MedPath GmbH, Mies-van-der-Rohe-Straße 8, 80807 Munich, Germany

To whom it may concern

MedPath GmbH

Mies-van-der-Rohe-Straße 8,
80807 Munich, Germany

Telefon: +49(0)89 189174474
Telefax: +49(0)89 5485 8884
E-Mail: info@medpath.pro

Digitally signed by Perminov Andrei
Date: 2021.12.08 17:51:14 EET
Reason: MoldSign Signature
Location: Moldova

Munich, 03.07.2020

Confirmation of EU Medical Device(s) Notification

This is to confirm that in accordance of Article 10 of Directive 98/79/EC concerning in vitro Diagnostic Medical Devices (IVDD), MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the manufacturer

Hunan Runmei Gene Technology Co., Ltd.

Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, 410153 Changsha, Hunan Province, China.

as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s)

- **New Coronavirus COVID-19 Nucleic Acid Detection Kit**
  (Fluorescent RT-PCR Method)
  Registration No. in DIMDI Database System: DE/CA61/221

The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity claiming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

Safety Officer
MedPath GmbH

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

EC DECLARATION OF CONFORMITY

CE

Manufacturer Address	Manufacture Name: Hunan Runmei Gene Technology Co., Ltd. Post Add: Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha, Hunan Province, China. 410153
European Representative	Authorized Representative Name: Lotus NL B.V. Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product Information	Product Name: Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit Cat. No.: RM-B Specification: 48Tests/kit, 96 Tests/kit
Classification	Others
Conformity Assessment **Route: Annex Ⅲ**	*We, Hunan Runmei Gene Technology Co., Ltd, under our sole responsibility declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.*
General Applicable Directives	*In vitro diagnostic medical devices directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLLAMENT AND OF THE COUNCIL OF 27 October 1998 on in vitro diagnostic medical devices.*
Standards Applied	EN 13612:2002/AC:2002 EN ISO 14971: 2012 EN ISO 18113-1: 2011 EN ISO 15223-1: 2016 EN ISO 13485:2016 EN ISO 23640:2015 EN ISO 18113-2: 2011 EN 13641: 2002

Place: Changsha City, Hunan Province, China.
Date: May 22, 2020

Name: Jian Gong
Position: Managing Director
Signature:

Hunan Runmei Gene Technology Co.

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
R.A.C. Ori

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20201800

Bijlagen
-

Uw aanvraag
29 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 11 mei 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 29 april 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Hunan Runmei Gene Technology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

New Coronavirus COVID-19 Nucleic Acid Detection Kit (Fluorescent RT-PCR Method),New Coronavirus COVID-19 Antibody Detection Kit (Colloidal Gold),Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit,Single-use Samplers
(geen merknaam) (NL-CA002-2020-50915)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Hunan Runmei Gene Technology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)
SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)

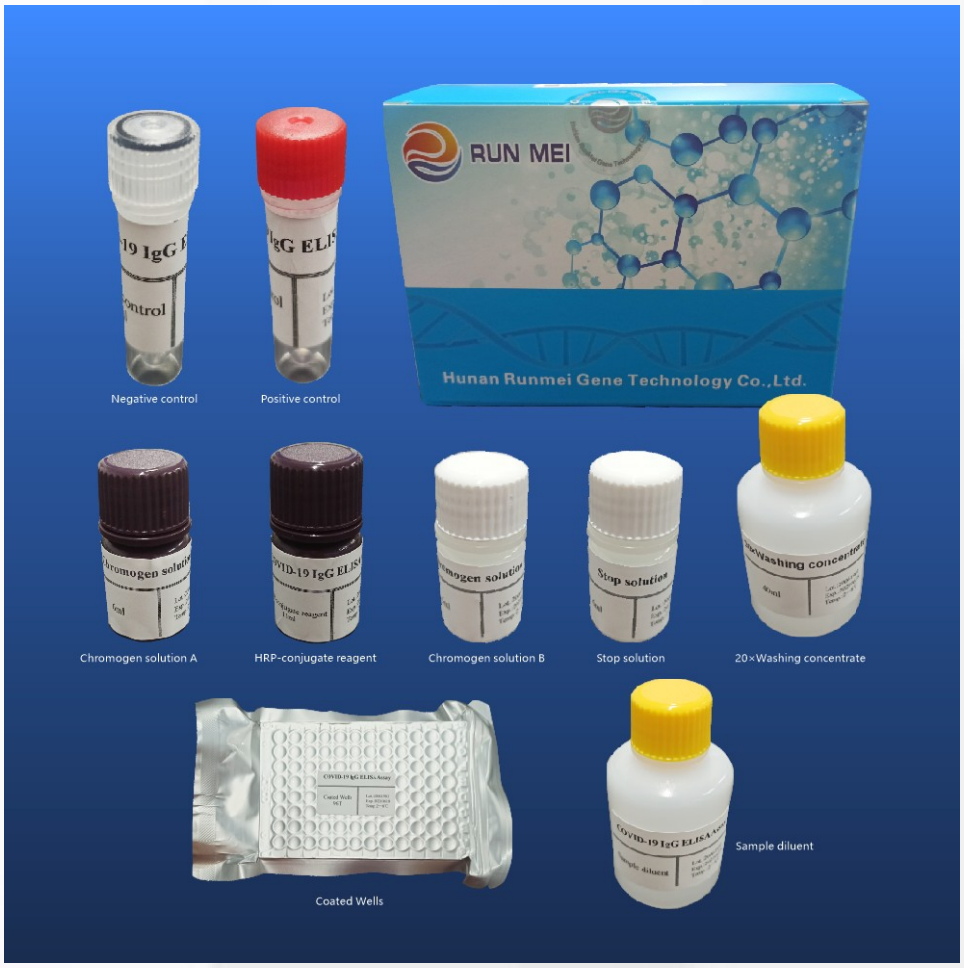
Hunan Runmei Gene Technology Co., Ltd.

Phone : (+86)-731-89919680/+(86)-18601454556
Email : sales@runmeigene.com

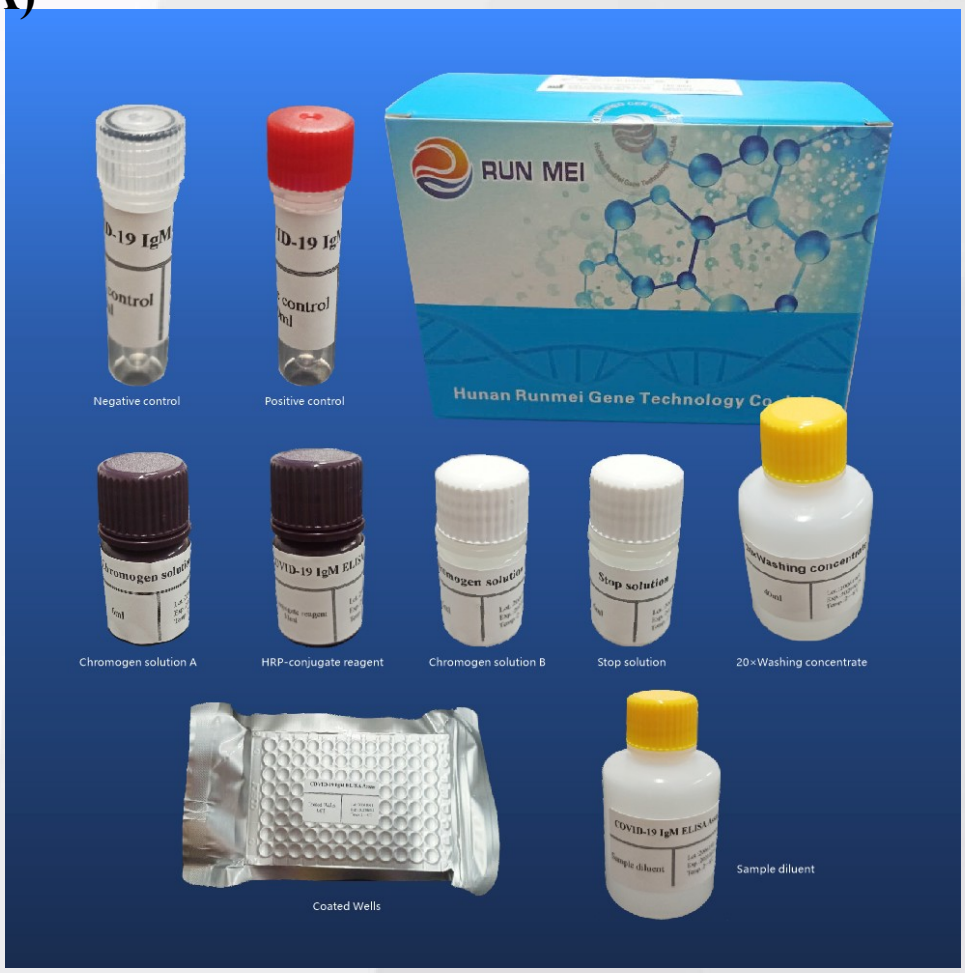
SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)
SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)

Product Features

SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)



SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)



CE IVD

SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)

PRODUCT NAME

SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)

PACKING SPECIFICATION

96 tests/kit

INTENDED USE

The SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA) is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for qualitative detection of total antibodies (IgM) to SARS-CoV-2 in human serum run manually. This kit is used for assisted diagnosis.

MAIN COMPONENTS

Number	Composition	96 Testing Kits/box
1	Enzyme Conjugate	22ml×1(red lid)
2	Specimen Diluent	26ml×1(yellow lid)
3	20X Wash Buffer Concentrate	40ml×2(white lid)
4	Chromogenic Reagent A	11ml×1(white lid)
5	Chromogenic Reagent B	11ml×1(brown lid)
6	Stop Solution	11ml×1(brown lid)
7	Positive Control	1.5 ml×1(red lid)
8	Negative Control	1.5 ml×1(transparent lid)
9	Microtiter plate	96T×2
10	Microplate Sealers	2
11	Instructions	1

STORAGE CONDITIONS

This product is ready for use and no further preparation is necessary. The product should be stored in its original container at 2-8°C until used. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile collection unit and the specimen transport tube label. The unopened reagents are stable until the expiration date when stored at 2 to 8°C, and the opened kit is stable for up to 1 month from the date of opening at 2 to 8°C.

SAMPLE REQUIREMENTS

Applicable sample types: Serum.

Handling and storage of samples:

- Follow procedures within your laboratory to avoid cross contamination of patient specimens.
- Samples may be stored at room temperature (15-30°C) for no longer than 8 hours. If the test will not be completed within 8 hours, refrigerate the serum samples at 2-8°C for no longer than 48 hours.
- Samples that will not be tested within the time frames outlined above should be stored at ≤ -20°C and may be subjected to 1 freeze-thaw cycle.
- As an alternative to the above, sample stability may be established by each laboratory.

Serum Preparation

Collect whole blood in a serum separator tube (SST) or a red top or equivalent tube appropriate for isolation of serum. Refer to the serum collection tube manufacturer's instructions for serum preparation, including centrifugation.

It is important to immediately transfer the liquid component (serum) after serum preparation into a clean polypropylene tube. If the serum is not analyzed immediately, the serum should be kept at 2-8°C for up to 48 hours, apportioned into preferred sized aliquots, stored at -20°C or lower if exceeding 9 days. It is important to avoid freeze-thaw cycles because this may be detrimental to serum components. Samples which are hemolyzed, icteric or lipemic can invalidate certain tests.

INSTRUCTIONS

1. Bring reagents to room temperature (15-30°C) for at least 30 minutes before use.
2. Allow for eight Blank/Control determinations (two Reagent Blank, two Negative Control, two Low Positive Control and two Positive Control) per run.
3. A full or partial plate may be run. Store the residual strips from a partial plate run in the original pouch and seal the entire opening with adhesive tape. Do not use broken strips.
4. Determine the volume of 1X Wash Buffer needed for the run. 24 mL total of 1X Wash Buffer is needed for each full strip of controls and/or samples run. Volume to be prepared is (24 mL x # strips) plus sufficient excess to ensure adequate quantity for use with manual or automated wash. To prepare a 1X Wash Buffer, mix 1 part of the 20X Wash Buffer with 19 parts of purified water thoroughly in an appropriately sized container to achieve homogeneity. The 1X Wash Buffer may be stored at 2-8°C for up to 30 days.
5. For control wells, add 50 µL control solution directly to individual wells (except for the two Reagent Blank wells).
6. For sample wells, add 50 µL sample serum to each well.
7. Mix well by gentle shaking, cover the microplate wells with an adhesive sealer, and incubate for 30 minutes at 37±2°C.
8. Microplate Washing: discard the liquid in the wells then fill each microwell with 300 µL of working Wash Buffer (1X). Leave the wash buffer in each well for 5 seconds and then remove the wash solution from all the wells. Repeat 4 times for a total of 5 washes. Firmly tap the inverted microplate on absorbent paper to thoroughly remove all residual liquid from the wells. The preceding manual wash may be performed with an automated plate washer.
9. Add 100 µL of the Enzyme Conjugate to each well at the same rate and in the same order as the samples. Cover the microplate with an adhesive sealer and incubate for 30 minutes at 37±2°C.
10. Microplate Washing: wash the microwells by following the procedure as described in step 8.
11. Add 50 µL each (100 µL total) of Chromogenic Reagent A and Chromogenic Reagent B, to each well at the same rate and in the same order as the addition of the patient specimens. Mix well by gentle shaking, cover the microplate with an adhesive sealer, and incubate for 10 minutes at 37±2°C protected from direct sunlight.
12. Add 50 µL of Stop Solution to each well at the same rate and in the same order as the Chromogenic Reagents. Gently tap the microplate several times to ensure that the reagents are thoroughly mixed.

13. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the mean of two Reagent Blank wells. Read the microplate within a maximum of 10 minutes of the addition of the Stop Solution.

Test Validation Criteria

- Negative Control OD < 0.15
- Positive Control OD ≥ 0.30
- Positive Control OD – Negative Control OD ≥ 0.30

Interpretative Guide	
Specimen OD450	Interpretation
< 0.15	Negative
0.15-0.30	Suspect
> 0.30	Positive

PRODUCT DETERIORATION

The SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA) should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the expiration date has passed, (4) the package is open, or (5) there are other signs of deterioration.

LIMITATIONS

1. This test has been authorized only for the presence of total antibodies against SARS-CoV-2, not for any other viruses or pathogens.
2. Assay results should not be used to diagnose or exclude acute COVID-19. Direct viral nucleic acid detection or antigen detection methods should be performed if acute infection is suspected.
3. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
4. The detection of anti-SARS-CoV-2 antibodies is dependent on the presence of the analyte in the specimen, a negative result can occur if the quantity of antibodies for SARS-CoV-2 present in the specimen are below the detection limit of the assay. During the acute infection phase and/or for immunosuppressed patients, anti-SARS-CoV-2 antibodies might not be detectable. Thus, a negative result does not preclude or rule out COVID 19 infection.
5. Heterophilic antibodies in samples may cause interference in immunoassays. These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results that are inconsistent with clinical observations indicate the need for additional testing.
6. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
7. SARS-CoV-2 total antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days.
8. The results obtained with this test should only be interpreted in conjunction with clinical findings and the results from other laboratory tests and evaluations.
9. It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
10. Performance characteristics have not been evaluated for neonatal or pediatric patients.
11. The test kit is validated for the qualitative determination of anti-SARS-CoV-2 total antibodies in human serum only.
12. This test should not be used for blood donor screening or screening of donated blood.

WARNINGS

1. Unused components should not be re-sterilized.
2. Do not mix materials from different kit lot numbers.
3. Do not use kits beyond the expiration date.
4. Directions for use must be followed carefully.
5. To be handled by trained personnel only.
6. It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens must be handled with appropriate precautions.
7. After use, tubes and funnels must be disposed of according to laboratory regulations for infectious waste. Observe CDC Biosafety Level 2 recommendations.

INDEX OF SYMBOL

Symbol	Used for	Symbol	Used for
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
CE	CE mark	EC REP	Authorized representative in the European Community
REF	Catalog number	Σ	Contains sufficient for<n>tests
	Please don't reuse it		Biological risks
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Avoid overexposure to the sun

Hunan Runmei Gene Technology Co., Ltd.
Address: Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha, Hunan Province, China. 410153
Tel: +86-731-89919680

EC REP
Lotus NL B.V.
Address : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email: peter@lotusnl.com

SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)

PRODUCT NAME

SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)

PACKING SPECIFICATION

96 tests/kit

INTENDED USE

The SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for qualitative detection of total antibodies (IgG) to SARS-CoV-2 in human serum run manually. This kit is used for assisted diagnosis.

MAIN COMPONENTS

Number	Composition	96 tests/kit
1	Enzyme Conjugate	22ml×1(red lid)
2	Specimen Diluent	26ml×1(yellow lid)
3	20 X Wash Buffer Concentrate	40ml×2(white lid)
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9	Microtiter plate	96T×2
10	Microplate Sealers	2
11	Instructions	1

STORAGE CONDITIONS

This product is ready for use and no further preparation is necessary. The product should be stored in its original container at 2-8°C until used. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile collection unit and the specimen transport tube label. The unopened reagents are stable until the expiration date when stored at 2 to 8°C, and the opened kit is stable for up to 1 month from the date of opening at 2 to 8°C.

SAMPLE REQUIREMENTS

Applicable sample types: Serum.

Handling and storage of samples:

- Follow procedures within your laboratory to avoid cross contamination of patient specimens.
- Samples may be stored at room temperature (15-30°C) for no longer than 8 hours. If the test will not be completed within 8 hours, refrigerate the serum samples at 2-8°C for no longer than 48 hours.
- Samples that will not be tested within the time frames outlined above should be stored at ≤ -20°C and may be subjected to 1 freeze-thaw cycle.
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Serum Preparation

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INSTRUCTIONS

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Interpretative Guide	
Specimen OD450	Interpretation
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PRODUCT DETERIORATION

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LIMITATIONS

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11. The test kit is validated for the qualitative determination of anti-SARS-CoV-2 total antibodies in human serum only.
12. This test should not be used for blood donor screening or screening of donated blood.

WARNINGS

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2. Do not mix materials from different kit lot numbers.
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REF	Catalog number	Σ	Contains sufficient for<n>tests
	Please don't reuse it		Biological risks
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Avoid overexposure to the sun

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Tel: +86-731-89919680

EC REP
Lotus NL B.V.
Address : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email: peter@lotusnl.com

Inspection Report

湖南润美基因科技有限公司
HuNan RunMei Gene Technology Co., Ltd

文件编号：RM-R07-002-1.0

Finished Product Inspection Report

Report No.20120101-1

Product Name	SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)				
Cat#	QY-E-E1001	Specification	192T	LOT	20120101
Inspection Department	Quality Department	Delivery Date	December 1, 2020		
		Inspection Date	December 1, 2020		
Basis of Inspection	Quality Standard of SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA)				
Quality Inspection Situation					
Inspection Items	Quality Inspection		Inspection Results		
Physical Inspection	The appearance is complete, clearly marked and not damaged. The instructions are clear and complete, and the product name, batch number and expiry date are clear.		The reagent card has a complete appearance, clearly marked and no damage. The instructions are clear and complete, and the product name, batch number and expiry date are clear.		
Detection of coincidence rate of positive and negative reference products	The test results of the 4 positive reference samples must all be positive and no false negatives; The test results of the 4 negative reference samples must all be negative and no false positives.		The test results of 4 positive reference samples were all positive and no false negatives; The test results of 4 negative reference samples were all negative and no false positives.		
Sensitivity Detection	1. If there is a national standard product, it shall be tested with the national standard product, and it is required to be able to be detected; 2. Detect with actual samples, and the detection rate is 100%.		The serum test results of 6 positive samples were all positive and no false negatives.		
Specific Detection	Check for cross-reactivity with antibodies from species with higher homology.		After testing, there is no cross-reactivity with antibodies produced by infection with the same virus.		
Precision Detection	Randomly check 10 positive samples, and all samples are colored. Repeat the test 3 times and the results are consistent. The coefficient of variation CV≤3%.				
Conclusion	This batch of reagents is qualified and meets quality standards.				
Inspector	Jiao Jiang		Reviewer	Yulin Wen	
Inspection Date	December 1, 2020		Review Date	December 1, 2020	

检验专用章

Finished Product Inspection Report

Report No.20120501-1

Product Name	SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)				
Cat#	QY-E-E1002	Specification	192T	LOT	20120105
Inspection Department	Quality Department	Delivery Date	December 5, 2020		
		Inspection Date	December 5, 2020		
Basis of Inspection	Quality Standard of SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA)				
Quality Inspection Situation					
Inspection Items	Quality Inspection		Inspection Results		
Physical Inspection	The appearance is complete, clearly marked and not damaged. The instructions are clear and complete, and the product name, batch number and expiry date are clear.		The reagent card has a complete appearance, clearly marked and no damage. The instructions are clear and complete, and the product name, batch number and expiry date are clear.		
Detection of coincidence rate of positive and negative reference products	The test results of the 4 positive reference samples must all be positive and no false negatives; The test results of the 4 negative reference samples must all be negative and no false positives.		The test results of 4 positive reference samples were all positive and no false negatives; The test results of 4 negative reference samples were all negative and no false positives.		
Sensitivity Detection	1. If there is a national standard product, it shall be tested with the national standard product, and it is required to be able to be detected; 2. Detect with actual samples, and the detection rate is 100%.		The serum test results of 6 positive samples were all positive and no false negatives.		
Specific Detection	Check for cross-reactivity with antibodies from species with higher homology.		After testing, there is no cross-reactivity with antibodies produced by infection with the same virus.		
Precision Detection	Randomly check 10 positive samples, and all samples are colored. Repeat the test 3 times and the results are consistent. The coefficient of variation CV≤3%.				
Conclusion	This batch of reagents is qualified and meets quality standards.				
Inspector	Jiao Jiang		Reviewer	Yulin Wen	
Inspection Date	December 5, 2020		Review Date	December 5, 2020	

统一社会信用代码

91430105MA4PJ2NG30

营业执照

（副 本）

副本编号：1 - 1

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名　　称　湖南润美基因科技有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　龚剑

经营范围　医学研究和试验发展；Ⅱ类:6840临床检验分析仪器的、Ⅱ类:6840体外诊断试剂的、生物制品、一类医疗器械的研发；医学检验技术服务；医学检验技术咨询；医学检验技术、医疗器械技术的开发；医疗器械技术咨询、交流服务；医疗器械技术转让服务；生物技术开发服务、咨询、交流服务、转让服务；科研成果的研发、孵化及转化；健康医疗产业项目的管理、的运营；健康管理；Ⅱ类:6840体外诊断试剂的、Ⅱ类:6840临床检验分析仪器的、生物制品的生产；自营和代理各类商品及技术的进出口，但国家限定公司经营或禁止进出口的商品和技术除外；一类医疗器械、兽用生物制品、Ⅱ类:6840临床检验分析仪器的、Ⅱ类:6840体外诊断试剂的、生物制品的销售。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　壹仟万元整

成立日期　2018年04月28日

营业期限　2018年04月28日 至 2068年04月27日

住　　所　长沙市开福区沙坪街道中青路1048号山河医药健康产业园标准厂房3栋401-1房

登记机关　长沙市开福区市场监督管理局

2019 年 11月 20日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

对外贸易经营者备案登记表

统一社会信用代码：91430105MA4PJ2NG30

备案登记表编号：03604216　　进出口企业代码：_____

经营者中文名称	湖南润美基因科技有限公司		
经营者英文名称	HuNan RumMei Gene Technology Co.,LTD		
组织机构代码	---------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	长沙市开福区沙坪街道中青路1048号山河医药健康产业园标准厂房3栋401-1房		
经营场所（中文）	长沙市开福区沙坪街道中青路1048号山河医药健康产业园标准厂房3栋401-1房		
经营场所（英文）	Room 401, Building No.3 in ChangSha Medical and Health Industrial Park. No.1048 Zhong Qing Road. Kai Fu District. ChangSha. HuNan Prov., P.R. China		
联系电话	0731-89919680	联系传真	0731-89919680
邮政编码	410153	电子邮箱	hnrunmei@163.com
工商登记注册日期	2018-4-28	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	龚剑	有效证件号	452329197710061411
注册资金	壹仟万元	（折美元）	

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产		（折美元）	

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2018　年　08　月　14　日

出入境检验检疫报检企业备案表

编　　号：

备案类别：☑自理报检企业 □代理报检企业 □快件运营企业　备案号: 4307100114

企业名称	中文	湖南润美基因科技有限公司		
	英文	HuNan Runmei Gene Technology Co., LTD		
住　所	长沙市开福区沙坪街道中青路1048号山河医药健康产业园标准厂房3栋401-1房			
经营场所	长沙市开福区沙坪街道中青路1048号山河医药健康产业园标准厂房3栋401-1房			
企业性质	私营企业		企业类别	有自营权的生产企业
统一社会信用代码	91430105MA4PJ2NG30		营业执照号	91430105MA4PJ2NG30
组织机构代码	MA4PJ2NG3		行政区划	430105
法定代表人/负责人	龚剑		有效证件号	452329197710061411
联系人	林小美		联系电话	0731-89919680
电子邮箱	hnrunmei@163.com			

快件运营企业备案还须填写以下内容

快递业务经营许可证号	
经营范围	

报检专用章印模、中英文原产地签证印章：(另附页)

填表前请认真阅读背面的条款，并由企业法定代表人/负责人签字、盖章。

备案机构(签章)

2018年8 月15日

QG07

中华人民共和国海关
报关单位注册登记证书

海关注册编码：4301967759

组织机构代码：MA4PJ2NG3

企业名称：湖南润美基因科技有限公司

企业住所：长沙市开福区沙坪街道中青路1048号山河医药健康产业园标准厂房3栋401-1房

企业经营类别：进出口货物收发货人

注册登记日期：2018年8月15日

法定代表人：龚剑

有效期：长期

注册海关：星沙海关

核发日期：2018年8月15日

重要提示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

中华人民共和国海关总署监制

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Hunan Runmei Gene Technology Co., Ltd.
Room 401-1, Building 3
Shanhe Medical and Health Industrial Park
No. 1048, Zhongqing Road, Shaping Street
Kaifu District, Changsha
Hunan
410153
China

湖南润美基因科技有限公司
中国
湖南省
长沙市
开福区沙坪街道
中青路1048号山河医药健康产业园
标准厂房3栋401-1房
邮编：410153

Holds Certificate No: **MD 729427**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture and Distribution of Nucleic Acid Detection Kit (Fluorescent RT-PCR Method) for Diagnosis of Viral Infections.
用于诊断病毒感染的核酸检测试剂盒（荧光 RT-PCR 方法）的制造和分销。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-06-24
Latest Revision Date: 2020-06-24

Effective Date: 2020-06-24
Expiry Date: 2023-06-23

...making excellence a habit.™

质量管理体系认证证书

湖南润美基因科技有限公司

证 书 注 册 号：46820Q50057R0S

统一社会信用代码：91430105MA4PJ2NG30

注 册 地 址：湖南省长沙市开福区沙坪街道中青路 1048 号山河医药健康产业园标准厂房 3 栋 401-1 房 P.C 410000

管理体系符合：GB/T 19001-2016 idt ISO9001:2015

证书覆盖范围：资质范围内核酸提取或纯化试剂、一次性使用采样器的研发、生产和销售

颁 证 日 期：2020 年 06 月 05 日

有 效 期 至：2023 年 06 月 04 日

誉邦检测认证有限公司

证书颁发后，3年有限期内要至少接受2次监督审核。证书即时有效性可通过网站查询www.ybtc.org.cn.

本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询。也可扫码右下角的二维码查询。

地址：长沙市开福区福元西路220号英祥苑2期1栋940-941房

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Hunan Runmei Gene Technology Co., Ltd.

Registration No : 46820Q50057R0S

Organization Code : 91430105MA4PJ2NG30

Registration Address : Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha, Hunan Province, China. P.C 410000

In conformity with : GB/T 19001-2016 idt IS09001:2015

Certification scope : R&D, production and sales of Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit, Single-use samplers within the scope of qualifications.

Issue Date : Jun 05, 2020

Expiry Date : Jun 04, 2023

YUBANG TESTINGAND CERTIFICATION CO.,LTD.

After this certificate is issued,there should be at least 2surveillance audits within the 3 year period of validity the current validity of the certificate can be checked on(www.ybtc. org.cn). The certificate information is available on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn) . It is also available by scanning the two-dimensional code at the bottom right corner.

Address:220 Fuyuan West Road,Kaifu District,Changsha City Hunan

CE Certification

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20205542

Bijlagen
-

Uw aanvraag
17 november 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 27 november 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 17 november 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Hunan Runmei Gene Technology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Full Automatic Nucleic Acid Extract Instrument.
(geen merknaam) (NL-CA002-2020-54351)
SARS-CoV-2 (COVID-19) IgG Antibody Detection Kit (ELISA),
SARS-CoV-2 (COVID-19) IgM Antibody Detection Kit (ELISA),
SARS-CoV-2 (COVID-19) /Influenza A /B Virus Nucleic Acid Detection Kit(Fluorescence RT-PCR Method),
(geen merknaam) (NL-CA002-2020-54350)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

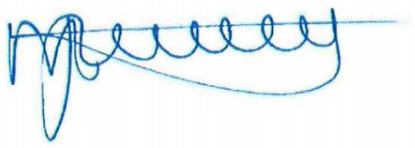
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Hunan Runmei Gene Technology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

SGS

SGS

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Connecting Buyers with Chinese Suppliers

Report Number: QIP-ASI209100

Audit Date : 09 Apr., 2020

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (SGS-CSTC Standards Technical Services Co., Ltd.) to confirm that:

Company Name	:	**Hunan Rummei Gene Technology Co., Ltd.** **湖南润美基因科技有限公司**
Showroom	:	**http://runmeigene.en.made-in-china.com**
Address	:	**Room 401-1, Building 3, Standard Workshop, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha City, Hunan Province, China**
Product	:	**Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit, Single-use Samplers, New Coronavirus COVID-19 Nucleic Acid Detection Kit(Fluorescent RT-PCR Method), New Coronavirus COVID-19 Antibody Detection Kit (Colloidal Gold), Real Time Fluorescence Quantitative PCR Detector, Portable Microplate Reader, Rapid Detection Kit, Nucleic Acid Detection Kit(Fluorescent RT-PCR Method), Antibody Detection Kit (ELISA), New Coronavirus（COVID-19）Antibody ELISA Kit, New Coronavirus COVID-19 Detection Kit (ELISA), New Coronavirus COVID-19 Detection Kit (Colloidal Gold), Canine Parvovirus Antibody Detection Kit (Colloidal Gold), Porcine Reproductive and Respiratory Syndrome Virus *Detection Kit (ELISA), Avian Influenza Virus H5 Subtype Nucleic Acid* Detection Kit (Fluorescent RT-PCR Method)**

has been on site audited for the Following Scope of Activity

1. General Information
2. Foreign Trade Capacity
3. Product Research & Development Capacity
4. Management System and Product Certification
5. Production Capacity & Quality Control
6. Working Environment
7. Energy Saving and Emission Reduction
8. Photos

Made-in-China.com Audited Supplier

General Comments:

Hunan Rummei Gene Technology Co., Ltd. is a manufacturer and trader combined company, it was established in 2018, located in Room 401-1, Building 3, Standard Workshop, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha City, Hunan Province, China. The company has its own brand, and they have obtained CE certificates and test report for products. Strong research team, and they have enough tests on the products to ensure the quality of the products and their goods will be delivered after strict quality inspection.

5/F, B-4 Building, Zijin (Beixia) Technology Incubation Special Park, No.1 Guanghua Road, Nanjing, China 210014 t (86-25) 87128385 f (86-25) 83407773 www.sgsgroup.com.cn
中国・南京・秦淮区光华路1号紫金白下创业特别社区4号楼B幢5楼 邮编: 210014 t (86-25) 87128385 f (86-25) 83407773 e as.cn@sgs.com

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Sign for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd.

SGS-CSTC Standards Technical Services Co., Ltd.
Consumer and Retail Services Technical Service
5/F, B-4 Building, Zijin (Baixia) Technology Incubation Special Park, No.1 Guanghua Road, Nanjing, China 210014 t (86-25) 87128385 f (86-25) 83407773 www.sgsgroup.com.cn
中国・南京・秦淮区光华路1号紫金白下创业特别社区4号楼B幢5楼 邮编: 210014 t (86-25) 87128385 f (86-25) 83407773 e as.cn@sgs.com

SGS No: QIP-ASI209100

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SUPPLIER ASSESSMENT REPORT

Audited Company	Hunan Rummei Gene Technology Co., Ltd.
Audited Site:	Room 401-1, Building 3, Standard Workshop, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha City, Hunan Province, China

Consigner of Assessment	**Made-in-China.com**		
Audit Type	☒ Initial Audit ☐ Re-audit		
Audit Date	09 Apr., 2020	Verify Report	www.sgs.com/ecv
Auditor	Vitor Chen	Reviewed by	Toby Han

CONTENTS

5/F, B-4 Building, Zijin (Baixia) Technology Incubation Special Park, No.1 Guanghua Road, Nanjing, China 210014 t (86-25) 87128385 f (86-25) 83407773 www.sgsgroup.com.cn
中国・南京・秦淮区光华路1号紫金白下创业特别社区4号楼B幢5楼 邮编: 210014 t (86-25) 87128385 f (86-25) 83407773 e as.cn@sgs.com

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Section 2: Photos of Company

5/F, B-4 Building, Zijin (Baixia) Technology Incubation Special Park, No.1 Guanghua Road, Nanjing, China 210014 t (86-25) 87128385 f (86-25) 83407773 www.sgsgroup.com.cn
中国·南京·秦淮区光华路1号紫金白下创业特别社区4号楼B幢5楼 邮编: 210014 t (86-25) 87128385 f (86-25) 83407773 e as.cn@sgs.com

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Part A: General Information

Section 1: Company Overview

1.1 Legal Validity			
Does the company have a valid business license?	☒ Yes ☐ No ☐ Others	Registration Number	91430105MA4PJ2NG30
Year of established	28 Apr., 2018	Valid Date	27 Apr., 2068
Registered address	Room 401-1, Building 3, Standard Workshop, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha City, Hunan Province, China		
Actual address	Room 401-1, Building 3, Standard Workshop, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha City, Hunan Province, China		
Does the company in abnormal operation status list of industrial and commercial bureau?	No		
Registered capital	RMB 10,000,000		
Name of legal representative	Mr. Jian Gong		
Business scope	Medical research and experimental development; Ⅱ class: 6840 clinical laboratory analytical instruments, Ⅱ class: 6840 in vitro diagnostic reagent, biological products, a class of medical equipment research and development; Medical inspection technical services; Technical consultation on medical examination; Development of medical examination technology and medical instrument technology; Technical consultation and exchange services for medical devices; Technology transfer services for medical devices; Biotechnology development services, consulting services, exchange services, transfer services; Research and development, incubation and transformation of scientific research achievements; Management and operation of health care industry projects; Health management; Ⅱ class: 6840 in vitro diagnostic reagent, Ⅱ class: 6840 clinical test analysis instrument, the production of biological products; Import and export of all kinds of commodities and technologies on its own or on its own behalf, except for commodities and technologies which are restricted by the state to operate or prohibited by the state; Kind of veterinary biological products, medical apparatus and instruments, Ⅱ class: 6840 clinical laboratory analytical instruments, Ⅱ: 6840 in vitro diagnostic reagent, biological products sales.		

1.2 Basic Information			
Contact person	Ms. Ann Lin		
Phone number	0086-731-89919680	Fax number	0086-731-89919680
URL/Web address	http://runmeigene.en.made-in-china.com		
Company type	☐ Manufacturer ☐ Trading Company ☒ Combined ☐ Group Corporation		
Type of ownership	☒ Limited Company ☐ Public Company ☐ Foreign joint venture ☐ State-Owned ☐ Private Owner ☐ Wholly foreign-owned enterprises		
Associated company	No		

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Products manufactured / sold scope	Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit, Single-use Samplers, New Coronavirus COVID-19 Nucleic Acid Detection Kit(Fluorescent RT-PCR Method), New Coronavirus COVID-19 Antibody Detection Kit (Colloidal Gold), Real Time Fluorescence Quantitative PCR Detector, Portable Microplate Reader, Rapid Detection Kit, Nucleic Acid Detection Kit(Fluorescent RT-PCR Method), Antibody Detection Kit (ELISA), New Coronavirus（COVID-19）Antibody ELISA Kit, New Coronavirus COVID-19 Detection Kit (ELISA), New Coronavirus COVID-19 Detection Kit (Colloidal Gold), Canine Parvovirus Antibody Detection Kit (Colloidal Gold), Porcine Reproductive and Respiratory Syndrome Virus Detection Kit (ELISA), Avian Influenza Virus H5 Subtype Nucleic Acid Detection Kit (Fluorescent RT-PCR Method)

1.3 Company Building Information

According to:

☐ Land certificate ☐ Real estate certificate

☒ Lease agreement ☐ Observation Estimated on site

The company area 1,000 square meters
The land occupies Confidential square meters.
The offices occupy 100 square meters.
The workshops occupy 800 square meters.

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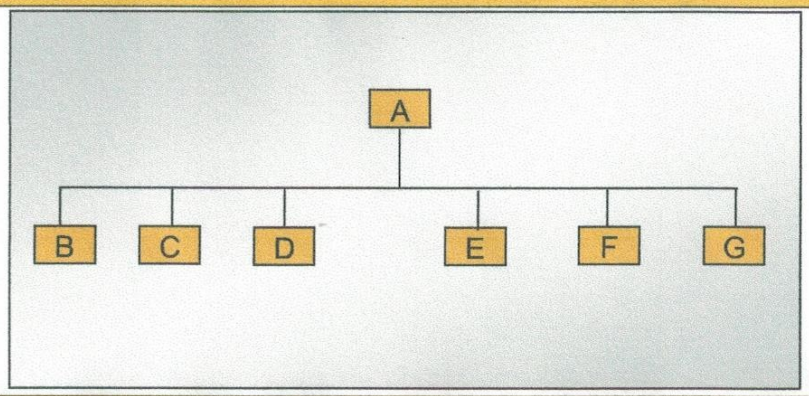
Section 2: Human Resources

2.1 Company Chart



2.2 Explanation of Code and Employee Details

Code	Department	Number of employees
A	General Manager Office	2
B	Production Dept.	5
C	R&D Dept.	4
D	Quality Dept.	2
E	Sales Dept.	6
F	Services Dept.	5
G	General Management Dept.	4
	Number in total:	28

2.3 Key Staff

Title	Full name	Education	Working experience for this trade / total experience
General Manager	Mr. Jian Gong	Doctor	23/23 Years

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Part B: Foreign Trade Capacity

Section 1: Export Overall Situation

1.1 Export Overall Situation	
Does the company have a valid Import and Export license?	☒ Yes ☐ No
The import and export enterprise code.	91430105MA4PJ2NG30
The number of foreign trading staff with relevant trading experience.	☐ within 1 year staff ☐ 1-5 years staff ☒ 6-10 years 4 staffs ☐ over 10 years staff Total 4 staffs
The language freely used by foreign trade staff	☒ English ☐ others
Annual revenue of previous year	Confidential
Annual export revenue of previous year	Confidential
Estimated export revenue for this year.	Confidential
Overseas agent / branch	☐ Yes ☒ No
Nearest port	Shenzhen Port
Acceptable quotation terms	☒ FOB ☐ CIF ☐ CFR Other: UPS, DHL
Acceptable payment terms	☐ LC ☒ T/T ☐ D/P ☐ PayPal ☐ Western Union ☐ Small-amount payment
Average lead time (Peak Season)	☒ within 15 workday ☐ one month ☐ 2-3 months ☐ 4-6 months ☐ 6-12 months ☐ more time
Average lead time (Off Season)	☒ within 15 workday ☐ one month ☐ 2-3 months ☐ *4-6 months* ☐ *6-12 months* ☐ *more time*

Section 2: Export Business Capacity

2.1 Market Distribution (please list top three areas)		
Market	Main Product	Main client
☐ North America		
☐ South America		
☐ Europe		
☐ Southeast Asia/ Mideast		
☐ Africa		
☐ East Asia (Japan/ South Korea)		
☐ Australia		

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☒ Domestic	Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit, Single-use Samplers, New Coronavirus COVID-19 Nucleic Acid Detection Kit(Fluorescent RT-PCR Method), New Coronavirus COVID-19 Antibody Detection Kit (Colloidal Gold), Real Time Fluorescence Quantitative PCR Detector, Portable Microplate Reader, Rapid Detection Kit, Nucleic Acid Detection Kit(Fluorescent RT-PCR Method), Antibody Detection Kit (ELISA), New Coronavirus （COVID-19）Antibody ELISA Kit, New Coronavirus COVID-19 Detection Kit (ELISA), New Coronavirus COVID-19 Detection Kit (Colloidal Gold), Canine Parvovirus Antibody Detection Kit (Colloidal Gold), Porcine Reproductive and Respiratory Syndrome Virus Detection Kit (ELISA), Avian Influenza Virus H5 Subtype Nucleic Acid Detection Kit (Fluorescent RT-PCR Method)	Confidential
☐ Others		

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Section 3: Supplier Management

3.1 Supplier Management		
Item	**Content**	**Observations /Comments**
1	Does the company establish and implement an effective suppliers' assessment procedure?	☒ Have the written procedures and followed records ☐ Have the written procedures but no records ☐ Have relevant records without written procedure ☐ No written procedures or followed records ☐ Other
2	Does the company have an updated list of approved suppliers?	☒ The approved suppliers list was updated in 2019 ☐ Have the written suppliers without approved signature or date. ☐ Provided some suppliers names ☐ No approved suppliers list ☐ Other

Section 4: After-sales Service Capacity

4.1 After-sales Service Capacity		
Item	**Content**	**Observations /Comments**
1	Is there a procedure to conduct random product inspection after final packaging in place?	☒ Have clear standards and written inspection records ☐ No written standards but had inspection reports ☐ Have the procedures but no inspection records ☐ It's not necessary to carry out the inspection ☐ Other
2	Is there a clear procedure for handling customer complaints?	☒ Has the clear procedure and followed records ☐ Has the procedure but no written records. ☐ No written procedures or records. ☐ Other
3	Can the finished/packaged product be traced by lot identification to the appropriate raw materials test reports?	☒ Have the procedures to trace the raw materials. ☐ Can trace main materials ☐ Can trace production date. ☐ Can't trace products ☐ Other
4	Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers/ sub-contractors control, incoming inspection, process control, final inspection and customer complaint)?	☐ Has the clear procedure and followed records ☒ Has the procedure but no written records. ☐ No written procedures or records. ☐ Other

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Part C: Product Research & Development Capacity

1.1 Product Research & Development Capacity	
The amount of R&D and relevant working experience.	☐ within 1year staff ☐ 1-5 years staff ☐ 6-10 years staff ☒ over 10 years 4 staffs Total 4 engineers
What is the main job responsibility for R&D engineers?	The main job responsibility is in charge of customers request, new product design and development.
Is there any relevant design input, output, review, verification and validation documentation available for auditor to review?	Yes Design per market trend and client's requirement.
Is there any special software or instrument used by the R&D staffs during the design process of new products? If yes, please list the main software or instrument.	No
Does the company have an effective design change control procedure in place?	Yes They will modify their design per client's requirement.
Please list the patent certificates and qualification license.	Nil

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Part D: Management System and Product Certification

1.1 Management System and Product Certification	
Management system certification	☒Others Certificate Name: Certificate of Good Manufacturing Practices For Animal Drugs No.: 18001 Issued by: Department of agriculture and rural areas of Hunan province Issued Date: 14 Feb., 2020 Valid Until: 13 Feb., 2025 Scope: Molecular biological diagnostic products (class B)
Product certification	☒ CE Certificate Name: CE No.: R A001 49/B Rev.01 Product Name: New Coronavirus COVID-19 Detection Kit (Colloidal Gold) Model: N/A Standard: 98/79/EC Issued by: Medpath Gmbh Issue Date: 26 Mar., 2020 Certificate Name: CE No.: R A001 49 Rev.01 Product Name: New Coronavirus COVID-19 Nucleic Acid Detection Kit(Fluorescent RT-PCR Method) Model: N/A Standard: 98/79/EC Issued by: Medpath Gmbh Issue Date: 17 Mar., 2020 ☐ UL ☐ CCC ☐ RoHS ☐ FCC ☐ Others ☒ NIL
Test reports for raw materials	☐ RoHS ☐ Reach ☐ Others ☒ NIL

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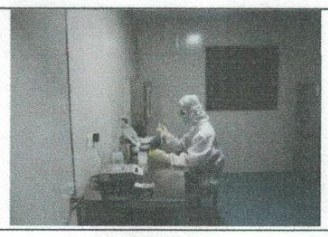
Part E: Production Capacity & Quality Control

Section 1: Production Capacity

1.1 Production Workflow Chart


Raw Material Inspection


Dosing


Skimming


Finished Product Testing


Packing

1.2 Products Situation (Top three Product Categories)

Product	Price range	Min. order quantity	Top monthly output	Average monthly output	Total in
 Virus Nucleic Acid Extraction Kit or Nucleic Acid Detection Kit	Confidential	Confidential	Confidential	Confidential	Confidential

1.3 Main Facilities

Picture	Facility name	Brand or Country/Region of origin	Target Value/machine*day	Quantity
	Water Purification System	China	Confidential	
	Dosing Line	China	Confidential	

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	Skimming Line	China	Confidential	1
	Testing Line	China	Confidential	2
	Freedom EVOlyzer	China	Confidential	1
	Microplate Reader	China	Confidential	1
	Washing Machine	China	Confidential	1
	High Temperature Sterilizer	China	Confidential	1

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Section 2: Production Process Control

2.1 Production Process Control		
Item	**Content**	**Observations /Comments**
1	Product R&D capacity	☒ Own brand ☒ ODM ☒ OEM
2	Are the environmental conditions, such as tidiness and cleanliness being controlled and suitable for the operation performed?	☐ Very tidy ☒ Normal ☐ Need to improve ☐ Very poor
3	Are the necessary items /documents provided at appropriate location and under control?	☒ Work Instructions /procedures ☐ Workmanship standard /acceptance ☐ Golden sample /Approval sample ☐ Product picture ☐ Verbal by workshop director
4	Are written instructions available for incoming material inspections /testing? Is the relevant record maintained?	☒ Has instructions and uniformly followed ☐ Has instruction but no written records ☐ Materials checked by storage staff
5	Are written inspections /testing instructions available for finished products? Is the relevant record maintained?	☒ Have instructions and uniformly followed ☐ Have instruction but no written records ☐ Finished product checked by packing staff
6	What type of inspection is used for finished products?	☐ Random inspection ☐ Visual inspection ☐ Function inspection ☒ 100% inspection ☐ Visual inspection ☒ Function inspection
7	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?	☒ Marked and segregated ☐ Segregated but not marked clearly ☐ Not found on site
8	How are the non-conforming units handled?	☐ Repaired and re-inspection ☒ Picked out ☐ Used under control ☐ Others

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Part G: Working Environment

Section 1: Working Environment

1.1 Welfare Benefits		
Item	**Content**	**Observations /Comments**
1	Does the company have effective procedures to verify the age of staff at the time of recruitment?	☒ Has written procedure and keeps adequate age documents of workers ☐ Has written procedure but doesn't follow records ☐ Hasn't written procedure or follows records
2	Do all workers sign employment contracts with the factory?	☒ All workers sign employment contracts ☐ Some workers sign employment contracts ☐ Only management staff sign employment contracts ☐ No staff sign employment contracts
3	Is statutory contribution required for all employees' social insurance (e.g. health insurance, unemployment insurance, accident insurance etc.) paid for by the enterprise?	☒ All workers have social insurance. ☐ Some workers have social insurance ☐ Only management staffs have social insurance ☐ No staff have social insurance
4	Does the company have a clear and effective policy on working hours, rest and vacations? If does, please list it.	☒ All staffs work kept to the policy ☐ Most of the time it keeps to the policy except midseason. ☐ Usually needs overtime. ☐ No relevant records for working hours Describe the working hours: 8:30-12:00, 14:00-17:30
5	Does the company pay extra remunerations for all overtime work?	☒ For all overtime work. ☐ For official holidays ☐ For official holidays except weekend. ☐ No extra remunerations for overtime.
6	Does the company have dormitories for staff? If yes, please describe the condition.	☒ Provide dormitories for all staff ☐ Provide dormitories for workers ☐ Provide dormitories for management staff ☐ No dormitories were provided. Describe the condition: 2 Staffs Per Room
1.2 Labor Protection		
Item	**Content**	**Observations /Comments**
1	Are there uniforms for all staff in company?	☒ Yes ☐ No ☐ Other
2	Is the emergency medical supplies enough and easily used in workshop?	☒ Yes ☐ No ☐ Other
3	Does the company arrange health and safety training for new workers?	☒ Yes ☐ No ☐ Other
4	Do the workers have the appropriate protective equipment during operation in workshop? Such as gloves, masks.	☒ Yes ☐ No ☐ Other
5	Is there training needed and carried out for fire protection?	☒ Yes ☐ No ☐ Other

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Part H: Energy Saving and Emission Reduction

Section 1: Environmental Management

1.1 Environmental Management		
Item	**Content**	**Observations /Comments**
1	Environmental Management System	☐ ISO 14001 Certificate ☐ Cleaner production management ☒ NIL
2	Environmental Impact Assessment	☒ The Report of Environmental impact assessment is approved by EPA Changsha in 2020. ☐ NIL
3	Check and Acceptance of Completed Constructive Projects	☒ The Report Completed Constructive Projects Inspection and Acceptance is approved. ☐ NIL
4	"Three Simultaneity" for Environmental protection	☐ The Report of "Three Simultaneity" for Environmental protection Inspection and Acceptance is available. ☒ NIL

Section 2: Water, Gas and Noise Control

2.1 Water, Gas and Noise Control		
Item	**Content**	**Observations /Comments**
1	Water-intaking	☐ Water-intaking license ☐ No water-intaking license ☒ No water taken from natural water body
2	Waste water	☐ Water-draining license or contract ☒ Having carried out waste water treatment before draining ☐ Having carried out waste water monitoring and the result of which being within the standard limit ☐ No detail activities were found
3	Emission to air	☐ Air pollutant emission license ☐ Having carried out air pollutant emission monitoring and the result of which being within the standard limit ☒ No detail activities were found to reduce emission to air
4	Classification and Recycling for solid waste	☒ Having applied trash classification recycling ☐ Having special warehouse for hazardous waste ☐ No detail activities were found
5	Noise	☒ The company carried out noise monitoring and the result of which being within the standard limit one time per year ☐ No detail activities were found

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