonia, Adenovirus, Enterovirus ,Respiratory syncytial virus and Varicella-zoster virus IgG antibodies positive sample.* *4. Interferences* *The test result of the kit do not be interfered with the substance at the following concentration:* *Substance — Concentration* *Bilirubin — 50mg/dL* *Hemoglobin — 50mg/mL*

	Triglyceride — 500mg/dL *Cholesterol — 500mg/dL* *Rheumatoid factors — 920 IU/mL* *Antinuclear antibody (ANA) titer — 1:1600* *Total IgM — 80mg/mL* *Total IgG — 55mg/mL* *5. Precision* *1). Within run precision: The negative agreement rate and the positive agreement rate should be 100% all the time.* *2). Between run precision: The negative agreement rate and the positive agreement rate should be 100% all the time.* *6. Reference assay* *The reference method used during our clinical study is based on the clinical diagnosed positive patient that a combination of clinical symptoms with PCR test was given.*
Clinical performance	*1. A total of 648 serum/plasma samples from 644 patients suspected of novel coronavirus pneumonia were tested, including homologous comparison and continuous monitoring samples. After removing 4 duplicate samples, A total of 644 samples were included for statistics, The results are as follows:* *Compared with the clinical reference standard, the sensitivity was 83.6% (95% CI:78.8% ~ 87.4%). The specificity was 99.4% (95% CI:98.0% ~ 99.8%), and the total agreement was 92.4% (95% CI:90.1% ~ 94.2%).* 2. *The combined statistical analysis of the combined detection results of this kit and IgG gold standard kit showed that the combined sensitivity was 90.2% (95% CI:86.2% ~ 93.1%). The combined specificity was 99.2% (95% CI: 97.6% ~ 99.7%), and the overall coincidence rate was 95.2% (95% CI:93.2% ~ 96.6%).*

GMMIT GmbH

IgM/IgG

Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)

Model:10 Test Sets/Kit 20 Test Sets/Kit

[Product Name]

Generic Name: Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)

[Intended Use]

This product is used for in vitro qualitative detection of Coronavirus (SARS-CoV-2) IgM/IgG antibody in human serum, plasma and whole blood samples.

[Test Principle]

This product contains one IgM test cassette and one IgG test cassette. The IgM test uses colloidal gold immunochromatography technology to detect the Coronavirus (SARS-CoV-2) IgM antibody. The anti-human IgM antibody labeled by colloidal gold is coated on the conjugate pad. Meanwhile, on the cellulose nitrate membrane, the antigens of Coronavirus (SARS-CoV-2) are coated in the test area, and goat anti-mouse antibody is coated in the control area. While testing, the IgM antibody in the test sample (the specific IgM antibody to Coronavirus (SARS-CoV-2) and non-specific IgM antibody) binds with the colloidal gold labeled anti-human IgM antibody and forms an immune complex. The immune complex moves along the membrane through chromatography. If there is specific IgM antibody to Coronavirus (SARS-CoV-2) in the test sample, it will be captured by the antigens coated in the test area, forming a visible band (test line); The free colloidal gold conjugate or immune complex continues to move forward, and binds specifically with the goat anti-mouse antibody coated in the control area, forming a visible band (control line). If the test sample doesn' t contain any Coronavirus (SARS-CoV-2) IgM antibody, only a control line will appear. The IgG test uses colloidal gold immunochromatography technology to detect the Coronavirus (SARS-CoV-2) IgG antibody. The anti-human IgG antibody labeled by colloidal gold is coated on the conjugate pad. Meanwhile, on the cellulose nitrate membrane, the antigens of Coronavirus (SARS-CoV-2) are coated in the test area, and goat anti-mouse antibody is coated in the control area. While testing, the IgG antibody in the test sample (the specific IgG antibody to Coronavirus (SARS-CoV-2) and non-specific IgG antibody) binds with the colloidal gold labeled anti-human IgG antibody and forms an immune complex. The immune complex moves along the membrane through chromatography. If there is specific IgG antibody to Coronavirus (SARS-CoV-2) in the test sample, it will be captured by the antigens coated in the test area, forming a visible band (test line); The free colloidal gold conjugate or immune complex continues to move forward, and binds specifically with the goat anti-mouse antibody coated in the control area, forming a visible band (control line). If the test sample doesn' t contain any Coronavirus (SARS-CoV-2) IgG antibody, only a control line will appear.

[Components]

No.	Components	Packaging Specification	
		10 Tests	20 Tests
1	IgM test cassette On the cellulose nitrate membrane, the test area is precoated with recombinant antigen of the Coronavirus (SARS-CoV-2), while the control area is precoated with the goat anti- mouse antibody. The fiberglass is precoated with the mouse anti-human IgM antibody labeled by colloidal gold	10 Tests	20 Tests
2	IgG test cassette On the cellulose nitrate membrane, the test area is precoated with recombinant antigen of the Coronavirus (SARS-CoV-2), while the control area is precoated with the goat anti- mouse antibody. The fiberglass is precoated with the mouse anti-human IgG antibody labeled by colloidal gold	10 Tests	20 Tests
3	Pipette	10pcs	20pcs
4	Sample diluent buffer solution containing sodium chloride	3 mL×1pc	3 mL×2pcs

Note: Components from the different batches can' t be mixed up for use.

[Materials required but not provided]

1. Timer
2. Container for collecting samples

[Storage and shelf life]

1. Store at 2～30°C. The shelf life is temporarily set as 6 months.
2. Keep dry and keep in dark place.
3. The test should be finished within 30 minutes after the aluminum foil bag is unsealed. In case of the ambient temperature above 30 °C or the humidity above 70%, it should be used as soon as possible.
4. The manufacture date and expiry date can be found in the label of the kit.

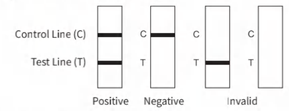
[Sample Collection, handling and storage]

1. The product can be used for testing serum, plasma or whole blood samples.
2. The plasma or whole blood sample to be tested can be anticoagulated with sodium citrate, EDTA-K_2 or heparin sodium.
3. Samples with hemolysis, high viscosity, high fat, bacteria growth or contamination are not suitable for this product.
4. Serum or plasma samples can be stored at 2-8 °C for 7 days. For long term storage, the samples should be kept at - 20 °C to avoid repeated freezing and thawing. The whole blood sample is recommended to be tested within 5days and stored at 2-8 °C. Frozen storage is prohibited.

[Test Procedures]

1. Preparation
   a) Take out the tested samples and the test kit needed from the storage condition and allow them to reach the room temperature.
   b) Take out the test cassette from the packaging bag and put it on a dry surface.
2. Testing
   a) Sample addition
   For serum / plasma sample: add 10μL of serum or plasma sample into the sample well (S) of IgM test cassette and IgG test cassette, and add vertically 2 drops (about 100μL) of sample diluent.
   For whole blood sample: add 20μL of whole blood sample into the sample well (S) of IgM test card and IgG test card, and add vertically 2 drops (about 100μL) of sample diluent.
   b) Within 1-15 minutes after sample addition, the result can be interpreted as positive while both the control line and test line appear. If only the control line appears and the test line does not appear in 15 minutes, the result can be interpreted as negative. It is invalid to read result after 15 minutes.

[Interpretation of Test Result]



1. Positive result:
   a) IgM positive, IgG positive: IgM test cassette appears both control line (C) and test line (T); IgG test cassette appears both control line (C) and test line (T).
   b) IgM positive, IgG negative: IgM test cassette appears both control line (C) and test line (T); IgG test cassette appears only control line(C), but no test line (T).
   c) IgM negative, IgG positive: IgM test cassette appears only control line(C), but no test line (T); IgG test cassette appears both control line (C) and test line (T).
2. Negative result: IgM test cassette appears only control line(C), but no test line (T); IgG test cassette appears only control line(C), but no test line (T).
3. Invalid result: If IgM and/or IgG test cassette appears no control line(C), no matter whether the test line (T) appears or not, the test result is invalid. A repeat test should be done in case of invalid result appears.

[Limitations of the Test Procedures]

1. The product can only be used for in vitro test of individual' s serum, plasma or whole blood samples.
2. A Coronavirus (SARS-CoV-2) infection may not be excluded if the test result is negative.
3. The test result is only for clinical reference and should not be regarded as the only reference for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, physical signs, medical history, other laboratory tests (especially etiology test), treatment response and epidemiological information.
4. In patients with impaired immune function or receiving immunosuppressive therapy, the value of serological antibody test is limited.
5. IgM antibody positive not only occurs in primary infection, but also in secondary infection.
6. The IgM and IgG antibody of Coronavirus (SARS-CoV-2) which this product targets does not directly reflect the presence of Coronavirus (SARS-CoV-2) in the sample.

[Warnings and Precautions]

1. The product is for in vitro diagnosis only.
2. Operation and interpretation of the result must be carried out in strict accordance with the insert.
3. The product is intended for qualitative test, and it cannot get a quantitative result.
4. The kit should be used within the shelf life.
5. The test cassettes and pipettes are for single use and cannot be reused.
6. Because of the difference in titers of the samples, the test line will show different color intensity, all of which indicate a positive result. The color intensity of the test line cannot be used as a reference base for determining the antibody titer in the sample.
7. Before testing, the samples stored at low temperature shall stand to reach the room temperature and be well mixed.
8. An inactivation of 56°C incubation for 30 minutes does not influence the test result.
9. Samples and wastes must be handled as potential infectious sources, and the desiccant in the aluminum foil bag is inedible.

【Manufacturer】
Name: Zhuhai Livzon Diagnostics Inc.
Address: No. 266 Tongchang Road, Xiangzhou District, 519060 Zhuhai, Guangdong, P. R. China
Contact: Tel: +86-0756-8919728 Fax:+86-0756-8204052

【EU Representative】
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Contact: Tel: +49-40-2513175 Fax: +49-40-255726

Glossary of Symbols

	Manufacturer
EC REP	Authorized Representative
IVD	*In Vitro* diagnostic medical device
LOT	Batch Code/Lot Number
	Date of Manufacture
	Temperature limit
Σ	Contains sufficient for <n> Tests
	Use By/Expiry Date
CE	CE marking according to IVD Medical Devices Directive 98/79/EC
	Consult instructions for Use
DIL	Sample Diluent
	Biological risks

V1.0

GMMIT GmbH
Wiesenstr.5 , 63225 Langen
info@gmmit.com
https://www.gmmit.com