HANDEL FÜR
INDIVIDUELLE
MEDIZINPRODUKTE

REALY”
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

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HANDEL FÜR
INDIVIDUELLE
MEDIZINPRODUKTE

Antigen-Schnelltestkassette (Tupfer) für das neuartige Coronavirus (SARS-Cov-2) Packungsbeilage

EIN SCHNELLTEST FÜR DEN QUALITATIVEN NACHWEIS VON NEUEN CORONAVIRUS-ANTIGENEN IN NASOPHARYNX- UND OROPHARYNX-ABSTRICHEN.
Nur für den professionellen Einsatz in der in-vitro-Diagnostik.

BESTIMMUNGSGEMÄSSER GEBRAUCH

Die Antigen-Schnelltestkassette (Abstrich) für neuartige Coronaviren (SARS-Cov-2) ist ein *in vitro*-diagnostischer Test für den qualitativen Nachweis von neuartigen Coronavirus-Antigenen in Nasopharynx- und Oropharynx-Abstrichen anhand der immunochromatographischen Schnellmethode. Die Identifizierung basiert auf den monoklonalen Antikörpern, die für das neue Coronavirus-Antigen spezifisch sind. Es wird Informationen für klinische Ärzte bereitstellen, um korrekte Medikamente zu verschreiben.

ÜBERBLICK

COVID-19 ist eine akute Infektionskrankheit der Atemwege. Menschen sind daf ̈r im Allgemeinen anfällig. Derzeit sind die mit dem neuartigen Coronavirus infizierten Patienten die Haupt infektionsquelle: Asymptomatisch infizierte Menschen können ebenfalls eine infektiöse Quelle sein. Nach der aktuellen epidemiologischen Untersuchung beträgt die Inkubationszeit 1 bis 14 Tage, meist 3 bis 7 Tage. Die Hauptsymptome sind Fieber, Müdigkeit und trockener Husten. In einigen Fällen treten verstopfte Nase, Schnupfen, Halsschmerzen, Myalgie und Durchfall auf.

PRINZIP

Die Antigen-Schnelltestkassette (Tupfer) des neuartigen Coronavirus (SARS-Cov-2) ist ein immunochromatographischer Membrantest, bei dem hochempfindliche monoklonale Antikörper gegen das neuartige Coronavirus verwendet werden.
Die Testvorrichtung besteht aus den folgenden drei Teilen, nämlich Probenkissen, Reagenzkissen und Reaktionsmembran. Der gesamte Streifen ist in einem Kunststoffgerät befestigt. Die Reagenzmembran enthält kolloidales Gold, das mit den monoklonalen Antikörpern gegen das neuartige Coronavirus konjugiert ist; die Reaktionsmembran enthält die sekundären Antikörper gegen das neuartige Coronavirus und die polyklonalen Antikörper gegen das Mausglobulin, die auf der Membran vorimmobilisiert sind.
Wenn die Probe in das Probenfenster gegeben wird, werden die im Reagenzpolster gefriergetrockneten Konjugate aufgelöst und wandern mit der Probe mit. Ist das neuartige Coronavirus in der Probe vorhanden, wird ein Komplex, der zwischen dem Anti-Coronavirus-Konjugat und dem Virus gebildet wird, von dem spezifischen monoklonalen Anti-Coronavirus gefangen, das auf der T-Region beschichtet ist.
Unabhängig davon, ob die Probe das Virus enthält oder nicht, wandert die Lösung weiter und trifft auf ein anderes Reagenz (einen Anti-Maus-IgG-Antikörper), das die verbleibenden Konjugate bindet und dadurch eine rote Linie auf der Region C erzeugt.

REAGENZIEN

Die Reagenzmembran enthält kolloidales Gold, das mit den monoklonalen Antikörpern gegen das neuartige Coronavirus konjugiert ist; die Reaktionsmembran enthält die sekundären Antikörper gegen das neuartige Coroinavirus und die polyklonalen Antikörper gegen das Mausglobulin, die auf der Membran vorimmobilisiert sind.

SICHERHEITSVORKEHRUNGEN

- Nur für die in-vitro-Diagnostik.
- Nicht nach dem Verfallsdatum verwenden.
- Sicherstellen, dass der Folienbeutel mit dem Testgerät nicht beschädigt ist, bevor er zur Verwendung geöffnet wird.
- Test bei Raumtemperatur von 15 bis 30 ° C durchführen.
- Beim Aufhängen der Proben Handschuhe tragen. Die Reagenzmembran und das Probenfenster nicht berühren.
- Alle Proben und gebrauchten Zubehörteile sollten gemäß den örtlichen Vorschriften als infektiös behandelt und entsorgt werden.
- Blutige Proben vermeiden.

LAGERUNG UND STABILITÄT

Lagern Sie die Antigen-Schnelltestkassette (Tupfer) für das neuartige Coronavirus (SARS-Cov-2) bei Raumtemperatur oder gekühlt (2-30 ° C). Nicht einfrieren. Alle Reagenzien sind bis zu den auf ihrer Umverpackung und Pufferflasche angegebenen Verfallsdaten stabil.

PROBENENTNAHME UND -VORBEREITUNG

1. Probenentnahme:

Für die Diagnose des neuartigen Coronavirus aus Nasopharynx-Abstrichproben anwendbar. Verwenden Sie frisch entnommene Proben für eine optimale Testdurchf ̈hrung. Eine unzureichende Probenentnahme oder eine unsachgemäße Probenhandhabung kann zu einem falsch negativen Ergebnis führen.

Für den Nasopharynx-Abstrich den in diesem Kit mitgelieferten sterilisierten Tupfer vollständig in das Nasenbecken einführen und mehrmals tupfen, um die Epidermiszellen des Schleims zu entnehmen.

Bei oropharyngealem Tupfer den in diesem Kit enthaltenen sterilisierten Tupfer vollständig in den hinteren Rachen, die Mandeln und andere entzündete Bereiche einführen. Zunge, Wangen und Zähne nicht mit dem Tupfer berühren.

Es wird empfohlen, Proben aus dem Nasopharyngeal zu entnehmen, um genauere Ergebnisse zu erzielen.

2. Probenvorbereitung:

1) Nehmen Sie 1 Flasche Probenextraktionspuffer heraus, entfernen Sie die Flaschenkappe, geben Sie den gesamten Extraktionspuffer in das in diesem Kit mitgelieferte Extraktionsröhrchen und stellen Sie es auf den Röhrchenständer.

2) **Nasopharynx- und Oropharynx-Abstriche**

Führen Sie den Tupfer in das Extraktionsröhrchen ein, das den Probenextraktionspuffer enthält. Tupfer im Röhrchen mit einer kreisenden Bewegung drehen, um die Seite des Extraktionsröhrchens so zu rollen, dass Flüssigkeit aus dem Tupfer austritt und wieder absorbiert wird. Tupfer entfernen. Die extrahierte Lösung wird als Testprobe verwendet.

MATERIALIEN

Zur Verfügung gestellte Materialien

- Test-Vorrichtung
- Sterilisierter Tupfer
- Extraktionsrohr
- Packungsbeilage
- Düse mit Filter
- Probenextraktionspuffer
- Rohrständer

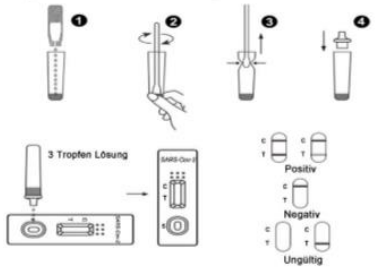
Erforderliche, aber nicht mitgelieferte Materialien

- Timer

GEBRAUCHSANWEISUNG

Lassen Sie den Test, die Probe und den Extraktionspuffer vor dem Test auf Raumtemperatur (15-30 ° C) äquilibrieren.

1. Entfernen Sie das Testgerät aus dem versiegelten Folienbeutel und verwenden Sie es so bald wie möglich. Stellen Sie das Testgerät auf eine saubere und ebene Oberfläche. Die besten Ergebnisse werden erzielt, wenn der Assay unmittelbar nach dem Öffnen des Folienbeutels durchgeführt wird.
2. Schrauben Sie die gesamte Kappe des Probensammelröhrchens ab.
3. Nehmen Sie 1 Flasche Probenextraktionspuffer heraus, entfernen Sie die Flaschenkappe, geben Sie den gesamten Extraktionspuffer in das in diesem Kit mitgelieferte Extraktionsröhrchen und stellen Sie es auf den Röhrchenständer.
4. Die sterilisierte Tupferprobe in den Probenextraktionspuffer legen. Drehen Sie den Tupfer ungefähr 10 Sekunden lang, während Sie den Kopf gegen die Innenseite des Röhrchens drücken, um das Antigen im Tupfer freizusetzen.
5.Entfernen Sie den sterilisierten Tupfer, während Sie den sterilisierten Tupferkopf gegen die Innenseite des Puffers drücken, während Sie ihn entfernen, um so viel Flüssigkeit wie möglich aus dem Tupfer zu entfernen. Entsorgen Sie den sterilisierten Tupfer gemäß Ihrem Entsorgungsprotokoll für biologische Gefahren.
6. Kappe auf das Probensammelröhrchen schrauben und festziehen. Dann das Probensammelröhrchen **kräftig schütteln**, um die Probe und den Probenentnahmepuffer zu mischen . Siehe Abbildung 4.
7. 3 Tropfen der Lösung (ca. 80 µl) in die Probenvertiefung geben und dann den Timer starten. Das Ergebnis nach 10 bis 20 Minuten ablesen. Das Ergebnis nicht nach 20 Minuten auswerten.



AUSWERTUNG DER ERGEBNISSE

(Bitte siehe Abbildung oben)

POSITIV: Es erscheinen zwei rote Linien. Eine rote Linie erscheint im Kontrollbereich (C) und eine rote Linie im Testbereich (T). Der Farbton kann variieren, sollte jedoch auch dann als positiv angesehen werden, wenn nur eine schwache Linie erscheint.

NEGATIV: Im Kontrollbereich (C) erscheint nur eine rote Linie und im Testbereich (T) keine Linie. Das negative Ergebnis zeigt an, dass sich keine neuartigen Coroinavirus-Partikel in der Probe befinden oder die Anzahl der Viruspartikel unter dem nachweisbaren Bereich liegt.

UNGÜLTIG: Im Kontrollbereich (C) erscheint keine rote Linie. Der Test ist ungültig, selbst wenn sich im Testbereich (T) eine Linie befindet. Unzureichendes Probenvolumen oder falsche Verfahrenstechniken sind die wahrscheinlichsten Gründe für einen Ausfall der Steuerleitung. Überprüfen Sie das Testverfahren und wiederholen Sie den Test mit einem neuen Testgerät. Wenn das Problem weiter besteht, beenden Sie die Verwendung der Streifen und wenden Sie sich an Ihren Händler.

EINSCHRÄNKUNGEN

- Die neuartige Antigen-Schnelltestkassette (Tupfer) f ̈r das neuartige Coronavirus (SARS-Cov-2) ist ein Akutphasen-Screening-Test zum qualitativen Nachweis. Die entnommene Probe kann eine Antigenkonzentration unterhalb der Empfindlichkeitsschwelle des Reagens enthalten, sodass ein negatives Testergebnis eine Infektion mit dem neuartigen Coronavirus nicht ausschließt
- Die Antigen-Schnelltestkassette (Tupfer) für das neuartige Coronavirus (SARS-Cov-2) erkennt lebensfähiges und nicht lebensfähiges neues Coronavirus-Antigen. Die Testleistung hängt von der Antigenbeladung in der Probe ab und korreliert möglicherweise nicht mit der an derselben Probe durchgef ̈hrten Zellkultur. Ein positiver Test schließt nicht aus, dass andere Krankheitserreger vorhanden sein können. Daher müssen die Ergebnisse mit allen anderen verf ̈gbaren klinischen und Laborinformationen verglichen werden, um eine genaue Diagnose zu stellen.
- Ein negatives Testergebnis kann auftreten, wenn der Gehalt an extrahiertem Antigen in einer Probe unter der Empfindlichkeit des Tests liegt oder wenn eine Probe von schlechter Qualität erhalten wird
- Die Durchf ̈hrung des Tests zur Überwachung der antiviralen Behandlung des neuartigen Coronavirus wurde nicht nachgewiesen.
- Positive Testergebnisse schließen eine Koinfektion mit anderen Krankheitserregern nicht aus.
- Negative Testergebnisse gelten nicht für andere Coronavirus-Infektionen außer SARS-Cov-2.
- Kinder neigen dazu, Viren länger als Erwachsene auszuscheiden, was zu einer unterschiedlichen Empfindlichkeit zwischen Erwachsenen und Kindern f ̈hrt.
- Ein negatives Ergebnis kann auftreten, wenn die Antigenkonzentration in einer Probe unter der Nachweisgrenze des Tests liegt oder wenn die Probe nicht ordnungsgemäß entnommen oder transportiert wurde. Ein negatives Testergebnis schließt daher die Möglichkeit einer SARS-Cov-2-Infektion nicht aus und sollte durch Viruskultur oder PCR bestätigt werden.

LEISTUNGSMERKMALE

Klinische Bewertung

Eine klinische Bewertung wurde durchgeführt, um die Ergebnisse zu vergleichen, die mit der Antigen-Schnelltestkassette (Tupfer) für das neuartige Coronavirus (SARS-Cov-2) und mit der PCR erhalten wurden. Die Ergebnisse stellen wir im Folgenden zusammenfassend dar:

Tabelle: Antigen-Schnelltestkassette (Tupfer) für das neuartige Coronavirus (SARS-Cov-2) vs. PCR

Methode		2019-nCoV-Nukleinsäuretestkit (RT-PCR)		Gesamtergebnisse
Realy tech Ergebnis	Ergebnisse	Positiv	Negativ	
	Positiv	201	0	201
	Negativ	8	450	458
Gesamtergebnisse		209	450	659

Klinische Sensitivität = 201/209=96.17 % (95%CI* 92.51% to 98.17%)
Klinische Spezifität = 450/450 :>99.9% (95%CI* 98.98% to 100%)
Genauigkeit: (201+450)/ (201+0+8+450) *100%=98.79% (95%CI* 97.58% to 99.43%)
*Konfidenzintervall

Nachweisgrenze (LoD)

Getestet in 2019-nCoV-Stamm	Realy Tech Produkt				
Lager 2019-nCoV Konzentration	1 X 10^5 TCID$_{50}$/mL				
Verdünnung	1/100	1/200	1/400	1/800	1/1600
Konzentration in der Verdünnung getestet (TCID$_{50}$/ml)	5X10^2	5X10^2	2.5X 10^2	1.25X10^2	6.25X10^1
Anmerkten von 20 Wiederholungen in der Nähe von Cut-Off	100 (20/20)	100 (20/20)	100 (20/20)	95 (19/20)	50 (2/20)
Elektroneigrenze (LoD) pro Virusstamm	6.25 X 10^1 TCID$_{50}$/mL				

Kreuzreaktion

Die Testergebnisse liegen unter der entsprechenden Konzentration der Substanzen in der nachstehenden Tabelle, was keinen Einfluss auf die negativen und positiven Testergebnisse dieses Reagens hat, und es gibt keine Kreuzreaktion.

Virus/Bakterien/Parasit	Stamm	Konzentration
MERS-Coronavirus	k. A.	72 µg/mL
Adenovirus	Typ 1	1,5 x 10^3TCID$_{50}$/mL
	Typ 3	7,5 x 10^3TCID$_{50}$/mL
	Typ 5	4,5 x 10^3TCID$_{50}$/mL
	Typ 7	1,0 x 10^3TCID$_{50}$/mL
	Typ 8	1,0 x 10^3TCID$_{50}$/mL
	Typ 11	2,5 x 10^3TCID$_{50}$/mL
	Typ 18	2,5 x 10^3TCID$_{50}$/mL
	Typ 23	6,0 x 10^3TCID$_{50}$/mL
	Typ 55	1,5 x 10^3TCID$_{50}$/mL
Influenza A	H1N1 Denver	3,0 x 10^3TCID$_{50}$/mL
	H1N1 WS/33	2,0 x 10^3TCID$_{50}$/mL
	H1N1 A/Mal/302/54	1,5 x 10^3TCID$_{50}$/mL
	H1N1 New Caledonia	7,6 x 10^3TCID$_{50}$/mL
	H3N2 A/Hong Kong/8/68	4,6 x 10^3TCID$_{50}$/mL
Influenza B	Nevada/03/2011	1,5 x 10^3TCID$_{50}$/mL
	B/Lee/40	8,5 x 10^3TCID$_{50}$/mL
	B/Taiwan/2/62	4,0 x 10^3TCID$_{50}$/mL
Respiratorische Syncytial-Virus	k. A.	2,5 x 10^3TCID$_{50}$/mL
Legionella pneumophila	Bloomington-2	1 x 10^5 PFU/mL
	Los Angeles-1	1 x 10^5 PFU/mL
	82A3105	1 x 10^5 PFU/mL
Rhinovirus A16	k. A.	1,5 x 10^3TCID$_{50}$/mL
Mycobacterium tuberculosis	K	1 x 10^5PFU/mL
	Erdman	1 x 10^5PFU/mL
	HN878	1 x 10^5PFU/mL
	CDC1551	1 x 10^5PFU/mL
	H37Rv	1 x 10^5PFU/mL
Streptococcus pneumonia	4752-98 [Maryland (D1) 6B-17]	1 x 10^5PFU/mL
	178 [Poland 23F-16]	1 x 10^5PFU/mL
	262 [CIP 104340]	1 x 10^5PFU/mL
	Slovakia 14-10 [29055]	1 x 10^5PFU/mL
Streptococcus pyrogens	Typstamm T1 [NCIB 11841, SF 130]	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10^5PFU/ml
	FH-Stamm von Eaton Agent [NCTC 10119]	1 x 10^5PFU/ml
	36M129-B7	1 x 10^5PFU/ml
Coronavirus	229E	1,5 x10^3TCID$_{50}$/ml
	OC43	1,5 x10^3TCID$_{50}$/ml
	NL63	1,5 x 10^3TCID$_{50}$/ml
	HKU1	1,5 x 10^3TCID$_{50}$/ml
Humanes Etapneumovirus (hMPV) 3 Typ B1	Peru2-2002	1,5 x 10^3TCID$_{50}$/ml
Humanes Metapneumovirus (hMPV) 16 Typ A1	IA10-2003	1,5 x 10^3TCID$_{50}$/ml
Parainfluenzavirus	Typ 1	1,5 x 106TCID$_{50}$/ml
	Typ 2	1,5 x 106TCID$_{50}$/ml
	Typ 3	1,5 x 106TCID$_{50}$/ml
	Typ 4A	1,5 x 106TCID$_{50}$/ml

Reaktion auf Störsubstanz

Bei der Prüfung mit der Schnelltestkassette für das neuartige Coronavirus (SARS-Cov-2) Antigen (Tupfer) gab es keine Interferenzen zwischen den Reagenzien des Geräts und den in der nachstehenden Tabelle aufgeführten potenziellen Störsubstanzen, die zu falsch positiven oder negativen Ergebnissen für das SARS-Cov-2-Antigen führen würden.

Substanz	Konzentration	Substanz	Konzentration
Mucine	100 µg/mL	Acetylsalicylsäure	3,0 mM
Vollblut	5 % (v/v)	Ibuprofen	2,5 mM
Biotin	100 µg/mL	Mupirocin	10 mg/mL
Neosynephrin (Phenylephrin)	5 %(v/v)	Tobramycin	10µg/mL
Afrin Nasenspray (Oxymetazolin)	5 %(v/v)	Erythromycin	50 uM
Nasenspray mit Kochsalzlösung	5 %(v/v)	Ciprofloxacin	50 uM
Homöopathie	5 %(v/v)	Ceftriaxon	110 mg/ml
Cromoglicinsäure	10 mg/mL	Meropenem	3,7 µg/ml
Olopatadinhydrochlorid	10 mg/mL	Tobramycin	100 µg/mL
Zanamivir	5 mg/mL	Histaminhydrochlorid	100 µg/mL
Oseltamivir	10 mg/mL	Peramivir	1 mmol/mL
Artemether-Lumefantrin	50 uM	Flunisolid	100 µg/mL
Doxycyclinhyclat	50 uM	Budesonid	0,64 nmol/L
Chinin	150 uM	Fluticasone	0,3 mg/mL
Lamivudin	1 mg/mL	Lopinavir	6 µg/mL
Ribavirin	1 mg/mL	Ritonavir	8,2 mg/mL
Daclatasvir	1 mg/mL	Abidor	417,8 ng/mL
Paracetamol	150 uM	Gepoolte humane Nasenbusche	k. A.

SYMBOLE

Symbol	Bedeutung	Symbol	Bedeutung
IVD	Medizinisches In-vitro-Diagnosegerät		Lagertemperaturgrenzwerte
	Hersteller	EC REP	Bevollmächtigter Vertreter in der Europäischen Gemeinschaft
	Herstellungsdatum		Verfallsdatum
	Nicht wiederverwenden		Gebrauchsanweisung beachten
LOT	Chargencode	CE	Erfüllen Sie die Anforderungen der EG-Richtlinie 98/79/EG

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Nummer:1101381605
Version: 1.604
Datum des Inkrafttretens: 29.10.2020

Clinical Validation report of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Product name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Package Specification: 25 tests/kit

Manufacturer: Hangzhou Realy Tech Co., Ltd

Validated by: Shijiazhuang Fifth People's Hospital

File No. MF-K511416D-0010
Version: 1.3
Effective date:2020-10-13

I. Clinical validation time

This clinical evaluation was conducted from July 2020 to Aug 14th,2020.

II. Background information for clinical evaluation

Since December 2019, world has successively discovered multiple cases of patients with new-type coronavirus pneumonia. With the spread of the epidemic, China and abroad have also been found. As an acute respiratory infectious disease, the disease has been included in the Class B infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases, and is managed as a Class A infectious disease. Based on the current epidemiological investigation, the incubation period is 1-14 days, mostly 3-7 days.

The main manifestations are fever, dry cough, and fatigue. A few patients have symptoms such as nasal congestion, runny nose, sore throat, myalgia and diarrhea. Severe patients usually have dyspnea and / or hypoxemia one week after the onset of symptoms, and severe patients can quickly progress to acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, coagulation dysfunction and multiple organ Functional failure, etc. It is worth noting that in the course of severe and critically ill patients, there may be moderate to low fever, even without obvious fever.

Mild patients showed only low fever, mild fatigue, and no pneumonia. Judging from the current cases, most patients have a good prognosis, and a few patients are critically ill. The elderly and those with chronic underlying disease have a better prognosis. Symptoms in children are relatively mild.

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab) developed by our company can help diagnose whether patients are infected with the Novel Coronavirus. It has further enriched the detection methods of Novel Coronavirus, expanded the supply of detection reagents, and fully served the needs of epidemic prevention and control.

III. Test purposes

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab) produced by Hangzhou Realy Technology Co., Ltd. was used to verify the feasibility of clinical evaluation and the reliability of test results for Chinese subjects.

The purpose of research of the clinical test is to calculate the consistency percentage of negative/positive and the total consistency percentage and Kappa coefficient by statistically analyzing test results through comparative experimental research.

IV. Test design

1. Test plan selection and reasons

In vitro diagnostic reagents for testing and reference reagents were used to conduct comparative research tests on clinically suspected Novel Coronavirus Nasopharyngeal swab samples, and it was proved that the in vitro diagnostic reagents used in the test can achieve the expected assistance in infection of the Novel Coronavirus.

2. Sample volume required

The total number of clinical trials of this product is not less than 100 cases. The samples is

classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the samples shall be tested via the qualitative test strip tested and by reference product from the same patient and then the test results of the product tested and the reference product shall be compared, with statistical analysis being made.

3. Sample inclusion/exclusion certification.

The positive group and negative group in this experiment are applicable to the following inclusion/exclusion criteria

Positive group inclusion:

PCR Test is positive;

CT test results and symptoms are clinically positive;

Negative inclusion:

PCR test is negative;

CT test results and symptoms are clinically negative;

Sample collection, processing

It is applicable to the diagnosis of the Novel coroinavirus from the samples of Nasopharyngeal swab.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

Sample collection procedure: Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.

It is recommended to collect sample from Nasopharyngeal for more accurate results.

Specimen preparation:

1) Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube supplied in this kit, and put it on the tube stand.

2) Insert the swab into the extraction tube which contains Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab, remove the swab. The extracted solution will be used as test sample.

4. In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name: The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Specification:25 tests/kit

REF: K511416D

LOT: 202007046

Expiry: June,2022(Tentative)

Storage Conditions: Store in a dry place at 2-30°C, protected from light. After opening the inner package, the test card will become invalid due to moisture absorption. Please use it within 1 hour.

Source: Hangzhou Realy Tech Co.,Ltd

5.2 Reference products

Name: Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Manufacturer: Sansure Biotech Inc.

Storage Conditions: Store in a dry place at 2-8°C, protected from light.

V. Experiment method

1. Get the Swab specimens from patients in positive and negative groups.
2. Pre-process the swab samples according to the instructions of the The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab), and label the samples randomly.

2.1 Add 10 drops (about 0.3 ml) of the sample extraction buffer into the extraction tube.

2.2 Place the swab specimen in the SARS-Cov-2 antigen Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

2.3 Remove the swab while squeezing the swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

2.4 Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the Buffer. Place the test device on a clean and level surface.

3. The operation steps of the in vitro diagnostic reagents for the test are as follows. For details, please refer to the product instruction manual:

3.1 remove the test sample and required reagents from the storage conditions and equilibrate to room temperature (15-30°C).

3.2 When preparing for testing, open the aluminum foil bag from the tear. Remove the test card and lay it flat on a horizontal table.

3.3 Label the sample number on the test card.

3.4 Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer.

3.5 Time counting and interpret the results within 10 minutes.

Note: The detection steps need to be completed under protection against infection.

VI. Statistical methods of statistical analysis of clinical research data

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the product tested and the reference product, to validate the accuracy and applicability of the product in clinical applications. The product tested shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile,different types of sample of the subjects shall be subject to determination by the product tested synchronously, and then the determination results of both shall be compared. The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples,to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards,

equivalence of both shall be evaluated as per these statistical indexes

B Statistical method

The products launched on the market shall be subject to comparative study and evaluation.Kappa inspection: each sample shall be tested with the product tested and the reference product respectively, and then the consistency in statistical results of these two inspection methods shall be compared through Kappa inspection.

The data shall be subject to Kappa inspection and analysis and the Kappa coefficient shall be calculated.Favorable consistency can be proven if Kappa is＞0.8. The consistency in test results of the product tested and the reference product is evaluated as per the evaluation standards.

VII Standards of clinical evaluation

The coincidence rate shall be calculated by comparing with the reference product whose marketing is approved. The product performance shall meet the following requirements.

1)Coincidence rate of negative: the sample whose test results are negative for both the product tested and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 95%.

2)Coincidence rate of positive: the sample whose test results are positive for both the product tested and the reference product and the proportion in the sample whose test results are positive for the reference product shall be more than 85%.

3)Total coincidence rate: the sample whose test results are the same for the product tested and the reference product and its proportion in the total number of samples shall be more than 90%.

Method		2019-nCoV nucleic acid test kit（RT-PCR）		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

Clinical sensitivity =A/(A+C)*100%

Clinical specificity = D/(B+D)*100%

Accuracy: (A+D)/(A+B+C+D)*100%

If the coincidence rate of positive/negative can meet clinical requirements, two methods or Products are considered as equivalent; If the coincidence rate of positive/negative is greatly different, the clinical scheme should be re-designed.

4)Kappa consistency analysis shall be adopted for statistical analysis of reference reagents.

The results of the product tested are statistical materials and can be per the table below:

		2019-nCoV nucleic acid test kit（RT-PCR）		
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)				

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)				
		201	0	201
		8	450	458
		209	450	659

96.17 92.51% to 98.17%)

> 98.98% to 100%)

97.58% to 99.43%)

>

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)

XI. Prediction of adverse events

Because the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab) is an in vitro diagnostic reagent product, no direct contact with patients is required in clinical trials, no test report is provided to patients, and the test results are only used for comparative studies. It involves personal privacy, does not serve as a basis for auxiliary diagnosis, does not bring any risk to the subject, and does not cause adverse events.

References：

1.The "Technical Review Points for the Registration of New Coronavirus Antigen / Antibody Detection Reagents in 2019 (Trial)" issued by the State Drug Administration Medical Device Technical Evaluation Center on February 25, 2020；

2. "Pneumonitis Diagnosis and Treatment Program for New Coronavirus Infection (Trial Version 7)" issued by the National Health Committee on February 19, 2020.

Annex 1:Package Insert

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB.

For professional In Vitro Diagnostic Use Only

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in Nasopharyngeal swab and Oropharyngeal swab, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. It aids in the early detection for clinical diagnosis of novel coronavirus.

SUMMARY

COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. 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.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to novel coronavirus.

The test device is composed of the following three parts: namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal gold conjugated with the monoclonal antibodies against Novel coronavirus,the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-embedded on the membrane.

When the sample is added into the sample window,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coronavirus is present in the sample, a complex formed between the anti- Novel coronavirus conjugate and the virus will be caught by the specific anti-Novel coronavirus monoclonal coated on the T region.

Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent can anti-mouse IgG antibody that binds the remaining conjugates, thereby showing a control line in the region C.

REAGENTS

The reagent membrane contains the colloidal gold conjugated with the monoclonal antibodies against Novel coronavirus, the reaction membrane contains the secondary antibodies for Novel coronavirus,and the polyclonal antibodies against the mouse globulin, which are pre-embedded on the membrane.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- Ensure kit pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30℃.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and disposed according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) at room temperature or refrigerated (2-30℃). Do not freeze. All reagents are stable until the expiration date marked on the outer box.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:

It is applicable to the diagnosis of the Novel coronavirus, from the samples of Nasopharyngeal swab.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

For nasopharyngeal swab completely insert the sterilized swab supplied in this kit into the nasal cavity, and swab several times to collect the epidermal cells of the mucosa.

For oropharyngeal swab completely insert the sterilized swab supplied in this kit into the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.

It is recommended to collect sample from Nasopharyngeal for more accurate results.

2. Specimen preparation:

1) Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.

2)**Nasopharyngeal and oropharyngeal Swabbing**

Insert the swab into the extraction tube which contains Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to rid the side of the extraction tube so that liquid is expressed and reabsorbed from the swab, remove the swab. The extracted solution will be used as test sample.

MATERIALS

Materials provided

- Test Device
- Sterilized Swab
- Extraction Tube
- Package Insert
- Nozzle with Filter
- Sample Extraction Buffer
- Tube Stand

Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30℃) prior to testing.

1.Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Unscrew the whole cap of the specimen collection tube.

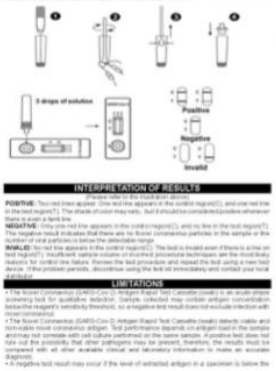
3. Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.

4.Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

5.Remove the sterilized swab while squeezing the sterilized swab head against the inside of buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your biohazard waste disposal protocol.

6. Screw on and tighten the cap onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the sample extraction buffer. See illustration 6.

7.Add 3 drops of the solution (approx 80ul) to the sample well and then start the timer. Read the result at 10-20 minutes. Don't interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral particles is below the detectable range.

INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentrations below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.
- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present; therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if poor quality specimen is obtained.
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children Ltd.
- A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly; therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) vs. PCR

Method		2019-nCoV Nucleic Acid Test kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	201	3	201
	Negative	4	450	454
Total Results		205	453	655

Clinical sensitivity = 201/205=98.1% (95%CI: 94.97% to 99.31%)

Clinical specificity = 450/453=99.3% (95%CI: 98.05% to 99.8%)

Accuracy: 651/655=99.39% (95%CI: 98.29% to 99.82%)

*Confidence interval

Limit of Detection (LoD)

2019-nCoV Strain (USA-WA1/2020)	100 TCID50/mL	1.0 x 10^2 TCID50/mL
Cultured 2019-nCoV Concentration	1.0 x 10^5 TCID50/mL	
Sample	Dilution Factor	Cutoff
Clinical Nasal Swab Matrix	1:100	1.0 x 10^2 TCID50/mL
Clinical Oropharyngeal Swab Matrix	1:100	1.0 x 10^2 TCID50/mL

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no affect on the negative and positive test results of this reagent, and there is no cross-reaction.

Virus/Bacterial/Parasite	Strain	Concentration
MERS-coronavirus	N/A	1 x10^5 PFU/mL
Adenovirus	Type 1	1.0 x 10^6 TCID50/mL
	Type 3	1.0 x 10^6 TCID50/mL
	Type 4	8.0 x 10^5 TCID50/mL
	Type 7	1.0 x 10^6 TCID50/mL
	Type 8	1.0 x 10^6 TCID50/mL
	Type 11	2.0 x 10^6 TCID50/mL
	Type 18	2.0 x 10^6 TCID50/mL
	Type 31	8.0 x 10^5 TCID50/mL
	Type 55	1.0 x 10^6 TCID50/mL
Influenza A	H1N1 (Denver)	2.0 x 10^5 TCID50/mL
	H1N1 (WSN33)	2.0 x 10^5 TCID50/mL
	H1N1 (California/07/2009)	2.0 x 10^5 TCID50/mL
	H3N2 (New Caledonia)	7.0 x 10^5 TCID50/mL
	H3N2 (Hong Kong/8/68)	4.0 x 10^5 TCID50/mL
Influenza B	B/Lee/40	8.0 x 10^5 TCID50/mL
	B/Taiwan/2/62	4.0 x 10^5 TCID50/mL
Respiratory syncytial virus	N/A	2.0 x 10^5 TCID50/mL
Legionella pneumophila	(Bloomington-)	1 x 10^6 CFU/mL
	(Lens Philadelphia-1)	1 x 10^6 CFU/mL
Rhinovirus A 16	N/A	1 x 10^6 TCID50/mL
Mycobacterium tuberculosis	H37Ra	1 x 10^6 CFU/mL
	H37Rv	1 x 10^6 CFU/mL
	CDC1551	1 x 10^6 CFU/mL
Streptococcus pneumoniae	ATCC	1 x 10^6 CFU/mL
	ATCC 49 (Wallace)	1 x 10^6 CFU/mL
	172 (Finland, 23F)	1 x 10^6 CFU/mL
	6A (GA41 Variant)	1 x 10^6 CFU/mL
	Strain 6B (ATCC)	1 x 10^6 CFU/mL

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Streptococcus pyogens	Typing strain T1 [NCIB 11841, SF 130]		1 x 10^6PFU/ml
Mycoplasma pneumoniae	Mutant 22		1 x 10^6PFU/ml
	FH strain(Eaton agent) [NCTC 10119]		1 x 10^6PFU/ml
	3/441/19-B7		1 x 10^6PFU/ml
Coronavirus	229E		1.5 x10^6TCID$_{50}$/ml
	OC43		1.5 x10^6TCID$_{50}$/ml
	NL63		1.5 x 10^6TCID$_{50}$/ml
	HKU1		1.5 x 10^6TCID$_{50}$/ml
Human wiegenvirus (HMPV) 3 Type B1	Peru2-2002		1.5 x 10^6TCID$_{50}$/ml
Human Metapneumovirus (HMPV) 16 Type A1	I-N10-2003		1.5 x 10^6TCID$_{50}$/ml
Parainfluenza virus	Type 1		1.5 x 10^{6}TCID$_{50}$/ml
	Type 2		1.5 x 10^{6}TCID$_{50}$/ml
	Type 3		1.5 x 10^{6}TCID$_{50}$/ml
	Type 4A		1.5 x 10^{6}TCID$_{50}$/ml

Interfering Substances Reaction

When tested using the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab), there was no interference between the device reagents and the Potential interference substances listed in below table that would create false positive or negative results for SARS-Cov-2 antigen.

Substance	Concentration	Substance	Concentration
Mucin	5 mg/mL	Acetylsalicylic acid	5 mg/mL
Whole Blood	4% (v/v)	Ibuprofen	2 mg/mL
Biotin	10 ug/mL	Mupirocin	10 mg/mL
Beta Interferon (Pharmacia)	10 IU/mL	Tobramycin	10 ug/mL
Afrin Nasal Spray (Oxymetazoline)	15 v/v%	Erythromycin	10 uM
Saline Nasal Spray	15 v/v%	Ciprofloxacin	10 uM
Homeopathic	15 v/v%	Ceftriaxone	10 mg/mL
Sodium Cromoglycate	10 mg/mL	Meropenem	10 ug/mL
Oxymetazoline Hydrochloride	10 mg/mL	Tobramycin	10 ug/mL
Levamisol	5 mg/mL	Phenylephrine Hydrochloride	10 ug/mL
Budesonid	10 mg/mL	Peramivir	10 mg/mL
Beclomethasone dipropionate	10 uM	Ribavirin	10 mg/mL
Dexamethasone	10 uM	Rimantadine	10 mg/mL
Zanamivir	10 ug/mL	Tobramycin	5 ug/mL
Peramivir	10 mg/mL	Lactobacillus	5 ug/mL
Ribavirin	5 mg/mL	Lactobacillus	5 ug/mL
Oseltamivir	5 mg/mL	Mupirocin	5 ug/mL
Zanamivir	5 mg/mL	Fluticasone	5 ug/mL
Mupirocin	10 ug/mL	Beclomethasone	5 ug/mL

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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CE

Number: 1101201901
Version:1.0(01)
Effective Date:2020-10-07

File No. MF-K511416D-0010
Version: 1.3
Effective date:2020-10-13

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Annex 2: Data of Clinical Tests

NO.	Age	Gender	Rapid Test	(RT-PCR)
1	49	F	Positive	Positive（RdRP and N gene)
2	32	F	Positive	Positive（RdRP and N gene)
3	31	F	Positive	Positive（RdRP and N gene)
4	32	F	Positive	Positive（RdRP and N gene)
5	21	F	Positive	Positive（RdRP and N gene)
6	51	M	Positive	Positive（RdRP and N gene)
7	22	F	Positive	Positive（RdRP and N gene)
8	46	F	Positive	Positive（RdRP and N gene)
9	23	F	Negative	Positive（N gene)
10	14	M	positive	Positive（RdRP and N gene)
11	42	M	Positive	Positive（RdRP and N gene)
12	51	M	Positive	Positive（RdRP and N gene)
13	80	M	Positive	Positive（RdRP and N gene)
14	39	F	Positive	Positive（RdRP and N gene)
15	67	M	Positive	Positive（RdRP and N gene)
16	44	M	positive	Positive（RdRP gene)
17	26	F	Positive	Positive（RdRP and N gene)
18	33	F	positive	Positive（N gene)
19	38	F	Positive	Positive（RdRP and N gene)
20	36	F	Positive	Positive（RdRP and N gene)
21	3	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
22	35	F	Positive	Positive（RdRP and N gene)
23	23	F	Positive	Positive（RdRP and N gene)
24	43	M	Positive	Positive（RdRP and N gene)
25	43	F	Positive	Positive（RdRP and N gene)
26	46	F	Positive	Positive（RdRP and N gene)
27	55	F	Positive	Positive（RdRP and N gene)
28	22	F	Positive	Positive（RdRP and N gene)
29	20	M	positive	Positive（N gene)
30	42	M	Positive	Positive（RdRP and N gene)
31	56	F	Positive	Positive（RdRP and N gene)
32	55	M	Positive	Positive（RdRP and N gene)
33	26	F	Positive	Positive（RdRP and N gene)
34	54	M	Positive	Positive（RdRP and N gene)
35	43	F	Positive	Positive（RdRP and N gene)
36	69	M	Positive	Positive（RdRP and N gene)
37	36	M	Positive	Positive（RdRP and N gene)
38	37	F	Positive	Positive（RdRP and N gene)
39	44	F	Positive	Positive（RdRP and N gene)
40	43	F	Positive	Positive（RdRP and N gene)
41	67	F	Positive	Positive（RdRP and N gene)
42	51	F	Positive	Positive（RdRP and N gene)

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NO.	Age	Gender	Rapid Test	(RT-PCR)
43	75	F	Positive	Positive（RdRP and N gene)
44	60	F	Positive	Positive（RdRP and N gene)
45	25	M	Positive	Positive（RdRP and N gene)
46	75	F	Positive	Positive（RdRP and N gene)
47	43	F	Positive	Positive（RdRP and N gene)
48	30	F	Positive	Positive（RdRP and N gene)
49	30	M	Negative	Positive（N gene)
50	26	F	Positive	Positive（RdRP and N gene)
51	32	F	Positive	Positive（RdRP and N gene)
52	73	M	Positive	Positive（RdRP and N gene)
53	58	F	Positive	Positive（RdRP and N gene)
54	66	F	Positive	Positive（RdRP and N gene)
55	29	F	Positive	Positive（RdRP and N gene)
56	56	M	Positive	Positive（RdRP and N gene)
57	24	M	Positive	Positive（N gene)
58	36	M	Positive	Positive（RdRP and N gene)
59	70	F	Positive	Positive（RdRP and N gene)
60	45	M	Positive	Positive（RdRP and N gene)
61	38	F	Positive	Positive（RdRP and N gene)
62	42	M	Positive	Positive（RdRP and N gene)
63	55	M	Positive	Positive（RdRP and N gene)
64	33	M	Positive	Positive（RdRP and N gene)
65	39	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
66	58	F	Positive	Positive（N gene)
67	20	F	Positive	Positive（RdRP and N gene)
68	42	M	Positive	Positive（RdRP and N gene)
69	27	F	Positive	Positive（RdRP and N gene)
70	49	M	Positive	Positive（RdRP and N gene)
71	49	M	positive	Positive（N gene)
72	39	M	Negative	Positive（RdRP and N gene)
73	17	F	Positive	Positive（RdRP and N gene)
74	60	M	Positive	Positive（RdRP and N gene)
75	44	M	Positive	Positive（RdRP and N gene)
76	49	F	Positive	Positive（RdRP and N gene)
77	11	M	Positive	Positive（RdRP and N gene)
78	32	M	positive	Positive（RdRP gene)
79	51	F	Positive	Positive（RdRP and N gene)
80	28	M	Negative	Positive（N gene)
81	31	F	Positive	Positive（RdRP and N gene)
82	50	M	Positive	Positive（RdRP and N gene)
83	47	M	Positive	Positive（RdRP and N gene)
84	44	F	Positive	Positive（N gene)
85	10	F	Positive	Positive（RdRP and N gene)
86	24	M	Positive	Positive（RdRP and N gene)
87	22	F	Positive	Positive（RdRP and N gene)
88	47	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
89	26	M	Positive	Positive（RdRP and N gene)
90	43	F	Positive	Positive（RdRP and N gene)
91	55	M	Positive	Positive（RdRP and N gene)
92	50	F	Positive	Positive（RdRP and N gene)
93	26	M	Positive	Positive（RdRP and N gene)
94	51	F	Positive	Positive（RdRP and N gene)
95	20	F	Positive	Positive（RdRP and N gene)
96	44	M	Positive	Positive（RdRP and N gene)
97	38	F	Positive	Positive（RdRP and N gene)
98	38	F	Positive	Positive（RdRP and N gene)
99	39	M	Positive	Positive（RdRP and N gene)
100	30	F	Positive	Positive（RdRP and N gene)
101	57	F	Positive	Positive（RdRP and N gene)
102	45	M	Positive	Positive（RdRP and N gene)
103	41	F	Positive	Positive（RdRP and N gene)
104	26	F	Positive	Positive（RdRP and N gene)
105	58	F	Negative	Positive（N gene)
106	39	F	Positive	Positive（RdRP and N gene)
107	60	F	Positive	Positive（RdRP and N gene)
108	11	M	Positive	Positive（RdRP and N gene)
109	12	F	Positive	Positive（RdRP and N gene)
110	17	M	Positive	Positive（RdRP and N gene)
111	59	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
112	15	M	Positive	Positive（RdRP and N gene)
113	53	F	Positive	Positive（RdRP and N gene)
114	10	M	Positive	Positive（RdRP and N gene)
115	25	F	Positive	Positive（RdRP and N gene)
116	39	M	Positive	Positive（RdRP and N gene)
117	56	M	Positive	Positive（RdRP and N gene)
118	49	M	Positive	Positive（RdRP and N gene)
119	20	M	Positive	Positive（RdRP and N gene)
120	25	M	Positive	Positive（RdRP and N gene)
121	37	F	Positive	Positive（RdRP and N gene)
122	52	F	Positive	Positive（RdRP and N gene)
123	60	F	Positive	Positive（RdRP and N gene)
124	25	M	Positive	Positive（RdRP and N gene)
125	19	F	Positive	Positive（RdRP and N gene)
126	32	M	Positive	Positive（RdRP and N gene)
127	28	F	Positive	Positive（RdRP and N gene)
128	52	F	Positive	Positive（RdRP and N gene)
129	40	F	Positive	Positive（RdRP and N gene)
130	28	F	Positive	Positive（RdRP and N gene)
131	31	F	Positive	Positive（RdRP and N gene)
132	48	M	Positive	Positive（RdRP and N gene)
133	33	F	positive	Positive（RdRP and N gene)
134	44	M	positive	Positive（RdRP and N gene)

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NO.	Age	Gender	Rapid Test	(RT-PCR)
135	34	F	Positive	Positive（RdRP and N gene)
136	18	M	Positive	Positive（RdRP and N gene)
137	59	M	Positive	Positive（RdRP and N gene)
138	18	M	Positive	Positive（RdRP and N gene)
139	38	M	Positive	Positive（RdRP and N gene)
140	20	F	Positive	Positive（RdRP and N gene)
141	54	F	Positive	Positive（RdRP and N gene)
142	43	F	Positive	Positive（RdRP and N gene)
143	23	M	Positive	Positive（RdRP and N gene)
144	27	F	Positive	Positive（RdRP and N gene)
145	39	M	Positive	Positive（RdRP and N gene)
146	60	M	Positive	Positive（RdRP and N gene)
147	52	M	Negative	Positive（RdRP gene)
148	49	M	Positive	Positive（RdRP and N gene)
149	42	M	positive	Positive（RdRP gene)
150	32	F	Positive	Positive（RdRP and N gene)
151	59	M	Positive	Positive（RdRP and N gene)
152	33	F	Positive	Positive（RdRP and N gene)
153	15	F	Positive	Positive（RdRP and N gene)
154	16	F	Negative	Positive（N gene)
155	24	M	Positive	Positive（RdRP and N gene)
156	52	F	Positive	Positive（RdRP and N gene)
157	60	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
158	24	M	Positive	Positive（RdRP and N gene)
159	36	F	Positive	Positive（RdRP and N gene)
160	19	F	Positive	Positive（RdRP and N gene)
161	33	F	Positive	Positive（RdRP and N gene)
162	53	M	Positive	Positive（RdRP and N gene)
163	43	M	Positive	Positive（RdRP and N gene)
164	12	F	Positive	Positive（RdRP and N gene)
165	14	M	Positive	Positive（RdRP and N gene)
166	56	M	Positive	Positive（RdRP and N gene)
167	52	F	Positive	Positive（RdRP and N gene)
168	32	F	Positive	Positive（RdRP and N gene)
169	50	M	Positive	Positive（RdRP and N gene)
170	18	F	Positive	Positive（RdRP and N gene)
171	35	F	Positive	Positive（RdRP and N gene)
172	12	M	Positive	Positive（RdRP and N gene)
173	14	F	Negative	Positive（RdRP and N gene)
174	13	F	Positive	Positive（RdRP and N gene)
175	42	M	Positive	Positive（RdRP and N gene)
176	13	F	Positive	Positive（RdRP and N gene)
177	14	F	Positive	Positive（RdRP and N gene)
178	60	M	Positive	Positive（RdRP and N gene)
179	13	F	Positive	Positive（RdRP and N gene)
180	51	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
181	56	M	Positive	Positive（RdRP and N gene)
182	14	F	Positive	Positive（RdRP and N gene)
183	45	F	Positive	Positive（RdRP and N gene)
184	24	F	Positive	Positive（RdRP and N gene)
185	15	M	Positive	Positive（RdRP and N gene)
186	51	F	Positive	Positive（RdRP and N gene)
187	31	M	Positive	Positive（RdRP and N gene)
188	49	M	Positive	Positive（RdRP and N gene)
189	28	M	Positive	Positive（RdRP and N gene)
190	80	M	Positive	Positive（RdRP and N gene)
191	47	M	Positive	Positive（RdRP and N gene)
192	22	F	Positive	Positive（RdRP and N gene)
193	49	F	Positive	Positive（RdRP and N gene)
194	23	M	Positive	Positive（RdRP and N gene)
195	30	F	Positive	Positive（RdRP and N gene)
196	55	F	Positive	Positive（RdRP and N gene)
197	75	F	Positive	Positive（RdRP and N gene)
198	49	M	Positive	Positive（RdRP and N gene)
199	81	M	Positive	Positive（RdRP and N gene)
200	51	F	Positive	Positive（RdRP and N gene)
201	12	F	Positive	Positive（RdRP and N gene)
202	47	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
203	78	F	Positive	Positive（RdRP and N gene)
204	73	M	Positive	Positive（RdRP and N gene)
205	11	M	Positive	Positive（RdRP and N gene)
206	11	M	Positive	Positive（RdRP and N gene)
207	12	F	Positive	Positive（RdRP and N gene)
208	60	M	Positive	Positive（RdRP and N gene)
209	77	F	Negative	Positive（RdRP and N gene)
210	62	F	Negative	Negative(Ct/Cq）>40
211	81	M	Negative	Negative(Ct/Cq）>40
212	18	F	Negative	Negative(Ct/Cq）>40
213	71	F	Negative	Negative(Ct/Cq）>40
214	37	M	Negative	Negative(Ct/Cq）>40
215	44	F	Negative	Negative(Ct/Cq）>40
216	79	M	Negative	Negative(Ct/Cq）>40
217	67	M	Negative	Negative(Ct/Cq）>40
218	61	F	Negative	Negative(Ct/Cq）>40
219	59	F	Negative	Negative(Ct/Cq）>40
220	28	F	Negative	Negative(Ct/Cq）>40
221	82	M	Negative	Negative(Ct/Cq）>40
222	63	F	Negative	Negative(Ct/Cq）>40
223	53	M	Negative	Negative(Ct/Cq）>40
224	43	M	Negative	Negative(Ct/Cq）>40

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NO.	Age	Gender	Rapid Test	(RT-PCR)
225	46	M	Negative	Negative(Ct/Cq）>40
226	46	F	Negative	Negative(Ct/Cq）>40
227	21	F	Negative	Negative(Ct/Cq）>40
228	46	F	Negative	Negative(Ct/Cq）>40
229	71	M	Negative	Negative(Ct/Cq）>40
230	60	F	Negative	Negative(Ct/Cq）>40
231	31	F	Negative	Negative(Ct/Cq）>40
232	72	M	Negative	Negative(Ct/Cq）>40
233	62	M	Negative	Negative(Ct/Cq）>40
234	39	F	Negative	Negative(Ct/Cq）>40
235	45	M	Negative	Negative(Ct/Cq）>40
236	21	M	Negative	Negative(Ct/Cq）>40
237	33	M	Negative	Negative(Ct/Cq）>40
238	83	M	Negative	Negative(Ct/Cq）>40
239	15	M	Negative	Negative(Ct/Cq）>40
240	59	M	Negative	Negative(Ct/Cq）>40
241	54	M	Negative	Negative(Ct/Cq）>40
242	84	F	Negative	Negative(Ct/Cq）>40
243	84	F	Negative	Negative(Ct/Cq）>40
244	42	F	Negative	Negative(Ct/Cq）>40
245	63	F	Negative	Negative(Ct/Cq）>40
246	29	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
247	50	M	Negative	Negative(Ct/Cq）>40
248	74	F	Negative	Negative(Ct/Cq）>40
249	43	M	Negative	Negative(Ct/Cq）>40
250	68	M	Negative	Negative(Ct/Cq）>40
251	29	M	Negative	Negative(Ct/Cq）>40
252	54	M	Negative	Negative(Ct/Cq）>40
253	49	M	Negative	Negative(Ct/Cq）>40
254	20	M	Negative	Negative(Ct/Cq）>40
255	26	M	Negative	Negative(Ct/Cq）>40
256	22	M	Negative	Negative(Ct/Cq）>40
257	32	F	Negative	Negative(Ct/Cq）>40
258	28	M	Negative	Negative(Ct/Cq）>40
259	44	M	Negative	Negative(Ct/Cq）>40
260	57	F	Negative	Negative(Ct/Cq）>40
261	64	F	Negative	Negative(Ct/Cq）>40
262	39	F	Negative	Negative(Ct/Cq）>40
263	38	F	Negative	Negative(Ct/Cq）>40
264	73	M	Negative	Negative(Ct/Cq）>40
265	45	M	Negative	Negative(Ct/Cq）>40
266	61	M	Negative	Negative(Ct/Cq）>40
267	13	F	Negative	Negative(Ct/Cq）>40
268	64	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
269	26	F	Negative	Negative(Ct/Cq）>40
270	28	M	Negative	Negative(Ct/Cq）>40
271	58	M	Negative	Negative(Ct/Cq）>40
272	35	F	Negative	Negative(Ct/Cq）>40
273	51	M	Negative	Negative(Ct/Cq）>40
274	60	M	Negative	Negative(Ct/Cq）>40
275	17	M	Negative	Negative(Ct/Cq）>40
276	18	F	Negative	Negative(Ct/Cq）>40
277	15	M	Negative	Negative(Ct/Cq）>40
278	52	M	Negative	Negative(Ct/Cq）>40
279	33	M	Negative	Negative(Ct/Cq）>40
280	41	F	Negative	Negative(Ct/Cq）>40
281	11	M	Negative	Negative(Ct/Cq）>40
282	19	F	Negative	Negative(Ct/Cq）>40
283	10	F	Negative	Negative(Ct/Cq）>40
284	62	F	Negative	Negative(Ct/Cq）>40
285	68	F	Negative	Negative(Ct/Cq）>40
286	38	M	Negative	Negative(Ct/Cq）>40
287	59	M	Negative	Negative(Ct/Cq）>40
288	76	F	Negative	Negative(Ct/Cq）>40
289	24	M	Negative	Negative(Ct/Cq）>40
290	68	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
291	82	F	Negative	Negative(Ct/Cq）>40
292	64	F	Negative	Negative(Ct/Cq）>40
293	59	M	Negative	Negative(Ct/Cq）>40
294	59	M	Negative	Negative(Ct/Cq）>40
295	83	M	Negative	Negative(Ct/Cq）>40
296	58	F	Negative	Negative(Ct/Cq）>40
297	68	M	Negative	Negative(Ct/Cq）>40
298	77	M	Negative	Negative(Ct/Cq）>40
299	47	F	Negative	Negative(Ct/Cq）>40
300	71	M	Negative	Negative(Ct/Cq）>40
301	21	F	Negative	Negative(Ct/Cq）>40
302	52	M	Negative	Negative(Ct/Cq）>40
303	70	M	Negative	Negative(Ct/Cq）>40
304	63	M	Negative	Negative(Ct/Cq）>40
305	59	M	Negative	Negative(Ct/Cq）>40
306	26	M	Negative	Negative(Ct/Cq）>40
307	36	F	Negative	Negative(Ct/Cq）>40
308	47	F	Negative	Negative(Ct/Cq）>40
309	45	M	Negative	Negative(Ct/Cq）>40
310	29	F	Negative	Negative(Ct/Cq）>40
311	30	M	Negative	Negative(Ct/Cq）>40
312	25	F	Negative	Negative(Ct/Cq）>40

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NO.	Age	Gender	Rapid Test	(RT-PCR)
313	73	M	Negative	Negative(Ct/Cq）>40
314	76	M	Negative	Negative(Ct/Cq）>40
315	25	M	Negative	Negative(Ct/Cq）>40
316	49	F	Negative	Negative(Ct/Cq）>40
317	62	M	Negative	Negative(Ct/Cq）>40
318	38	M	Negative	Negative(Ct/Cq）>40
319	33	M	Negative	Negative(Ct/Cq）>40
320	39	M	Negative	Negative(Ct/Cq）>40
321	69	M	Negative	Negative(Ct/Cq）>40
322	79	F	Negative	Negative(Ct/Cq）>40
323	32	M	Negative	Negative(Ct/Cq）>40
324	35	M	Negative	Negative(Ct/Cq）>40
325	39	M	Negative	Negative(Ct/Cq）>40
326	61	F	Negative	Negative(Ct/Cq）>40
327	10	F	Negative	Negative(Ct/Cq）>40
328	37	M	Negative	Negative(Ct/Cq）>40
329	52	F	Negative	Negative(Ct/Cq）>40
330	41	M	Negative	Negative(Ct/Cq）>40
331	74	M	Negative	Negative(Ct/Cq）>40
332	51	F	Negative	Negative(Ct/Cq）>40
333	56	M	Negative	Negative(Ct/Cq）>40
334	62	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
335	60	F	Negative	Negative(Ct/Cq）>40
336	54	F	Negative	Negative(Ct/Cq）>40
337	81	F	Negative	Negative(Ct/Cq）>40
338	79	F	Negative	Negative(Ct/Cq）>40
339	73	F	Negative	Negative(Ct/Cq）>40
340	35	F	Negative	Negative(Ct/Cq）>40
341	76	F	Negative	Negative(Ct/Cq）>40
342	23	M	Negative	Negative(Ct/Cq）>40
343	13	F	Negative	Negative(Ct/Cq）>40
344	14	M	Negative	Negative(Ct/Cq）>40
345	43	M	Negative	Negative(Ct/Cq）>40
346	30	F	Negative	Negative(Ct/Cq）>40
347	57	M	Negative	Negative(Ct/Cq）>40
348	30	F	Negative	Negative(Ct/Cq）>40
349	65	M	Negative	Negative(Ct/Cq）>40
350	66	F	Negative	Negative(Ct/Cq）>40
351	38	F	Negative	Negative(Ct/Cq）>40
352	49	M	Negative	Negative(Ct/Cq）>40
353	23	F	Negative	Negative(Ct/Cq）>40
354	51	M	Negative	Negative(Ct/Cq）>40
355	64	F	Negative	Negative(Ct/Cq）>40
356	67	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
357	34	M	Negative	Negative(Ct/Cq）>40
358	55	M	Negative	Negative(Ct/Cq）>40
359	58	M	Negative	Negative(Ct/Cq）>40
360	67	F	Negative	Negative(Ct/Cq）>40
361	20	F	Negative	Negative(Ct/Cq）>40
362	42	M	Negative	Negative(Ct/Cq）>40
363	59	M	Negative	Negative(Ct/Cq）>40
364	12	M	Negative	Negative(Ct/Cq）>40
365	37	F	Negative	Negative(Ct/Cq）>40
366	63	M	Negative	Negative(Ct/Cq）>40
367	39	F	Negative	Negative(Ct/Cq）>40
368	38	M	Negative	Negative(Ct/Cq）>40
369	37	M	Negative	Negative(Ct/Cq）>40
370	37	F	Negative	Negative(Ct/Cq）>40
371	56	F	Negative	Negative(Ct/Cq）>40
372	56	F	Negative	Negative(Ct/Cq）>40
373	59	M	Negative	Negative(Ct/Cq）>40
374	13	M	Negative	Negative(Ct/Cq）>40
375	80	F	Negative	Negative(Ct/Cq）>40
376	59	M	Negative	Negative(Ct/Cq）>40
377	61	F	Negative	Negative(Ct/Cq）>40
378	70	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
379	20	M	Negative	Negative(Ct/Cq）>40
380	75	F	Negative	Negative(Ct/Cq）>40
381	49	M	Negative	Negative(Ct/Cq）>40
382	47	M	Negative	Negative(Ct/Cq）>40
383	65	F	Negative	Negative(Ct/Cq）>40
384	78	M	Negative	Negative(Ct/Cq）>40
385	84	M	Negative	Negative(Ct/Cq）>40
386	72	F	Negative	Negative(Ct/Cq）>40
387	20	F	Negative	Negative(Ct/Cq）>40
388	23	F	Negative	Negative(Ct/Cq）>40
389	18	F	Negative	Negative(Ct/Cq）>40
390	67	M	Negative	Negative(Ct/Cq）>40
391	39	F	Negative	Negative(Ct/Cq）>40
392	80	M	Negative	Negative(Ct/Cq）>40
393	74	F	Negative	Negative(Ct/Cq）>40
394	14	M	Negative	Negative(Ct/Cq）>40
395	62	M	Negative	Negative(Ct/Cq）>40
396	24	F	Negative	Negative(Ct/Cq）>40
397	13	M	Negative	Negative(Ct/Cq）>40
398	39	F	Negative	Negative(Ct/Cq）>40
399	32	M	Negative	Negative(Ct/Cq）>40
400	15	M	Negative	Negative(Ct/Cq）>40

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NO.	Age	Gender	Rapid Test	(RT-PCR)
401	16	M	Negative	Negative(Ct/Cq）>40
402	11	M	Negative	Negative(Ct/Cq）>40
403	29	M	Negative	Negative(Ct/Cq）>40
404	83	F	Negative	Negative(Ct/Cq）>40
405	66	F	Negative	Negative(Ct/Cq）>40
406	20	M	Negative	Negative(Ct/Cq）>40
407	73	F	Negative	Negative(Ct/Cq）>40
408	54	M	Negative	Negative(Ct/Cq）>40
409	61	M	Negative	Negative(Ct/Cq）>40
410	14	M	Negative	Negative(Ct/Cq）>40
411	29	F	Negative	Negative(Ct/Cq）>40
412	63	F	Negative	Negative(Ct/Cq）>40
413	56	M	Negative	Negative(Ct/Cq）>40
414	28	M	Negative	Negative(Ct/Cq）>40
415	50	F	Negative	Negative(Ct/Cq）>40
416	21	F	Negative	Negative(Ct/Cq）>40
417	24	M	Negative	Negative(Ct/Cq）>40
418	51	F	Negative	Negative(Ct/Cq）>40
419	63	M	Negative	Negative(Ct/Cq）>40
420	22	M	Negative	Negative(Ct/Cq）>40
421	55	F	Negative	Negative(Ct/Cq）>40
422	11	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
423	37	F	Negative	Negative(Ct/Cq）>40
424	60	F	Negative	Negative(Ct/Cq）>40
425	78	M	Negative	Negative(Ct/Cq）>40
426	48	M	Negative	Negative(Ct/Cq）>40
427	39	M	Negative	Negative(Ct/Cq）>40
428	31	F	Negative	Negative(Ct/Cq）>40
429	24	M	Negative	Negative(Ct/Cq）>40
430	51	F	Negative	Negative(Ct/Cq）>40
431	43	M	Negative	Negative(Ct/Cq）>40
432	49	F	Negative	Negative(Ct/Cq）>40
433	18	F	Negative	Negative(Ct/Cq）>40
434	32	M	Negative	Negative(Ct/Cq）>40
435	77	M	Negative	Negative(Ct/Cq）>40
436	47	M	Negative	Negative(Ct/Cq）>40
437	82	F	Negative	Negative(Ct/Cq）>40
438	38	F	Negative	Negative(Ct/Cq）>40
439	51	M	Negative	Negative(Ct/Cq）>40
440	40	F	Negative	Negative(Ct/Cq）>40
441	21	F	Negative	Negative(Ct/Cq）>40
442	60	M	Negative	Negative(Ct/Cq）>40
443	80	F	Negative	Negative(Ct/Cq）>40
444	12	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
445	68	F	Negative	Negative(Ct/Cq）>40
446	11	M	Negative	Negative(Ct/Cq）>40
447	55	M	Negative	Negative(Ct/Cq）>40
448	83	M	Negative	Negative(Ct/Cq）>40
449	83	M	Negative	Negative(Ct/Cq）>40
450	84	F	Negative	Negative(Ct/Cq）>40
451	29	F	Negative	Negative(Ct/Cq）>40
452	53	F	Negative	Negative(Ct/Cq）>40
453	42	M	Negative	Negative(Ct/Cq）>40
454	48	M	Negative	Negative(Ct/Cq）>40
455	34	F	Negative	Negative(Ct/Cq）>40
456	40	M	Negative	Negative(Ct/Cq）>40
457	77	F	Negative	Negative(Ct/Cq）>40
458	39	F	Negative	Negative(Ct/Cq）>40
459	81	M	Negative	Negative(Ct/Cq）>40
460	63	M	Negative	Negative(Ct/Cq）>40
461	15	M	Negative	Negative(Ct/Cq）>40
462	81	F	Negative	Negative(Ct/Cq）>40
463	79	M	Negative	Negative(Ct/Cq）>40
464	58	M	Negative	Negative(Ct/Cq）>40
465	23	M	Negative	Negative(Ct/Cq）>40
466	15	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
467	82	M	Negative	Negative(Ct/Cq）>40
468	48	M	Negative	Negative(Ct/Cq）>40
469	73	F	Negative	Negative(Ct/Cq）>40
470	71	M	Negative	Negative(Ct/Cq）>40
471	69	F	Negative	Negative(Ct/Cq）>40
472	22	M	Negative	Negative(Ct/Cq）>40
473	52	M	Negative	Negative(Ct/Cq）>40
474	26	M	Negative	Negative(Ct/Cq）>40
475	82	M	Negative	Negative(Ct/Cq）>40
476	36	M	Negative	Negative(Ct/Cq）>40
477	46	M	Negative	Negative(Ct/Cq）>40
478	47	F	Negative	Negative(Ct/Cq）>40
479	24	F	Negative	Negative(Ct/Cq）>40
480	33	M	Negative	Negative(Ct/Cq）>40
481	17	M	Negative	Negative(Ct/Cq）>40
482	34	F	Negative	Negative(Ct/Cq）>40
483	76	F	Negative	Negative(Ct/Cq）>40
484	53	M	Negative	Negative(Ct/Cq）>40
485	53	M	Negative	Negative(Ct/Cq）>40
486	76	F	Negative	Negative(Ct/Cq）>40
487	66	F	Negative	Negative(Ct/Cq）>40
488	57	F	Negative	Negative(Ct/Cq）>40

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NO.	Age	Gender	Rapid Test	(RT-PCR)
489	21	F	Negative	Negative(Ct/Cq）>40
490	35	M	Negative	Negative(Ct/Cq）>40
491	21	F	Negative	Negative(Ct/Cq）>40
492	21	M	Negative	Negative(Ct/Cq）>40
493	28	F	Negative	Negative(Ct/Cq）>40
494	58	M	Negative	Negative(Ct/Cq）>40
495	37	M	Negative	Negative(Ct/Cq）>40
496	22	M	Negative	Negative(Ct/Cq）>40
497	65	M	Negative	Negative(Ct/Cq）>40
498	29	M	Negative	Negative(Ct/Cq）>40
499	48	M	Negative	Negative(Ct/Cq）>40
500	11	M	Negative	Negative(Ct/Cq）>40
501	29	F	Negative	Negative(Ct/Cq）>40
502	11	F	Negative	Negative(Ct/Cq）>40
503	79	M	Negative	Negative(Ct/Cq）>40
504	46	F	Negative	Negative(Ct/Cq）>40
505	14	M	Negative	Negative(Ct/Cq）>40
506	17	M	Negative	Negative(Ct/Cq）>40
507	72	F	Negative	Negative(Ct/Cq）>40
508	83	F	Negative	Negative(Ct/Cq）>40
509	30	F	Negative	Negative(Ct/Cq）>40
510	71	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
511	79	M	Negative	Negative(Ct/Cq）>40
512	84	F	Negative	Negative(Ct/Cq）>40
513	62	M	Negative	Negative(Ct/Cq）>40
514	50	F	Negative	Negative(Ct/Cq）>40
515	21	F	Negative	Negative(Ct/Cq）>40
516	81	F	Negative	Negative(Ct/Cq）>40
517	76	F	Negative	Negative(Ct/Cq）>40
518	41	F	Negative	Negative(Ct/Cq）>40
519	73	M	Negative	Negative(Ct/Cq）>40
520	83	F	Negative	Negative(Ct/Cq）>40
521	71	M	Negative	Negative(Ct/Cq）>40
522	10	M	Negative	Negative(Ct/Cq）>40
523	63	M	Negative	Negative(Ct/Cq）>40
524	72	M	Negative	Negative(Ct/Cq）>40
525	59	M	Negative	Negative(Ct/Cq）>40
526	35	M	Negative	Negative(Ct/Cq）>40
527	58	M	Negative	Negative(Ct/Cq）>40
528	46	F	Negative	Negative(Ct/Cq）>40
529	79	M	Negative	Negative(Ct/Cq）>40
530	76	M	Negative	Negative(Ct/Cq）>40
531	77	F	Negative	Negative(Ct/Cq）>40
532	45	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
533	73	M	Negative	Negative(Ct/Cq）>40
534	38	F	Negative	Negative(Ct/Cq）>40
535	41	F	Negative	Negative(Ct/Cq）>40
536	32	F	Negative	Negative(Ct/Cq）>40
537	50	M	Negative	Negative(Ct/Cq）>40
538	31	M	Negative	Negative(Ct/Cq）>40
539	74	F	Negative	Negative(Ct/Cq）>40
540	16	F	Negative	Negative(Ct/Cq）>40
541	69	M	Negative	Negative(Ct/Cq）>40
542	72	M	Negative	Negative(Ct/Cq）>40
543	40	F	Negative	Negative(Ct/Cq）>40
544	78	F	Negative	Negative(Ct/Cq）>40
545	53	M	Negative	Negative(Ct/Cq）>40
546	44	F	Negative	Negative(Ct/Cq）>40
547	28	M	Negative	Negative(Ct/Cq）>40
548	14	M	Negative	Negative(Ct/Cq）>40
549	80	F	Negative	Negative(Ct/Cq）>40
550	40	F	Negative	Negative(Ct/Cq）>40
551	26	M	Negative	Negative(Ct/Cq）>40
552	11	F	Negative	Negative(Ct/Cq）>40
553	53	F	Negative	Negative(Ct/Cq）>40
554	19	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
555	21	M	Negative	Negative(Ct/Cq）>40
556	60	M	Negative	Negative(Ct/Cq）>40
557	12	F	Negative	Negative(Ct/Cq）>40
558	58	M	Negative	Negative(Ct/Cq）>40
559	62	M	Negative	Negative(Ct/Cq）>40
560	45	M	Negative	Negative(Ct/Cq）>40
561	34	F	Negative	Negative(Ct/Cq）>40
562	35	F	Negative	Negative(Ct/Cq）>40
563	82	M	Negative	Negative(Ct/Cq）>40
564	59	F	Negative	Negative(Ct/Cq）>40
565	59	F	Negative	Negative(Ct/Cq）>40
566	38	F	Negative	Negative(Ct/Cq）>40
567	82	M	Negative	Negative(Ct/Cq）>40
568	22	F	Negative	Negative(Ct/Cq）>40
569	50	M	Negative	Negative(Ct/Cq）>40
570	25	M	Negative	Negative(Ct/Cq）>40
571	52	M	Negative	Negative(Ct/Cq）>40
572	13	M	Negative	Negative(Ct/Cq）>40
573	33	M	Negative	Negative(Ct/Cq）>40
574	60	F	Negative	Negative(Ct/Cq）>40
575	43	F	Negative	Negative(Ct/Cq）>40
576	46	M	Negative	Negative(Ct/Cq）>40

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NO.	Age	Gender	Rapid Test	(RT-PCR)
577	76	F	Negative	Negative(Ct/Cq）>40
578	34	M	Negative	Negative(Ct/Cq）>40
579	52	F	Negative	Negative(Ct/Cq）>40
580	50	F	Negative	Negative(Ct/Cq）>40
581	64	F	Negative	Negative(Ct/Cq）>40
582	52	M	Negative	Negative(Ct/Cq）>40
583	57	M	Negative	Negative(Ct/Cq）>40
584	50	F	Negative	Negative(Ct/Cq）>40
585	52	M	Negative	Negative(Ct/Cq）>40
586	60	F	Negative	Negative(Ct/Cq）>40
587	16	F	Negative	Negative(Ct/Cq）>40
588	18	F	Negative	Negative(Ct/Cq）>40
589	58	M	Negative	Negative(Ct/Cq）>40
590	26	F	Negative	Negative(Ct/Cq）>40
591	62	F	Negative	Negative(Ct/Cq）>40
592	28	M	Negative	Negative(Ct/Cq）>40
593	50	M	Negative	Negative(Ct/Cq）>40
594	26	M	Negative	Negative(Ct/Cq）>40
595	82	F	Negative	Negative(Ct/Cq）>40
596	24	F	Negative	Negative(Ct/Cq）>40
597	77	M	Negative	Negative(Ct/Cq）>40
598	13	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
599	62	M	Negative	Negative(Ct/Cq）>40
600	47	M	Negative	Negative(Ct/Cq）>40
601	62	M	Negative	Negative(Ct/Cq）>40
602	33	F	Negative	Negative(Ct/Cq）>40
603	37	F	Negative	Negative(Ct/Cq）>40
604	60	F	Negative	Negative(Ct/Cq）>40
605	70	M	Negative	Negative(Ct/Cq）>40
606	30	F	Negative	Negative(Ct/Cq）>40
607	23	M	Negative	Negative(Ct/Cq）>40
608	23	M	Negative	Negative(Ct/Cq）>40
609	70	M	Negative	Negative(Ct/Cq）>40
610	41	F	Negative	Negative(Ct/Cq）>40
611	50	M	Negative	Negative(Ct/Cq）>40
612	26	F	Negative	Negative(Ct/Cq）>40
613	22	F	Negative	Negative(Ct/Cq）>40
614	44	M	Negative	Negative(Ct/Cq）>40
615	79	F	Negative	Negative(Ct/Cq）>40
616	64	F	Negative	Negative(Ct/Cq）>40
617	83	F	Negative	Negative(Ct/Cq）>40
618	76	M	Negative	Negative(Ct/Cq）>40
619	25	M	Negative	Negative(Ct/Cq）>40
620	41	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
621	30	F	Negative	Negative(Ct/Cq）>40
622	30	M	Negative	Negative(Ct/Cq）>40
623	37	F	Negative	Negative(Ct/Cq）>40
624	46	F	Negative	Negative(Ct/Cq）>40
625	48	F	Negative	Negative(Ct/Cq）>40
626	20	F	Negative	Negative(Ct/Cq）>40
627	77	F	Negative	Negative(Ct/Cq）>40
628	55	F	Negative	Negative(Ct/Cq）>40
629	55	F	Negative	Negative(Ct/Cq）>40
630	80	F	Negative	Negative(Ct/Cq）>40
631	45	F	Negative	Negative(Ct/Cq）>40
632	17	F	Negative	Negative(Ct/Cq）>40
633	47	F	Negative	Negative(Ct/Cq）>40
634	48	F	Negative	Negative(Ct/Cq）>40
635	30	F	Negative	Negative(Ct/Cq）>40
636	55	F	Negative	Negative(Ct/Cq）>40
637	16	F	Negative	Negative(Ct/Cq）>40
638	43	F	Negative	Negative(Ct/Cq）>40
639	35	F	Negative	Negative(Ct/Cq）>40
640	67	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
641	82	F	Negative	Negative(Ct/Cq）>40
642	55	F	Negative	Negative(Ct/Cq）>40
643	75	F	Negative	Negative(Ct/Cq）>40
644	56	F	Negative	Negative(Ct/Cq）>40
645	16	F	Negative	Negative(Ct/Cq）>40
646	21	F	Negative	Negative(Ct/Cq）>40
647	18	F	Negative	Negative(Ct/Cq）>40
648	20	F	Negative	Negative(Ct/Cq）>40
649	63	F	Negative	Negative(Ct/Cq）>40
650	49	F	Negative	Negative(Ct/Cq）>40
651	63	F	Negative	Negative(Ct/Cq）>40
652	18	F	Negative	Negative(Ct/Cq）>40
653	27	F	Negative	Negative(Ct/Cq）>40
654	29	F	Negative	Negative(Ct/Cq）>40
655	47	F	Negative	Negative(Ct/Cq）>40
656	26	F	Negative	Negative(Ct/Cq）>40
657	65	F	Negative	Negative(Ct/Cq）>40
658	28	F	Negative	Negative(Ct/Cq）>40
659	67	F	Negative	Negative(Ct/Cq）>40

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Product Service

Certificate

No. Q5 094846 0002 Rev. 01

Holder of Certificate: **Hangzhou Realy Tech Co., Ltd.**
4th Floor, #12 Building
Eastern Medicine Town
Xiasha Economic&Technology Development
310018 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Realy Tech Co., Ltd.
4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic&Technology Development, 310018 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of POCT Analyzers and Related Diagnostic Kits**

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

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

Report No.: SH19105604

Valid from: 2020-03-05
Valid until: 2023-01-23

Date, 2020-03-05

Christoph Dicks
Head of Certification/Notified Body

A4 / 07.17

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