SENTINELTECH
前哨科技

华夏帮服科技有限公司

产品展示

全球动态基因检测“开创者”

产品信息

04 EMBEDDED SOLUTIONS

WORKING LOCATION

CDC PCR Lab

Clinical Hospital PCR Laboratory

Third-party testing Medical Laboratory Centre

APPLICABLE INSTRUMENTS

- NUCLEIC ACID EXTRACTOR (INCLUDING ALL THE MAINSTREAM BRANDS)

AMY 32(Aisen)

Thermo KingFisher Flex

- FLUORESCENCE QUANTITATIVE PCR AMPLIFIER (INCLUDING ALL DOMESTIC AND IMPORTED MAINSTREAM BRANDS)

SLAN®-96P(Hongshi)

QuantStudio-5-Front -Trans-5in

SUGGESTION PROGRAM

Collecting throat swab specimens

Nucleic acid extractor or workstation

Fluorescence quantitative PCR

普瑞康 puruikang

普瑞康 puruikang

Shenzhen Puruikang Biotechnology Co., Ltd., founded in 2009, is a professional high-tech enterprises, engaged in molecular diagnostic products R & D, production, sales and technical services. With international PCR compound probe technology and visualization biochip technology platform, puruikang, which has advanced PCR and biochip production line, is the special demand drug production base of Central Military Commission. Puruikang and Military Medicine, Academy of Military Sciences, PLA are long time of friendly relations of cooperation. They had accomplished 15 key program of the national and national high-tech RD program of china （863 program） together.

2019-nCoV DETECTION KIT FOR 2019-NOVEL CORONAVIRUS RNA

RT-PCR-Fluorescence Probing

WELCOME YOUR CALL

400-160-1991

139-0137-5668

SHENZHEN PURUIKANG BIOTECH CO.,LTD

Registration Address: No.9, TaoHuaYuan Science and Technology Innovation Park, Xixiang Street,Bao'an District, Shenzhen,China.

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01 CLINICAL BACKGROUND

Since Dec 31, 2019, the Chinese city of Wuhan has reported an outbreak of atypical pneumonia caused by the 2019 novel coronavirus (2019-nCoV). Cases have been exported to other Chinese cities, as well as internationally, threatening to trigger a global outbreak.

Facing the rapidly rising epidemic, the Chinese government has timely amended the Law of the PRC on the Prevention and Treatment of Infectious Diseases on 20th January 2020 to include the 2019-nCov as a class-B infection but manage it as a class-A infection due to its severity.

2019-nCoV is enveloped single-stranded plus stranded RNA virus with a diameter of 60–140 nm,spherical or elliptical in shape and pleomorphic.The new type of coronavirus belongs to genus β.The β-CoVs are further divided into four lineages: lineage B, which includes SARS-CoV and the newly emerging 2019-nCoV, lineage C, which includes MERSCoV, were obviously difference.

It has been reported that the consistency of whole genome-wide nucleotide sequences of 2019-nCoV with SARS-like coronavirus in bats (bat-SL-CoVZC45) ranges are almostly 85%.

This kit, adopting Real-Time PCR-Fluorescence technology, is used for qualitative detection of 2019-ncov virus in the specimen of suspected patient infected with 2019-ncov virus. It can be used for the laboratory diagnosis and monitoring of the virus infection. The test results are only for clinical reference, not alone for case confirmation or exclusion.

02 PRODUCT DEVELOPMENT

Based on analysising the complete sequence of the 2019-Novel Coronavirus genome,puruikang and Academy of Military Medicine, Academy of Military Sciences, PLA have recently cooperate to develope the new Detection kit of 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing).

The kit,which had authorized by the legal diagnostic institution of the army, was obtained the refistration certification (Military Drug Standard Q 2020001).

03 PRODUCT DESCRIPTION

This kit, adopting Real-Time PCR-Fluorescence technology, was used for qualitative detection of 2019 -Novel Coronavirus virus in the specimen(sputum, throat swab, nasopharyngeal swab, alveolar lavage fluid or other respiratory secretions, etc).

PRODUCT OVERVIEW

This kit was used for qualitative detection of 2019-nCoV virus in clinical samples (sputum,throat swab, nasopharyngeal swab,alveolar lavage fluid or other respiratory secretions,etc.).

PRODUCT PROPERTY

• RAPID DIAGNOSIS

It takes only 60 minutes from sample extraction to complete detection.

• SPECIFICITY

The kit can specifically detect 2019-ncov virus. There was no cross reaction with influenza A virus, influenza B virus adenovirus Staphylococcus aureus, HCoV-SARS, HCoV-MERS,HCoV-OC43, HCoV-HKUI, Streptococcus pneumoniae, Klebsiella pneumoniae, etc.

• SENSITIVITY

The Minimum detection limit of the kit is 1.0×103 copies/mL.

• PRECISION

The 2019-nCoV precision reference R or national precision reference were tested 10 times with positive results, and coefficient of variation (CV) of Ct value of the fam channel was less than 5%, the results demonstrated that the diagnostic kit has good repeatability.

• ACCURACY

5 enterprise positive reference of 2019-nCoV and national positive reference were tested, and the positive coincidence rate was 100% .

• WHOLE-PROCESS CONTROL

The use of internal standard participate the extraction and amplification, allowing the identification of false negatives.

AREAS OF APPLICATION

Hospital clinical diagnosis

Public health and disease prevention and control

Physical examination and health control

CLINICAL SIGNIFICANCE

RAPID SCREENING

AUXILIARY DIAGNOSIS

TEST PRINCIPLE

This kit ,targeting N protein of 2019-Novel Coronavirus and designing specific primers and probes, is used for detection of 2019-Novel Coronavirus RNA in the samples by adopting Real-Time PCR-Fluorescence technology.

APPLICABLE INSTRUMENTS

PCR instrument with dual-color fluorescence channel FAM and ROX,including 7500 (ABI)、Quant Studio5(ABI)、Roche Light Cycler 480、Bio-Rad CFX96、SLAN®-96P (Hongshi)、CFX96 (Bio-Rad) etc.

产品实物


Detection Kit for 2019-
Novel Coronavirus RNA
(RT-PCR-Fluorescence Probing)
普瑞康®
puruikang
普瑞康
puruikang
【Product Name】


Detection Kit for 2019-
Novel Coronavirus RNA
(RT-PCR-Fluorescence Probing)
普瑞康®
puruikang

产品说明

普瑞康 puruikang

Instructions of Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

Instructions of Detection Kit for 2019-Novel Coronavirus RNA
(RT-PCR-Fluorescence Probing)

[Product name]
Detection Kit for 2019-Novel Coronavirus RNA
(RT-PCR-Fluorescence Probing)

[Package Specifications]
24 tests/kit

[Intended use]
This kit, adopting Real-Time PCR-Fluorescence technology, is used for qualitative detection of 2019-Novel Coronavirus in respiratory specimens. It can be used for the laboratory diagnosis and monitoring of the virus infection. The test results are only for clinical reference, not alone for case confirmation or exclusion.

[Test principle]
This kit is used to detect 2019-Novel Coronavirus RNA in the samples by adopting Real-Time PCR-Fluorescence technology, including targeting N protein of 2019-Novel Coronavirus,designing specific primers and probes and then detecting the fluorescence signals.

[Main components]

Type	Reagent	Specification	Components
PCR Amplification Reagents	PCR Reaction mixA	332μL×1 tube	Primers, probes, ,dNTP Mixture,PCR Buffer
	PCR Reaction mixB	29μL×1 tube	DNA polymerase, ReverseTranscriptase
Control Reagents	Negative control	400μL×1 tube	Recombinant plasmid Containing RNase P
	Positive control	400μL×1 tube	Recombinant plasmid containing 2019-ncov target fragment

Notes: components of kits from different batches should not be used interchangeably.

[Storage conditions and expiry date]
The kit is stored under -20℃ and protected from light. Avoid repeated freezing-thawing (no more than 4 times). Its period of validity is 12 months.

[Applicable instruments]
PCR instrument with dual-color fluorescence channel FAM and ROX, including 7500 (ABI)、Quant Studio5(ABI)、SLAN®-96P(Hongshi)、CFX96 (Bio-Rad) etc.

Samples and detection

I.Sample requirements
Applicable sample types: sputum, throat swab, nasopharyngeal swab, alveolar lavage fluid or other respiratory secretions, etc.

II. Sample preservation and transportation
The samples are temporarily stored at 4℃ and delivered to the laboratory within 12 hours. It is stored in freezing below -20℃. The samples that need to be preserved for a long time should be stored in the refrigerator at -70℃ and below. Avoid repeated freezing-thawing (no more than 3 times of freezing-thawing).

III. Sample transportation
The transported samples shall be tightly packed in accordance with the basic triple package system, which consists of absorbent package (which is sealed sample bag) as the first layer, containment vessel (waterproof and leakproof) as the second layer and transport package as the outer layer. Samples shall be delivered by professional personnel. Keep cool with ice bag in short-distance transportation, and with dry ice in long-distance transportation. Sample transportation shall comply with the relevant regulations of the State.

[Test method]

I. Preparation of PCR reagents (conduct in the reagent preparation zone)
1. Prepare PCR reaction solution according to the following compositions (n is the number of reaction tubes):
PCR reaction mixA is 13.8μL×n, and PCR reaction mix B is 1.2μL× n.
(Notes: make sure that PCR solution is fully dissolved before use, and centrifuge PCR reaction mix B before use to ensure that all liquid is concentrated at the bottom)
2. Mix evenly the PCR reaction mix A and B, divide them into the PCR
reaction tube by 15 μL per tube, and move the reaction tubes containing the PCR reaction solution to the sample processing zone.

II. Nucleic acid extraction (conduct in sample processing zone)
1. Select the appropriate Nucleic acid extraction reagent such as Column magnetic beadsor Column extraction kit to extract the samples nucleus acid, according to the instructions of the

普瑞康 puruikang

Instructions of Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

Instructions of Detection Kit for 2019-Novel Coronavirus RNA
(RT-PCR-Fluorescence Probing)

[Product name]
Detection Kit for 2019-Novel Coronavirus RNA
(RT-PCR-Fluorescence Probing)

[Package Specifications]
24 tests/kit

[Intended use]
This kit, adopting Real-Time PCR-Fluorescence technology, is used for qualitative detection of 2019-Novel Coronavirus in respiratory specimens. It can be used for the laboratory diagnosis and monitoring of the virus infection. The test results are only for clinical reference, not alone for case confirmation or exclusion.

[Test principle]
This kit is used to detect 2019-Novel Coronavirus RNA in the samples by adopting Real-Time PCR-Fluorescence technology, including targeting N protein of 2019-Novel Coronavirus,designing specific primers and probes and then detecting the fluorescence signals.

[Main components]

Type	Reagent	Specification	Components
PCR Amplification Reagents	PCR Reaction mixA	332μL×1 tube	Primers, probes, ,dNTP Mixture,PCR Buffer
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Notes: components of kits from different batches should not be used interchangeably.

[Storage conditions and expiry date]
The kit is stored under -20℃ and protected from light. Avoid repeated freezing-thawing (no more than 4 times). Its period of validity is 12 months.

[Applicable instruments]
PCR instrument with dual-color fluorescence channel FAM and ROX, including 7500 (ABI)、Quant Studio5(ABI)、SLAN®-96P(Hongshi)、CFX96 (Bio-Rad) etc.

Samples and detection

I.Sample requirements
Applicable sample types: sputum, throat swab, nasopharyngeal swab, alveolar lavage fluid or other respiratory secretions, etc.

II. Sample preservation and transportation
The samples are temporarily stored at 4℃ and delivered to the laboratory within 12 hours. It is stored in freezing below -20℃. The samples that need to be preserved for a long time should be stored in the refrigerator at -70℃ and below. Avoid repeated freezing-thawing (no more than 3 times of freezing-thawing).

III. Sample transportation
The transported samples shall be tightly packed in accordance with the basic triple package system, which consists of absorbent package (which is sealed sample bag) as the first layer, containment vessel (waterproof and leakproof) as the second layer and transport package as the outer layer. Samples shall be delivered by professional personnel. Keep cool with ice bag in short-distance transportation, and with dry ice in long-distance transportation. Sample transportation shall comply with the relevant regulations of the State.

[Test method]

I. Preparation of PCR reagents (conduct in the reagent preparation zone)
1. Prepare PCR reaction solution according to the following compositions (n is the number of reaction tubes):
PCR reaction mixA is 13.8μL×n, and PCR reaction mix B is 1.2μL× n.
(Notes: make sure that PCR solution is fully dissolved before use, and centrifuge PCR reaction mix B before use to ensure that all liquid is concentrated at the bottom)
2. Mix evenly the PCR reaction mix A and B, divide them into the PCR
reaction tube by 15 μL per tube, and move the reaction tubes containing the PCR reaction solution to the sample processing zone.

II. Nucleic acid extraction (conduct in sample processing zone)
1. Select the appropriate Nucleic acid extraction reagent such as Column magnetic beadsor Column extraction kit to extract the samples nucleus acid, according to the instructions of the

corresponding kit. Note:The negative control is processed synchronously with the samples to be tested ,no extraction is needed for the positive control, which could be added directly).

2. The treated samples, negative control and positive control of 15μL are pipetted (with filter) to PCR tubes containing PCR solution respectively.Cover the tube, centrifuge for a few seconds, and move to the amplification detection zone.

III. PCR amplification detection (conduct in the amplification detection zone)

1. Put the PCR reaction tubes into the Fluorescence PCR amplification instrument for amplification detection.

2. Cycle parameter settings are as follows:

3. Instrument detection channel selection: FAM is the amplified signal of 2019-Novel Coronavirus virus, and ROX is the internal standard amplified signal.

Step	No. of cycles	T (℃)	Time (min:sec)	Whether collect fluorescence signal
1	1	50	20:00	NO
2	1	95	03:00	NO
3	45	95	00:05	NO
		53	00:45	Yes
4	1	25	00:10	NO

3.1 ABI 7500 Real Time PCR System and ABI Quant Studio5

1) FAM（Reporter：FAM，Quencher：None）is the amplified signal of 2019-Novel Coronavirus virus；

2) ROX（Reporter：ROX，Quencher：None）is the internal standard amplified signal；

3) reaction volume was 30μL.

3.2 SLAN®-96P(Hongshi)

1) FAM（Reporter：FAM，Quencher：None）is the amplified signal of 2019-Novel Coronavirus virus；

2) ROX（Reporter：ROX，Quencher：None）is the internal standard amplified signal；

3) reaction volume was 30μL.

IV.Result analysis

1. After the experiment, analyze the data according to the software of related instruments. FAM and ROX channels need to be analyzed separately, and the corresponding fluorescence channels should be selected separately. When analysising FAM channel , it was recommended to select only FAM channel, not to select all channels at the same time; when analyzing theROX channel, it was recommended to select only ROX channel, not all channels at the same time.

2. The setting principle for threshold shall be that the threshold line just exceeds the highest point of the normal negative control curve (irregular noise line).

3.ABI 7500 Real Time PCR System and ABI Quant Studio5，baseline is selected in 3~15 circulating regions, and SLAN®-96P(Hongshi) baseline is selected in 6 ~12 circulating regions.

4. The Ct value of the sample is automatically analyzed and calculated by the recording instrument.

V. Quality control standards

1. Negative control: the result is negative; meanwhile, the internal standard result is positive with Ct value≤36 .

2. Positive control: the result is positive; Ct value of positive control is≤36,the internal standard result is negative with no Ct value or CT value 0 .

3. The above two items should be met simultaneously in one experiment. Otherwise, the experiment is invalid and should be repeated.

【Positive judgement or reference range】

1. Determination of negative results: if amplification curve of FAM channel shows no significant logarithmic growth period; meanwhile, the amplification curve of ROX channel shows a logarithmic growth period, and the Ct value of internal standard is ≤40, then the result is determined to be negative.

2. Determination of positive results: if the amplification curve of FAM channel shows a logarithmic growth period and Ct value is≤ 40, the result should be positive.(ROX channel result is not required when the positive result).

3. Experimental gray zone: if the amplification curve of FAM channel shows a logarithmic growth period and Ct value is between 40~45 , the determination result is located in the experimental gray zone, indicating that the sample should be re-examined or re-sampled and re-examined. If there is an obvious logarithmic growth period, the result is positive; if there is no obvious logarithmic growth period, then the result is negative.

【Interpretation of test results】

I.For each experiment, the negative control and positive control in the kit should be tested with the samples to be tested, and the test results should meet their property indexes, otherwise this experiment is invalid.

II.. Recommends the following format of the report：

1 if the experimental results meet the criteria for positive results, the report format should be as follows: FAM channel as positive,2019-nCoV nucleic acid is detected in the sample, and the concentration is higher than the detection limit of the kit;

2 if the experimental results meet the criteria for the determination of negative results, the report format is as follows: no 2019-nCoV nucleic acid is detected in the sample, and the concentration is lower than the detection limit of the kit;

3 if the re-examined result of the sample that needs reexamination is positive, report it the same as the report format of 1; if negative, report it the same as the report format of 2.

【Limitation of test methods】

I. The test results of this kit are only for clinical reference. Clinical diagnosis and treatment for sick patients should be considered in combination with their symptoms/signs, medical history and results of other laboratory examinations.

II. Possibility analysis of false negative results

1 Unreasonable sample collection, transportation and treatment, and excessively low virus droplets in samples may lead to false negative results;

2 False negative results may be caused by mutations in the target sequence of 2019-nCoV or changes in the sequence caused by other reasons.

3. Other untested interference or PCR inhibitors may lead to false negative results.

III. False positive results may occur if cross contamination is not well controlled during sample processing.

【Property indexes of product】

Minimum detection limit: 1.0×10^3copies/mL

Cross reaction: The detection results of this kit have no cross reaction with influenza A virus, influenza B virus, adenovirus, Staphylococcus aureus, HCoV-SARS, HCoV-OC43, HCoV-HKU1, Klebsiella pneumoniae, etc.

【Attentions】

1. This product is only used for testing in vitro.
2. According to the relevant regulations of the state, the samples of the 2019-nCoV are temporarily managed according to the highly microorganism (category II), and the experimental activities related to the pathogen should be carried out in the biosafety laboratory with the corresponding protection level.
3. In order to avoid any potential biological hazard in the sample, the test sample should be considered as an infectious substance to avoid contact with the skin and mucous membrane; the sample should be handled in a biosafety cabinet that prevents aerosol outflow, and the sample operation and handling should comply with the relevant regulatory requirements: 'general guidelines for biosafety in microbial biomedical laboratories ' (WS233-2002) and 'Regulation on the Administration of Medical Treatment Wastes'.
4. The quality control products in the kit have been inactivated and verified. But none of the tests are absolutely safe, so they should still be treated as infectious substances.
5. The laboratory management should be strictly carried out in accordance with the national regulations on molecular biology laboratory and clinical gene amplification laboratory. The experiment personnel must be professionally trained; the experimental process shall be conducted in different zones (reagent preparation zone, sample processing zone, amplification zone and product analysis zone). Special instruments and equipment shall be used in the special stage of the experimental operation, and supplies shall not be used in different zones. Personnel flow and air flow direction in each zone should be strictly required to avoid cross pollution to the maximum extent; consumables (such as centrifuge tubes and suction heads) should be properly cleaned and checked to avoid false negative results due to inhibitors of amplified reaction.
6. Wear work clothes and disposable gloves (one should often replace the gloves), and use disposable supplies throughout the experiment.
7. Each component of the kit should be fully melted and shaken before use, but repeated freezing-thawing should be avoided. The reagent in the centrifuge tube should be centrifuged for several seconds before use.
8. After the extraction of nucleic acid samples, it is recommended to conduct the next experiment immediately, otherwise, please store it at -20℃ and complete the test within a week.
9. Avoid bubbles as far as possible when sub-packing the reaction liquid. Please check whether the reaction tubes are tightly closed before starting the machine, so as not to leak fluorescent substances and contaminate the instrument.
10. After the experiment, the table and pipettes are treated with 50~ 1000 ppm sodium hypochlorite or 75% alcohol and ultraviolet ray lamp.
11. Disposal of sterilized waste from biosafety laboratories shall comply with the relevant national, regional and local regulations, and the latest version of relevant documents shall be referred to when designing regulations for biohazard waste disposal, transportation and discard. All wastes (including contaminated pad materials, used suction head), other disposal materials and clothes to be washed shall be sterilized with high-pressure steam sterilizer, and the disposal wastes shall be incinerated.

【Development organization】

Academy of military medicine, Academy of Military Sciences, PLA

Address: No.27 Taiping Road, Haidian District, Beijing

Tel :010-66932274, Fax :010-6693044

【Production organization】

Shenzhen Puruikang Biotech Co.,Ltd

Registration Address: No.9, TaoHuaYuan Science and Technology Innovation Park, Xixiang

普瑞康 puruikang

Instructions of Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

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【Medical Device Manufacturing Enterprise License】Guangdong Food and Drug Supervision Machinery Production Permit No .20152684

I comparation of 2019-NCoV kit and sequences of WHO recommended

This kit ,that is Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing) has been compared with the sequence recommended by WHO. The method is as follows:

1 Preparation of PCR reagents of WHO recommended

synthesized primers and probes recommended by WHO. The amplification system used was the same as the kit of 2019-NCoV.

2 Nucleic acid extraction

Select clinical samples and dilute samples with physiological salt solution , Concentration is below the minimum detection limit reference of the kit. Using Magnetic bead nucleic acid extraction reagent kit to extract the samples nucleus acid, according to the instructions of the corresponding kit.

3 Preparation of PCR reagents of 2019-NCoV

Prepare PCR reaction solution according to the Instructions of Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

4 PCR amplification detection

Then test the kit and reagents of WHO recommendedon the same SLAN®-96P(Hongshi) to examine the linear of which tested samples can be directly detected. repeated 11 times of tests for each to determine the detection bottom line of the diagnostic kit which means the analysis sensitivity.

5Test result for samples

Graph 1-1 Test result of linear of samples

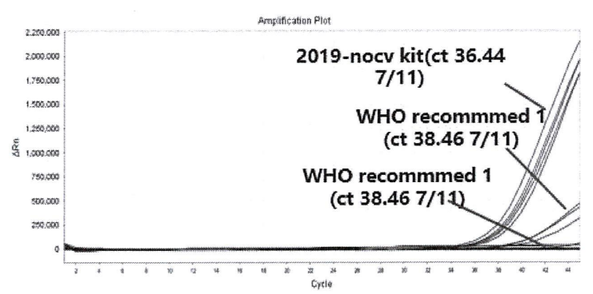


Table1-1 Test result of samples of CT values

1	35.75	39.19	40.03
2	36.52	38.98	44.78
3	36.15	37.42	41.50
4	35.25	39.20	41.57
5	35.91	38.22	
6	37.77	38.16	
7	37.73	38.06	
No. of positive / sample	7/11	7/11	4/11
Average ct Value	36.44	38.46	41.9699
regments	2019-ncov kit	WHO recommmed 1	WHO recommmed 2

6 .Conclusion:

1） from graph 1-1and Table 1-1, it can be seen that after detected by 2019-nCoV diagnostic kit and 2 of WHO recommended seqences , detection rate for sample of 2019-nCoV diagnostic kit reached 63.6%, while detection rate for sample of WHO recommended 1 reached 63.6%，and detection rate for sample of WHO recommended 2 reached 36.3%.

2） from graph 1-1and Table 1-1, it can be seen that after detected by 2019-nCoV diagnostic kit and 2 of WHO recommended seqences ,CT value of 2019-nCoV diagnostic kit is advanced 2-5 CT values than WHO recommended seqences.

3） from graph 1-1and Table 1-1, it can be seen that after detected by 2019-nCoV diagnostic kit and 2 of WHO recommended seqences , therefore, it is determined that the analysis sensitivity of the diagnostic kit is higher than WHO recommended seqences .

II **comparation of 2019-NCoV kit of puruikang and a domestic company**

In order to verify the performance evaluation of 2019-nCOV diagnostic kit of puruikang(P), it was compared with reagent from a domestic manufacturer(called company A). The kit of company A was authorized by SFDA.The method is as follows:

1 **Nucleic acid extraction**

Select 8 clinical samples from different sources, including throat swab samples (C07,C12,G09,D12) and sputum samples (E08,E09,G09,H09). Extraction of nucleic acids by magnetic bead method, following the instructions.

2 **Preparation of PCR reagents of company A**

according to the instructions， prepare the reaction reagents of company A.

3 Preparation of PCR reagents of 2019-NCoV of puruikang

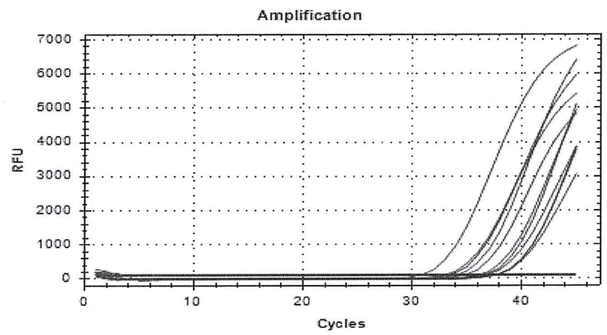
Prepare PCR reaction solution according to the Instructions of Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing) of puruikang.

4 PCR amplification detection

Then test the kit of company A and company P on fluorescence PCR detectors of CFX96 (Bio-Rad) to examine the linear of samples .

5Test result for samples

Graph 2-1 Test result of linear of samples of company Puruikang(P)



Graph 2-1 Test result of linear of samples of companyA(A)

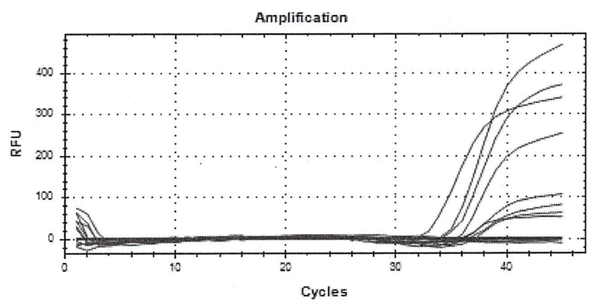


Table2-1 Test result of samples of CT values

Sample well	Sample number	ct value	
		Puruikang	companyA
C07	1	37.18	35.85
C12	2	32.71	34.18
D09	3	30.52	31.5
D12	4	35.91	36.66
E08	5	33.15	33.92
E09	6	33.81	35.46
G09	7	36.14	37.25
H09	8	34.5	36.13

6 .Conclusion:

1）from graph 2-1 to 2-2and Table 2-1, it can be seen that after detected 8 samples by 2019-nCoV diagnostic kit of company A and puruikang,therefor， 7samples of CT values of Puruikang were advanced 0.5-1.5 CT values than company A，one sample of Puruikang was Delayed 1.33 CT values than company A.

2）from graph 2-1 to 2-2 and Table 2-1, it can be seen that after detected 8 samplesby 2019-nCoV diagnostic kit of company A and puruikang，the value of the fluorescence signal of puruikang (7000) is much higher than company A(400) .

3）from graph 2-1 to 2-2 and Table 2-1, it can be seen that after detected 8 samples by 2019-nCoV diagnostic kit of company A and puruikang，amplification efficiency of puruikang is higher than company A.

Shenzhen Puruikang Biotech Co.,Ltd

04/(Day) 03 /(Month) of 2020

IVD Reagent

Clinical Trial Report of Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

Time periods：January 2020 to February 2020

Application for product registration：Shenzhen Puruikang Biotech Co.,Ltd

Report date：February 09,2020

Location of original data：Shenzhen Puruikang Biotech Co.,Ltd

Clinical Trial Report

1.Summary

The "Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)" produced by Shenzhen Puruikang Biotech Co.,Ltd.is used as reagent to be tested,According the " Registration of in vitro diagnostic products"(Order No .5 of the State Administration of Food and Drug Administration) and the "Technical guidelines for clinical studies of in vitro diagnostic products",on the basis of the trial production and laboratory evaluation of three batches of the kit,the clinical application value of the kit was evaluated.

This clinical trial is a clinical study of new diagnostic reagents.The test was carried out from January to February 2020.In this trial,we chose the man who have a history of travel or residence in Wuhan within two weeks before the onset of the disease,or had been exposed to patients with fever and respiratory symptoms from Wuhan within 14 days before the onset of the disease.The patients With fever,normal or reduced white blood cell count or reduced lymphocyte count,the chest imaging showed multiple plaques and interstitial changes,and then developed into the double lung multiple grinding glass shadow,infiltration shadow and even pulmonary consolidation of the population were our study subject.There were 523 effective sample completed ,the sample type is sputum,pharynx swab,nasal swab,alveolar lavage fluid or other respiratory secretions,and the clinical diagnosis results were used as the control method for comparative detection.

Results： There were 523 effective sample tests in this study,of which 202 were positive group samples and 321 were negative group samples.According to the statistical analysis,the positive coincidence rate of the two methods was 97.52%,the negative coincidence rate was 99.38%,and the total coincidence rate was 98.66%.

The results show that the "Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)" produced by Shenzhen Puruikang Biotech Co.,Ltd is in high agreement with the clinical diagnosis results,and there is no significant difference in statistics.Therefore,the kit is satisfied the requirements of clinical laboratory application.

2.Analysis of results and conclusions

2.1 Clinical Research Samples

A total of 523 samples of throat swab were detected in this study.

2.2 Test results of Test Reagents

A total of 197 samples were detected in the Test Reagents were 2019-nCov positive and 319 were 2019-nCov negative.

2.3 The test results of Test Reagents and controled method

The test results of the controled method were compared with those of the Test Reagents to be evaluated,as shown in Table 1

Table1 The test results of Test Reagent and Controled Method

Test Reagents \ Controlled method	Positive	Negative	Total
Positive	197	2	199
Negative	5	319	324
Total	202	321	523

According to the test results of the control method,the subjects were divided into the positive group and the negative group,and the test results of the Test Reagents were compared with the results.The results of the the coincidence rate were as follows:

Positive coincidence rate= 197/（197＋5）×100%=97.52%

Negative coincidence rate= 319/（2＋319）×100%=99.38%

Total coincidence rate= (197+319)/（197＋5+2＋319）×100%=98.66%

3. Conclusion

The above results show that the "Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)" produced by Shenzhen Puruikang Biotech Co.,Ltd is in high agreement with the clinical diagnosis results,and there is no significant difference in statistics.Therefore,the kit is satisfied the requirements of clinical laboratory application.

体外诊断试剂三类

新型冠状病毒（2019-nCoV)核酸检测试剂盒

（RT-PCR 荧光探针法）临床试验总结报告

临床试验起止时间：2020 年 1 月至 2020 年 2 月

产品注册申请人： 深圳市普瑞康生物技术有限公司

报告日期：2020 年 2 月 09 日

原始资料保存地点： 深圳市普瑞康生物技术有限公司

临床试验报告

一、概述

深圳市普瑞康生物技术有限公司生产的“新型冠状病毒（2019-nCoV)核酸检测试剂盒（RT-PCR 荧光探针法）”作为待考核试剂，依据《体外诊断试剂注册管理办法》（国家食品药品监督管理总局令第 5 号）和《体外诊断试剂临床研究技术指导原则》，在其完成该试剂盒的连续三批产品的试生产、实验室评价基础上，对该试剂盒进行临床应用价值的考核。

本次临床试验属于新诊断试剂的临床研究。试验于 2020 年 1 月~2 月进行。本次试验选择发病前两周内有武汉市旅行史或居住史，或发病前 14 天内曾经接触过来自武汉的发热伴有呼吸道症状的患者；具有发热、白细胞总数正常或降低或淋巴细胞计数减少，胸部影像学呈多发小斑片影及间质改变、肺外带明显，进而发展为双肺多发磨玻璃影、浸润影甚至肺实变的人群作为研究对象，完成 523 例有效样本试验，样本类型为痰、咽拭子、鼻拭子、肺泡灌洗液或其它呼吸道分泌物，并采用临床确诊结果作为对照方法进行对比检测。

结果：本次研究有效样本试验 523 例，其中 202 例阳性组样本，321 例阴性组样本，经统计分析，两种方法阳性符合率为 97.52%，阴性符合率为 99.38%，总符合率为 98.66%。

以上结果表明深圳市普瑞康生物技术有限公司生产的“新型冠状病毒（2019-nCoV)核酸检测试剂盒（RT-PCR 荧光探针法）”的检测结果与临床确诊结果在统计学上无显著差异，两种方法检测结果的一致性好，在新型冠状病毒（2019-nCoV）核酸检测功能上能满足临床应用的需要。

二、结果分析及结论

1.临床研究的结果及分析

1.1 临床研究样本基本情况

本次研究共检测咽拭子样本 523 例。

1.2 待考评试剂盒检测结果

待考评试剂盒共检测到 197 例为样本新型冠状病毒(2019-nCoV)核酸阳，319

例为样本新型冠状病毒（2019-nCoV)核酸阴性。

1.3 待考评试剂盒与对照方法的检测结果对比

将对照方法检测结果与待考评试剂盒结果进行比较，检测结果见表 1

表 1 待考核试剂与对照方法试验结果的四格表分析

对照方法 / 待考核试剂	阳性	阴性	合计
阳性	197	2	199
阴性	5	319	324
合计	202	321	523

根据对照方法检测结果，将研究对象分为阳性组和阴性组，将待考评试剂盒检测结果与此结果进行比较，符合率计算结果如下：

阳性符合率= 197/（197＋5）×100%=97.52%

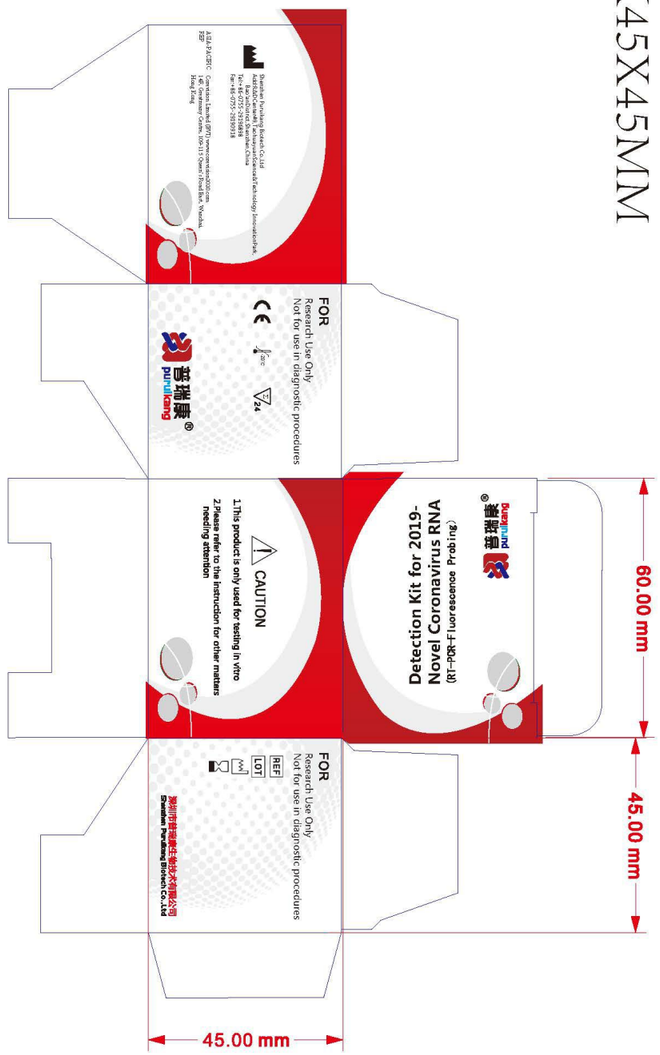
阴性符合率= 319/（2＋319）×100%=99.38%

总符合率= (197+319)/（197＋5+2＋319）×100%=98.66%

2 结论

以上结果表明深圳市普瑞康生物技术有限公司生产的“新型冠状病毒（2019-nCoV)核酸检测试剂盒(RT-PCR 荧光探针法)”与临床确诊结果符合度高，在统计学上无显著差异，因此，该试剂盒能满足临床检验应用的需要。

60X45X45MM



CMA 180000100599

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中国食品药品检定研究院

检验报告

报告编号：RW202000459

检品名称：新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）

生产单位/产地：深圳市普瑞康生物技术有限公司

检验目的：委托检验

检验依据：产品技术要求（按国家参考品检测）

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中国食品药品检定研究院检验报告

报告编号：RW202000459 共2页，第1页

检品名称	新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）	检品编号	RW2804202000824
生产单位/产地	深圳市普瑞康生物技术有限公司	批　　号	20200102
供样单位	中国人民解放军联勤保障部队药品仪器监督检验总站	规　　格	24人份/盒
检验目的	委托检验	剂型/型号	体外诊断试剂
检验项目	全检	包装规格	24人份/盒
收样日期	2020年1月28日	有效期至	2021年1月13日
检品数量	10盒	签封数量	/
检验依据	产品技术要求（按国家参考品检测）		

检验项目	标准规定	检验结果
2.1外观	试剂盒各组分齐全，无破损。标签字迹清晰，说明书内容完整、详细，外包装盒完整。澄清均一液体，无肉眼可见浑浊或不溶性杂质	符合规定
2.2阴性参考品符合率	检测国家阴性参考品，应均为阴性	N1～N22均为阴性
2.3阳性参考品符合率	检测国家阳性参考品，应符合相应规定	符合规定
P1～P5	应均为阳性	均为阳性
P6	可为阳性或阴性	阴性
P7	若检测靶基因为2019-nCoV的N基因，应为阳性，其余应为阴性	N基因为阳性，其余为阴性
2.4最低检出限	检测国家灵敏度参考品，S1～S3应为阳性	S1～S3为阳性，S4～S10为阴性
2.5精密性	检测国家精密性参考品，Ct值的变异系数（CV，%）应不高于5.0%	符合规定

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报告编号：RW202000459 共2页，第2页

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检验项目	标准规定	检验结果
	N基因	0.6%

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备注：1、检验用参考品为2019-nCoV核酸检测试剂国家参考品（应急用），批号370099-202001， 由中国食品药品检定研究院提供。2、灵敏度参考品按照产品技术要求检验方法的规定，共完成10个3倍系列稀释梯度的检测（本报告中S1的稀释度与国家参考品说明书中S1一致）。

检验结论	本品按产品技术要求（按国家参考品检测）检验，结果符合规定。		
授权签字人		签发日期	2020年1月29日

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中国食品药品检定研究院

检验报告

报告编号：RW202000460

检品名称：新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）

生产单位/产地：深圳市普瑞康生物技术有限公司

检验目的：委托检验

检验依据：产品技术要求（按国家参考品检测）

中国食品药品检定研究院检验报告

报告编号：RW202000460 共2页，第1页

检品名称	新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）	检品编号	RW2804202000825
生产单位/产地	深圳市普瑞康生物技术有限公司	批　　号	20200103
供样单位	中国人民解放军联勤保障部队药品仪器监督检验总站	规　　格	24人份/盒
检验目的	委托检验	剂型/型号	体外诊断试剂
检验项目	全检	包装规格	24人份/盒
收样日期	2020年1月28日	有效期至	2021年1月15日
检品数量	10盒	签封数量	/
检验依据	产品技术要求（按国家参考品检测）		

检验项目	标准规定	检验结果
2.1外观	试剂盒各组分齐全，无破损。标签字迹清晰，说明书内容完整、详细，外包装盒完整。澄清均一液体，无肉眼可见浑浊或不溶性杂质	符合规定
2.2阴性参考品符合率	检测国家阴性参考品，应均为阴性	N1～N22均为阴性
2.3阳性参考品符合率	检测国家阳性参考品，应符合相应规定	符合规定
P1～P5	应均为阳性	均为阳性
P6	可为阳性或阴性	阴性
P7	若检测靶基因为2019-nCoV的N基因，应为阳性，其余应为阴性	N基因为阳性，其余为阴性
2.4最低检出限	检测国家灵敏度参考品，S1～S3应为阳性	S1～S3为阳性，S4～S10为阴性
2.5精密性	检测国家精密性参考品，Ct值的变异系数（CV，%）应不高于5.0%	符合规定

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报告编号：RW202000460 共2页，第2页

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检验项目	标准规定	检验结果
	N基因	0.8%

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备注：1、检验用参考品为2019-nCoV核酸检测试剂国家参考品（应急用），批号370099-202001， 由中国食品药品检定研究院提供。2、灵敏度参考品按照产品技术要求检验方法的规定，共完成10个3倍系列稀释梯度的检测（本报告中S1的稀释度与国家参考品说明书中S1一致）。			
检验结论	本品按产品技术要求（按国家参考品检测）检验，结果符合规定。		
授权签字人		签发日期	2020年1月29日

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中国食品药品检定研究院

检验报告

报告编号：RW202000461

检品名称：新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）

生产单位/产地：深圳市普瑞康生物技术有限公司

检验目的：委托检验

检验依据：产品技术要求（按国家参考品检测）

中国食品药品检定研究院检验报告

报告编号：RW202000461 共2页，第1页

检品名称	新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）	检品编号	RW2804202000826
生产单位/产地	深圳市普瑞康生物技术有限公司	批　　号	20200104
供样单位	中国人民解放军联勤保障部队药品仪器监督检验总站	规　　格	24人份/盒
检验目的	委托检验	剂型/型号	体外诊断试剂
检验项目	全检	包装规格	24人份/盒
收样日期	2020年1月28日	有效期至	2021年1月17日
检品数量	10盒	签封数量	/
检验依据	产品技术要求（按国家参考品检测）		

检验项目	标准规定	检验结果
2.1外观	试剂盒各组分齐全，无破损。标签字迹清晰，说明书内容完整、详细，外包装盒完整。澄清均一液体，无肉眼可见浑浊或不溶性杂质	符合规定
2.2阴性参考品符合率	检测国家阴性参考品，应均为阴性	N1～N22均为阴性
2.3阳性参考品符合率	检测国家阳性参考品，应符合相应规定	符合规定
P1～P5	应均为阳性	均为阳性
P6	可为阳性或阴性	阴性
P7	若检测靶基因为2019-nCoV的N基因，应为阳性，其余应为阴性	N基因为阳性，其余为阴性
2.4最低检出限	检测国家灵敏度参考品，S1～S3应为阳性	S1～S3为阳性，S4～S10为阴性
2.5精密性	检测国家精密性参考品，Ct值的变异系数（CV，%）应不高于5.0%	符合规定

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中国食品药品检定研究院检验报告

报告编号：RW202000461 共2页，第2页

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检验项目	标准规定	检验结果
	N基因	0.9%

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备注：1、检验用参考品为2019-nCoV核酸检测试剂国家参考品（应急用），批号370099-202001， 由中国食品药品检定研究院提供。2、灵敏度参考品按照产品技术要求检验方法的规定，共完成10个3倍系列稀释梯度的检测（本报告中S1的稀释度与国家参考品说明书中S1一致）。

检验结论	本品按产品技术要求（按国家参考品检测）检验，结果符合规定。		
授权签字人		签发日期	2020年1月29日

厂家信息

普瑞康 puruikang

About Shenzhen PURIKANG Biotechnology Co., Ltd

Found in July 2009, Shenzhen PURUIKANG biotechnology Co., Ltd., is a high-tech molecular diagnostic company dedicated to the research & development, manufacture and sales of innovative molecular diagnostic products, locating in Taohuayuan Science and Technology Innovation Park, Baoan District, Shenzhen, Guangdong Province, P.R.China.

For a decade's developing, Shenzhen PURUIKANG has patented composite probe technology and visual chip technology. The company integrated these technologies into two R&D platforms, and based on them, more than 90 products have been developed, of which include fluorescent quantitative PCR reagent, immunochromatography, biochip, chemiluminescent ELISA and biosensor.

At present, Shenzhen PURUIKANG has established advanced PCR production lines, biochip production lines, and a quality management system in accordance with ISO13485 and the requirements of IVD production quality management standard. It's accredited as Guangdong Quality Credit Class A Medical Device Manufacturing Enterprise in 2011. The annual production capacity of the company exceeds 10 million assays.

Since foundation, Shenzhen PURUIKANG undertook more than 16 national and local scientific and technological projects, such as major national infectious disease projects, national 863 program, the project of Industry-Academy-Research Integration, etc. In August 2014, the company developed the first Ebola virus nucleic acid diagnostic kit in China. It is also the first and only enterprise in China to obtain both the CFDA registration certificate and the military registration certificate.

普瑞康 puruikang

Puruikang core technology and new crown product advantages

1. overview of the enterprise

Established in July 2009, Shenzhen Puruikang Biotech Co., Ltd., hereinafter referred to as Puruikang, is a high-tech enterprise specialized in the research, production and sales of molecular diagnosis and other medical and health products, as well as the provision of relevant technical services. Puruikang has been developing the nucleic acid detection technology of pathogenic microorganisms for a long time, and is a first-class molecular diagnosis enterprise in China.

Puruikang now forms a joint research center with top medical research institutions in China, and has completed more than 10 national major projects and National 863 Program tasks, with strong comprehensive r & d strength and the ability to produce special drugs for the army.

2. Industry status

First, in the biological industry, Puruikang has advanced bio-visualization chip technology, and is the only high-tech enterprise that owns the patent of dual-chain probe technology in China.

Secondly, Puruikang has been developing the nucleic acid detection technology of pathogenic microorganisms for a long time. In terms of production and quality control, Puruikang has passed the national system assessment and certification for many times, and obtained the registration certificate of a series of pathogenic microorganism detection products.

Third, Puruikang is the core member of several national medical and health professional associations.

3. Comparative advantages of Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing)

3.1 The products of other manufacturers

At present, there are many new coronavirus detection reagents in the market based on the principle of real-time fluorescence PCR. What is different is the type, number and location of target genes, and most of them have the following deficiencies:

First, most manufacturers use two sets of primers/probes, the production cost is high, increasing the economic burden of customers.

Second, the use of primers/probes recommended or disclosed by WHO may lead to intellectual property disputes.

Third, the products of other manufacturers need three channels and more than three channels fluorescence PCR equipment, the application cost is high, so it is not conducive to the promotion of this product.

3.2 The product of Puruikang

Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing) developed by Puruikang has the following comparative advantages:

First, in terms of product design, based on the newly released gene sequence information of novel coronavirus (2019-ncov), the product adopts the "single target" design and the detection strategy of "100 to 100" for its specific gene sequence, and the 2019-ncov can be determined without mutual verification of the two genes. Primers/probes were designed according to the analyzed pathogen target sequences, and the detection sensitivity of primers obtained by the kit was higher after a large number of screening.

Second, the kit is used to qualitatively detect the novel coronavirus nucleic acid in clinical samples, and the results from sample extraction to detection are completed within 90 minutes.

Third, the specific test results of the kit showed that there was no cross-reaction with the known 6 human coronavirus hcov-oc43, hcov-229e, sars-cov, hcov-nl63, hcov-hku1 and hcov-mers.

Fourth, the kit includes monitoring sampling process, adding endogenous internal standards and participating in extraction and amplification detection, which guarantees the specificity and accuracy of detection results.

Fifth, the kit only needs a two-channel fluorescence PCR instrument, which is suitable for a wider range of instruments, lower cost, easy to promote and use, and is also conducive to reducing the cost of screening detection for large-scale epidemic prevention and control.

出口证明

医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号
Certificate No.：粤深市监械出 2020W026

产品名称：新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR 荧光探针法）
Product(s): Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

规格型号：24 人份/盒
Model: 24 tests/kit

生产企业：深圳市普瑞康生物技术有限公司
Manufacturer: Shenzhen Puruikang Biotech Co.,Ltd

生产企业地址：深圳市宝安区西乡街道桃花源科技创新园 9 号研发中心一、二层（办公场所）
Address of manufacturer: Floor 1 and 2(Office space) No. 9, TaoHuaYuan Science and Technology Innovation Park, Xixiang Street, Bao' an District, Shenzhen, China

生产许可或备案凭证号
Manufacturing License(s)：粤食药监械生产许 20152684 号

兹证明上述产品未在中国注册。该产品出口不受限制。
This is to certify that the above product(s) are not registered in China. The exportation of the product(s) is not restricted.

深圳市市场监督管理局
Market Supervision Administration of Shenzhen Municipality

2020 年/ Year 3 月/Month 13 日/Day.

（此证明书从发证时起有效期 2 年）
(This certificate is valid for two years from the date of issuance)

dgm CHINA

CNAS 中国认可 检验 INSPECTION CNAS IB0078

非限制性货物 NOT RESTRICTED

航空运输条件鉴别报告书

Identification and Classification Report for Air Transport of Goods

此报告本年度有效 有效期至2020年12月31日

报告编号：
Issued No.: PEKSZ202003177175ZY570001

签发日期：
Issued Date: 2020.03.17

委托单位：
Applicant: 深圳市普瑞康生物技术有限公司
Shenzhen Puruikang Biotech Co.,Ltd

物品名称：
Name of Goods: 新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）
Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR Fluorescence Probing)

北京迪捷姆空运技术开发有限公司
Beijing DGM Air Transport Technology Development Co.,Ltd.

报 告 书 使 用 约 定

Terms of the Using of the Report

1. 本公司依据本年度国际航协《危险品规则》以及委托人（托运人或其代理人）提供的物品及其运输信息，确定货物的航空运输条件并出具此报告书。
   The report is issued by DGM China according to IATA ***Dangerous Goods Regulations*** published in the current year and the information of the goods and the information of its shipping provided by the applicant (shipper or his agent).

2. 依据鉴别的需要，本公司要求委托人提供真实、完整的货物样品及资料。
   According to the demand of identification and classification, DGM China requires the applicant to provide true and exact sample and data of the cargo.

3. 委托人保证申报的物品和/或提供的样品与交运的货物是同一种物质。
   The applicant guarantees that the declared goods and/or the sample who provides should be identical with the contents of cargo that is to be transported.

4. 本公司仅对样品的鉴别结果负责。
   DGM China is only responsible for the identification and classification of the sample provided by the applicant.

5. 本报告书经主检员、审核人和批准人签字并加盖本公司印章后生效。
   This report will be effective only after it is signed by the inspector, checker and approver, and stamped by DGM China.

6. 未经本公司书面批准，不得复制本报告书。
   The duplicating of this report is prohibited without the written approval of DGM China.

7. 私自转让、复制、盗用、冒用、涂改、或以任何媒体形式篡改的报告书无效。
   The report is invalid when anything of the following happens - illegal transfer, reproduce, embezzlement, imposture, modification or tampering in any media form.

8. 为适应国际航协《危险品规则》的年度变化，报告书仅在本年度内有效。
   This report is only valid within the year in which the IATA ***Dangerous Goods Regulations*** is effective.

地址：北京首都国际机场货运北路天竺综合保税区BGS货运楼249室 邮编：101300

电话：010-69479673 传真：010-69479621

网址：www.dgmchina.com.cn E-mail: test@dgmchina.com.cn

项目编号 Item No.	PEKSZ202003177175		
鉴别目的 Identification Purpose	是否属于航空运输危险物品 Dangerous Goods or not restricted	鉴别日期 Identification Date	2020. 03. 17
鉴别依据 Identification Criteria	IATA DGR 61st, 2020		
物品名称 Name of Goods 中文 Chinese	新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）		
物品名称 Name of Goods 英文 English	Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR Fluorescence Probing)		
生产厂家 Manufacturer	深圳市普瑞康生物技术有限公司 Shenzhen Puruikang Biotech Co.,Ltd		
件数 Pieces		注：本栏内容为托运人或其代理人在使用本报告书时候填写的运输信息，不属于鉴定内容。运输信息与报告书的关联性以及实际运输货物与报告书的一致性由托运人或其代理人保证，如发生任何不一致由托运人或其代理人承担全部责任。（请认真填写本栏内容，并盖章） 负责人： 联系方式：	
运单号 Air waybill No.			
目的港 Destination			
物品信息 Nature of the goods	该样品为新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法），内含4种（4瓶）液体试剂（低温下为固体），略有气味。 商标：普瑞康。 闪点：>70℃。 The sample is Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR Fluorescence Probing), containing 4 kinds (4 bottles) of liquid reagent (solid at low temperature) with slight odor. Trademark: puruikang. Flash point: >70℃.		

北京迪捷姆空运技术开发有限公司 **

项目编号 Item No.		PEKSZ202003177175
物品名称 Name of Goods	中文 Chinese	新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）
	英文 English	Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR Fluorescence Probing)
鉴别结论 Conclusions		根据IATA的"Dangerous Goods Regulation"中的标准进行闪点试验，该样品闪点为>70℃，不属易燃液体。 该样品与多种还原剂不发生反应，不属5.1项氧化剂。 该样品与锌、铝等金属不反应，对皮肤无伤害，不属腐蚀品。 根据有关资料和使用经验分析,该物质不会引起人员急性中毒，不属毒害品。 该样品无刺激性、麻醉性，不属第9类危险物品。该样品无其他危险性。 根据DGR特殊规定A3，本品不受限制，即"NOT RESTRICTED,AS PER SPECIAL PROVISION A3"。 The flash point test is operated according to the criteria of IATA Dangerous Goods Regulations, the flash point of this substance is >70℃. So it does not belong to the flammable liquids. The sample does not react with many deoxidizing materials, so it does not belong to oxidizer of division 5.1. The sample does not react with metals such as Zn or Al and has no harm to skin, so it does not belong to corrosives. According to the experience and the relevant materials, the substance does not cause acute poisoning to human. It does not belong to toxic substance. The sample does not have narcotic, noxious, irritating and other characters to cause extreme annoyance or discomfort to crewmembers and passengers, so it does not belong to miscellaneous dangerous goods. According to IATA DGR,this product can be classified as "NOT RESTRICTED,AS PER SPECIAL PROVISION A3".

建议运输条件 Suggestion for Transport Condition	UN/ID 编号 UN/ID No.	运输专用名称 Proper Shipping Name	类或项 Class or Div. (次要危险性) (Subsidiary Risk)	包装等级 Packing Group
	/	/	/	/
包装说明 Packing Inst.	客货机 Passenger and Cargo Aircraft	/		
	仅限货机 Cargo Aircraft only	/		
注意事项 Remarks	建议包装符合质检部门或航空公司关于空运包装要求 Packaging is suggested to meet the requirements of Department of Quality Supervision, Inspection and Quarantine or Airline's criteria			

主检员 Prepared by: 李春燕 审核人 Checked by: 批准人 Approved by:

报告单位（盖章） Stamp

制单： 李春燕

北京迪捷姆空运技术开发有限公司

新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）

PEKSZ202003177175

冷却剂干冰运输保函

FedEx 运单号码：_____

件数：_____

被冷却物品名称（中文）：新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR荧光探针法）

被冷却物品化工品需要填写下表内容。

货物运输条件鉴定书编号：PEKSZ202003177175ZY570001

该类货物无爆炸、无氧化、无腐蚀、无放射性、非易燃、非有毒有害、非用于制造化学武器的原料，经鉴定，无危险性，可按普通货物条件运输。

由于所寄物品需严格温控，以干冰为冷却剂包装运输。以下是具体信息：

危险品正式运输名称（干冰或固体二氧化碳）：固体二氧化碳

类别：9

UN 号码：1845

每件干冰的净重：_____

我司保证包装操作流程完全符合 IATA 规定干冰作为冷却剂的包装运输要求。

我公司以上申报属实，若由于我公司申报不符，而造成运输过程中的一切损失，我公司承担一切法律责任和经济赔偿。

公司（盖章）：

签名：

日期：

备注：该保函需提供一式两份，均为正本原件；品名注意填写中文；签名：必须手签，签全名，中文名。不能打印或者复印；公司盖章，盖鲜章。

时效7天内							
	泡沫箱内尺寸（mm）	试剂盒（mm）	单箱可装	单箱剩余空间	泡沫箱加纸箱重	1000盒箱数	外箱尺寸（mm）
	370*265*300	45*45*60	120盒	370*265*115		10箱	457*352*392
重量			2.04kg	可装13kg干冰	1.4kg		
			16.44			170kg	
费用	干冰费+泡沫箱+纸箱+运费+产品鉴定费		13*10*10+10*28+10*8+170*114+1400=22440元				

注册信息

CE

EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:	Shenzhen Puruikang Biotech Co.,Ltd
Address:	2 factories Room 1A, Tiegang Road OysterIndustrial Park,Xixiang Street, Bao' an District, Shenzhen, China. No.9, TaoHuaYuan Science and Technology Innovation Park, Xixiang Street, Bao' an District, Shenzhen, China.
EC-Representatice:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestrasse 80, 20537 Hamburg, Germany
Product:	Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing)
Model:	24 tests/kit
Category:	98/79/EC Others

Conformity assessment route: Annex III EC Declaration of conformity in 98/79/EC Directive

Applicable Standards:

- Directive 98/79/EC
  Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998on in vitro diagnostic medical devices
- EN ISO 13485:2016
  Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012
  Medical devices – Application of risk management to medical devices
- EN ISO 18113-1:2011
  In vitro diagnostic medical device – Information supplied by the manufacturer (labelling)- Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011
  In vitro diagnostic medical device – Information supplied by the manufacturer (labelling)- Part 2: In vitro diagnostic reagents for professional use
- EN 980:2008
  Symbols for use in the labelling of medical devices
- EN 13641:2002
  Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- EN 13612:2002
  Performance evaluation of in vitro diagnostic medical devices
- EN 23640:2015
  In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
- EN 62366:2008
  Medical devices - Application of usability engineering to medical devices

We, the Manufacturer, herewith declare with sole responsibility that our product mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Shanghai International Holding Corp. GmbH (Europe) to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 04 /(Day) 03 /(Month) of 2020 . Place: Shenzhen,China .

Represented by
Signature: Seal/Stamp:
Name of authorized signatory: Simao Huang
Position held in the company: Manager Representive

Statement on the Compliance of the Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing) with IVDD 98/79/EC

IVDR was officially promulgated by the EU on May 5, 2017, with a 5-year transitional period. During the transitional period, both IVDD (98/79/EC) and IVDR (EU 2017/746) are valid. Manufactures can choose any suitable conformity assessment route according to the article 110 "transitional provisions" (see Annex 1) in IVDR, here is the original partial information showed in Article 110 of IVDR:

Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market 26 May 2022 by virtue of a certificate as referred to in paragraph 2 of this Article ,may continue to be made available on the market or put into service until 27 May 2025.

According to the current CE requirements, IVD can accomplish CE certification through either IVDD (98/79/EC) or IVDR (EU 2017/746) which depends on the product's classification. Our company's Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing) is classified as "others" in IVDD, we have fully met the requirements of IVDD through Annex III: established full QMS, set up and maintain CE technical documentation, issued declaration of conformity(see Annex 2), registered in the European Union(see Annex 3 for the application form).

So, We hereby state that our company's Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing) fully complies with the EU medical device requirements.

Shenzhen Puruikang Biotech Co.,Ltd

DATE:12th March,2020

FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

3/19/2020

Ma Xiao, Registered Engineer
ShenZhen Puruikang BioTech Co., LTD.
Xixiang Street
Shenzhen, Guangzhou 518102
CHINA

Dear Ma Xiao:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200141
Received: 3/19/2020
Applicant: ShenZhen Puruikang BioTech Co., LTD.
Device: Detection Kit for 2019-Novel Coronavirus RNA(RT-PCR-Fluorescence Probing)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

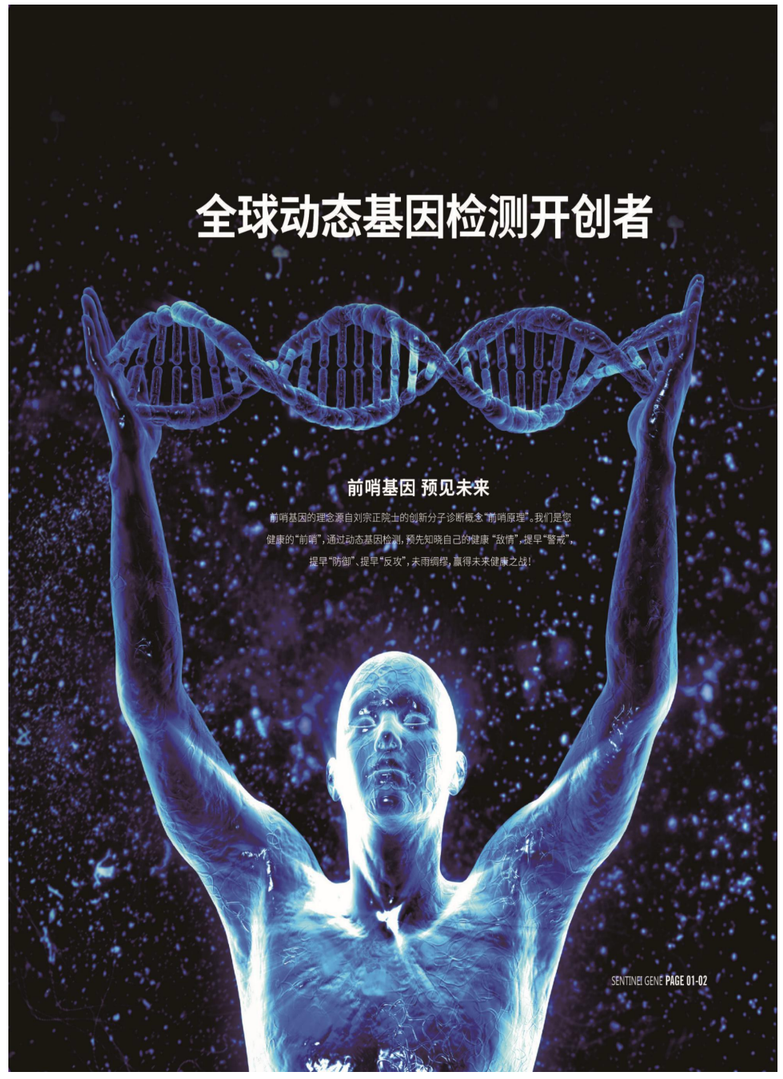
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

销售信息

华夏帮服科技有限公司（以下简称华夏帮服）专注肿瘤动态基因超早期筛查服务， 是国内“第一家也是唯一一家”开展动态基因检测的法人机构。

动态基因检测技术由华裔科学家、英国皇家医学会终身院士、加拿大临床医学学 院院士刘宗正先生全球首创，该技术可对无症状人群当下和未来5-10年患肿瘤、心脑 血管及精神疾病等重大疾病的风险性进行无创性检测、评估及复发监测。华夏帮服是 国内唯一一个对刘院士的动态基因检测技术进行成果转化的机构。

华夏帮服创立“前哨科技”品牌，以“让人人更健康”为愿景，公司坚持“政、 产、学、研、用”的创新合作机制，与中关村医学工程转化中心、中金资本、廿一资 本、海南第一投资控股集团有限公司、中科院合肥肿瘤医院、青岛莲池妇婴医院、海 南博鳌超级医院等国内相关机构深入开展合作，力争3年内打造成基因检测服务行业 的独角兽。



前哨基因 预见未来　专注肿瘤超早期无创筛查服务

首席科学家—刘宗正院士

诺贝尔医学奖提名者

皇家医学会终身院士（Life Fellow）

加拿大临床医学院院士

哈佛大学医学院教授和资深遗传专家

多伦多大学病理化学博士 临床生物化学和医学终身荣誉教授

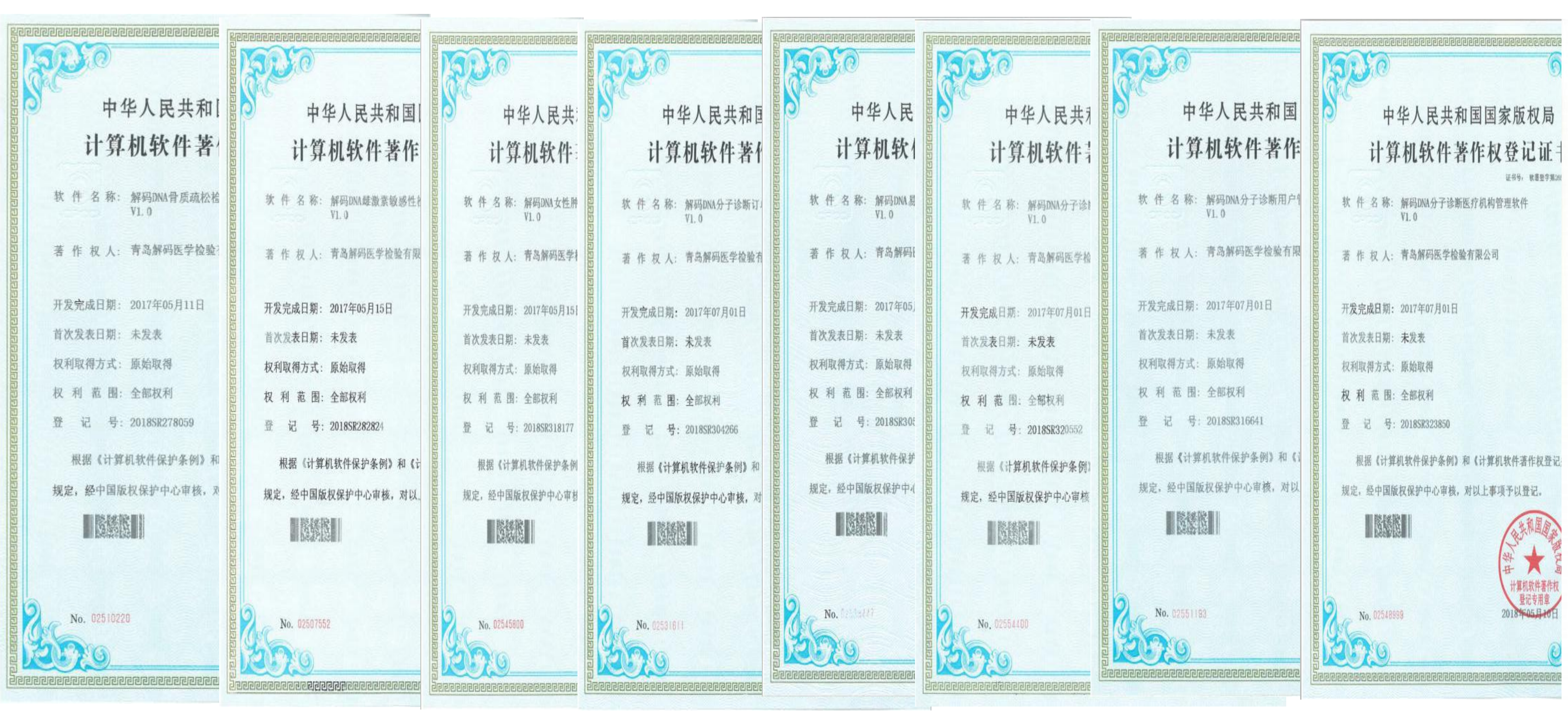
多伦多上市生物技术公司GeneNews的共同创始人和首席科学家

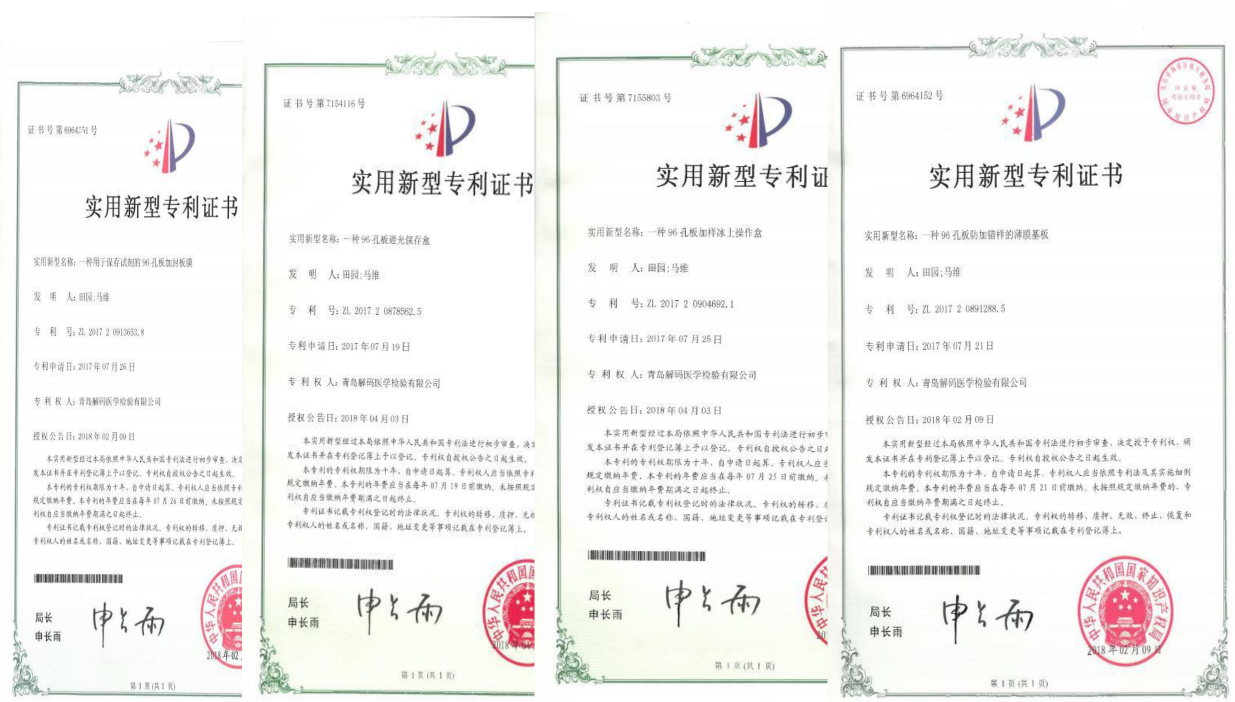
动态基因检测技术的开拓者和奠基人，前哨原理创立者；

外周血动态基因检测技术被评为北美Frost&Sullivan技术创新大奖；

迄今在全球知名学术刊物上发表科学论文300多篇；

共有发明专利2项，实用新型专利4项，计算机软件 著作权8项





统一社会信用代码
91110105MA009KPN80

营业执照

（副 本）(1-1)

名　　称　华夏帮服科技有限公司
类　　型　有限责任公司(法人独资)
法定代表人　陈文权
经营范围　技术推广、技术服务；医学研究与试验发展；销售医疗器械Ⅰ类、医疗器械Ⅱ类、仪器仪表、计算机、软件及辅助设备；健康管理（须经审批的诊疗活动除外）；健康咨询（须经审批的诊疗活动除外）；货物进出口、代理进出口、技术进出口；互联网信息服务；销售Ⅲ类医疗器械。（企业依法自主选择经营项目，开展经营活动；互联网信息服务、销售Ⅲ类医疗器械以及依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

注册资本　5000万元
成立日期　2016年11月16日
营业期限　2016年11月16日 至 2046年11月15日
住　　所　北京市海淀区永丰屯538号1号楼2层218/220

登记机关　北京市海淀区市场监督管理局　2019 年 11 月 01 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

营业执照

（副 本）

1-1

统一社会信用代码　91370212MA3CDG4P8F

名　　称　青岛解码医学检验有限公司
类　　型　有限责任公司(自然人投资或控股的法人独资)
住　　所　山东省青岛市崂山区株洲路168号海洋生化孵化中心6楼
法定代表人　程昌明
注册资本　壹仟万元整
成立日期　2016年07月08日
营业期限　2016年07月08日至　　年　月　日
经营范围　临床检验（依据卫生部门核发的《医疗机构执业许可证》开展经营活动），生物领域、基因检测领域以及医药领域内相关的技术研发、技术咨询、技术转让，生物基因检测设备、仪器仪表、实验室试剂（除危险化学品、监控化学品、烟花爆竹、民用爆炸物品、易制毒化学品）、一类医疗器械的销售，健康管理咨询（不得从事诊疗活动、心理咨询），计算机科技领域内的技术开发、技术转让、技术服务、技术咨询，计算机软件及辅助设备的销售（除计算机信息系统安全产品），从事货物与技术的进出口业务（法律、行政法规禁止的项目除外，法律、行政法规限制的项目取得许可后方可经营）（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）。

登记机关　青岛市崂山区市场监督管理局　2018 年 12 月 14 日

企业信用信息公示系统网址：http://sdxy.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

营业执照

中国（上海）自由贸易试验区

统一社会信用代码 91310115MA1K45467Q

证照编号 410000020180711016O

名　　称　上海盟儒慧基因科技有限公司

类　　型　有限责任公司（自然人投资或控股的法人独资）

住　　所　中国（上海）自由贸易试验区新灵路 118 号 1801、1802、1803（产证房间 1701、1702、1703）

法定代表人　毛郁川

注册资本　人民币 600.0000 万元整

成立日期　2018 年 7 月 11 日

营业期限　2018 年 7 月 11 日 至 2048 年 7 月 10 日

经营范围　从事基因科技、生物科技领域内的技术开发、技术转让、技术咨询、技术服务，医疗器械的销售，从事货物及技术的进出口业务，软件开发，商务信息咨询、企业管理咨询。【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】

登记机关

2018 年 07 月 11 日

企业信用信息公示系统网址：https://www.sgs.gov.cn/notice

中华人民共和国国家工商行政管理总局监制

医疗器械经营许可证

许可证编号：沪浦食药监械经营许 20190047 号

企业名称：上海盟儒慧基因科技有限公司

法定代表人：毛郁川

经营方式：批发

企业负责人：毛郁川

住　　所：中国（上海）自由贸易试验区新灵路 118 号 1801、1802、1803（产证房间 1701、1702、1703）

经营范围：三类：6840 临床检验分析仪器及诊断试剂（诊断试剂需低温冷藏运输贮存）***

经营场所：中国（上海）自由贸易试验区新灵路 118 号 1801、1802、1803（产证房间 1701、1702、1703）

库房地址：所营产品全部委托上海外高桥医药分销中心有限公司物流储运(含冷藏、冷冻品)

发证部门：上海市浦东新区市场监督管理局

有效期限：至 2024 年 3 月 13 日　发证日期：2019 年 3 月 14 日

国家食品药品监督管理总局制

普瑞康 puruikang

Authorization

Shenzhen Puruikang Biotech Co., Ltd., hereinafter referred to as the company authorized Huaxia bangfu technology Co., Ltd. to carry out the company' sales business in Netherlands, Japan, France, Italy and Australia.

The authorization is limited to the sale for the company's Detection Kit for 2019-Novel Coronavirus RNA (RT-PCR-Fluorescence Probing).

The company has the final right to interpret the letter of authorization.

This authorization is valid from March 10, 2020 to September 9, 2020.

Shenzhen Puruikang Biotech Co., Ltd.

Date: March 25, 2020

普瑞康 puruikang

授权书

深圳市普瑞康生物技术有限公司现授权华夏帮服科技有限公司在荷兰、日本、法国、意大利和澳大利亚开展本公司新型冠状病毒（2019-nCoV）核酸检测试剂盒（RT-PCR 荧光探针法）销售业务。

我司对此《授权书》有最终解释权。

此授权书有效期为：2020 年 3 月 10 日～2020 年 9 月 9 日

深圳市普瑞康生物技术有限公司

日期： 2020 年 3 月 25 日

华夏帮服科技有限公司作为深圳市普瑞康生物技术有限公司的分销代理商，欢迎国内外用户洽谈合作

运 输 尺 寸	**24 tests/kit , 42 kits per carton , 20KG per carton add dry ice**
建议市场销售价	23美金/人/份
授权单位	**华夏帮服科技有限公司**
联 系 人	秦先生 138 1725 1860