MERCADO NACIONAL

PROPOSTA COMERCIAL Nº 0072/2020
DATA: 04/05/2020

BIOTECNOLOGIA
mbbiotecnologia@gmail.com

A
Gerencia de Compras

VENDEDOR	ENTREGA	REQUISITANTE	ENVIADO VIA	VALIDADE	PAGAMENTO
MB Biotecnologia	**Conforme Proposta**		***E-MAIL***	***10 Dias***	***ANTECIPADO NO PEDIDO***

ITEM	DESCRIÇÃO	CODIGO	QUANTIDADE	PREÇO UNITÁRIO	TOTAL
001	***Kit IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2), 10 Test Sets/ Kit 20 Test Sets/Kit.*** ***Prazo de Entrega: Imediato*** ***Fabricante; LIVZON Diagnostic*** ***Pagamento: Antecipado***	20020	01	170,00	170,00
				SUBTOTAL	170,00
				TOTAL DEVIDO	170,00

FATURAMENTO MINIMO: 50.000 Kits
FRETE FOB

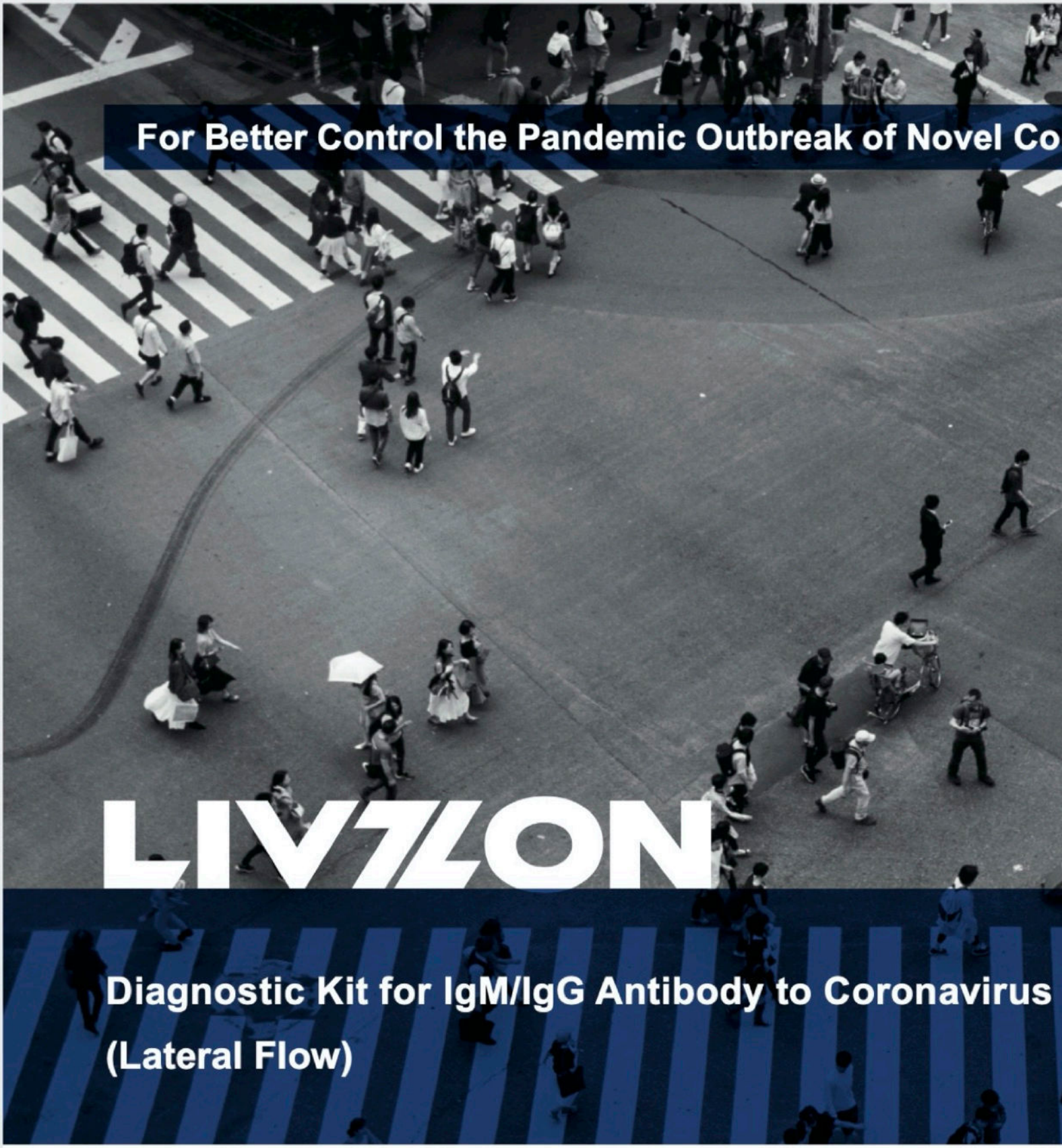
Dados Bancários:
BANCO DO BRASIL
AGÊNCIA: 1898-8
CONTA CORRENTE: 35856-8
MB Biotecnologia Comercio e Servicos
,'
****CANCELAMENTO DE PEDIDO: SOMENTE SERÁ ACEITO ATÉ 48 HORAS APÓS A CONFIRMAÇÃO.***

MB Biotecnologia Comercio e Servicos
(Evandra Regina dos Santos Ramos-ME)
RUA DR. LUIZ MIGLIANO, 2050 – SALA 44 – JD. CABORÉ
SÃO PAULO/SP – CEP. 05711-001
TEL/FAX (11)97319-9656
CNPJ. 14.738.325/0001-80
INSCRIÇÃO ESTADUAL 119.008.709.113
Equipamentos, Reagentes, Plásticos, Assistência Técnica
MERCADO NACIONAL / IMPORTAÇÃO DIRETA

丽珠医药

LIVZON

Diagnostic Kit for IgM / IgG Antibody Coronavirus



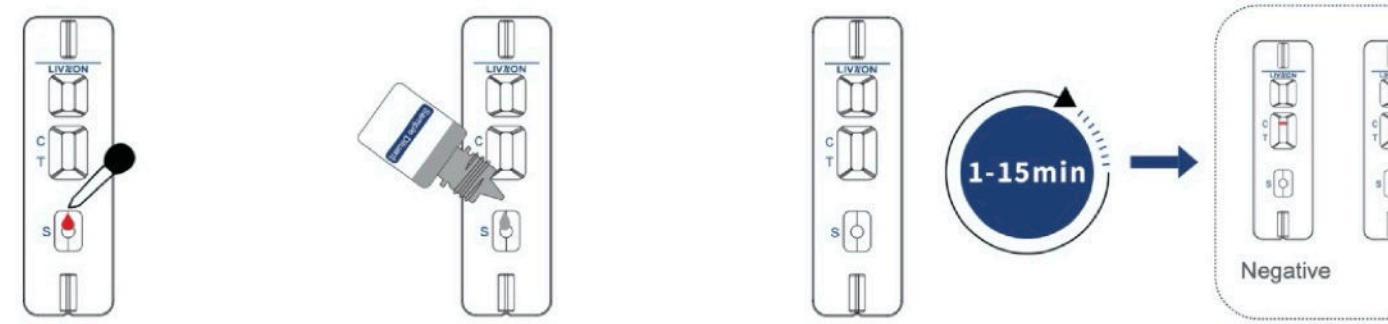
CE IVD CFDA(NMPA) FSC WHO

- *Whole Blood, Serum and Plasma Sample Types*
- *Result in 1-15min visually*
- *Independent IgM and IgG results*

Rapid and Easy to Use, Auxiliary test for the diagnos

- Ideal complement to coronavirus nucleic acid tests (RT-PCR etc.) to avoi
- Independent IgM and IgG results in one kit, capable for confirma
  (according to the *Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia 7th Edition* by the National Health Comm
- Much easier and faster way to test people on site
- Possible to find asymptomatic carriers and to confirm

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	
		Diagnosed	Excluded
IgM/IgG	Positive	259	3
	Negative	27	355
Total		286	358

Diagnostic Performance Evaluation and Clinical Validation Data

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

Livzon Diagnostics Inc. March 2020

IgM Antibody to Coronavirus (SARS-CoV-2)	
Test description	*The product is intended for qualitative detection of Corona IgM antibody in human serum, plasma or whole blood sam is an auxiliary diagnosis method for early infection of Coron 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 different series. The results show that when the antibody co 2019-ncov novel coronavirus in the samples was ⩾1:256, t detection rate of the reagent was ⩾95%. So the lowest limi*

	Enterovirus ,Respiratory syncytial virus and Varicella-zoste antibodies positive sample. *4. Interferences* *The test result of the kit do not be interfered with the subst following concentration:* *5. Precision* *1). Within run precision: The negative agreement rate and t agreement rate should be 100% all the time.* *2). Between run precision: The negative agreement rate and agreement rate should be 100% all the time.* *6. Reference assay* *The reference method used during our clinical study is base diagnosed positive patient that a combination of clinical sy test was given.*
Clinical performance	*1. A total of 648 serum/plasma samples from 644 patient coronavirus pneumonia were tested, including homolo and continuous monitoring samples. After removing 4 A total of 644 samples were included for statistics, The follows:* *Compared with the clinical reference standard, the clini 78.7% (95% CI:73.6% ~ 83.0%). The clinical specificity was CI:98.4% ~ 100.0%), and the total coincidence rate was 9 92.4%).* *2. The combined statistical analysis of the combined dete kit and IgG gold standard kit showed that the combine 90.2%, (95% CI:86.2% ~ 93.1%). The combined specificity 97.6% ~ 99.7%), and the overall coincidence rate was 95. 96.6%).*

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*

IgG Antibody to Coronavirus (SARS-CoV-2)	
Test description	*The product is intended for qualitative detection of Corona* *IgG antibody in human serum, plasma or whole blood sam* *an auxiliary diagnosis method for early infection of Corona* *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* *different series. The results show that when the antibody co* *2019-ncov novel coronavirus in the samples was ⩾1:128, t* *detection rate of the reagent was ⩾95%. So the lowest limi* *kit is determined as no less than 1:128.* ***3. Cross-reactivity*** *Specimens which tested positive with following various age* *were investigated with the kit. The results showed no cross* *Endemic human coronaviruses (HKU1, OC43, NL63 and 229* *Influenza B, Nasal virus, EB virus, Mumps virus, Measles viru* *Mycoplasma pneumoniae, Chlamydia pneumonia, Adenovi* *Enterovirus ,Respiratory syncytial virus and Varicella-zoster*

IgG Antibody to Coronavirus (SARS-CoV-2)	
Test description	*The product is intended for qualitative detection of Corona* *IgG antibody in human serum, plasma or whole blood sam* *an auxiliary diagnosis method for early infection of Corona* *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* *different series. The results show that when the antibody co* *2019-ncov novel coronavirus in the samples was ⩾1:128, t* *detection rate of the reagent was ⩾95%. So the lowest limi* *kit is determined as no less than 1:128.* ***3. Cross-reactivity*** *Specimens which tested positive with following various age* *were investigated with the kit. The results showed no cross* *Endemic human coronaviruses (HKU1, OC43, NL63 and 229* *Influenza B, Nasal virus, EB virus, Mumps virus, Measles viru* *Mycoplasma pneumoniae, Chlamydia pneumonia, Adenovi* *Enterovirus ,Respiratory syncytial virus and Varicella-zoster*

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);

[Components]

No.	Components
1	IgM test cassette On the cellulose nitrate membrane, the test area i precoated with recombinant antigens of the Coronaviru (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 antibod labeled by colloidal gold
2	IgG test cassette On the cellulose nitrate membrane, the test area i 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
3	Pipette
4	Sample diluent buffer solution containing sodium chloride

Note: Components from the different b

[Materials required but not provid

1. Timer
2. Container for collecting samples

[Storage and shelf life]

1. Store at 2～30°C. The shelf life is t
2. Keep dry and keep in dark place.
3. The test should be finished within foil bag is unsealed. In case of the aml the humidity above 70%, it should be
4. The manufacture date and expiry the kit.

[Sample Collection, handling and

1. The product can be used for testin samples.
2. The plasma or whole blood sample with sodium citrate, EDTA-K_2 or hepa
3. Samples with hemolysis, high visc contamination are not suitable for th
4. Serum or plasma samples can be s term storage, the samples should be freezing and thawing. The whole bloc tested within 5days and stored at 2-8

[Test Procedures]

1. Preparation

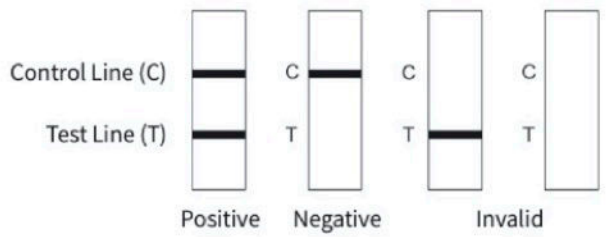
a) Take out the tested samples and condition and allow them to reach th

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

3. The product is intended for qualitative te
result.
4. The kit should be used within the sh
5. The test cassettes and pipettes are for
6. Because of the difference in titers o
show different color intensity, all of whic
color intensity of the test line cannot b
determining the antibody titer in the sa
7. Before testing, the samples stored a
to reach the room temperature and be
8. An inactivation of 56°C incubation fo
the test result.
9. Samples and wastes must be handled
and the desiccant in the aluminum foil

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

【EU Representative】
Name: Shanghai International Holding
Address: Eiffestrasse 80, 20537 Hambu
Contact: Tel: +49-40-2513175 Fax: +4

Glossary of Symbols

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

码

114A

营业执照

(副 本) (副本号:5-2)

珠海丽珠试剂股份有限公司

份有限公司(外商投资企业投资，未上市)

法定代表人 陶德胜

成 立 日 期 1989年01月26日

住　　所 珠海市香洲区同昌路266号1栋

主体的经营范围在章程中载明（其中合伙企业的经营范围在合伙协议中载明，
体工商户的经营范围在设立登记申请书中载明）。经营范围中属于法律、
准的项目，在依法取得许可审批后方可从事该经营活动。
事主体应当在每年的成立周年之日起两个月内提交上一年度的年度报告。
事主体经营范围、出资情况、营业期限、许可审批项目等有关事项和其他监管
市商事主体登记许可及信用信息公示平台（网址：http://sags.zhuhai.gov.cn）
息公示系统或扫描执照上的二维码查询。

医疗器械生产许可证

许可证编号：粤食药监械生产许 20020579 号

名称：珠海丽珠试剂股份有限公司

生产地址：珠海市香洲区同昌路 266 号

代表人：陶德胜

生产范围：见医疗器械生产产品登记表

负责人：林艳

所：珠海市香洲区同昌路 266 号 1 栋

发证部门：广东省药品监督管理局

医疗器械经营许可证

许可证编号： 粤珠食药监械经营许20150120号

业名称： 珠海丽珠试剂股份有限公司

法定代表人： 陶德胜

营方式： 批发

企业负责人： 林艳

所： 珠海市香洲区同昌路266号1栋

经营范围： III类：6815注射穿刺器械，6824医用激光仪器设备，6833医用核素设备，6840临床检验分析仪器及诊断试剂（诊断试剂不需低温冷藏运输贮存），6840临床检验分析仪器及诊断试剂（诊断试剂需低温冷藏运输贮存），6845体外循环及血液处理设备，6854手术室、急救室、诊疗室设备及器具，6857消毒和灭菌设备及器具，6858医用冷疗、低温、冷藏设备及器具，6870软件**

营场所： 珠海市香洲区同昌路266号1栋3层A区

房地址： 珠海市香洲区同昌路266号2栋1层

发证部门： 珠海市食品药品监督管理局

中华人民共和国

药品生产许可证

海丽珠试剂股份有限公司

海市香洲区同昌路266号1栋

91440400617488114A

陶德胜

林艳

臧峻英

2020 年 12 月 31 日

编号 粤20160266

分类码 T

生产地址和生产范围

珠海市香洲区同昌路266号
体外诊断试剂。

中华人民共和国

药品经营许可证

证　　号：粤AA7560123

：珠海丽珠试剂股份有限公司

经营方式：批　发

：珠海市香洲区同昌路266号1栋3层

经营范围：体外诊断试剂**

：陶德胜

：林艳

：廖桂芳

：珠海市香洲区同昌路266号3栋1层3101、 3102、 3103

中 华 人 民 共 和 国

药品经营质量管理规范认证证书

证书编号：A-GD-19-0537

：珠海丽珠试剂股份有限公司

：珠海市香洲区同昌路266号1栋3层

：药品批发

经审查，符合《药品经营质量管理规范》要求，特发此证。

发证机关

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

Declaration of Conformit

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 Z
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 A Coronavirus (SARS-CoV-2) (
	Type/model, batch/serial number, possibly sources and number of items (Where applicable)	:	Model: 10 Test Sets/Kit 20 T
of class	according to directive 98/79/EC	:	Other device ,not in Annex testing ,not for performanc

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

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
	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 Ⅲ：EC合格声明

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MI PRODUCTS

证书编号：粤食药监械出 20200244 号
Certificate NO.：粤食药监械出 20200244 号

产品名称：新型冠状病毒（2019-nCoV）IgM/IgG 抗体检测试剂盒（胶体金法
Product(s)： **Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-**
Flow)

规格型号：**10 人份/盒，20 人份/盒**
Model： **10 Test Sets/Kit 20 Test Sets/Kit**

产品注册或备案凭证号：国械注准 20203400240
Registration certificate(s)：国械注准 20203400240

生产企业：珠海丽珠试剂股份有限公司
Manufacturer： **Zhuhai Livzon Diagnostics Inc.**

生产企业住所：珠海市香洲区同昌路 266 号 1 栋
Address of manufacturer： **Building 1, No.266, Tongchang Road, Xiangzhou D**
PEOPLE'S REPUBLIC OF CHINA

生产许可或备案凭证号：粤食药监械生产许 20020579 号
Manufacturing License(s)：粤食药监械生产许 20020579 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to manufactured and sold in China.

证明有效日期至：2021 年 03 月 13 日
This certification valid until:13/03/2021

备注：/
Remark: /

2020 年 03 月
（出具单位盖章）

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

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
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 Me
Instruments for Clinical Laboratory an**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management syste
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the com
above has established and is maintaining a quality management system, which
requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1829511

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

UNIFESP 25 ANOS

VANIA SIMOES LOPES <vania.simoes@unifesp.br>

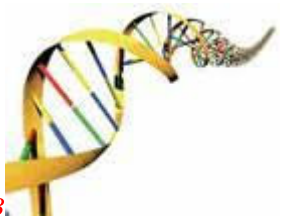
cotação kit COVID19

1 mensagem

WR Research Products <wr@wrresearch.com> 4 de maio de 2020 18:30
Para: compras@lge.ibi.unicamp.com.br, compras.csp@unifesp.br, compras.heverton@santamarcelina.org, comprasbertioga@ints.org.br, "Compras - Hospital Dr. Fajardo" <compras.fajardo@saude.am.gov.br>, Setor de Compras <compras@igen.org.br>, anamsilva@hcrp.usp.br, ana.requejo@unisantos.br, ANGELOFRANCA@ints.com.br, silvialima@ints.org.br, GRACIELLEOLIVEIRA@ints.org.br, patricia.uchima@santacasasp.org.br, sildelanhesi@gmail.com, silvanadelanhesi@hsav.com.br, Renato Ferreira De Alencar <renato.alencar@uhgbrasil.com.br>, Thalita Camargo <camargo.thalita@huhsp.org.br>, Thaís Monteiro <thais.monteiro@idor.org>, ctapenna@valinhos.sp.gov.br, fabio.martins@msenior.com.br, hosp_fajardo@saude.am.gov.br, anderson20a@hotmail.com, compra.28agosto@saude.am.gov.br, leticia.costa@santacasasorocaba.com.br, compras.chid@spdm-pais.org.br

Segue cotação kit COVID19, entrega imediata, com registro ANVISA.

Atenciosamente,



MB.

BIOTECNOLOGIA

Evandra Ramos

MB Biotecnologia Comercio e Servicos

CNPJ. 14.738.325/0001-80

Rua Dr. Luiz Migliano, 2050 - Sl. 78 – Morumbi

São Paulo/SP - Cep. 05711-001 – Fone ***(11)973199656 e (11)99970-0017***

WhatsApp: 11-99970-0017 - E-mail: Evandra@wrresearch.com

***Por gentileza Confirmar o recebimento desta mensagem!**

2 anexos

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COVID.pdf
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