Novel Coronavirus (SARS-CoV-2) Nucleic Acid Diagnostic Kit
(PCR-Fluorescence Probing)

Company Profile:

TBG

MEDIGEN BIOTECHNOLOGY CORP

Manufactured:

Taiwan

Offical Website:

http://www.tbgbio.com/en

http://www.medigen.com.tw/zh/%e9%a6%96%e9%a0%81/

http://www.medigen.com.tw/en/tbg-diagnostics-limited-listed-on-australian-securities-exchange-asx-on-february-3-2016/

Certification:

CE

MOQ:

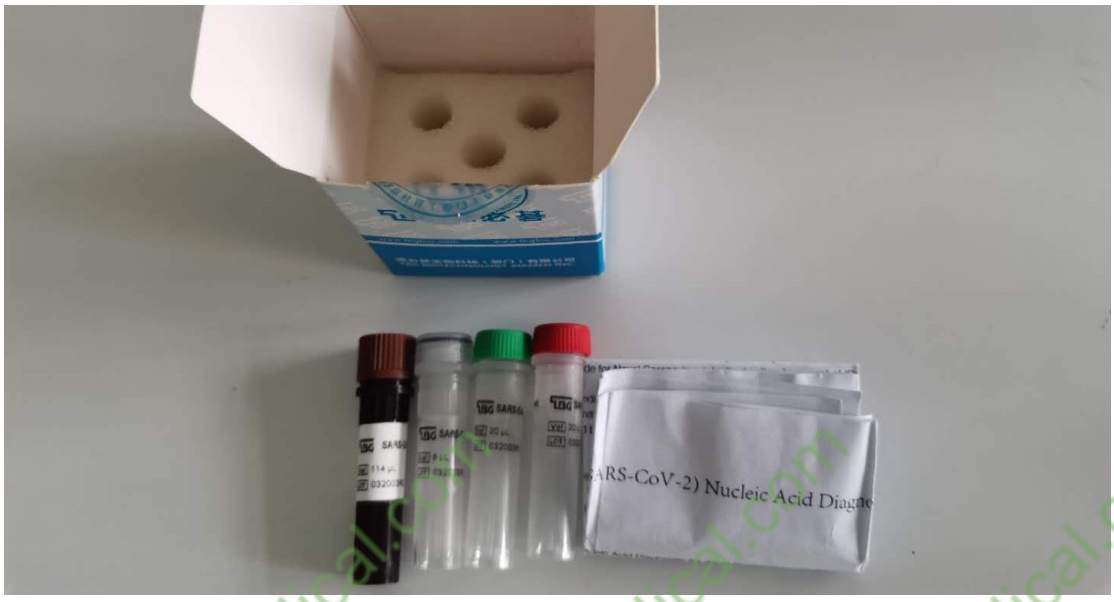
5000 and Up

Press Reference (in Chinese):

https://money.udn.com/money/story/11074/4424882

https://ctee.com.tw/news/stock/237906.html

Product Photo



Certification

EC Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name: TBG BIOTECHNOLOGY XIAMEN INC.
Address: Building 3，2004 wengjiao west Road, Haicang District, Xiamen, 361027, China.

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Product Name	Type	Cat. No.
Novel Coronavirus(SARS-CoV-2) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	24 tests/kit	04D026

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223-1:2016
EN ISO 18113-1:2011
EN ISO 18113-3:2011
EN 62366-1:2015
EN 13612:2002
EN ISO 18113-2:2011
EN ISO 23640:2015

Signature:

TBG BIOTECHNOLOGY XIAMEN INC. 维必基生物科技 (厦门) 有限公司

Date: 2020.03.10

Certificate of CE-Registration

mdiEuropa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

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221 New Taipei City
Taiwan

as stipulated and demanded by the afore-mentioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

EDMA Code	Description	Classification	Registration Number
1601040100	HLA Typing	Annex II, List B	DE/CA09/0760/T04/IVD/003-04
1402060200	Nucleic Acid Identification - Automated	other IVD	DE/CA09/0760/T04/IVD/001-02
220305	Nucleic Acid Processors	other IVD	DE/CA09/0760/T04/IVD/002-02
1601040100	HLA Typing	other IVD	DE/CA09/0760/T04/IVD/004
26.03.10.01	NA Amplification Detection Hardware + Accessories + Consumables + Software	other IVD	DE/CA09/0760/T04/IVD/005

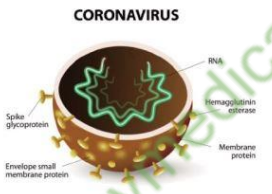
Product Information

Novel Coronavirus(SARS-CoV-2) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Triple labeled targets

Internal control included

INTENDED USE OF NOVEL CORONAVIRUS(SARS-CoV-2; COVID-19) NUCLEIC ACID DIAGNOSTIC KIT



NOVEL CORONAVIRUS (SARS-CoV-2) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE RDRP, N AND E GENES OF NOVEL CORONAVIRUS (SARS-CoV-2) IN SERUM, PLASMA AND PHARYNGEAL SWABS SAMPLES. THE TEST RESULTS OF THIS KIT CAN QUALITATIVELY DETERMINE WHETHER THE SUSPECTED SUBJECT IS INFECTED WITH NOVEL CORONAVIRUS (SARS-CoV-2) OR NOT.

PRODUCT INFORMATION

- USE FOR IN VITRO QUALITATIVE DETECTION OF SARS-CoV-2 RNA
- PACKAGE SPEC: 24 TESTS/KIT, 48 TESTS/KIT, 96 TESTS/KIT
- MAIN COMPONENTS: SARS-CoV-2-PCR-REACTION LIQUID, SARS-CoV-2-PCR-ENZYME MIX, SARS-CoV-2-PCR-POSITIVE CONTROL, SARS-CoV-2-PCR-NEGATIVE CONTROL
- APPLICABLE INSTRUMENTS: ABI 7500, LIGHTCYCLER 480, AGS4800, ETC.
- APPLICABLE SAMPLE: THROAT SWABS, BRONCHOALVEOLAR LAVAGE FLUID(BALF) AND SPUTUM

PRODUCT CHARACTERISTICS	PERFORMANCE
STORAGE & VALIDITY PERIOD	-20±5°C, 6 MONTHS
AMPLIFICATION SAMPLE VOLUME	5 μL
DETECTION SENSITIVITY	LOD: 5 COPIES
DETECTION PRECISION	CV<5%
CROSS REACTION	NO CROSS REACTION WITH OTHER PATHOGENS OF THE SAME INFECTION SITE OR SIMILAR INFECTION SYMPTOM

TBG Biotechnology Corp.

Better Test, Better Care

Q6000 Real-Time PCR System Specifications Table:

Specifications:	
Product Name:	Q 6000
Dimensions (WxDxH)	354 x 567 x 455 mm
Potential Applications	SNP Genotyping / Gene Expression Analysis / MicroRNA Expression / Protein Expression / Translocation Analysis / Gene Detection / Viral Load Analysis, Melting Curve Analysis.
Detection System	6 excitation and 6 emission filters, CCD camera
Sensitivity	Distinguish between 5,000–10,000 genome equivalentswith 99.7% confidence
Temperature Range	RT~99.9°C
Optimum Range of Rxn Vol.	10~100μL
Reaction Plate Format	96-well plates (100μL) or 8-tube strips (100 μL)
Run Time	< 2 hrs/run (depends on the test program)
Excitation Source	Halogen- Tungsten lamp
Heating Rate	Standard :2.5°C/sec; Low: 1.5°C/sec
Cooling Rate	Standard: 2.5°C/sec; Low: 1.5°C/sec
Temperature Uniformity	±0.5°C
Weight	35 kg

Multiplex Detection System			
Channels	**Excitation**	**Emission**	**Usage Dye**
1	469/35	520/28	SYBER GREEN, FAM
2	520/15	556/20	JOE, HEX, VIC
3	549/15	586/20	CY3, TRMRA
4	580/23	628/32	ROX, TEXAS RED
5	635/18	676/29	CY5
6	680/22	720/24	CY5.5

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Better Test, Better Care

Q6000 Real-Time PCR System

6-Color Multiplexing

Automation

Reliable Results

Faster Analysis Time

Ready to Use Reagents