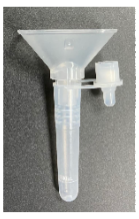
Stock Code: 002932

COVID-19 Antigen Rapid Test Kit (Saliva&Swab)

Product Catalogue

COVID-19 Antigen Rapid Test Kit(Saliva/Swabs)

1. Swab(Nasal/Throat)
2. Saliva collection bag
3. Test card
4. Pipette/Dropper
5. Extraction fluid
6. Extraction tube
7. Tube stand



Funnel saliva collection kit
Selective option

1 2 3 4 5 6 7

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

Company Profile

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

- **TOP 3** in China POCT market
- Offical Covid-19 Test Kit Supplier

15% of the Market Share in China

Company Overview

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

- Founded in **2008**
- Headquarters **Wuhan**, China
- Listed on the Shenzhen Stock Exchange in **2018**
- Employees **1000+** Globally-Based
- Export to **100+** Countries and Regions

Research & Development

Invest 20% of the main business revenue

Patents
100+

R&D

Master or PHD
70%

New products
5 annually

Production Capacity

- Cleanroom workshop area **20,000+**m^2
- **ISO13485** certificate
- Daily Production Capacity of COVID-19 Antigen Test Kit Over **2M Tests/Day**

- Daily Production Capacity of COVID-19 Nucleic Acid Test Kit Over **6M Tests/Day**

Domestic Market

- **10,000+** Hospitals, Medical Institutions and Laboratories are Using Easydiagnosis Products
- Official COVID-19 Nucleic Acid Test Supplier of **25 Provinces,** Ranking the **Top 3** in China

Global Market

- Our Products Has been Distributed to **100+ Countries and Regions**

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg 25,Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone
Wuhan,430074 Hubei P.R. China

Scope: Design and Development, Manufacture and Distribution of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care, Immune Quantitative Analyzer, Full-automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbA1c Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.

武汉明德生物科技股份有限公司
2021 -01- 28
Wuhan EasyDiagnosis Biomedicine Co., Ltd

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190129510 110

Effective date: 2021-01-27

Expiry date: 2024-01-26

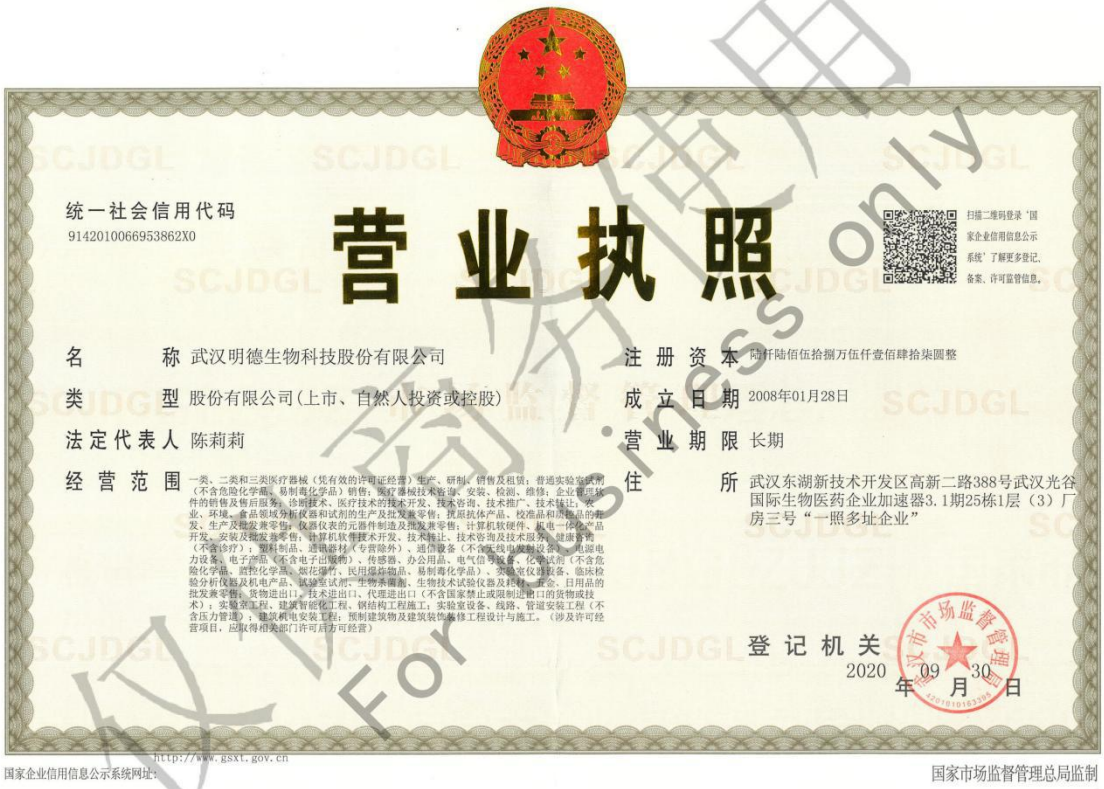
Issue date: 2021-01-25

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

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

1 / 3

Enterprise Qualifications



统一社会信用代码
91420100669538620X0

营业执照

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　武汉明德生物科技股份有限公司
类　　型　股份有限公司(上市、自然人投资或控股)
法定代表人　陈莉莉
经营范围　一类、二类和三类医疗器械（凭有效的许可证经营）生产、研制、销售及租赁；普通实验室试剂（不含危险化学品、易制毒化学品）销售；医疗器械技术咨询、安装、检测、维修；企业管理软件的销售及售后服务。诊断技术、医疗技术的技术开发、技术咨询、技术推广、技术转让；农业、环境、食品领域分析仪器和试剂的生产及批发兼零售；抗原抗体产品、校准品和质控品的研发、生产及批发兼零售；仪器仪表的元器件制造及批发兼零售；计算机软硬件、机电一体化产品开发、安装及批发兼零售；计算机软件技术开发、技术转让、技术咨询及技术服务；健康咨询（不含诊疗）；塑料制品、通讯器材（专营除外）、通信设备（不含无线电发射设备）、电源电力设备、电子产品（不含电子出版物）、传感器、办公用品、电气信号设备、化学试剂（不含危险化学品、监控化学品、烟花爆竹、民用爆炸物品、易制毒化学品）、实验室仪器设备、临床检验分析仪器及机电产品、试验室试剂、生物制品、生物技术试验仪器及耗材、五金、日用品的批发兼零售；货物进出口、技术进出口、代理进出口（不含国家禁止或限制进出口的货物或技术）；实验室工程、建筑智能化工程、钢结构工程施工；实验室设备、线路、管道安装工程（不含压力管道）；建筑机电安装工程；预制建筑物及建筑装饰装修工程设计与施工。（涉及许可经营项目，应取得相关部门许可后方可经营）

注册资本　陆仟陆佰伍拾捌万伍仟壹佰肆拾柒圆整
成立日期　2008年01月28日
营业期限　长期
住　　所　武汉东湖新技术开发区高新二路388号武汉光谷国际生物医药企业加速器3.1期25栋1层（3）厂房三号"一照多址企业"

登记机关　2020 年 09 月 30 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn　　国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：鄂食药监械生产许20120393号

企业名称：武汉明德生物科技股份有限公司
生产地址：1、武汉市东湖开发区高新大道858号光谷生物医药产业园二期A8 2-2栋；2、武汉市东湖新技术开发区高新二路388号武汉光谷国际生物医药企业加速器3.1期25幢1层4号房；3、武汉市东湖新技术开发区高新二路388号武汉光谷国际生物医药企业加速器3.1期25幢2层3、4号房

法定代表人：陈莉莉
生产范围：二类、三类：6840临床检验分析仪器及体外诊断试剂；二类：6821医用电子仪器设备；二类：22-04免疫分析设备、21-03数据处理软件、22-03电解质及血气分析设备。***

企业负责人：陈莉莉

住　　所：武汉东湖新技术开发区高新二路388号武汉光谷国际生物医药企业加速器3.1期25栋1层（3）厂房三号
发证部门：湖北省药品监督管理局

有效期限：至　2022　年　9　月　5　日
发证日期：　2020　年　3　月　15　日

查询网址：http://www.hubfda.gov.cn　　国家药品监督管理局制

对外贸易经营者备案登记表

备案登记表编号：03026823　　统一社会信用代码：91420100669538862X0
进出口企业代码：----------

经营者中文名称	武汉明德生物科技股份有限公司		
经营者英文名称	Wuhan EasyDiagnosis Biomedicine Co.,Ltd		
组织机构代码	----------	经营者类型（由备案登记机关填写）	私营股份有限公司
住　所	武汉市东湖开发区关东科技园东信路特1号留学生创业园E栋2楼		
经营场所（中文）	武汉市东湖开发区关东科技园东信路特1号留学生创业园E栋2楼		
经营场所（英文）	2nd Floor,Building E,Wuhan Overseas Scholar Business Park,No.1 Dongxin Road,Guandong Technology Park,Wuhan East Lake Development Zone,430074 Wuhan,China		
联系电话	87808955	联系传真	87808005
邮政编码	430074	电子邮箱	info@ediagnosis.cn
工商登记注册日期	2008-1-28	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	陈莉莉	有效证件号	422726197405080226
注册资金	肆仟玖佰玖拾叁点捌捌陆万元	（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

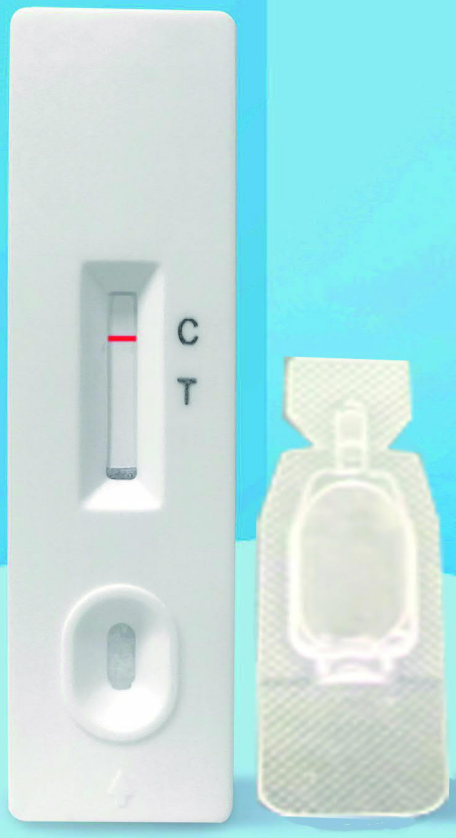
签　章

2016 年 11 月 01 日

eDiagnosis | Stock Code 002932

COVID-19(SARS-CoV-2) Antigen Test Kit

Faster Detection for Earlier Diagnosis of COVID-19



Specificity	Accuracy	Sensitivity
99.26%	98.50%	96.15%

CE

Fast

The Result Is Available In 15 Minutes

Early

Identify Acute or Early Infection

Convenient

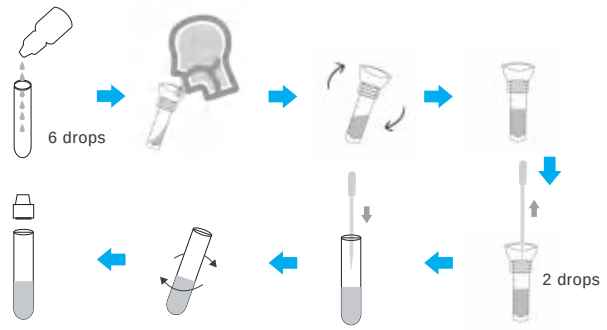
No Need Instrument and Fewer Steps Needed to Get Result

Comparation of Different Test Technologies

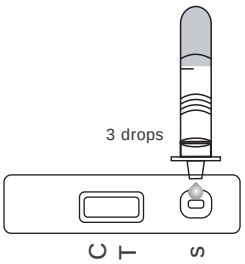
	Antibody Test	Molecular Test	Antigen Test
What to Test	COVID-19 IgG/IgM Antibody	RNA of SARS-CoV-2	Protein of SARS-CoV-2
Ideal Time to Take Test	5-7 Days after Onset	3-7 Days after Infection	3-7 Days after Infection
Time to Get Result	<20 Minutes	>1.5 Hours	15 Minutes
Operation	Simple	Complex	Simple

Measurement Procedure

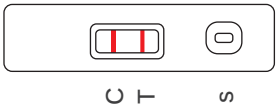
01 Sample Collection



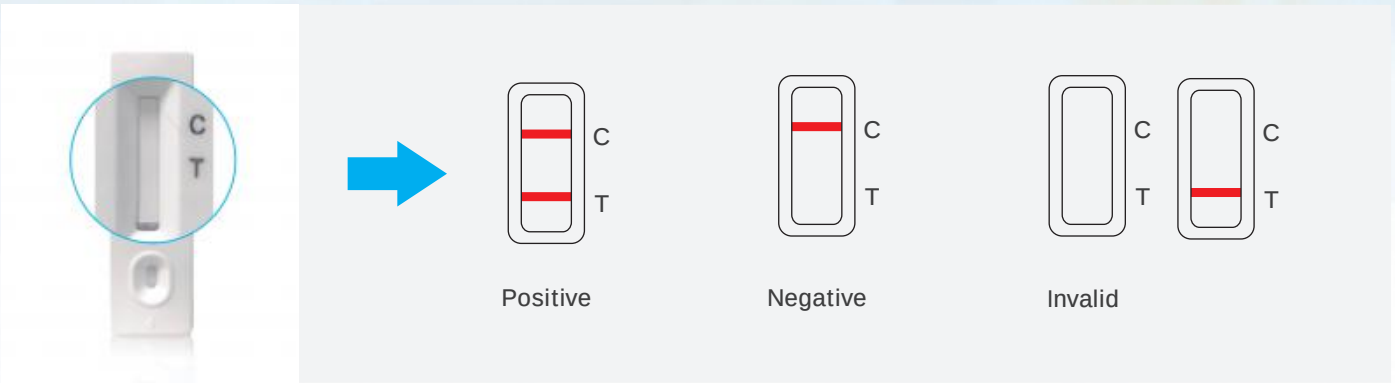
02 Sample Test



03 Read The Test Result



Interpretation of Result



Main Components

Components	Storage Temperature
Test Cassette	2℃~30℃
Antigen Extract R1	
Saliva Collector (Paper Bag or Funnel collector)	Room Temperature
Pipette /Dropper	
Extraction Tube	
Tube Stand	

0086-27-65523649

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

www.easydiagnosis.com.cn sales@easydiagnosis.com.cn

Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1, Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No. 388, Gaoxin 2nd Road, East Lake Hi-Tech Development Zone, Wuhan, 430074, Hubei, P.R. China

IVD CE

COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)

Instruction for Use

[Product name]

COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)

[Packing specification]

Saliva:

20 Tests/Kit, 10 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit, 1 Test/Kit

Oropharyngeal/Nasopharyngeal swabs:

40 Tests/Kit, 20 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit, 1 Test/Kit

[Intended use]

This product is intended for in vitro qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in saliva and oropharyngeal (throat)/nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider. The kit is intended for use by laboratory trained personnel.

Coronaviruses are a large family of viruses which could cause illness in animals or humans. The Novel Coronaviruses (SARS-CoV-2) belong to the RNA virus of the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[Test principle]

This kit employs immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the SARS-CoV-2 nucleocapsid protein antigen is present, they will be bound to the colloidal gold-labeled SARS-CoV-2 specific antibodies. The immune complex will be captured by coronavirus monoclonal antibody fixed in the T line. A fuchsia line would form, and the test result would be positive. If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

[Main components]

Saliva:

Spec. / Components	20 tests/kit	10 tests/kit	5 tests/kit	2 tests/kit	1 test/kit
Antigen test cassette	20 pieces	10 pieces	5 pieces	2 pieces	1 piece
Desiccant	20 pieces	10 pieces	5 pieces	2 pieces	1 piece
Antigen extract R1	0.5mL X20 tubes	0.5mL X10 tubes	0.5mL X5 tubes	0.5mL X2 tubes	0.5mL X1 tube
Instruction for use	1 piece	1 piece	1 piece	1 piece	1 piece
Saliva Collector	20 pieces	10 pieces	5 pieces	2 pieces	1 piece
Saliva Dropper	20 pieces	10 pieces	5 pieces	2 pieces	1 piece
Antigen extraction tube (with tube and dropper head)	20 pieces	10 pieces	5 pieces	2 pieces	1 piece
Tube stand	1 piece	1 piece	1 piece	1 piece	1 piece

Oropharyngeal/Nasopharyngeal swabs:

Spec. / Components	40 tests/kit	20 tests/kit	5 tests/kit	2 tests/kit	1 test/kit
Antigen Test cassette	40 pieces	20 pieces	5 pieces	2 pieces	1 piece
Desiccant	40 pieces	20 pieces	5 pieces	2 pieces	1 piece
Antigen extract R1	0.5mL X40 tubes	0.5mL X20 tubes	0.5mL X5 tubes	0.5mL X2 tubes	0.5mL X1 tube
Instruction for use	1 piece	1 piece	1 piece	1 piece	1 piece
Oropharyngeal/Nasopharyngeal swabs	40 pieces	20 pieces	5 pieces	2 pieces	1 piece
Antigen extraction tube (with tube and dropper head)	40 pieces	20 pieces	5 pieces	2 pieces	1 piece
Tube stand	1 piece	1 piece	1 piece	1 piece	1 piece

[Storage conditions & period of validity]

1. Store at 2℃~30℃, and it is valid for 24 months. DO NOT FREEZE.

2. After the aluminum foil bag is unsealed, the test card should be used as soon as possible .

3. For best performance, it is recommended to test immediately after sample collection.

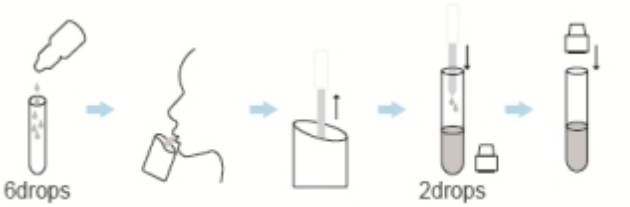
4. The saliva sample/Oropharyngeal (throat) swabs/ Nasopharyngeal swabs in the airtight container can be stored at room temperature for 1 hours or at 2-8°C for 24 hours or at -20°C for 7 days.

[Specimen request]

Saliva:

Relax the cheeks and gently massage for 15-30 seconds with the fingers before the specimen collection. Hold the tongue against the upper and lower jaws including the roots to enrich the saliva. To collect the saliva, install the saliva collector over the collection tube or open the collection bag, and collect saliva specimen according to the following procedure:

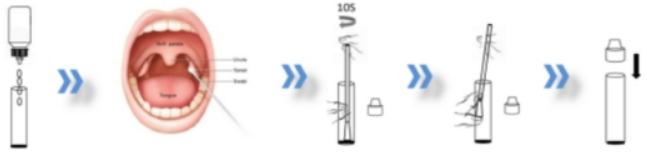
Bring close to the lips and gently spit in the saliva collector or collection bag and let the saliva flow into the collection tube or collection bag.



- Oropharyngeal (throat) swabs:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe on both sides of the patient's pharyngeal tonsils, wipe it back and forth for at least 3 times and do it with moderate pressure applied. Place the swab specimen in the extraction tube with the Antigen extract R1 added in advance, rotate the swab for about 10 seconds, and press the swab head against the wall to release the antigen in the swab.

- Nasopharyngeal swabs:



Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way; place the swab specimen in the extraction tube with the Antigen extract R1 added in advance, rotate the swab for about 10 seconds, and then squeeze the swab head from the tube wall to release the antigen in the swab

[Test methods]

1. Unseal the package and take out the antigen test cassette.

2. Place the extraction tube on the tube stand. Place the Antigen extract R1 bottle vertically downward to allow the solution to drip freely into the extraction tube without touching the edge of the tube. Add 6 drops of R1 to the extraction tube.

3. Specimen Preparation

Saliva: Add 2 drops of saliva into the extraction tube by saliva dropper, shake the extraction tube vigorously to mix the saliva and the extraction buffer. Squeeze the tube about 10 times to allow a thorough mixing.

Oropharyngeal/Nasopharyngeal swabs: Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head while taking the swab out of the extraction tube to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.

4. Install the dropper head on the extraction tube, put 3 drops into the specimen well of the test cassette, and start the timer.

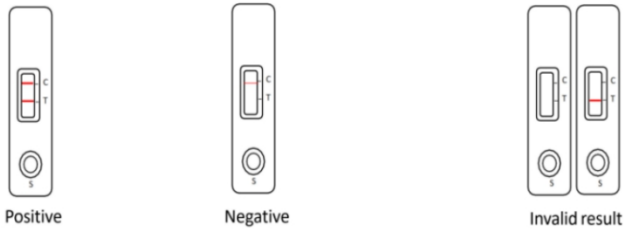
5. Read the results within 15 minutes. Strong positive results can be reported within 15 minutes, however, negative results must be reported after 15 minutes, and the results after 25 minutes are no longer valid.

[Interpretation of test results]

- Positive result: if both the quality control line C and the detection line appear, novel coronavirus antigen has been detected and the result is positive for antigen.

- Negative result**:** if there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.

- Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be repeated.



[Limitations of inspection methods]

1. This reagent is for in vitro diagnostic use only.

2. This reagent is only used to detect human sterile swab extracts or saliva sample. The results of other specimens maybe inaccurate.

3. This reagent is only used for qualitative detection and can not indicate the level of novel coronavirus antigen in the specimen.

4. This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

[Product Performance Indicators]

1. **LoD:** The LoD for direct swab was established using heat-inactivated SARS-CoV-2. The strain was spiked into the pooled human oropharyngeal swab matrix obtained from multiple healthy volunteers eluted in R1 and confirmed as SARS-CoV-2negative by RT-PCR to prepare positive samples. The estimated LoD found from the initial serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 5 x 10^2 TCID50/ml.

2. **Negative Agreement:** Test the negative reference, and the negative accordance rate shall be 100%.

3. **Positive Agreement:** Test the positive reference, and the positive accordance rate shall be 100%.

4. Precision: Test the precision references, the test results shall be positive with uniform color.

5. Analytical Specificity

1) Cross-reactivity:

No false positive test results for COVID-19 (SARS-CoV-2) Antigen Test Kit were observed on specimens from the following disease states or specific conditions:

Staphylococcus aureus, streptococcus pneumonia, measles, mumps virus, Adenovirus (type 3,C1,71), Mycoplasma pneumonia, Parainfluenza virus (1-4)(2), Mycobacterium tuberculosis,CoronavirusOC43, Coronavirus229E, CoronavirusNL63, CoronavirusHKU1, bordetella pertussis, Influenza B Virus (Victoria), Influenza B Virus (Yamagata), H1N1, H3N2, EBV, Coxsackievirus A16 (CVA16), Rhinovirus, Respiratory syncytial virus, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pyrogenes, Pneumocystis jirovecii (PJP), Pooled human nasal wash .

2) Interference:

No interference was observed with the potentially interfering substances listed below at the indicated concentration:

Commonly used drugs, i.e., 5mg/mL Phenylephrine, 5mg/mL Oxymetazoline, 0.9% sodium chloride, 200μg/L beclomethasone, 150μg/L dexamethasone, 400μg/L flunisolide, 60mg/mL triamcinolone acetonide, 2mg/mL budesonide, 5mg/mL mometasone, 250μg/L fluticasone, 1mg/mL Histamine hydrochloride, 60μg/L alpha- interferon, 142ng/mL zanamivir, 0.25mg/L ribavirin, 24.6mg/mL oseltamivir, 0.1mg/L peramivir, 4mg/L Lopinavir, 250mg/L Ritonavir, 100mg/L Arbidol, 500mg/L levofloxacin, 500mg/L azithromycin, 100mg/mL ceftriaxone, 50mg/mL meropenem, 4μg/mL tobramycin, 0.9mg/ml mucin, 50% blood (human), Human Anti-mouse Antibody (HAMA), biotin have no effect on the test results of this kit.

6. Clinical Performance

1) Oropharyngeal swabs and nasopharyngeal swabs specimens:

Contrast Results Statistics of Clinically Confirmed/Excluded Results

Evaluation Reagent	Clinical Confirmed/Excluded Results		Total
	Confirmed	Excluded	
Positive	125	3	128
Negative	5	401	406
Total	130	404	534

Result calculation:

(1) Clinical sensitivity: 96.15%, 95% confidence interval: [91.31%，98.35%].

(2) Clinical specificity: 99.26%, 95% confidence interval: [97.84%，99.75%].

(3) Clinical accuracy: 98.50%, 95% confidence interval: [97.07%，99.24%].

*In the stratified statistics of different stages of the disease, 52 specimens from 0-3 days, and the positive detection rate is 98.08%.

2) Saliva specimens:

Contrast Results Statistics of Clinically Confirmed/Excluded Results

Evaluation Reagent	Clinical Confirmed/Excluded Results		Total
	Confirmed	Excluded	
Positive	123	4	127
Negative	5	423	428
Total	128	427	555

Result calculation:

(1) Clinical sensitivity: 96.09%, 95% confidence interval: [91.49%,98.01%].

(2) Clinical specificity: 99.06%, 95% confidence interval: [97.72%, 99.53%].

(3) Clinical accuracy: 98.38%, 95% confidence interval: [97.00%, 99.09%].

*In the stratified statistics of different stages of the disease, 52 specimens from 0-3 days, and the positive detection rate is 98.04%.

[Precautions]

1. This reagent must be used by trained or professional clinical testing personnel by following all laboratory management regulations.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
3. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
4. Keep away from moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use when the aluminum foil bag is damaged or the test card is damp.
5. Please use it within the validity period.
6. Wait all reagents and specimens come to room temperature (15 ~ 30 ℃) before use.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
10. The test methods and results must be interpreted in strict accordance with this specification.

[Index of Symbols]

2℃ 30℃	Temperature Limit		Use-by date
LOT	Batch/Lot code	IVD	In vitro diagnostic medical device
	Manufacturer	REF	Catalogue number
Σ n	Contains sufficient for <N> tests		Consult instructions for use
	Do not re-use	CE	
	Date of manufacture	EC REP	Authorized representative in the European Community

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

	Do not use if package is damaged	STERILE R	Sterilized using irradiation
CE 0197	CE Certification		

[INFORMATIONENINQUIRIES AND GENERAL INFORMATION]

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

Address: Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, 430074 Wuhan, China

Tel: +86(0)27-87808955

Fax: +86(0)27-87808005

WEB: www.mdeasydiagnosis.com

Email: info@ediagnosis.cn

MedNet EC-REP GmbH

EC REP Borkstrasse 10, 48163 Münster, Deutschland

[**SWAB INFORMATION**]

ShenzhenKangDaAn Biological Technologyco, LTD

East- 1, 3rd floor, Building 2, Shunheda factory, Liuxiandong industrial zone, Xili street, Nanshan district, Shenzhen .

Tel: +86 0755- 82836262

Fax: +86 0755- 83426595

WEB: www.kdasw.com

EC REP **Name**: Share Info Consultant Service LLC Repräsentanzbüro

Address: Heerdter Lohweg 83, 40549 Düsseldorf

eDiagnosis
明德生物

CE

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

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**Wuhan EasyDiagnosis Biomedicine Co., Ltd** Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone,430074 Wuhan, China
EU-Vertreter/ Authorized EU Representative/ représentants européens / Presentanti dell'UE:	**MedNet EC-REP GmbH Borkstrasse 10, 48163 Münster, Germany**
DIMDI No.:	**DE/0000048589**

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

das Medizinprodukt: / the medical device: / Product Name:/ Type/Model: le dispositif médical: / il dispositivo medico:	**COVID-19 Antigen Rapid Test Kit (Saliva/Swabs) Analyte:antigen from SARS-CoV-2 in saliva and oropharyngeal (throat)/nasopharyngeal swabs** **Saliva:** **20 Tests/Kit, 10 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit, 1 Test/Kit** **Oropharyngeal/Nasopharyngeal swabs:** **40 Tests/Kit, 20 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit, 1 Test/Kit**
der Klasse: / of class: / de la classe: / di classe:	**Others**

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

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

Conformity assessment procedure: /	**Directive 98/79/EC Annex III**
list of applied standard:	EN ISO 14971:2019, EN ISO 15223-1: 2016, EN ISO 13485:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN13612:2002 EN 13612:2002/AC:2002, EN ISO 23640:2015

Wuhan,January 22, 2021
Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function: Yingwen.Zhao/regulatory representative
Nom et fonction / Nome e funzione

CERTIFICATE OF REGISTRATION

MedNet EC-REP GmbH
Borkstraße 10
48163 Münster
Germany

in its function of the European Authorized Representative, in accordance with the In Vitro Diagnostic Directive 98/79/EC, hereby confirms the submission of the registration of the following *in vitro* diagnostic medical devices into the German DIMDI data base

COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)
Analyte: antigen from SARS-CoV-2 in saliva and oropharyngeal (throat)/nasopharyngeal swabs

on behalf of

Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg. 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No. 388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, 430074 Wuhan, P.R. China

according to the directive 98/79/EC of the European Parliament and of the Council of the European Union relating to *in vitro* diagnostic medical devices.

Münster, 24 February 2021

i.A. M. Hapke
MedNet EC-REP GmbH

MEDNET EC-REP
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Borkstrasse 10, 48163 Muenster, Germany
Phone: +49 251 322 66-61
ecrep@mednet-europe.com www.mednet-eurep.com

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00158820

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA22**		
	Bezeichnung / Name **Bezirksregierung Münster, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48143**
	Straße, Haus-Nr. / Street, house no. **Domplatz 36**		
	Telefon / Phone **+49-251-4110**		Telefax / Fax **+49-251-4112525**
	E-Mail / E-mail **mitteilungen-dimdi@brms.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **27.11.2020**		Registriernummer / Registration number **DE/CA22/1311-538-IVD**
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000048589**		
	Bezeichnung / Name **MedNet EC-REP GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **025132266-61**		Telefax / Fax **025132266-22**
	E-Mail / E-mail **ear-admin@medneteurope.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Wuhan EasyDiagnosis Biomedicine Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Wuhan**		Postleitzahl / Postal code **430074**
	Straße, Haus-Nr. / Street, house no. **Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise accelerator, No.388, Gaoxin 2nd RD, East Lake**		
	Telefon / Phone **+86(0)27-87808955**		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **David Thaler**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **025132266-50**		Telefax / Fax
	E-Mail / E-mail **david.thaler@medneteurope.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name **Ole Stein**		
	Telefon / Phone **025132266-16**		Telefax / Fax
	E-Mail / E-mail **ole.stein@medneteurope.com**		
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification £ Produkt der Liste A, Anhang II / Device of List A, Annex II £ Produkt der Liste B, Anhang II / Device of List B, Annex II £ Produkt zur Eigenanwendung / Device for self-testing S Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG £ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device
	Produktbezeichnung / Name of device **COVID-19 (SARS-CoV-2) Antigen Test Kit**
	Angabe der benutzten Nomenklatur / Nomenclature used S EDMS-Klassifikation / EDMS Classification £ GMDN
	Nomenklaturcode / Nomenclature code
	Nomenklaturbezeichnung / Nomenclature term
	Kurzbeschreibung / Short description In Deutsch / In German **Analyte: Antigen des neuartigen Coronavirus in menschlichen Rachenabstrichen oder Nasenabstrichen. Dieses Produkt ist für den qualitativen In-vitro-Nachweis des Antigens des neuartigen Coronavirus in menschlichen Rachenabstrichen oder Nasenabstrichen bestimmt.**
	In Englisch / In English **Analyte: antigen of novel coronavirus in human throat swabs or nasal swabs. This product is intended for in vitro qualitative detection of the antigen of novel coronavirus in human throat swabs or nasal swabs.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Produktbezeichnung / Name of device
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	£ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Münster**

Datum
Date **2020-10-21**

Name **Nadezda Levanova**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Silvia Wenge**		Telefon / Phone **0251-4115936**