

From: s 11C(1)(a)
To: Devices
Cc: Devices
Subject: COVID-19 application - Class 3 IVD RT-PCR test kit [SEC=No Protective Marking]
Date: Monday, 30 March 2020 6:55:44 PM
Attachments: [Annex14 Package Label Template.pdf](#)
[Annex15 Design Drafts of Labels on The Tube Body.pdf](#)
[Annex16 Instruction For Use.pdf](#)
Importance: High

Dear Devices Team,

Medical Device - IVD Application DV-2020-IVA-06521-1 has been submitted for processing. It is for a RT-PCR test kit for Covid-19. Please also find attached the labels and IFU for this product. If more information is needed please let me know.

Kind regards

s 11C(1)(a)

 **AEA** Archer Emery & Associates
Archer Emery & Associates Pty Ltd
Regulatory affairs consultants
Medicines, medical devices, cosmetics, GMP and manufacturing
Australia and New Zealand

T: s 47F
M: s 47F
E: s 47F
W: www.archeremery.com.au

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REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING SARS-COV-2

Annex 16 Instruction For Use

Document No. BGI-STP-WHO-01-14

Version V1.0

Written by:

s 47F

Date: 2020. 03. 18

Verified by:

S 47F

Date: 2020. 03. 20

Approved by:

S 47F

Date: 2020. 03. 23



Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2

1 Generic product name

Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2

2 Package size

50 tests/kit

3 Catalogue Number

MFG030011

4 Intended use

The kit is a qualitative in vitro nucleic acid amplification assay to detect the new coronavirus identified in China in 2019 (SARS-CoV-2) using Reverse transcription PCR in specimen of throat swab and Bronchoalveolar Lavage Fluid (BALF) from suspects.

In end of 2019, some pneumonia cases were reported in Wuhan, China and the pathogen was confirmed as a new strain. World Health organization has named the newly identified coronavirus as COVID19. Although more intensive researches must be conducted later to well understand the virus, in response to the emergency in disease control, simple and rapid kit is necessary to identify the virus timely and implement efficient interventions to contain the spread. The kit will qualitatively detect the nucleic acid of SARS-CoV-2 in specimen from suspects enabling to assess the infection situation of SARS-CoV-2 in suspects in clinical and public health practice.

The kit is manually operated, the intended user is operator of the kits should be trained professionally on operating pathogenic microorganism, molecular laboratory techniques and relevant knowledge and regulations of biosafety and molecular laboratory management

This product is not for self-testing.

5 Principle of the procedures

The kit is based on in vitro RT-PCR combining fluorescent probing. Primers and a sequence-specific fluorescence probes were designed tailored to high conservative region in SARS-CoV-2 genome. The probes are oligonucleotide attached fluorophores at the 5' end with FAM as reporter and 3' end with quencher. In a meantime, specific primers and probes were developed as internal reference with fluorophores VIC/HEX attached at 5' end as reporter. During the PCR procedures, the DNA polymerase cleaves the probe at the 5' end and separates the reporter dye from the quencher dye when the probes hybridize to the target DNA. This cleavage results in the fluorescent signal generated by

the cleaved reporter dye, which is monitored real-time by the PCR detection system. Monitoring the fluorescence intensities during Real Time allows the qualitative detection of SARS-CoV-2 in specimens.

6 Key contents

Item (50 tests/kit)	Specification	Quantity	Description
2019-nCoV Reaction Mix	1mL /vial	1 vial	Composed of reagent for amplification and probes and primers of target gene and internal reference
2019-nCoV Enzyme Mix	80µL /vial	1 vial	Taq polymerase, Reverse transcriptase and UDG
2019-nCoV Positive control	750µL/vial	1 vial	Mix solution of pseudo-virus with target virus genes and internal reference
2019-nCoV Blank control	750µL/vial	1 vial	DNase/RNase free water

7 Materials required but not provided

- Reagents: TIANamp Virus RNA extraction Kit (DP315-R) manufactured by TIANGEN, or QIAamp Viral RNA Mini Kit (52904) by QIAGEN.
- 1.5 mL RNase/DNase-free microcentrifuge tube, RNase/DNase-free tips for pipettes, 0.2mL 8-tube strips for real-time PCR, Bench centrifuge, Vortex mixer.
- Notes: Components contained within a kit are intended to be used together. Do not mix components from different kit lots.

8 Storage and shelf-life

- The RT-PCR Kit should be stored at temperature lower than -18°C in dark. It is stable with shelf-life at 2-8 °C for 5 days and at -18°C for 6 months (tentative) . Unpacked kit should avoid repeated thaw-freeze cycle (within 4 times)
- The PCR Kit can be transported at -18°C in dark stable for 5 days. The manufacture date and shelf life would be provided in the labelling.

9 Applicable instruments

Applied Biosystems™ Real time PCR system 7500; SLAN-96P PCR system

10 Specimen

10.1 Sample collection

- Collect fresh specimen of throat swabs and BALF from suspects. The operation of specimen should avoid possible contamination in collection, storage and transportation. The specimen should be presumed contagious and be operated according to related regulations.
- **Throat swabs:** Carefully take out the swab from package and quickly rotate it around two sides of fauces, throat and tonsil a few times applying pressure to collect as much secretions as possible. Avoid touching tongue. Break the swab stick and put the head into sampling solution in specimen tubes. Screw the tube cap tightly to ensure no leakage.
- **BALF:** Collect 3ml of unprocessed BALF in sterile, dry and clean DNase/RNase free Storage
- The specimen should be kept in proper condition, at -18°C for not longer than 1 weeks and at -70°C for not longer than 6 months.
- Frozen specimen should be thawed thoroughly while avoiding repeated thaw-freeze cycle.

10.2 Transportation

- The specimen should be shipped in low temperature condition using dry ice or ice bag.

11 Laboratory procedures

Please read the procedures carefully before your operation

11.1 Sample processing

- The fresh specimen should be collected to ensure the qualified RNA in terms of quality and quantity for the assay. RNA should be extracted using Nucleic Acid extracting Kit in line with the manufacturer's instruction. Equivalent volume of positive control and blank control should be processed simultaneously. The assay was validated by the recommended RNA extraction kits by TIANGEN (DP315-R) and QIAGEN (52904) .
- The extracted RNA should be tested immediately or stored at -70°C for test later.

11.2 Reagent preparation

- Take out all the kit contents and thaw them thoroughly at ambient temperature. Vortex and centrifuge briefly. The Enzyme Mix should be kept in ice continuously.
- Estimate the number of reactions (N) in the test, which includes the number of Blank control (1 tube), Positive control (1 tube), and specimens prepared. Prepare 8-tube strips for PCR based on the estimated N of reaction and develop the PCR mix as ingredients in following table. Pipette 20µL PCR Mix per tube into the 8-tube strips. Capped them fastened and transfer

them to sample processing Area. The remaining Nucleic acid reaction Mix and Enzyme Mix should be stored at -18°C immediately.

	2019-nCoV Reaction Mix(µL)	2019-nCoV Enzyme Mix(µL)
PCR-Mix (µL)	18.5×N	1.5×N

11.3 Add sample

- Add 10µL the extracted RNA of specimens, Blank control and Positive controls respectively into the 8-tube strips prefilled with PCR Mix. Capped them fastened and centrifuge them at 2000rpm for 10 seconds. Place the tubes into thermal cycler and record the exact location of controls and every specimen.

11.4 Real time PCR

- Set the fluorescent channels: Please refer to the manufacturer's instructions of thermocycler for detailed information on channel setting.

FAM channel (Reporter: FAM, Quencher: None) for RNA of SARS-CoV-2 ;

VIC/HEX channel (Reporter: VIC/HEX, Quencher: None) for internal reference;

Reference Dye: None (only for ABI PCR system) ;

Sample Volume: 30.

- Configure PCR protocol

Step	Cycle	Temperature	Duration	Fluorescence measured(Y/N?)
1	1 cycle	50°C	20minutes	N
2	1 cycle	95°C	10minutes	N
3	40cycles	95°C	15 seconds	N
		60°C	30 seconds	Y

11.5 Data analysis

- Baseline and threshold for ABI7500 PCR system

Baseline starting point at 3 and ending at 15

The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, the blank control should be selected firstly and click off the Automatic standard curve by changing the option from “Auto” to “Auto”. Set the threshold manually just above

the maximum level of blank control curve (random noise curve) at FAM channel.

- Data from SLAN-96P PCR system

The starting and ending points of baseline should be set as 6 and 12 respectively.

The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, change the configuration of baseline optimization in basic parameter from automatic to manual. Then, manually set the threshold just above the maximum level of blank control curve (random noise curve) at FAM/ VIC(HEX).

11.6 Quality control

- Blank control: Ct values at FAM and VIC/HEX channels are 0 or no data available.
- Positive control: Standard curves at channel FAM and VIC/HEX channels are in S-shape with Ct values not higher than 32.
- Testing specimen: Standard curves at VIC/HEX channel is in S-shape with Ct not higher than 32.
 - Above requirements should be met in a single test. Otherwise, the test is invalid. Please operate the retest strictly in line with the package insert.

12 Threshold and reference range

- Cut-off value of the kit was determined based on the Receiver Operator characteristic curve from testing clinical samples. Ct value for SARS-CoV-2 positive by the kit is not high than 38.

13 Testing result interpretation

- The specimen is positive of SARS-CoV-2 if standard curve at FAM channel is in S-shape with Ct value not higher than 38.
- The specimen is negative of SARS-CoV-2 if standard curve at FAM channel is not in S-shape with Ct at FAM as 0 or no data available while Ct at VIC/HEX not higher than 32.
- The specimen should be retested if standard curve at FAM is in S-shape with Ct higher than 38. The specimen can be reported on basis of retesting results as positive of SARS-CoV-2 for Ct higher than 38 and as negative of SARS-CoV-2 for standard curve not in S-shape and Ct of internal reference not higher than 32 at VIC/HEX.
- In case that standard curve at FAM is not in S-shape with Ct value as 0 or no data available, the specimen should be retested if Ct at VIC is higher than 32 or no data available.

14 Limitation of the assay

- The Results of the test is just for information in clinical practices to assess infection condition of patients combining with clinical presentations and other laboratory markers.
- The incorrect result can be caused by incorrect operations in sample collection, transportation or processing, very low concentration of target virus in the specimens, mutations within the viral genome covered by the kit's primers and/or probe, and unproved external interference factors, such as PCR inhibitor.

15 Performance characteristics

- The package is intact and liquid contents are clear, transparent and no sediments. All contents are in correct quantity as the package insert listed.
- Positive control is positive at both FAM and VIC/HEX channel in testing while blank control is negative at both channels.
- Limitation of Detection (LOD) of the kit is 100 copies/mL for detecting SARS-CoV-2.
- The kit was validated by national positive and negative standards.
- A potential cross-reactivity of the RT-PCR Kit was tested and none of the tested pathogens and human gene have been reactive. The tested pathogens include 54 pathogens, such as human coronavirus includes OC43,229E, HKU1 and NL63(HCoV-OC43, HCoV-229E, HCoV-HKU1, HCoV-NL63) and other pathogens.
- The reproducibility of the assay was validated by manufacturer's precision standards (CV1 and CV 2), LOD standard and negative standard. All samples were tested repeatedly for 20 times, respectively. Coefficient of variance (CV) for Ct values were analyzed to evaluate the variability of inter- and intra-batches, within day and day-to-day operation. The CVs are all less than 5% respective (n=20).
- The repeatability of assay was validated by manufacturer's repeatability standards, LOD standard and negative standard repeatedly for 20 times. Coefficient of variance (CV) for Ct values were analyzed to evaluate the inter-batch variability. They are all less than 5%.
- Interference trial shows that performance of the kit is stable with endogenous and exogenous interfering substances such as some anti-microorganism drugs, nasal sprays and nasal drops in specimen. Specimen with elevated level of mucoprotein at a concentration of 60 mg / mL and other substances do not influence the kit performance at virus concentration higher than Limit of Detection.

16 Warning and precautions

- FOR IN VITRO TEST ONLY. Please read the package insert carefully before your operation. The appropriate operations from specimen collection, storage and transportation, and laboratory test should be strictly manipulated in line with relevant regulations of biosafety and molecular laboratory management. Please contact BGI sales for the most up-to-date information in the event of damage to the protective packaging
- The false positive or negative testing result can be led by poor quality of specimen, incorrect operations in sample collection, transportation or laboratory processing, or limitation of the technology. Operator should understand well the principles of the procedures and its limitation in performance in advance and avoid any potential mistakes intentionally.
- Separate laboratory areas are recommended to performing predefined procedures of the assay.
 - a) 1st Area: Preparation Area—Prepare testing reagent;
 - b) 2nd Area: Sample processing—Process the specimen and controls;
 - c) 3rd: Amplification Area—PCR conducted.
- All materials used in one area should always be remained in the area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected timely.
- All contents in the package are prepared dedicatedly for the intended testing purpose and validated. Replacing any of them will affect the testing performance of the kit. Components contained within a kit are intended to be used together. Do not mix components from different kit lots.
- Thaw all kit components thoroughly and centrifuge them briefly before starting an assay. Avoid repeated thaw-freeze cycle.
- 8-tube strips for real time PCR capped fasten and transferred to specimen processing area immediately after addition of Nucleic Acid reaction Mix.
- To prevent the contamination from exogenous RNA, sample addition should follow the sequence of negative control, specimen RNA and positive control. Filtered tips should be prepared and used separately in preparing reagent and sample addition.
- Ensure to pipette the samples exactly into the reaction mix in PCR tubes and avoid sticking the samples to the inside tube wall. The tubes should be capped fasten immediately after the addition.
- After the protocol of amplification is done, remove PCR tubes from the thermal cycler and

discard them in a sealable plastic bag for autoclave and decontamination.

- Ensure no foam or bubbles present in the tubes when aliquoting nucleic acid Mix. All PCR tubes capped fasten before loading them into the thermal cycler to avoid any possible leakage and contamination.
- The workbench and lab supplies should be cleaned and disinfected regularly using 75% ethanol or UV light.
- All pipette tips and centrifuge tubes in the assay should be DNase/RNase-free. The used centrifuge tubes and pipette tips should be discarded in waste bin with Clorox (84) disinfectant and disposed with other laboratory wastes after decontamination.
- Operator should receive professional training before operating.

17 References

17.1 LU Rou-jian, ZHANG Ling-lin, TAN Wen-jie, ZHOU Wei-min, WANG Zhong, PENG Kun, RUAN Li. Development and Comparison of Real-Time and Conventional RT-PCR Assay for Detection of Human Coronavirus NL63 and HKU1[J]. CHINESE JOURNAL OF VIROLOGY, 2008(4).

17.2 NIU P, LU R, LAN J, LIU G, WANG W, TAN W. Development of Novel Multiplex Real-time RT-PCR Assays for Detection of MERS-CoV Infection[J]. CHINESE JOURNAL OF VIROLOGY, 2016(3).

17.3 CHEN Yu-jing. Development of two-panel reactions of real-time PCR for detection of 18 types/subtypes of respiratory viruses[D]. 2015

18 Contact details

Manufacturer: BGI Europe A/S

Manufacturer Address: Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark

Manufacturing Site: BGI Biotechnology (Wuhan) Co.,Ltd

Site Address: Building B2, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan

Please contact: BGI Europe A/S

Service hotline: Copenhagen, Denmark: 0045-80300800/ 0045-70260806

Website: <http://www.genomics.cn>,

19 Language edition

For the requirements of Instruction for Use in other languages, please contact BGI Europe A/S.

20 Release date of the Instruction for Use

This manual was released on 2020-03-20, version 1.

21 Key to symbols used

IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	MANUFACTURER
	USE BY DATE
LOT	BATCH CODE
	DATE OF MANUFACTURE
REF	CATALOGUE NUMBER
	CAUTION
	UPPER LIMIT OF TEMPERATURE
	CONSULT INSTRUCTIONS FOR USE
	KEEP AWAY FROM SUNLIGHT
	KEEP DRY
	DO NOT RE-USE
CONTROL +	POSITIVE CONTROL
	CONTAINS SUFFICIENT FOR N TESTS

From: [Recalls](#)
To: **s 47F**
Cc: [Recalls](#)
Subject: Enquiry regarding TaqPath COVID-19 CE-IVD RT-PCR kit - Thermo Fisher Scientific [SEC=OFFICIAL]
Date: Wednesday, 26 August 2020 12:00:47 PM
Attachments: [WHO Info Notice_TFS TaqpathCOVID.pdf](#)

Good morning **s 47F**,

I am writing to you regarding the Field Safety Corrective Action for TaqPath COVID-19 CE-IVD RT-PCR kit. I note an overseas action has been undertaken on this product (see attached notice from the WHO).

Can you please confirm by COB today whether this action impacts Australia and if so, is a similar communication regarding the mandatory upgrade and IFU reinforcing planned (or has it already been undertaken).

Best regards,

s 47F

s 47F

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: **s 47F** | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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WHO INFORMATION NOTICE FOR USERS

Product name: TaqPath™ COVID-19 CE-IVD RT-PCR kit

manufactured by **Thermo Fisher Scientific** (product code **A48067**) used with:

- Applied Biosystems COVID-19 Interpretive Software **v1.2** (used with the 7500 series Real-Time PCR instruments)
- Applied Biosystems COVID-19 Interpretive Software **v2.0 or v2.2** (used with the QuantStudio Real-Time PCR platforms)

Date: 25 August 2020

WHO-identifier: 2020/4, version 1

Type of action: Advice to users

Purpose of this notice: To ensure users of TaqPath™ COVID-19 CE-IVD RT-PCR kit are aware of a mandatory software update and reinforce certain parts in the instructions for use that must be followed to avoid misclassification of test results.

Description of the problem: Thermo Fisher Scientific identified the need to conduct a field safety corrective action to reduce the risk related to use of their product, the issues were identified through customer feedback and internal review.

Issue 1:

Poorly extracted patient specimens were called valid using MS2 Assay. A cycle threshold (Ct) cutoff of 37 was not adequate to detect specimens with poor extraction efficiency or a large amount of impurities post-extraction. This issue *may* potentially cause a weakly positive specimen that sub-optimally extracted to be falsely called a valid negative specimen, thereby constituting a false negative. However, no customer has reported false negative results due to this issue to date.

Issue 2:

The MS2 assay, which detects the Internal Positive Control (IPC), was erroneously called amplified in a small percentage of Positive Control (PC) samples. This issue caused a plate to be designated incorrectly as invalid, thereby requiring unnecessary retesting of an entire batch of specimens.

As a result of the above two issues, Thermo Fisher Scientific recommends a mandatory upgrade for the Applied Biosystems COVID-19 Interpretive Software used with the TaqPath COVID-19 CE-IVD COVID-19 RT-PCR Kit:

- If you are using **Applied Biosystems COVID-19 Interpretive Software v1.2 (used with the 7500 series Real-Time PCR instruments)** you need to upgrade to **software v1.3**.
- If you are using **Applied Biosystems COVID-19 Interpretive Software v2.0 or v2.2 (used with the QuantStudio Real-Time PCR platforms)**, you need to upgrade to **software v2.3**.

Issue 3:

Thermo Fisher Scientific has updated the Instructions for Use (IFU) to highlight the importance of vortexing the RT-PCR reaction plates to mitigate potential for false positive results. The vortexing instructions are detailed in the “Prepare RT-PCR reactions” step of the Instructions for Use, recorded under the publication number MAN0019215 Revision E and all translations of this publication.

Thermo Fisher Scientific strongly recommends that all users participate in training on how to properly run the workflow as offered by the local representative.

Advice on action to be taken by users:

1. Please check if your local representative for Thermo Fisher Scientific has communicated a field safety notice to your facility on this topic.
 - a. If they have, please follow the instructions contained in the field safety notice specific for your regulatory jurisdiction. Thermo Fisher Scientific will provide a subscription code to access and complete e-learning. You will be required to pass an exam and acknowledge that you reviewed information to upgrade the Applied Biosystems COVID-19 Interpretive Software.
 - b. If they have not, please contact your local representative for Thermo Fisher immediately, or the economic operator who provided you with the product.
2. **Stop using Applied Biosystems COVID-19 CE-IVD Interpretive Software v1.2, v2.0 and v2.2.**
3. **Do not test specimens until the mandatory e-learning and software upgrade has been conducted.**
4. Consider any positive result (SARS-CoV-2 detected) or negative results (SARS-CoV-2 not detected) in combination with clinical observations, patient history, and epidemiological information.
5. Ensure that you sign and return acknowledgement of receipt of the field safety notice issued by Thermo Fisher Scientific, as per their request.

Transmission of this WHO Information Notice for Users:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected product has been deployed and used.

Contact person for further information:

Anita SANDS, Regulation and Prequalification, World Health Organization, e-mail: sandsa@who.int

From: **s 47F**
To: **Recalls**
Cc: **s 47F**
Subject: RE: Enquiry regarding TaqPath COVID-19 CE-IVD RT-PCR kit - Thermo Fisher Scientific - **s 47F**
[SEC=No Protective Marking]
Date: Wednesday, 26 August 2020 12:07:13 PM
Attachments: [WHO Info Notice_TFS TaqpathCOVID.PDF](#)
Importance: High

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Hello **s 47F**

Thank you for your email.

This is not a product for which I have any overlap or visibility on.

I have cc'ed the relevant colleagues here who will be better placed to answer your questions, or refer to the appropriate personnel..

s 47F , **see below. NB: timeline for reply.**

If I may be of further assistance, please contact me by return email or as detailed below.

Yours Sincerely,

s 47F

Thermo Fisher Scientific
20 Dalgleish Street
Thebarton, South Australia, 5031
Phone: **s 47F**

s 47F
<https://www.thermofisher.com/au/en/home/industrial/microbiology.html>

From: Recalls [mailto:Recalls@health.gov.au]
Sent: Wednesday, 26 August 2020 11:31 AM
To: **s 47F** @thermofisher.com>
Cc: Recalls <Recalls@health.gov.au>
Subject: Enquiry regarding TaqPath COVID-19 CE-IVD RT-PCR kit - Thermo Fisher Scientific
[SEC=OFFICIAL]

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[REDACTED]
Recalls Coordinator

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Phone: **s 47F** | Email: recalls@health.gov.au

Therapeutic Goods Administration
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PO Box 100
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Anita SANDS, Regulation and Prequalification, World Health Organization, e-mail: sandsa@who.int

From: **s 47F** @misterwolfconsulting.com.au>
Sent: Monday, 28 September 2020 1:39 PM
To: **s 47F**
Cc: Devices: **s 11C(1)(a)**
Subject: DV-2020-IVA-25229-1 - DA-2020-07250-1 - Aug2020_IVD_Ustar_Analyzer_Class I
Attachments: 20200928_Emergence_IVD_Analyser_Audit Complete Response.zip

Document 4

REMINDER : Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear **s 47F**

Please find attached a zipped file containing documentation in response to the audit request for the following application:

DV-2020-IVA-25229-1 - DA-2020-07250-1 - Aug2020_IVD_Ustar_Analyzer_Class I

Please do not hesitate to contact me if you have any questions

Kind Regards

s 47F

s 47F

Mister Wolf Consulting Pty Ltd

s 47F

<https://www.misterwolfconsulting.com.au/>

Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA (Isothermal amplification-real time fluorescence assay) Data summary table

NO	Sample ID	Sex	Age	Sample Type	Clinical symptoms at the time of enrollment	The results of tested kits					Test Date	The results of comparison kit				COVID-19 Confirmed Case/COVID-19 ruled-out Case	Remarks
						ORF1ab Tt	N Tt	ICl	ICr	Results		ORF1ab Ct	N Ct	ROX	Results		
1	BJXH001	Female	69	Oropharyngeal swab	Infective endocarditis	N/A	N/A	26.33	29.83	Negative	2020.02.27	NA	NA	32.1003	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
2	BJXH002	Female	11	Oropharyngeal swab	Cough	N/A	N/A	26.33	21.50	Negative	2020.02.27	NA	NA	30.3221	Negative	Ruled-out Case	
3	BJXH003	Female	40	Oropharyngeal swab	Cough	N/A	N/A	25.66	18.00	Negative	2020.02.27	NA	NA	33.0094	Negative	Ruled-out Case	
4	BJXH004	Male	41	Oropharyngeal swab	Sore throat	N/A	N/A	21.16	22.66	Negative	2020.02.27	NA	NA	32.6557	Negative	Ruled-out Case	
5	BJXH005	Female	27	Oropharyngeal swab	Cough	N/A	N/A	24.5	22.0	Negative	2020.02.27	NA	NA	29.9329	Negative	Ruled-out Case	
6	BJXH006	Male	60	Oropharyngeal swab	Fever	N/A	N/A	13.66	19.83	Negative	2020.02.27	NA	NA	29.082	Negative	Ruled-out Case	
7	BJXH007	Female	36	Oropharyngeal swab	Screening	N/A	N/A	22.50	18.33	Negative	2020.02.27	NA	NA	31.9026	Negative	Ruled-out Case	Other need to identify new coronavirus
8	BJXH008	Female	62	Oropharyngeal swab	Cerebral infarction; diabetes; hyperlipidemia; atherosclerosis	N/A	N/A	19.50	14.33	Negative	2020.02.27	NA	NA	28.8991	Negative	Ruled-out Case	Other need to identify new coronavirus
9	BJXH009	Female	35	Oropharyngeal swab	Lung infection	N/A	N/A	21.66	27.50	Negative	2020.02.27	NA	NA	27.1196	Negative	Ruled-out Case	
10	BJXH010	Male	40	Oropharyngeal swab	Respiratory infection	N/A	N/A	N/A	26.33	Negative	2020.02.27	NA	NA	28.8542	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
11	BJXH011	Female	30	Oropharyngeal swab	Fever	N/A	N/A	26.66	22.16	Negative	2020.02.27	NA	NA	28.614	Negative	Ruled-out Case	
12	BJXH012	Male	88	Oropharyngeal swab	Fever	N/A	N/A	18.33	20.66	Negative	2020.02.27	NA	NA	31.082	Negative	Ruled-out Case	
13	BJXH013	Male	27	Oropharyngeal swab	Fever	N/A	N/A	23.5	21.66	Negative	2020.02.27	NA	NA	26.1568	Negative	Ruled-out Case	
14	BJXH014	Male	67	Oropharyngeal swab	Fever	N/A	N/A	28.16	16.33	Negative	2020.02.27	NA	NA	27.2281	Negative	Ruled-out Case	
15	BJXH015	Male	34	Oropharyngeal swab	Fever;Diarrhea	N/A	N/A	21.16	25.33	Negative	2020.02.27	NA	NA	28.8122	Negative	Ruled-out Case	
16	BJXH016	Female	26	Oropharyngeal swab	Fever	N/A	N/A	16.16	21.00	Negative	2020.02.27	NA	NA	26.3248	Negative	Ruled-out Case	
17	BJXH017	Female	56	Oropharyngeal swab	Fever	N/A	N/A	29.83	25.66	Negative	2020.02.28	NA	NA	28.0385	Negative	Ruled-out Case	
18	BJXH018	Female	23	Oropharyngeal swab	Fever	N/A	N/A	27.66	18.83	Negative	2020.02.28	NA	NA	28.4026	Negative	Ruled-out Case	
19	BJXH019	Male	47	Oropharyngeal swab	Chest pain	N/A	N/A	23.33	20.83	Negative	2020.02.28	NA	NA	23.0655	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus

20	BJXH020	Male	63	Oropharyngeal swab	Physical examination	N/A	N/A	17.00	18.50	Negative	2020.02.28	NA	NA	13.2885	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
21	BJXH021	Male	31	Oropharyngeal swab	Screening	N/A	N/A	20.66	24.16	Negative	2020.02.28	NA	NA	20.4001	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
22	BJXH022	Male	35	Oropharyngeal swab	Fever	N/A	N/A	26.83	28.33	Negative	2020.02.28	NA	NA	13.0822	Negative	Ruled-out Case	
23	BJXH023	Male	54	Oropharyngeal swab	Fever	N/A	N/A	20.83	19.83	Negative	2020.02.28	NA	NA	24.3054	Negative	Ruled-out Case	
24	BJXH024	Female	32	Oropharyngeal swab	Fever	N/A	N/A	22.66	30.16	Negative	2020.02.28	NA	NA	26.9411	Negative	Ruled-out Case	
25	BJXH025	Female	68	Oropharyngeal swab	Cough	N/A	N/A	N/A	33.66	Negative	2020.02.28	NA	NA	25.2927	Negative	Ruled-out Case	
26	BJXH026	Male	28	Oropharyngeal swab	Fever	N/A	N/A	21.33	20.83	Negative	2020.02.28	NA	NA	26.4911	Negative	Ruled-out Case	
27	BJXH027	Male	46	Oropharyngeal swab	Cerebral hemorrhage	N/A	N/A	30.00	16.33	Negative	2020.02.28	NA	NA	22.9177	Negative	Ruled-out Case	Other need to identify new coronavirus WBC12.05*10^9/L, CRP 15.82
28	BJXH028	Female	26	Oropharyngeal swab	Fever	N/A	N/A	23.66	24.66	Negative	2020.02.28	NA	NA	25.9785	Negative	Ruled-out Case	
29	BJXH029	Male	37	Oropharyngeal swab	stomach ache	N/A	N/A	23.16	21.16	Negative	2020.02.28	NA	NA	23.8693	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
30	BJXH030	Female	22	Oropharyngeal swab	Fever	N/A	N/A	25.50	25.66	Negative	2020.02.28	NA	NA	27.9911	Negative	Ruled-out Case	
31	BJXH031	Male	29	Oropharyngeal swab	Fever	N/A	N/A	14.00	18.83	Negative	2020.02.28	NA	NA	23.1491	Negative	Ruled-out Case	
32	BJXH032	Female	77	Oropharyngeal swab	Lung shadow	N/A	N/A	23.33	26.83	Negative	2020.02.28	NA	NA	27.102	Negative	Ruled-out Case	
33	BJXH033	Male	15	Oropharyngeal swab	Fever	N/A	N/A	13.50	23.50	Negative	2020.02.28	NA	NA	30.3278	Negative	Ruled-out Case	
34	BJXH034	Female	27	Oropharyngeal swab	Fever	N/A	N/A	21.33	23.66	Negative	2020.02.28	NA	NA	27.6263	Negative	Ruled-out Case	
35	BJXH035	Female	3	Oropharyngeal swab	Fever	N/A	N/A	23.00	25.50	Negative	2020.02.28	NA	NA	28.5974	Negative	Ruled-out Case	
36	BJXH036	Female	12	Oropharyngeal swab	Bacterial infection	N/A	N/A	24.16	24.33	Negative	2020.02.28	NA	NA	26.9771	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
37	BJXH037	Female	44	Oropharyngeal swab	Fever	N/A	N/A	21.5	20.16	Negative	2020.02.28	NA	NA	25.2486	Negative	Ruled-out Case	
38	BJXH038	Male	15	Oropharyngeal swab	Fever;Bacterial infection	N/A	N/A	24.00	20.66	Negative	2020.02.28	NA	NA	24.8407	Negative	Ruled-out Case	
39	BJXH039	Female	56	Oropharyngeal swab	Fever	N/A	N/A	20.50	23.16	Negative	2020.02.28	NA	NA	23.2964	Negative	Ruled-out Case	
40	BJXH040	Male	36	Oropharyngeal swab	Lung infection	N/A	N/A	18.16	18.83	Negative	2020.02.28	NA	NA	25.0503	Negative	Ruled-out Case	

41	BJXH041	Male	51	Oropharyngeal swab	腹水	N/A	N/A	06.00	25.16	Negative	2020.02.28	NA	NA	27.1672	Negative	Ruled-out Case	Other need to identify new coronavirus WBC26.48*10^9/L, PCT 1.4ng/ml
42	BJXH042	Female	32	Oropharyngeal swab	Fever	N/A	N/A	21.33	20.33	Negative	2020.02.28	NA	NA	27.041	Negative	Ruled-out Case	
43	BJXH043	Male	41	Oropharyngeal swab	Fever	N/A	N/A	31.00	30.33	Negative	2020.02.28	NA	NA	29.8167	Negative	Ruled-out Case	
44	BJXH044	Male	67	Sputum	Interstitial lung disease, primary thrombocytopenia	N/A	N/A	21.00	22.66	Negative	2020.02.28	NA	NA	19.4378	Negative	Ruled-out Case	
45	BJXH045	Female	80	Sputum	Aplastic anemia, Lung infection	N/A	N/A	13.83	25.66	Negative	2020.02.28	NA	NA	24.0637	Negative	Ruled-out Case	
46	BJXH046	Male	64	Sputum	Lung shadow, Lung infection	N/A	N/A	20.66	27.33	Negative	2020.02.28	NA	NA	20.2139	Negative	Ruled-out Case	
47	BJXH047	Female	38	Sputum	Unexplained fever, central nervous system infection	N/A	N/A	24.16	N/A	Negative	2020.02.28	NA	NA	20.4459	Negative	Ruled-out Case	
48	BJXH048	Male	64	Sputum	Allergic bronchopulmonary aspergillosis	N/A	N/A	20.16	23.83	Negative	2020.02.28	NA	NA	20.7834	Negative	Ruled-out Case	
49	BJXH049	Female	32	Sputum	Bronchiectasis	N/A	N/A	27.33	23.66	Negative	2020.02.28	NA	NA	18.135	Negative	Ruled-out Case	
50	BJXH050	Female	57	Sputum	Lung infection, Fever	N/A	N/A	22.66	19.50	Negative	2020.02.28	NA	NA	18.1314	Negative	Ruled-out Case	
51	BJXH051	Male	10	Sputum	Systemic lupus erythematosus, lupus nephritis, suffocation, Lung infection	N/A	N/A	N/A	18.00	Negative	2020.02.28	NA	NA	20.1942	Negative	Ruled-out Case	
52	BJXH052	Male	69	Sputum	Fever, Lung infection	N/A	N/A	30.83	23.00	Negative	2020.02.28	NA	NA	19.789	Negative	Ruled-out Case	
53	BJXH053	Female	60	Oropharyngeal swab	Severe osteoporosis; aseptic necrosis of the femoral head; IgA nephropathy	N/A	N/A	29.66	25.50	Negative	2020.02.29	NA	NA	30.562	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
54	BJXH054	Male	44	Oropharyngeal swab	stomach ache	N/A	N/A	06.00	20.16	Negative	2020.02.29	NA	NA	28.231	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
55	BJXH055	Female	56	Oropharyngeal swab	Fever	N/A	N/A	18.16	20.00	Negative	2020.02.29	NA	NA	29.722	Negative	Ruled-out Case	
56	BJXH056	Female	27	Oropharyngeal swab	Fever	N/A	N/A	20.00	17.16	Negative	2020.02.29	NA	NA	26.385	Negative	Ruled-out Case	
57	BJXH057	Male	66	Oropharyngeal swab	Cough	N/A	N/A	20.83	19.33	Negative	2020.02.29	NA	NA	27.756	Negative	Ruled-out Case	
58	BJXH058	Female	61	Oropharyngeal swab	stomach ache;pancreatitis	N/A	N/A	18.66	22.00	Negative	2020.02.29	NA	NA	23.0355	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
59	BJXH059	Male	25	Oropharyngeal swab	Fever	N/A	N/A	22.00	21.83	Negative	2020.02.29	NA	NA	26.2412	Negative	Ruled-out Case	
60	BJXH060	Male	32	Oropharyngeal swab	Respiratory infection	N/A	N/A	25.16	26.33	Negative	2020.02.29	NA	NA	26.8092	Negative	Ruled-out Case	
61	BJXH061	Male	27	Oropharyngeal swab	Fever, Lung infection	N/A	10.83	N/A	N/A	Positive	2020.02.29	29.5171	31.68	32.06348	Positive	Confirmed Case	
62	BJXH062	Male	7	Oropharyngeal swab	Fever	21.16	N/A	N/A	N/A	Positive	2020.02.29	25.33	32.912	24.2383	Positive	Confirmed Case	
63	BJXH063	Male	62	Oropharyngeal swab	Fever	10.83	9.66	N/A	34.16	Positive	2020.02.29	28.444	30.358	23.9903	Positive	Confirmed Case	
64	BJXH064	Male	63	Oropharyngeal swab	Fever	11.50	9.33	N/A	N/A	Positive	2020.02.29	34.118	34.282	24.055	Positive	Confirmed Case	
65	BJXH065	Female	31	Oropharyngeal swab	Fever	14.83	12.16	N/A	25.16	Positive	2020.02.29	25.998	27.089	22.9009	Positive	Confirmed Case	

66	BJXH066	Female	38	Oropharyngeal swab	Fever	18.66	9.16	N/A	18.16	Positive	2020.02.29	30.056	30.152	20.806	Positive	Confirmed Case	
67	BJXH067	Female	39	Oropharyngeal swab	Respiratory infection	9.83	10.33	N/A	N/A	Positive	2020.02.29	32.022	32.119	24.2111	Positive	Confirmed Case	
68	BJXH068	Male	40	Oropharyngeal swab	Fever	9.16	9.00	31.83	34.00	Positive	2020.02.29	26.248	27.046	25.9922	Positive	Confirmed Case	
69	BJXH069	Female	61	Oropharyngeal swab	Fever	16.00	14.33	N/A	N/A	Positive	2020.02.29	34.84264	36.5	25.47841	Positive	Confirmed Case	
70	BJXH070	Male	25	Oropharyngeal swab	Fever	N/A	N/A	20.16	17.66	Negative	2020.02.29	NA	NA	21.3682	Negative	Ruled-out Case	
71	BJXH071	Female	65	Oropharyngeal swab	Fever;diarrhea	N/A	N/A	27.16	23.00	Negative	2020.02.29	NA	NA	28.8672	Negative	Ruled-out Case	
72	BJXH072	Female	74	Oropharyngeal swab	stomach ache	N/A	N/A	21.16	25.83	Negative	2020.02.29	NA	NA	24.1871	Negative	Ruled-out Case	Other need to identify new coronavirus WBC14.55*10^9/L, PCT 6.9ng/ml
73	BJXH073	Male	19	Oropharyngeal swab	Fever;Bacterial infection	N/A	N/A	25.16	21.16	Negative	2020.02.29	NA	NA	26.9741	Negative	Ruled-out Case	
74	BJXH074	Female	62	Oropharyngeal swab	Fever	N/A	N/A	22.5	25.16	Negative	2020.02.29	NA	NA	25.5917	Negative	Ruled-out Case	
75	BJXH075	Female	84	Oropharyngeal swab	Hypoxemia	N/A	N/A	25.00	19.66	Negative	2020.02.29	NA	NA	24.0031	Negative	Ruled-out Case	
76	BJXH076	Female	38	Oropharyngeal swab	stomach ache;infection	N/A	N/A	21.66	28.16	Negative	2020.02.29	NA	NA	25.0432	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
77	BJXH077	Female	53	Oropharyngeal swab	stomach ache	N/A	N/A	23.50	18.83	Negative	2020.02.29	NA	NA	25.1675	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
78	BJXH078	Female	39	Oropharyngeal swab	Fever	N/A	N/A	19.66	23.0	Negative	2020.02.29	NA	NA	27.3484	Negative	Ruled-out Case	
79	BJXH079	Male	32	Oropharyngeal swab	Fever	N/A	N/A	26.5	30.0	Negative	2020.02.29	NA	NA	21.8475	Negative	Ruled-out Case	
80	BJXH080	Female	71	Oropharyngeal swab	Fever;Bacterial infection	N/A	N/A	22.00	19.33	Negative	2020.02.29	NA	NA	24.9054	Negative	Ruled-out Case	
81	BJXH081	Female	32	Oropharyngeal swab	Fever	N/A	N/A	20.50	22.16	Negative	2020.02.29	NA	NA	25.7943	Negative	Ruled-out Case	
82	BJXH082	Male	42	Oropharyngeal swab	stomach ache	N/A	N/A	30.16	26.50	Negative	2020.02.29	NA	NA	17.5678	Negative	Ruled-out Case	fever clinics, Suspected infection coronavirus
83	BJXH083	Female	35	Oropharyngeal swab	Fever	N/A	N/A	27.66	18.66	Negative	2020.02.29	NA	NA	24.8857	Negative	Ruled-out Case	
84	BJXH084	Female	84	Oropharyngeal swab	Coronary atherosclerotic heart disease	N/A	N/A	09.50	24.83	Negative	2020.02.29	NA	NA	29.1823	Negative	Ruled-out Case	Other need to identify new coronavirus LYM%16.5%, NT-proBNP 1772pg/ml
85	BJXH085	Female	30	Oropharyngeal swab	Medical examination	N/A	N/A	16.16	18.33	Negative	2020.02.29	NA	NA	26.2615	Negative	Ruled-out Case	
86	BJXH086	Female	22	Oropharyngeal swab	Vaginal bleeding; ectopic pregnancy	N/A	N/A	20.83	30.00	Negative	2020.02.29	NA	NA	24.7568	Negative	Ruled-out Case	Other need to identify new coronavirus

87	BJXH087	Male	38	Oropharyngeal swab	Lung fungal infection; hemoptysis	N/A	N/A	N/A	13.33	Negative	2020.02.29	NA	NA	23.6437	Negative	Ruled-out Case	
88	BJXH088	Male	38	Oropharyngeal swab	Fever	13.33	10.33	N/A	32.66	Positive	2020.03.01	NA	NA	34.0414	Negative	Confirmed Case	
89	SZJK001	Male	38	Oropharyngeal swab	Suspected infection coronavirus	25.66	24.83	N/A	N/A	Positive	27/2/20	37.80	37.01	29.63	Positive	Confirmed Case	
90	SZJK002	Female	37	Oropharyngeal swab	Suspected infection coronavirus	10.66	9.83	N/A	N/A	Positive	27/2/20	37.97	35.70	29.21	Positive	Confirmed Case	
91	SZJK003	Male	41	Oropharyngeal swab	Suspected infection coronavirus	12.00	10.83	N/A	N/A	Positive	27/2/20	34.37	35.69	32.96	Positive	Confirmed Case	
92	SZJK004	Female	7	Oropharyngeal swab	Confirmed Case	21.33	18.00	N/A	N/A	Positive	27/2/20	34.02	35.30	31.01	Positive	Confirmed Case	
93	SZJK005	Female	30	Oropharyngeal swab	Confirmed Case	19.83	18.33	N/A	N/A	Positive	27/2/20	32.42	34.73	26.49	Positive	Confirmed Case	
94	SZJK006	Female	78	Oropharyngeal swab	Confirmed Case	20.66	22.83	N/A	N/A	Positive	27/2/20	NA (NA)	37.96 (37.76)	29.04 (26.80)	Retest (Negative)	Confirmed Case	Retest
95	SZJK007	Female	59	Oropharyngeal swab	Suspected infection coronavirus	9.16	9.33	N/A	N/A	Positive	27/2/20	33.00	32.90	28.18	Positive	Confirmed Case	
96	SZJK008	Female	75	Oropharyngeal swab	Confirmed Case	15.33	19.66	N/A	N/A	Positive	27/2/20	33.40	32.45	27.73	Positive	Confirmed Case	
97	SZJK009	Female	34	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	21.33	23.33	Negative	27/2/20	NA	NA	28.39	Negative	Ruled-out Case	
98	SZJK010	Male	58	Oropharyngeal swab	Suspected infection coronavirus	13.83	11.66	N/A	N/A	Positive	27/2/20	32.98	32.41	28.24	Positive	Confirmed Case	
99	SZJK011	Male	55	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	26.00	25.16	Negative	27/2/20	NA	NA	28.55	Negative	Ruled-out Case	
100	SZJK012	Male	36	Oropharyngeal swab	Suspected infection coronavirus	20.33	18.00	34.16	N/A	Positive	27/2/20	NA	NA	31.13	Negative	Confirmed Case	
101	SZJK013	Female	41	Oropharyngeal swab	Close contacts	N/A	N/A	30.50	35.83	Negative	28/2/20	NA	NA	26.33	Negative	Ruled-out Case	
102	SZJK014	Male	31	Oropharyngeal swab	Close contacts	N/A	N/A	29.50	33.00	Negative	28/2/20	NA	NA	27.07	Negative	Ruled-out Case	
103	SZJK015	Male	24	Oropharyngeal swab	Close contacts	N/A	N/A	31.00	28.16	Negative	28/2/20	NA	NA	31.82	Negative	Ruled-out Case	
104	SZJK016	Female	41	Oropharyngeal swab	Close contacts	N/A	N/A	31.33	31.66	Negative	28/2/20	NA	NA	29.62	Negative	Ruled-out Case	
105	SZJK017	Male	65	Oropharyngeal swab	Close contacts	N/A	N/A	29.66	34.83	Negative	28/2/20	NA	NA	27.91	Negative	Ruled-out Case	
106	SZJK018	Female	33	Oropharyngeal swab	Close contacts	N/A	N/A	29.16	33.16	Negative	28/2/20	NA	NA	29.99	Negative	Ruled-out Case	
107	SZJK019	Male	36	Oropharyngeal swab	Close contacts	N/A	N/A	27.00	23.00	Negative	28/2/20	NA	NA	30.73	Negative	Ruled-out Case	
108	SZJK020	Male	8	Oropharyngeal swab	Close contacts	N/A	N/A	24.50	27.33	Negative	28/2/20	NA	NA	32.01	Negative	Ruled-out Case	

109	SZJK021	Female	46	Oropharyngeal swab	Close contacts	N/A	N/A	28.50	33.16	Negative	28/2/20	NA	NA	29.39	Negative	Ruled-out Case	
110	SZJK022	Female	38	Oropharyngeal swab	Close contacts	N/A	N/A	21.33	21.16	Negative	28/2/20	NA	NA	33.24	Negative	Ruled-out Case	
111	SZJK023	Female	6	Oropharyngeal swab	Close contacts	N/A	N/A	28.83	26.33	Negative	28/2/20	NA	NA	28.19	Negative	Ruled-out Case	
112	SZJK024	Female	63	Oropharyngeal swab	Close contacts	10.83	11.33	N/A	N/A	Positive	28/2/20	35.40	31.44	27.48	Positive	Confirmed Case	
113	SZJK025	Female	6	Oropharyngeal swab	Close contacts	N/A	N/A	31.66	29.00	Negative	28/2/20	NA	NA	30.27	Negative	Ruled-out Case	
114	SZJK026	Female	66	Oropharyngeal swab	Confirmed Case	20.33	16.83	N/A	N/A	Positive	28/2/20	31.38	31.32	27.75	Positive	Confirmed Case	
115	SZJK027	Male	56	Oropharyngeal swab	Confirmed Case	16.66	21.83	N/A	N/A	Positive	28/2/20	NA (NA)	35.21 (36.69)	25.99 (23.26)	Retest (Negative)	Confirmed Case	Retest
116	SZJK028	Female	19	Oropharyngeal swab	Confirmed Case	21.00	19.50	N/A	30.83	Positive	28/2/20	NA	NA	31.27	Negative	Confirmed Case	
117	SZJK029	Male	63	Oropharyngeal swab	Confirmed Case	17.33	18.16	N/A	N/A	Positive	28/2/20	NA (NA)	30.09 (31.24)	22.62 (20.35)	Retest (Negative)	Confirmed Case	Retest
118	SZJK030	Male	43	Oropharyngeal swab	Confirmed Case	18.50	22.16	N/A	N/A	Positive	28/2/20	33.12	31.19	27.98	Positive	Confirmed Case	
119	SZJK031	Male	37	Oropharyngeal swab	Confirmed Case	22.66	18.00	N/A	N/A	Positive	28/2/20	30.61	30.74	28.24	Positive	Confirmed Case	
120	SZJK032	Female	1	Oropharyngeal swab	Confirmed Case	20.16	22.00	N/A	N/A	Positive	28/2/20	NA	NA	24.98	Negative	Confirmed Case	
121	SZJK033	Female	35	Oropharyngeal swab	Confirmed Case	20.16	20.83	N/A	N/A	Positive	28/2/20	30.79	30.54	29.43	Positive	Confirmed Case	
122	SZJK034	Male	36	Oropharyngeal swab	Confirmed Case	17.16	16.50	N/A	N/A	Positive	28/2/20	29.69	30.39	28.69	Positive	Confirmed Case	
123	SZJK035	Female	61	Oropharyngeal swab	Confirmed Case	8.66	10.66	N/A	N/A	Positive	28/2/20	31.66	30.03	27.53	Positive	Confirmed Case	
124	SZJK036	Male	61	Oropharyngeal swab	Confirmed Case	16.83	21.16	N/A	N/A	Positive	28/2/20	29.91	29.83	30.12	Positive	Confirmed Case	
125	SZJK037	Male	28	Oropharyngeal swab	Confirmed Case	21.66	22.83	29.83	30.66	Positive	28/2/20	NA (NA)	36.27 (NA)	28.03 (27.14)	Retest (Negative)	Confirmed Case	Retest
126	SZJK038	Female	64	Oropharyngeal swab	Confirmed Case	9.33	7.16	N/A	N/A	Positive	28/2/20	30.21	29.83	30.83	Positive	Confirmed Case	
127	SZJK039	Male	25	Oropharyngeal swab	Confirmed Case	19.33	20.33	N/A	N/A	Positive	28/2/20	28.77	29.40	26.81	Positive	Confirmed Case	
128	SZJK040	Female	59	Oropharyngeal swab	Confirmed Case	18.50	20.33	N/A	N/A	Positive	28/2/20	27.62	27.88	31.68	Positive	Confirmed Case	
129	SZJK041	Female	50	Sputum	Community-acquired pneumonia	N/A	N/A	29.33	33.50	Negative	29/2/20	NA	NA	29.19	Negative	Ruled-out Case	
130	SZJK042	Female	86	Sputum	Community-acquired pneumonia	N/A	N/A	23.50	27.66	Negative	29/2/20	NA	NA	25.22	Negative	Ruled-out Case	
131	SZJK043	Female	65	Sputum	Community-acquired pneumonia	N/A	N/A	23.50	22.00	Negative	29/2/20	NA	NA	28.37	Negative	Ruled-out Case	
132	SZJK044	Male	66	Sputum	Community-acquired pneumonia	N/A	N/A	28.83	31.16	Negative	29/2/20	NA	NA	30.14	Negative	Ruled-out Case	
133	SZJK045	Female	65	Sputum	Community-acquired pneumonia	N/A	N/A	30.83	32.00	Negative	29/2/20	NA	NA	29.31	Negative	Ruled-out Case	
134	SZJK046	Female	47	Sputum	Community-acquired pneumonia	N/A	N/A	26.00	24.66	Negative	29/2/20	NA	NA	33.02	Negative	Ruled-out Case	

135	SZJK047	Male	70	Sputum	Community-acquired pneumonia	N/A	N/A	27.66	27.00	Negative	29/2/20	NA	NA	28.23	Negative	Ruled-out Case	
136	SZJK048	Female	68	Sputum	Community-acquired pneumonia	N/A	N/A	21.16	21.16	Negative	29/2/20	NA	NA	27.04	Negative	Ruled-out Case	
137	SZJK049	Female	42	Oropharyngeal swab	Close contacts	N/A	N/A	32.66	28.33	Negative	29/2/20	NA	NA	31.05	Negative	Ruled-out Case	
138	SZJK050	Female	13	Oropharyngeal swab	Close contacts	N/A	N/A	22.83	26.83	Negative	29/2/20	NA	NA	32.78	Negative	Ruled-out Case	
139	SZJK051	Female	28	Oropharyngeal swab	Cure the discharged	N/A	N/A	32.83	33.16	Negative	29/2/20	NA	NA	32.68	Negative	Ruled-out Case	
140	SZJK052	Male	49	Oropharyngeal swab	Close contacts	N/A	N/A	23.00	27.33	Negative	29/2/20	NA	NA	31.34	Negative	Ruled-out Case	
141	SZJK053	Female	53	Oropharyngeal swab	Close contacts	N/A	N/A	22.00	25.00	Negative	29/2/20	NA	NA	31.86	Negative	Ruled-out Case	
142	SZJK054	Female	61	Oropharyngeal swab	Close contacts	N/A	N/A	24.33	29.16	Negative	29/2/20	NA	NA	30.27	Negative	Ruled-out Case	
143	SZJK055	Female	65	Oropharyngeal swab	Close contacts	N/A	N/A	23.16	29.00	Negative	29/2/20	NA	NA	28.41	Negative	Ruled-out Case	
144	SZJK056	Female	32	Oropharyngeal swab	Close contacts	N/A	N/A	27.83	23.16	Negative	29/2/20	NA	NA	27.92	Negative	Ruled-out Case	
145	SZJK057	Female	45	Oropharyngeal swab	Close contacts	N/A	N/A	25.00	24.33	Negative	29/2/20	NA (NA)	NA (NA)	NA (26.38)	Retest (Negative)	Ruled-out Case	Retest
146	SZJK058	Female	51	Oropharyngeal swab	Close contacts	N/A	N/A	27.16	27.33	Negative	29/2/20	NA (NA)	NA (NA)	NA (25.73)	Retest (Negative)	Ruled-out Case	Retest
147	SZJK059	Male	38	Oropharyngeal swab	Close contacts	N/A	N/A	26.00	26.00	Negative	29/2/20	NA	NA	26.58	Negative	Ruled-out Case	
148	SZJK060	Female	30	Oropharyngeal swab	Close contacts	N/A	N/A	33.33	35.83	Negative	29/2/20	NA	NA	28.50	Negative	Ruled-out Case	
149	SZJK061	Female	43	Oropharyngeal swab	Close contacts	N/A	N/A	21.33	26.83	Negative	29/2/20	NA	NA	28.99	Negative	Ruled-out Case	
150	SZJK062	Female	64	Oropharyngeal swab	Close contacts	N/A	N/A	24.66	26.66	Negative	29/2/20	NA	NA	30.45	Negative	Ruled-out Case	
151	SZJK063	Female	55	Oropharyngeal swab	Close contacts	N/A	N/A	25.16	25.83	Negative	29/2/20	NA	NA	26.27	Negative	Ruled-out Case	
152	SZJK064	Female	5	Oropharyngeal swab	Close contacts	N/A	N/A	27.33	29.83	Negative	29/2/20	NA	NA	28.53	Negative	Ruled-out Case	
153	SZJK065	Female	57	Oropharyngeal swab	Close contacts	N/A	N/A	32.50	29.00	Negative	29/2/20	NA	NA	27.88	Negative	Ruled-out Case	
154	SZJK066	Male	52	Oropharyngeal swab	Close contacts	N/A	N/A	27.66	24.33	Negative	29/2/20	NA	NA	28.06	Negative	Ruled-out Case	
155	SZJK067	Male	39	Oropharyngeal swab	Close contacts	N/A	N/A	31.50	29.00	Negative	29/2/20	NA	NA	27.62	Negative	Ruled-out Case	
156	SZJK068	Female	40	Oropharyngeal swab	Close contacts	N/A	N/A	31.83	32.33	Negative	29/2/20	NA	NA	27.56	Negative	Ruled-out Case	
157	SZJK069	Male	3	Oropharyngeal swab	Close contacts	N/A	N/A	28.50	24.50	Negative	29/2/20	NA	NA	27.50	Negative	Ruled-out Case	

158	SZJK070	Female	22	Oropharyngeal swab	Close contacts	N/A	N/A	23.50	23.00	Negative	29/2/20	NA	NA	26.12	Negative	Ruled-out Case	
159	SZJK071	Female	39	Oropharyngeal swab	Confirmed Case	10.00	9.83	N/A	N/A	Positive	1/3/20	24.30	26.51	29.66	Positive	Confirmed Case	
160	SZJK072	Female	22	Oropharyngeal swab	Confirmed Case	7.83	8.50	N/A	N/A	Positive	1/3/20	24.36	26.09	26.48	Positive	Confirmed Case	
161	SZJK073	Male	56	Oropharyngeal swab	Suspected infection coronavirus	18.00	18.50	N/A	N/A	Positive	1/3/20	24.46	25.02	25.02	Positive	Confirmed Case	
162	SZJK074	Female	43	Oropharyngeal swab	Confirmed Case	16.16	16.00	N/A	N/A	Positive	1/3/20	21.14	21.87	26.63	Positive	Confirmed Case	
163	SZJK075	Female	64	Oropharyngeal swab	Suspected infection coronavirus	20.00	23.16	N/A	N/A	Positive	1/3/20	19.54	21.00	29.24	Positive	Confirmed Case	
164	ZJFY001	Male	51	Sputum	contracting the novel coronavirus.	16.66	24.16	N/A	N/A	Positive	26/2/20	27.58	28.69	24.13	Positive	Confirmed Case	
165	ZJFY002	Male	50	Sputum	contracting the novel coronavirus.	18.16	17.00	N/A	N/A	Positive	26/2/20	28.39	29.67	27.26	Positive	Confirmed Case	
166	ZJFY003	Female	30	Sputum	contracting the novel coronavirus.	13.16	14.83	N/A	N/A	Positive	26/2/20	29.96	30.50	26.17	Positive	Confirmed Case	
167	ZJFY004	Female	55	Sputum	contracting the novel coronavirus.	16.50	14.33	N/A	35.16	Positive	26/2/20	29.84	30.68	32.94	Positive	Confirmed Case	
168	ZJFY005	Female	38	Sputum	contracting the novel coronavirus.	11.66	13.50	N/A	37.83	Positive	26/2/20	28.28	29.20	27.19	Positive	Confirmed Case	
169	ZJFY006	Female	34	Sputum	contracting the novel coronavirus.	N/A	N/A	29.16	33.33	Negative	26/2/20	NA	NA	26.65	Negative	Confirmed Case	
170	ZJFY007	Male	35	Sputum	contracting the novel coronavirus.	20.50	12.83	N/A	N/A	Positive	26/2/20	28.71	30.05	27.48	Positive	Confirmed Case	
171	ZJFY008	Male	53	Sputum	Lung infection, Respiratory failure	8.16	7.83	N/A	27.33	Positive	26/2/20	21.93	23.17	26.43	Positive	Confirmed Case	
172	ZJFY009	Male	70	Sputum	Suspected infection coronavirus	13.66	12.83	23.83	37.33	Positive	26/2/20	24.41	25.60	24.71	Positive	Confirmed Case	
173	ZJFY010	Female	30	Sputum	contracting the novel coronavirus.	8.50	7.83	N/A	N/A	Positive	26/2/20	23.38	24.62	25.13	Positive	Confirmed Case	
174	ZJFY011	Male	62	Sputum	contracting the novel coronavirus.	19.33	18.66	27.00	30.50	Positive	26/2/20	23.95	25.07	23.02	Positive	Confirmed Case	
175	ZJFY012	Male	45	Sputum	contracting the novel coronavirus.	11.16	13.83	19.33	25.66	Positive	26/2/20	24.45	26.10	24.96	Positive	Confirmed Case	
176	ZJFY013	Male	74	Sputum	contracting the novel coronavirus.	8.16	10.66	N/A	N/A	Positive	27/2/20	23.78	25.49	26.67	Positive	Confirmed Case	
177	ZJFY014	Male	13	Sputum	contracting the novel coronavirus.	10.83	20.66	N/A	N/A	Positive	27/2/20	22.15	23.93	25.55	Positive	Confirmed Case	
178	ZJFY015	Male	46	Sputum	contracting the novel coronavirus.	9.50	7.83	N/A	N/A	Positive	27/2/20	22.61	23.39	29.84	Positive	Confirmed Case	
179	ZJFY016	Male	51	Sputum	Lung infection, Respiratory failure	14.33	16.16	N/A	N/A	Positive	27/2/20	NA (NA)	37.71 (27.05)	26.25 (2 5.62)	Retest (Negative)	Confirmed Case	Retest
180	ZJFY017	Male	29	Sputum	contracting the novel coronavirus.	9.00	8.66	N/A	N/A	Positive	27/2/20	25.23	26.56	31.55	Positive	Ruled-out Case	Early detection Negative Remaining samples (late nucleic acid Positive Confirmed Case)
181	ZJFY018	Male	56	Sputum	Fever	N/A	N/A	35.83	34.33	Negative	27/2/20	NA	NA	24.98	Negative	Ruled-out Case	
182	ZJFY019	Female	59	Sputum	Suspected infection coronavirus	15.33	13.83	N/A	N/A	Positive	27/2/20	31.23	30.88	28.39	Positive	Confirmed Case	
183	ZJFY020	Male	59	Sputum	contracting the novel coronavirus.	14.00	16.83	N/A	N/A	Positive	27/2/20	31.95	30.94	22.81	Positive	Confirmed Case	
184	ZJFY021	Male	77	Sputum	Lung infection	N/A	N/A	32.00	27.33	Negative	27/2/20	NA	NA	28.27	Negative	Ruled-out Case	
185	ZJFY022	Female	45	Sputum	contracting the novel coronavirus.	8.33	7.83	N/A	N/A	Positive	27/2/20	18.11	18.51	22.22	Positive	Confirmed Case	
186	ZJFY023	Male	44	Sputum	contracting the novel coronavirus.	14.66	12.83	N/A	N/A	Positive	27/2/20	31.58	32.02	24.30	Positive	Confirmed Case	
187	ZJFY024	Female	36	Sputum	contracting the novel coronavirus.	N/A	N/A	33.83	35.50	Negative	27/2/20	NA	NA	26.88	Negative	Confirmed Case	
188	ZJFY025	Male	48	Sputum	contracting the novel coronavirus.	12.16	12.50	N/A	N/A	Positive	27/2/20	30.44	31.62	28.03	Positive	Confirmed Case	
189	ZJFY026	Female	47	Sputum	contracting the novel coronavirus.	15.00	17.33	N/A	N/A	Positive	27/2/20	27.04	27.55	23.07	Positive	Confirmed Case	
190	ZJFY027	Female	66	Sputum	contracting the novel coronavirus.	10.16	13.33	N/A	N/A	Positive	27/2/20	15.90	18.18	23.61	Positive	Confirmed Case	
191	ZJFY028	Male	55	Sputum	contracting the novel coronavirus.	10.00	11.16	N/A	N/A	Positive	27/2/20	26.02	27.09	25.20	Positive	Confirmed Case	
192	ZJFY029	Male	26	Sputum	Chest tightness	N/A	N/A	29.50	30.66	Negative	28/2/20	NA	NA	25.98	Negative	Ruled-out Case	
193	ZJFY030	Female	31	Sputum	Fever	N/A	N/A	28.66	27.00	Negative	28/2/20	NA	NA	19.76	Negative	Ruled-out Case	
194	ZJFY031	Male	29	Sputum	Fever	N/A	N/A	30.50	28.66	Negative	28/2/20	NA	NA	24.11	Negative	Ruled-out Case	
195	ZJFY032	Male	32	Sputum	Cough	N/A	N/A	32.66	30.00	Negative	29/2/20	NA	NA	26.13	Negative	Ruled-out Case	
196	ZJFY033	Male	33	Sputum	Cough	N/A	N/A	30.16	27.16	Negative	29/2/20	NA	NA	27.62	Negative	Ruled-out Case	
197	ZJFY034	Female	36	Sputum	Fever	N/A	N/A	30.66	28.50	Negative	29/2/20	NA	NA	27.59	Negative	Ruled-out Case	
198	ZJFY035	Female	32	Sputum	Cough	N/A	N/A	32.33	30.83	Negative	1/3/20	NA	NA	19.46	Negative	Ruled-out Case	
199	ZJFY036	Female	38	Sputum	In hospital	8.50	7.00	N/A	N/A	Positive	2/3/20	25.63	26.95	31.01	Positive	Confirmed Case	Early detection Negative Remaining samples (late nucleic acid Positive Confirmed Case)
200	ZJFY037	Male	53	Sputum	contracting the novel coronavirus.	9.33	12.33	N/A	N/A	Positive	2/3/20	32.49	33.26	26.94	Positive	Confirmed Case	
201	ZJFY038	Male	24	Sputum	Respiratory infection	N/A	N/A	26.33	28.00	Negative	2/3/20	NA	NA	21.55	Negative	Ruled-out Case	

202	ZIFY039	Female	66	Sputum	contracting the novel coronavirus.	10.66	9.83	N/A	N/A	Positive	2/3/20	22.63 (20.66)	23.28 (24.67)	39.60 (29.68)	Retest (Positive)	Confirmed Case	Retest
203	ZIFY040	Male	57	Sputum	Suspected infection coronavirus	12.83	27.16	N/A	N/A	Positive	2/3/20	24.00	25.10	26.90	Positive	Confirmed Case	
204	ZIFY041	Male	32	Sputum	Chest pain	N/A	N/A	29.83	30.66	Negative	2/3/20	NA	NA	23.94	Negative	Ruled-out Case	
205	ZIFY042	Male	48	Sputum	contracting the novel coronavirus.	11.00	7.83	N/A	N/A	Positive	2/3/20	23.73	25.02	32.13	Positive	Confirmed Case	
206	ZIFY043	Female	50	Sputum	contracting the novel coronavirus.	11.16	10.00	N/A	N/A	Positive	2/3/20	19.92	21.34	26.30	Positive	Confirmed Case	
207	ZIFY044	Male	52	Sputum	contracting the novel coronavirus.	6.33	6.33	N/A	N/A	Positive	2/3/20	18.48	19.50	23.51	Positive	Confirmed Case	
208	ZIFY045	Male	61	Sputum	contracting the novel coronavirus.	11.33	9.66	N/A	N/A	Positive	2/3/20	32.14	32.94	32.89	Positive	Confirmed Case	
209	ZIFY046	Male	61	Sputum	Lung infection	N/A	N/A	28.66	24.00	Negative	2/3/20	NA	NA	24.05	Negative	Ruled-out Case	
210	ZIFY047	Male	17	Sputum	Respiratory infection	N/A	N/A	27.50	29.00	Negative	2/3/20	NA	NA	23.26	Negative	Ruled-out Case	
211	ZIFY048	Male	52	Sputum	contracting the novel coronavirus.	11.83	13.16	N/A	N/A	Positive	2/3/20	14.41	15.96	21.64	Positive	Confirmed Case	
212	ZIFY049	Female	46	Sputum	Respiratory infection	N/A	N/A	33.33	30.00	Negative	2/3/20	NA	NA	24.73	Negative	Ruled-out Case	
213	ZIFY050	Female	57	Sputum	contracting the novel coronavirus.	15.00	13.83	N/A	N/A	Positive	2/3/20	35.76	34.29	23.47	Positive	Confirmed Case	
214	ZIFY051	Female	48	Sputum	Cough	N/A	N/A	29.66	33.00	Negative	2/3/20	NA	NA	23.65	Negative	Ruled-out Case	
215	ZIFY052	Female	48	Sputum	Fever	N/A	N/A	27.33	24.66	Negative	2/3/20	NA	NA	33.82	Negative	Ruled-out Case	
216	ZIFY053	Male	64	Sputum	contracting the novel coronavirus.	N/A	N/A	29.33	29.50	Negative	2/3/20	NA	NA	24.39	Negative	Confirmed Case	
217	ZIFY054	Female	62	Sputum	contracting the novel coronavirus.	8.50	7.33	N/A	N/A	Positive	2/3/20	27.76	28.52	24.10	Positive	Confirmed Case	
218	ZIFY055	Male	70	Sputum	contracting the novel coronavirus.	11.33	10.16	N/A	N/A	Positive	2/3/20	30.16	30.12	25.79	Positive	Confirmed Case	
219	ZIFY056	Male	29	Sputum	contracting the novel coronavirus.	9.66	10.00	N/A	N/A	Positive	2/3/20	27.98	29.32	27.94	Positive	Confirmed Case	
220	ZIFY057	Female	40	Sputum	Cough	N/A	N/A	29.16	24.66	Negative	2/3/20	NA	NA	20.85	Negative	Ruled-out Case	
221	ZIFY058	Female	64	Sputum	Suspected infection coronavirus	12.00	11.33	N/A	N/A	Positive	2/3/20	24.44	25.55	26.54	Positive	Confirmed Case	
222	ZIFY059	Female	57	Sputum	contracting the novel coronavirus.	19.33	21.66	N/A	N/A	Positive	2/3/20	35.94	35.13	25.70	Positive	Confirmed Case	
223	ZIFY060	Male	53	Sputum	Fever	N/A	N/A	30.83	28.50	Negative	2/3/20	NA	NA	22.91	Negative	Ruled-out Case	
224	ZIFY061	Female	70	Sputum	contracting the novel coronavirus.	12.16	14.66	N/A	N/A	Positive	2/3/20	23.06	23.97	23.56	Positive	Confirmed Case	
225	ZIFY062	Male	39	Sputum	contracting the novel coronavirus.	6.66	6.00	N/A	N/A	Positive	2/3/20	19.74	21.39	25.22	Positive	Confirmed Case	
226	ZIFY063	Male	59	Sputum	Respiratory infection	N/A	N/A	24.66	26.00	Negative	2/3/20	NA	NA	22.20	Negative	Ruled-out Case	
227	ZIFY064	Female	56	Sputum	上感	N/A	N/A	25.50	24.50	Negative	2/3/20	NA	NA	21.90	Negative	Ruled-out Case	
228	ZIFY065	Female	54	Sputum	contracting the novel coronavirus.	14.16	12.00	N/A	N/A	Positive	2/3/20	26.86	27.48	23.72	Positive	Confirmed Case	
229	ZIFY066	Male	90	Sputum	contracting the novel coronavirus.	17.50	26.16	N/A	N/A	Positive	2/3/20	31.14	32.19	28.72	Positive	Confirmed Case	
230	ZIFY067	Female	29	Sputum	Fatigue	N/A	N/A	29.66	24.83	Negative	2/3/20	NA	NA	25.37	Negative	Ruled-out Case	
231	ZIFY068	Female	33	Sputum	Cough	N/A	N/A	32.50	33.83	Negative	2/3/20	NA	NA	25.59	Negative	Ruled-out Case	
232	ZIFY069	Female	29	Sputum	Fever	N/A	N/A	21.16	22.33	Negative	2/3/20	NA	NA	22.54	Negative	Ruled-out Case	
233	ZIFY070	Male	65	Sputum	Fever	N/A	N/A	28.66	31.16	Negative	2/3/20	NA	NA	25.41	Negative	Ruled-out Case	
234	ZIFY071	Female	30	Sputum	contracting the novel coronavirus.	5.66	5.83	N/A	N/A	Positive	2/3/20	16.84	18.25	23.10	Positive	Confirmed Case	
235	ZIFY072	Female	80	Sputum	contracting the novel coronavirus.	12.16	11.33	N/A	N/A	Positive	2/3/20	33.64	34.12	29.30	Positive	Confirmed Case	
236	ZIFY073	Female	48	Sputum	Fever	N/A	N/A	34.83	32.16	Negative	2/3/20	NA	NA	23.18	Negative	Ruled-out Case	
237	ZIFY074	Male	57	Sputum	Fever	N/A	N/A	33.66	30.16	Negative	2/3/20	NA	NA	25.64	Negative	Ruled-out Case	
238	ZIFY075	Male	83	Sputum	Suspected infection coronavirus	18.33	19.16	N/A	N/A	Positive	2/3/20	29.51 (27.63)	30.50 (31.34)	NA(28.63)	Retest (Positive)	Confirmed Case	Retest
239	ZIFY076	Female	33	Sputum	contracting the novel coronavirus.	N/A	N/A	28.16	28.83	Negative	2/3/20	NA	NA	25.35	Negative	Ruled-out Case	
240	ZIFY077	Male	29	Sputum	contracting the novel coronavirus.	5.33	6.33	N/A	N/A	Positive	2/3/20	23.51	25.09	26.17	Positive	Confirmed Case	
241	ZIFY078	Male	55	Sputum	contracting the novel coronavirus.	14.33	14.00	N/A	N/A	Positive	2/3/20	20.78	21.42	28.70	Positive	Confirmed Case	
242	ZIFY079	Female	66	Sputum	contracting the novel coronavirus.	14.66	14.50	N/A	N/A	Positive	2/3/20	22.77	23.40	29.92	Positive	Confirmed Case	
243	ZIFY080	Male	61	Sputum	contracting the novel coronavirus.	8.16	8.33	N/A	N/A	Positive	2/3/20	27.43	28.02	24.10	Positive	Confirmed Case	
244	ZIFY081	Female	63	Sputum	contracting the novel coronavirus.	6.83	5.83	N/A	N/A	Positive	2/3/20	23.08	23.88	25.80	Positive	Confirmed Case	
245	ZIFY082	Female	64	Sputum	Fever	N/A	N/A	28.66	25.83	Negative	2/3/20	NA	NA	24.06	Negative	Ruled-out Case	
246	ZIFY083	Female	29	Sputum	Fever	N/A	N/A	27.83	30.16	Negative	2/3/20	NA	NA	25.20	Negative	Ruled-out Case	
247	ZIFY084	Male	48	Sputum	Cough	N/A	N/A	24.00	21.16	Negative	2/3/20	NA	NA	23.21	Negative	Ruled-out Case	
248	ZIFY085	Female	62	Sputum	Fever	N/A	N/A	27.66	28.83	Negative	2/3/20	NA	NA	25.46	Negative	Ruled-out Case	
249	ZIFY086	Male	56	Sputum	contracting the novel coronavirus.	14.33	16.50	N/A	N/A	Positive	2/3/20	19.52	21.21	23.30	Positive	Confirmed Case	
250	ZIFY087	Male	32	Sputum	Cough	N/A	N/A	24.50	20.66	Negative	2/3/20	NA	NA	36.00	Negative	Ruled-out Case	
251	ZIFY088	Male	70	Sputum	contracting the novel coronavirus.	14.50	14.00	N/A	N/A	Positive	2/3/20	15.66	17.32	21.90	Positive	Confirmed Case	
252	ZIFY089	Male	32	Sputum	contracting the novel coronavirus.	12.66	12.16	N/A	N/A	Positive	2/3/20	15.38	17.01	24.64	Positive	Confirmed Case	
253	ZIFY090	Female	87	Sputum	Fever	N/A	N/A	30.33	30.33	Negative	2/3/20	NA	NA	23.67	Negative	Ruled-out Case	
254	ZIFY091	Male	51	Sputum	contracting the novel coronavirus.	9.16	8.00	N/A	N/A	Positive	2/3/20	22.93	22.87	25.83	Positive	Confirmed Case	
255	ZIFY092	Female	81	Sputum	contracting the novel coronavirus.	12.00	11.83	N/A	N/A	Positive	2/3/20	32.32	32.69	27.02	Positive	Confirmed Case	
256	ZIFY093	Male	27	Sputum	Fever	N/A	N/A	24.83	30.50	Negative	2/3/20	NA	NA	25.12	Negative	Ruled-out Case	
257	ZIFY094	Female	29	Sputum	contracting the novel coronavirus.	14.16	13.83	N/A	N/A	Positive	2/3/20	19.55	21.16	27.40	Positive	Confirmed Case	
258	ZIFY095	Male	85	Sputum	contracting the novel coronavirus.	14.50	15.33	N/A	N/A	Positive	2/3/20	27.78	29.09	34.11	Positive	Confirmed Case	
259	ZIFY096	Male	62	Sputum	contracting the novel coronavirus.	5.50	5.33	N/A	N/A	Positive	2/3/20	12.35	13.82	23.12	Positive	Confirmed Case	
260	ZIFY097	Female	40	Sputum	Fever	N/A	N/A	31.16	29.16	Negative	2/3/20	NA	NA	22.81	Negative	Ruled-out Case	
261	ZIFY098	Male	34	Sputum	Novel coronavirus RNA assay	N/A	N/A	34.66	33.83	Negative	3/3/20	NA	NA	22.04	Negative	Ruled-out Case	
262	ZIFY099	Male	73	Sputum	contracting the novel coronavirus.	9.16	8.83	N/A	N/A	Positive	3/3/20	24.46	25.20	22.90	Positive	Confirmed Case	

263	ZJFY100	Female	53	Sputum	Novel coronavirus RNA assay	N/A	N/A	31.83	31.33	Negative	3/3/20	NA	NA	21.55	Negative	Ruled-out Case		
264	ZJFY101	Female	24	Sputum	体检	N/A	N/A	29.00	22.16	Negative	3/3/20	NA	NA	35.96	Negative	Ruled-out Case		
265	ZJFY102	Female	25	Sputum	Novel coronavirus RNA assay	N/A	N/A	21.66	28.16	Negative	3/3/20	NA	NA	24.54	Negative	Ruled-out Case		
266	ZJFY103	Female	81	Sputum	Fever	N/A	N/A	28.66	29.16	Negative	3/3/20	NA	NA	28.81	Negative	Ruled-out Case		
267	ZJFY104	Female	38	Sputum	Suspected infection coronavirus	N/A	N/A	24.66	23.50	Negative	3/3/20	NA	NA	23.64	Negative	Ruled-out Case		
268	ZJFY105	Female	30	Sputum	Fever	N/A	N/A	27.66	25.50	Negative	3/3/20	NA	NA	24.63	Negative	Ruled-out Case		
269	ZJFY106	Female	37	Sputum	Fever	N/A	N/A	23.83	33.00	Negative	3/3/20	NA	NA	31.94	Negative	Ruled-out Case		
270	ZJFY107	Female	55	Sputum	Novel coronavirus RNA assay	N/A	N/A	25.66	28.50	Negative	3/3/20	NA	NA	22.57	Negative	Ruled-out Case		
271	ZJFY108	Female	28	Sputum	Novel coronavirus RNA assay	N/A	N/A	23.83	21.83	Negative	3/3/20	NA	NA	23.60	Negative	Ruled-out Case		
272	ZJFY109	Female	50	Sputum	Fever	N/A	N/A	20.83	24.66	Negative	3/3/20	NA	NA	32.39	Negative	Ruled-out Case		
273	ZJFY110	Female	36	Sputum	Fever	N/A	N/A	28.66	28.33	Negative	3/3/20	NA	NA	28.10	Negative	Ruled-out Case		
274	ZJFY111	Female	44	Sputum	Novel coronavirus RNA assay	N/A	N/A	29.00	29.50	Negative	3/3/20	NA	NA	25.61	Negative	Ruled-out Case		
275	ZJFY112	Female	23	Sputum	Cough	N/A	N/A	34.66	32.83	Negative	3/3/20	NA	NA	31.19	Negative	Ruled-out Case		
276	ZJFY113	Female	68	Sputum	Suspected infection coronavirus	N/A	N/A	32.66	33.33	Negative	3/3/20	NA	NA	23.19	Negative	Ruled-out Case		
277	ZJFY114	Female	55	Sputum	Novel coronavirus RNA assay	N/A	N/A	31.83	28.66	Negative	3/3/20	NA	NA	24.64	Negative	Ruled-out Case		
278	ZJFY115	Male	33	Sputum	Chest pain	N/A	N/A	29.33	33.16	Negative	3/3/20	NA	NA	29.52	Negative	Ruled-out Case		
279	ZJFY116	Female	53	Sputum	contracting the novel coronavirus.	15.66	12.16	N/A	N/A	Positive	3/3/20	35.88	36.31	29.98	Positive	Confirmed Case		
280	ZJFY117	Male	51	Sputum	contracting the novel coronavirus.	15.33	15.16	N/A	N/A	Positive	3/3/20	36.54	25.31	25.24	Positive	Confirmed Case		
281	ZJFY118	Female	45	Sputum	contracting the novel coronavirus.	18.66	29.16	N/A	N/A	Positive	3/3/20	34.24	32.99	30.40	Positive	Confirmed Case		
282	ZJFY119	Male	30	Sputum	Fever	N/A	N/A	30.33	30.50	Negative	3/3/20	NA	NA	23.66	Negative	Ruled-out Case		
283	ZJFY120	Male	58	Sputum	Lung infection	N/A	N/A	27.16	32.33	Negative	3/3/20	NA	NA	26.78	Negative	Ruled-out Case		
284	ZJFY121	Female	26	Sputum	Fever	N/A	N/A	26.33	28.16	Negative	3/3/20	NA	NA	27.48	Negative	Ruled-out Case		
285	ZJFY122	Female	28	Sputum	Fever	N/A	N/A	25.50	30.16	Negative	3/3/20	NA	NA	21.55	Negative	Ruled-out Case		
286	ZJFY123	Female	41	Sputum	Suspected infection coronavirus	N/A	N/A	22.83	25.66	Negative	3/3/20	NA	NA	24.77	Negative	Ruled-out Case		
287	ZJFY124	Female	57	Sputum	Fever	N/A	N/A	29.50	27.83	Negative	3/3/20	NA	NA	25.32	Negative	Ruled-out Case		
288	ZJFY125	Female	30	Sputum	Lung infection	N/A	N/A	23.50	22.16	Negative	3/3/20	NA	NA	25.42	Negative	Ruled-out Case		
289	ZJFY126	Female	68	Sputum	Fever	N/A	N/A	22.50	23.00	Negative	3/3/20	NA	NA	26.13	Negative	Ruled-out Case		
290	ZJFY127	Male	37	Sputum	Cough	N/A	N/A	29.16	30.66	Negative	3/3/20	NA	NA	25.27	Negative	Ruled-out Case		
291	ZJFY128	Female	50	Sputum	Fever	N/A	N/A	31.50	28.33	Negative	3/3/20	NA	NA	22.38	Negative	Ruled-out Case		
292	ZJFY129	Female	26	Sputum	Fever	N/A	N/A	27.83	25.00	Negative	3/3/20	NA	NA	23.31	Negative	Ruled-out Case		
293	ZJFY130	Male	36	Sputum	Cough	N/A	N/A	38.66	32.33	Negative	3/3/20	NA	NA	30.30	Negative	Ruled-out Case		
294	ZJFY131	Male	34	Sputum	contracting the novel coronavirus.	9.83	15.50	N/A	N/A	Positive	3/3/20	NA (35 .64)	36.52 (39.23)	27.09 (1.58)	Retest (Negative)	Confirmed Case	Retest	
295	ZJFY132	Male	41	Sputum	Fever	N/A	N/A	29.33	25.00	Negative	3/3/20	NA	NA	23.15	Negative	Ruled-out Case		
296	ZJFY133	Female	35	Sputum	Novel coronavirus RNA assay	N/A	N/A	21.50	20.33	Negative	3/3/20	NA	NA	23.72	Negative	Ruled-out Case		
297	ZJFY134	Male	27	Sputum	Novel coronavirus RNA assay	N/A	N/A	25.83	25.00	Negative	3/3/20	NA	NA	24.66	Negative	Ruled-out Case		
298	ZJFY135	Female	24	Sputum	Novel coronavirus RNA assay	N/A	N/A	31.33	29.33	Negative	3/3/20	NA	NA	21.86	Negative	Ruled-out Case		
299	ZJFY136	Male	33	Sputum	Cough	N/A	N/A	22.50	25.66	Negative	3/3/20	NA	NA	27.99	Negative	Ruled-out Case		
300	ZJFY137	Male	31	Sputum	Fever	N/A	N/A	26.50	15.66	Negative	3/3/20	NA	NA	22.79	Negative	Ruled-out Case		
301	ZJFY138	Female	21	Sputum	Novel coronavirus RNA assay	N/A	N/A	30.16	28.16	Negative	3/3/20	NA	NA	23.10	Negative	Ruled-out Case		
302	ZJFY139	Female	24	Sputum	Novel coronavirus RNA assay	N/A	N/A	25.50	30.33	Negative	3/3/20	NA	NA	22.72	Negative	Ruled-out Case		
303	ZJFY140	Male	42	Sputum	Fever	N/A	N/A	29.83	31.16	Negative	3/3/20	NA	NA	26.98	Negative	Ruled-out Case		
304	ZJFY141	Male	30	Sputum	Cough	N/A	N/A	30.83	27.50	Negative	3/3/20	NA	NA	27.48	Negative	Ruled-out Case		
305	ZJFY142	Female	24	Sputum	Fever	N/A	N/A	24.83	28.16	Negative	3/3/20	NA	NA	24.56	Negative	Ruled-out Case		
306	ZJFY143	Female	65	Sputum	pneumonia	N/A	N/A	25.66	26.33	Negative	3/3/20	NA	NA	20.86	Negative	Ruled-out Case		
307	ZJFY144	Male	54	Sputum	contracting the novel coronavirus.	12.16	14.50	N/A	N/A	Positive	3/3/20	28.98	29.20	27.85	Positive	Confirmed Case		
308	ZJFY145	Female	39	Sputum	Novel coronavirus RNA assay	N/A	N/A	31.83	32.66	Negative	3/3/20	NA	NA	25.10	Negative	Ruled-out Case		
309	ZJFY146	Female	28	Sputum	Fever	N/A	N/A	31.50	30.50	Negative	3/3/20	NA	NA	21.28	Negative	Ruled-out Case		
310	ZJFY147	Female	27	Sputum	Fever	N/A	N/A	18.00	24.83	Negative	3/3/20	NA	NA	26.34	Negative	Ruled-out Case		
311	ZJFY148	Male	51	Sputum	Infectious fever	N/A	N/A	33.50	24.16	Negative	3/3/20	NA	NA	34.83	Negative	Ruled-out Case		
312	ZJFY149	Female	64	Sputum	Fever	N/A	N/A	26.50	27.66	Negative	3/3/20	NA	NA	26.85	Negative	Ruled-out Case		
313	ZJFY150	Male	46	Sputum	Cough	N/A	N/A	23.00	19.33	Negative	3/3/20	NA	NA	24.49	Negative	Ruled-out Case		
314	ZJFY151	Male	25	Sputum	Cough	N/A	N/A	30.16	34.83	Negative	3/3/20	NA	NA	26.02	Negative	Ruled-out Case		
315	ZJFY152	Female	32	Sputum	Novel coronavirus RNA assay	N/A	N/A	23.16	20.33	Negative	3/3/20	NA	NA	31.69	Negative	Ruled-out Case		
316	ZJFY153	Female	36	Sputum	Novel coronavirus RNA assay	N/A	N/A	23.33	23.83	Negative	3/3/20	NA	NA	21.11	Negative	Ruled-out Case		
317	ZJFY154	Male	49	Sputum	Novel coronavirus RNA assay	N/A	N/A	26.33	28.00	Negative	3/3/20	NA	NA	21.81	Negative	Ruled-out Case		
318	ZJFY155	Female	36	Sputum	Fever	N/A	N/A	24.50	21.66	Negative	3/3/20	NA	NA	26.52	Negative	Ruled-out Case		
319	ZJFY156	Female	28	Sputum	Chronic pharyngitis	N/A	N/A	33.83	30.16	Negative	3/3/20	NA	NA	32.40	Negative	Ruled-out Case		
320	ZJFY157	Male	55	Sputum	Fever	N/A	N/A	35.50	30.33	Negative	3/3/20	NA	NA	27.24	Negative	Ruled-out Case		
321	ZJFY158	Male	33	Sputum	Novel coronavirus RNA assay	N/A	N/A	24.16	22.16	Negative	3/3/20	NA	NA	24.11	Negative	Ruled-out Case		
322	ZJFY159	Female	64	Sputum	Confirmed Case	15.66	14.83	N/A	N/A	Positive	3/3/20	NA (37.89)	38.46 (36.97)	29.56 (3 0.56)	Retest (Positive)	Confirmed Case	Retest	
323	ZJFY160	Female	28	Sputum	Cough	N/A	N/A	26.16	25.50	Negative	3/3/20	NA	NA	28.97	Negative	Ruled-out Case		

324	ZJFY161	Male	48	Sputum	contracting the novel coronavirus.	16.83	14.00	N/A	N/A	Positive	3/3/20	34.97 (31.93)	35.97 (35.61)	NA(29.32)	Retest (Positive)	Confirmed Case	Retest
325	ZJFY162	Male	48	Sputum	Acute mumps	N/A	N/A	31.50	29.16	Negative	3/3/20	NA	NA	24.16	Negative	Ruled-out Case	
326	ZJFY163	Male	59	Sputum	contracting the novel coronavirus.	10.83	10.33	N/A	N/A	Positive	3/3/20	22.92	24.41	26.36	Positive	Confirmed Case	
327	ZJFY164	Female	23	Sputum	Novel coronavirus RNA assay	N/A	N/A	33.33	28.83	Negative	3/3/20	NA	NA	23.37	Negative	Ruled-out Case	
328	ZJFY165	Female	24	Sputum	contracting the novel coronavirus.	N/A	N/A	24.66	30.83	Negative	3/3/20	NA (37.22)	36.11 (37.44)	31.80 (3.1.67)	Retest (Positive)	Confirmed Case	Retest
329	ZJFY166	Female	36	Sputum	Novel coronavirus RNA assay	N/A	N/A	37.33	37.66	Negative	3/3/20	NA	NA	23.49	Negative	Ruled-out Case	
330	ZJFY167	Male	37	Sputum	Fever	N/A	N/A	19.00	15.33	Negative	3/3/20	NA	NA	24.00	Negative	Ruled-out Case	
331	ZJFY168	Male	29	Sputum	Fever	N/A	N/A	31.33	30.50	Negative	3/3/20	NA	NA	29.81	Negative	Ruled-out Case	
332	ZJFY169	Male	30	Sputum	contracting the novel coronavirus.	9.50	9.00	N/A	N/A	Positive	3/3/20	NA (34.47)	35.72 (36.27)	31.09 (2.8.00)	Retest (Positive)	Confirmed Case	Retest
333	ZJFY170	Male	90	Sputum	contracting the novel coronavirus.	7.16	5.83	N/A	N/A	Positive	3/3/20	28.42	29.36	28.24	Positive	Confirmed Case	
334	ZJFY171	Male	49	Sputum	Fever	N/A	N/A	14.66	30.50	Negative	3/3/20	NA	NA	27.83	Negative	Ruled-out Case	
335	ZJFY172	Male	72	Sputum	contracting the novel coronavirus.	12.16	11.16	N/A	N/A	Positive	3/3/20	18.81	19.24	30.05	Positive	Confirmed Case	
336	ZJFY173	Male	60	Sputum	contracting the novel coronavirus.	9.83	10.33	N/A	N/A	Positive	3/3/20	26.99	28.48	23.27	Positive	Confirmed Case	
337	ZJFY174	Male	62	Sputum	Fever	N/A	N/A	29.33	34.50	Negative	3/3/20	NA	NA	30.39	Negative	Ruled-out Case	
338	ZJFY175	Female	30	Sputum	Lung infection	N/A	N/A	28.83	26.66	Negative	3/3/20	NA	NA	20.61	Negative	Ruled-out Case	
339	ZJFY176	Male	54	Sputum	Novel coronavirus RNA assay	N/A	N/A	30.33	31.33	Negative	3/3/20	NA	NA	24.88	Negative	Ruled-out Case	
340	ZJFY177	Male	29	Sputum	Novel coronavirus RNA assay	20.83	23.16	N/A	N/A	Positive	6/3/20	25.14	26.56	32.35	Positive	Confirmed Case	核酸PositiveConfirmed Case剩余样本 (前期核酸Negative)
341	ZJFY178	Female	38	Sputum	Novel coronavirus RNA assay	N/A	N/A	27.83	23.16	Negative	6/3/20	NA	NA	21.71	Negative	Ruled-out Case	前期核酸Negative剩余样本 (后期核酸PositiveConfirmed Case)
342	WZFY001	Male	67	Oropharyngeal swab	Lung infection	7.00	7.00	N/A	N/A	Positive	28/2/20	NA (NA)	33.97 (37.00)	30.55 (2.6.04)	Retest (NA)	Confirmed Case	Retest
343	WZFY029	Male	67	Oropharyngeal swab	Lung infection	9.33	9.33	26.83	32.66	Positive	28/2/20	37.00	36.89	29.10	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
344	WZFY072	Male	67	Oropharyngeal swab	Lung infection	N/A	N/A	32.16	39.83	Negative	1/3/20	NA	NA	29.29	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
345	WZFY105	Male	67	Oropharyngeal swab	Lung infection	N/A	N/A	29.66	24.83	Negative	2/3/20	NA	NA	30.62	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
346	WZFY002	Female	67	Oropharyngeal swab	contracting the novel coronavirus.	7.83	7.16	N/A	N/A	Positive	28/2/20	31.26	31.40	27.13	Positive	Confirmed Case	
347	WZFY020	Female	67	Oropharyngeal swab	contracting the novel coronavirus.	9.16	10.66	25.50	N/A	Positive	28/2/20	28.29	28.97	28.29	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
348	WZFY003	Male	18	Oropharyngeal swab	Lung infection	8.66	9.66	N/A	N/A	Positive	28/2/20	34.28	34.52	30.57	Positive	Confirmed Case	
349	WZFY021	Male	18	Oropharyngeal swab	Lung infection	9.83	6.50	N/A	N/A	Positive	28/2/20	34.09	36.50	34.09	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
350	WZFY030	Male	18	Oropharyngeal swab	Lung infection	11.50	7.50	N/A	N/A	Positive	28/2/20	NA	36.70	28.22	Negative	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
351	WZFY035	Male	18	Oropharyngeal swab	Lung infection	N/A	N/A	27.50	24.66	Negative	29/2/20	NA	NA	30.56	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
352	WZFY068	Male	18	Oropharyngeal swab	Lung infection	N/A	N/A	28.16	26.83	Negative	1/3/20	NA	NA	30.03	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
353	WZFY004	Female	73	Oropharyngeal swab	Lung infection	9.16	13.83	N/A	30.50	Positive	28/2/20	NA (NA)	35.43 (37.61)	28.39 (2.8.66)	Retest (Negative)	Confirmed Case	Retest

354	WZFY005	Male	72	Oropharyngeal swab	Lung infection	9.00	10.83	32.16	N/A	Positive	28/2/20	NA (NA)	36.10 (35.01)	28.76 (34.96)	Retest (Negative)	Confirmed Case	Retest
355	WZFY032	Male	72	Oropharyngeal swab	Lung infection	11.83	9.16	N/A	N/A	Positive	28/2/20	31.32	32.00	28.11	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
356	WZFY060	Male	72	Oropharyngeal swab	Lung infection	9.50	10.33	36.16	26.00	Positive	1/3/20	30.60	31.72	27.52	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
357	WZFY086	Male	72	Oropharyngeal swab	contracting the novel coronavirus.	8.83	8.66	N/A	N/A	Positive	1/3/20	28.39	28.35	28.88	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
358	WZFY006	Male	50	Oropharyngeal swab	contracting the novel coronavirus.	17.60	16.33	N/A	N/A	Positive	28/2/20	37.76	37.82	31.90	Positive	Confirmed Case	
359	WZFY018	Male	50	Oropharyngeal swab	contracting the novel coronavirus.	15.33	7.00	N/A	22.66	Positive	28/2/20	33.91	35.07	31.36	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
360	WZFY007	Female	60	Oropharyngeal swab	Lung infection	23.33	26.33	N/A	N/A	Positive	28/2/20	30.21	30.79	29.57	Positive	Confirmed Case	
361	WZFY008	Male	76	Oropharyngeal swab	Lung infection	8.66	9.66	N/A	N/A	Positive	28/2/20	28.24	30.92	27.08	Positive	Confirmed Case	
362	WZFY009	Female	60	Oropharyngeal swab	contracting the novel coronavirus.	12.66	13.00	N/A	N/A	Positive	28/2/20	NA (NA)	38.59 (37.97)	27.53 (28.47)	Negative	Confirmed Case	Retest
363	WZFY010	Male	35	Oropharyngeal swab	Lung infection	9.66	10.50	25.83	N/A	Positive	28/2/20	36.16	37.86	28.61	Positive	Confirmed Case	
364	WZFY011	Male	69	Oropharyngeal swab	Lung infection	8.83	9.16	N/A	N/A	Positive	28/2/20	31.18	30.96	26.57	Positive	Confirmed Case	
365	WZFY016	Male	69	Oropharyngeal swab	Lung infection	13.33	9.83	N/A	N/A	Positive	28/2/20	35.18	37.45	31.10	Positive	Confirmed Case	Reject, duplicate cases
366	WZFY031	Male	69	Oropharyngeal swab	Lung infection	10.00	11.83	24.00	27.83	Positive	28/2/20	37.24	33.60	25.26	Positive	Confirmed Case	Reject, duplicate cases
367	WZFY075	Male	69	Oropharyngeal swab	Lung infection	N/A	N/A	16.33	14.50	Negative	1/3/20	NA	NA	28.70	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
368	WZFY106	Male	69	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	14.83	29.66	Negative	2/3/20	NA	NA	28.20	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
369	WZFY012	Male	39	Oropharyngeal swab	Lung infection	6.33	6.33	25.00	N/A	Positive	28/2/20	21.11	22.45	27.65	Positive	Confirmed Case	
370	WZFY014	Male	39	Oropharyngeal swab	Lung infection	7.50	7.66	27.83	N/A	Positive	28/2/20	27.17	29.07	34.51	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
371	WZFY025	Male	39	Oropharyngeal swab	Lung infection	9.16	10.33	26.66	N/A	Positive	28/2/20	27.39	27.90	32.43	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
372	WZFY033	Male	39	Oropharyngeal swab	Lung infection	12.33	9.00	N/A	N/A	Positive	28/2/20	NA	34.75	30.20	Negative	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
373	WZFY069	Male	39	Oropharyngeal swab	Lung infection	N/A	N/A	26.83	24.50	Negative	1/3/20	NA	NA	27.95	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
374	WZFY104	Male	39	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	27.66	25.66	Negative	2/3/20	NA	NA	27.37	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
375	WZFY013	Male	93	Oropharyngeal swab	Lung infection	9.33	8.33	N/A	22.16	Positive	28/2/20	26.47	26.69	24.90	Positive	Confirmed Case	

376	WZFY022	Male	93	Oropharyngeal swab	Lung infection	9.83	8.83	N/A	N/A	Positive	28/2/20	28.64	28.64	30.40	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
377	WZFY024	Male	93	Oropharyngeal swab	Lung infection	9.51	14.00	N/A	N/A	Positive	28/2/20	30.06	30.46	28.46	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
378	WZFY028	Male	93	Oropharyngeal swab	Lung infection	7.83	8.33	N/A	34.83	Positive	28/2/20	32.94	32.81	28.30	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
379	WZFY097	Male	93	Oropharyngeal swab	Lung infection	N/A	N/A	27.83	30.16	Negative	2/3/20	NA	NA	30.43	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
380	WZFY015	Female	82	Oropharyngeal swab	Lung infection	12.50	10.16	N/A	N/A	Positive	28/2/20	30.61	32.23	27.77	Positive	Confirmed Case	
381	WZFY026	Female	82	Oropharyngeal swab	Lung infection	9.16	11.00	N/A	N/A	Positive	28/2/20	35.93	35.31	28.87	Positive	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
382	WZFY017	Male	53	Oropharyngeal swab	Lung infection	12.16	12.00	N/A	N/A	Positive	28/2/20	36.64	33.88	26.84	Positive	Confirmed Case	
383	WZFY023	Male	53	Oropharyngeal swab	Lung infection	10.33	13.66	N/A	N/A	Positive	28/2/20	NA	37.43	28.47	Negative	Confirmed Case	Repeated enrollment,repeatedly sampled in different days
384	WZFY019	Male	56	Oropharyngeal swab	contracting the novel coronavirus.	15.50	17.16	36.00	N/A	Positive	28/2/20	34.93	37.56	33.18	Positive	Confirmed Case	
385	WZFY076	Male	56	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	24.33	15.16	Negative	1/3/20	NA	NA	35.08	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
386	WZFY027	/	/	Oropharyngeal swab	Lung infection	13.83	21.16	31.50	N/A	Positive	28/2/20	/	/	/	/	Confirmed Case	Ruled-out Case, 无结果也无溯源信息
387	WZFY034	Male	81	Oropharyngeal swab	Community-acquired pneumonia, Severe	N/A	N/A	28.83	31.16	Negative	29/2/20	NA	NA	30.92	Negative	Ruled-out Case	
388	WZFY073	Male	81	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	26.00	21.16	Negative	1/3/20	NA	NA	32.05	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
389	WZFY036	Female	60	Oropharyngeal swab	Respiratory infection,Fever	N/A	N/A	28.16	31.83	Negative	29/2/20	NA	NA	28.85	Negative	Ruled-out Case	
390	WZFY037	Male	39	Oropharyngeal swab	Lung infection	N/A	N/A	19.83	21.16	Negative	29/2/20	NA	NA	32.48	Negative	Ruled-out Case	
391	WZFY038	Female	74	Oropharyngeal swab	Respiratory failure,Schizophrenia,Lung infection	N/A	N/A	27.50	24.33	Negative	29/2/20	NA	NA	28.33	Negative	Ruled-out Case	
392	WZFY050	Female	74	Oropharyngeal swab	Lung infection,Respiratory failure,Schizophrenia, hypertension	N/A	N/A	30.66	26.00	Negative	29/2/20	NA	NA	28.35	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
393	WZFY039	Male	56	Oropharyngeal swab	Myelodysplastic syndrome(?)Lung infection	N/A	N/A	25.00	26.16	Negative	29/2/20	NA	NA	37.90	Negative	Ruled-out Case	
394	WZFY049	Male	56	Oropharyngeal swab	Myelodysplastic syndrome(?)Lung infection	N/A	N/A	23.50	20.83	Negative	29/2/20	NA	NA	31.52	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
395	WZFY040	Male	26	Oropharyngeal swab	pneumonia	N/A	N/A	20.33	28.00	Negative	29/2/20	NA	NA	30.40	Negative	Ruled-out Case	
396	WZFY041	Female	62	Oropharyngeal swab	Fever	N/A	N/A	25.00	19.00	Negative	29/2/20	NA	NA	26.82	Negative	Ruled-out Case	
397	WZFY066	Female	62	Oropharyngeal swab	Fever,Skin infections(?)	N/A	N/A	23.33	30.83	Negative	1/3/20	NA	NA	27.46	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days

398	WZFY042	Male	71	Oropharyngeal swab	Lung infection,Cerebral infarction	N/A	N/A	28.16	26.83	Negative	29/2/20	NA	NA	27.61	Negative	Ruled-out Case	
399	WZFY063	Male	71	Oropharyngeal swab	Cerebral infarction,Lung infection	N/A	N/A	25.00	33.00	Negative	1/3/20	NA	NA	28.33	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
400	WZFY043	Female	29	Oropharyngeal swab	Fever,Confirm pregnancy	N/A	N/A	30.50	30.83	Negative	29/2/20	NA	NA	29.98	Negative	Ruled-out Case	
401	WZFY044	Male	70	Oropharyngeal swab	Lung infection(?),Esophageal malignancy (postoperative), secondary to colon	N/A	N/A	18.50	21.66	Negative	29/2/20	NA	NA	28.94	Negative	Ruled-out Case	
402	WZFY045	Male	47	Oropharyngeal swab	Lung shadow(?),Kidney transplant	N/A	N/A	21.33	9.33	Negative	29/2/20	NA	NA	26.34	Negative	Ruled-out Case	
403	WZFY046	Female	53	Oropharyngeal swab	Lung infection	N/A	N/A	26.16	22.50	Negative	29/2/20	NA	NA	30.36	Negative	Ruled-out Case	出院
404	WZFY061	Female	53	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	25.66	17.16	Negative	1/3/20	NA	NA	26.96	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
405	WZFY047	Female	31	Oropharyngeal swab	Lung infection	N/A	N/A	28.33	31.16	Negative	29/2/20	NA	NA	30.39	Negative	Ruled-out Case	
406	WZFY048	Male	84	Oropharyngeal swab	Lung infection,Acute coronary syndrome, cardiac insufficiency	N/A	N/A	34.66	22.00	Negative	29/2/20	NA	NA	27.78	Negative	Ruled-out Case	
407	WZFY051	Female	56	Oropharyngeal swab	Lung infection,Optic neuromyelitis (after treatment), pancytopenia	N/A	N/A	27.83	29.00	Negative	29/2/20	NA	NA	30.61	Negative	Ruled-out Case	
408	WZFY052	Female	68	Oropharyngeal swab	Lung infection	N/A	N/A	24.00	19.00	Negative	29/2/20	NA	NA	30.46	Negative	Ruled-out Case	
409	WZFY053	Male	82	Oropharyngeal swab	Lung infection	N/A	N/A	19.16	12.16	Negative	29/2/20	NA	NA	29.35	Negative	Ruled-out Case	
410	WZFY054	Male	49	Oropharyngeal swab	Cough(),Lung infection	N/A	N/A	18.50	15.33	Negative	29/2/20	NA	NA	29.04	Negative	Ruled-out Case	
411	WZFY055	Female	80	Oropharyngeal swab	Chronic obstructive pulmonary disease with acute exacerbation,Lung infection,	N/A	N/A	21.66	22.83	Negative	1/3/20	NA	NA	31.13	Negative	Ruled-out Case	
412	WZFY056	Male	68	Oropharyngeal swab	Lung infection,Acute coronary syndrome (?), Cardiac insufficiency	N/A	N/A	23.83	23.66	Negative	1/3/20	NA	NA	29.61	Negative	Ruled-out Case	
413	WZFY096	Male	68	Oropharyngeal swab	Cardiac insufficiency, acute coronary syndrome(?),Lung infection	N/A	N/A	25.33	26.33	Negative	2/3/20	NA	NA	31.02	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
414	WZFY057	Male	56	Oropharyngeal swab	Fever,Cough,Malignant tumor of trachea,Difficulty breathing	N/A	N/A	33.16	28.00	Negative	1/3/20	NA	NA	32.58	Negative	Ruled-out Case	
415	WZFY058	Female	32	Oropharyngeal swab	Lung infection	N/A	N/A	15.00	11.00	Negative	1/3/20	NA	NA	29.35	Negative	Ruled-out Case	
416	WZFY059	Female	56	Oropharyngeal swab	Cough	N/A	N/A	16.16	13.16	Negative	1/3/20	NA	NA	30.92	Negative	Ruled-out Case	
417	WZFY062	Female	64	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	19.83	21.16	Negative	1/3/20	NA	NA	29.52	Negative	Ruled-out Case	
418	WZFY064	Male	33	Oropharyngeal swab	Lung infection(?)	N/A	N/A	23.33	30.83	Negative	1/3/20	NA	NA	29.52	Negative	Ruled-out Case	

419	WZFY065	Female	25	Oropharyngeal swab	Fever,diarrhea	N/A	N/A	23.83	24.33	Negative	1/3/20	NA	NA	29.00	Negative	Ruled-out Case	
420	WZFY067	Male	30	Oropharyngeal swab	Fever(To be investigated),Lung infection	N/A	N/A	31.33	29.16	Negative	1/3/20	NA	NA	28.38	Negative	Ruled-out Case	
421	WZFY070	Female	70	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	20.00	18.83	Negative	1/3/20	NA	NA	31.61	Negative	Ruled-out Case	
422	WZFY071	Female	74	Oropharyngeal swab	Lung infection	N/A	N/A	28.00	24.16	Negative	1/3/20	NA	NA	29.45	Negative	Ruled-out Case	
423	WZFY074	Female	61	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	24.83	22.50	Negative	1/3/20	NA	NA	33.29	Negative	Ruled-out Case	
424	WZFY077	Male	72	Oropharyngeal swab	contracting the novel coronavirus.	N/A	N/A	26.66	32.83	Negative	1/3/20	NA	NA	28.35	Negative	Ruled-out Case	
425	WZFY078	Male	70	Oropharyngeal swab	Lung infection	N/A	N/A	25.50	26.83	Negative	1/3/20	NA	NA	29.06	Negative	Ruled-out Case	
426	WZFY079	Male	66	Oropharyngeal swab	Chronic renal insufficiency, uremia,Lung infection,Hemodialysis	N/A	N/A	20.33	28.00	Negative	1/3/20	NA	NA	30.66	Negative	Ruled-out Case	
427	WZFY103	Male	66	Oropharyngeal swab	Lung infection,Chronic renal insufficiency, uremia	N/A	N/A	35.83	31.00	Negative	2/3/20	NA	NA	24.62	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
428	WZFY080	Male	80	Oropharyngeal swab	Difficulty breathing(To be investigated), chronic obstructive pulmonary disease with acute exacerbation	N/A	N/A	20.00	18.00	Negative	1/3/20	NA	NA	27.71	Negative	Ruled-out Case	
429	WZFY081	Female	35	Oropharyngeal swab	Fever	N/A	N/A	28.50	39.16	Negative	1/3/20	NA	NA	28.52	Negative	Ruled-out Case	
430	WZFY082	Male	26	Oropharyngeal swab	Lung infection	N/A	N/A	24.00	25.83	Negative	1/3/20	NA	NA	32.71	Negative	Ruled-out Case	
431	WZFY083	Male	50	Oropharyngeal swab	Lung infection(治疗后)	N/A	N/A	35.66	32.66	Negative	1/3/20	NA	NA	25.84	Negative	Ruled-out Case	
432	WZFY084	Female	50	Oropharyngeal swab	contracting the novel coronavirus.(Retest)	N/A	N/A	38.83	34.16	Negative	1/3/20	NA	NA	26.80	Negative	Ruled-out Case	
433	WZFY085	Male	67	Oropharyngeal swab	间质性肺病(?)，烟草依赖综合征	N/A	N/A	31.16	28.00	Negative	1/3/20	NA	NA	26.99	Negative	Ruled-out Case	
434	WZFY087	Male	32	Oropharyngeal swab	Lung infection	N/A	N/A	21.66	22.00	Negative	2/3/20	NA	NA	28.46	Negative	Ruled-out Case	
435	WZFY088	Female	53	Oropharyngeal swab	Fever,Food poisoning(?)	N/A	N/A	18.66	26.50	Negative	2/3/20	NA	NA	29.74	Negative	Ruled-out Case	
436	WZFY089	Male	68	Oropharyngeal swab	pneumonia	N/A	N/A	26.83	27.00	Negative	2/3/20	NA	NA	27.28	Negative	Ruled-out Case	
437	WZFY090	Male	84	Oropharyngeal swab	pneumonia	N/A	N/A	36.66	33.83	Negative	2/3/20	NA	NA	28.20	Negative	Ruled-out Case	
438	WZFY091	Female	50	Oropharyngeal swab	Fever,Sore throat	N/A	N/A	34.33	28.16	Negative	2/3/20	NA	NA	28.60	Negative	Ruled-out Case	
439	WZFY092	Male	82	Oropharyngeal swab	Lung infection,Respiratory failure	N/A	N/A	30.50	30.83	Negative	2/3/20	NA	NA	29.37	Negative	Ruled-out Case	

440	WZFY112	Male	82	Oropharyngeal swab	Lung infection,Respiratory failure	N/A	N/A	31.16	31.83	Negative	2/3/20	NA	NA	35.64	Negative	Ruled-out Case	Repeated enrollment,repeatedly sampled in different days
441	WZFY093	Male	56	Oropharyngeal swab	Difficulty breathing,Personal history of esophageal malignancy (after chemotherapy)	N/A	N/A	27.66	23.83	Negative	2/3/20	NA	NA	32.01	Negative	Ruled-out Case	
442	WZFY094	Female	56	Oropharyngeal swab	Cough	N/A	N/A	19.00	25.83	Negative	2/3/20	NA	NA	32.08	Negative	Ruled-out Case	
443	WZFY095	Female	28	Oropharyngeal swab	Fever	N/A	N/A	26.33	31.16	Negative	2/3/20	NA	NA	31.46	Negative	Ruled-out Case	
444	WZFY098	Male	55	Oropharyngeal swab	Acute respiratory distress syndrome	N/A	N/A	20.33	19.66	Negative	2/3/20	NA	NA	29.58	Negative	Ruled-out Case	
445	WZFY099	Female	83	Oropharyngeal swab	Pulmonary embolism,Lung infection	N/A	N/A	24.50	26.50	Negative	2/3/20	NA	NA	30.51	Negative	Ruled-out Case	
446	WZFY100	Male	39	Oropharyngeal swab	Lung infection	N/A	N/A	18.00	18.16	Negative	2/3/20	NA	NA	28.11	Negative	Ruled-out Case	
447	WZFY101	Male	47	Oropharyngeal swab	Lung shadow	N/A	N/A	18.00	17.00	Negative	2/3/20	NA	NA	27.86	Negative	Ruled-out Case	
448	WZFY102	Male	17天	Oropharyngeal swab	Respiratory infection	N/A	N/A	15.00	14.66	Negative	2/3/20	NA	NA	30.63	Negative	Ruled-out Case	
449	WZFY107	Male	49	Oropharyngeal swab	contracting the novel coronavirus	N/A	N/A	31.16	19.16	Negative	2/3/20	NA	NA	26.95	Negative	Ruled-out Case	
450	WZFY108	Male	64	Oropharyngeal swab	Lung infection,Thrombocytopenia, chronic lymphocytic leukemia	N/A	N/A	24.50	26.33	Negative	2/3/20	NA	NA	31.76	Negative	Ruled-out Case	
451	WZFY109	Female	55	Oropharyngeal swab	Fever,lumbago	N/A	N/A	25.00	19.00	Negative	2/3/20	NA	NA	29.37	Negative	Ruled-out Case	
452	WZFY110	Female	50	Oropharyngeal swab	Lung infection	N/A	N/A	36.16	24.00	Negative	2/3/20	NA	NA	26.97	Negative	Confirmed Case	
453	WZFY111	Female	72	Oropharyngeal swab	Difficulty breathing	N/A	N/A	21.33	23.16	Negative	2/3/20	NA	NA	31.14	Negative	Ruled-out Case	
454	WZFY113	Male	69	Oropharyngeal swab	Lung infection	N/A	N/A	20.50	22.16	Negative	2/3/20	NA	NA	30.04	Negative	Ruled-out Case	
455	WZFY114	Male	65	Oropharyngeal swab	Lung infection(?)	N/A	N/A	21.83	24.33	Negative	3/3/20	NA	NA	27.41	Negative	Ruled-out Case	
456	WZFY115	Female	60	Oropharyngeal swab	Lung infection(?)	N/A	N/A	28.00	17.33	Negative	3/3/20	NA	NA	28.29	Negative	Ruled-out Case	
457	WZFY116	Female	52	Oropharyngeal swab	Lung infection(Retest)	N/A	N/A	26.83	22.00	Negative	3/3/20	NA	NA	31.45	Negative	Ruled-out Case	
458	WZFY117	Female	47	Oropharyngeal swab	Lung infection(治疗后)	N/A	N/A	31.33	27.33	Negative	3/3/20	NA	NA	32.24	Negative	Ruled-out Case	
459	WZFY118	Male	62	Oropharyngeal swab	Lung infection(Retest)	N/A	N/A	26.50	26.83	Negative	3/3/20	NA	NA	30.40	Negative	Ruled-out Case	
460	WZFY119	Female	66	Oropharyngeal swab	Lung infection	N/A	N/A	23.33	26.33	Negative	3/3/20	NA	NA	27.61	Negative	Ruled-out Case	

461	WZFY120	Female	53	Oropharyngeal swab	感染性Fever	N/A	N/A	17.16	19.16	Negative	3/3/20	NA	NA	28.76	Negative	Ruled-out Case	
462	WZFY121	Male	68	Oropharyngeal swab	Lung infection	N/A	N/A	21.66	17.16	Negative	3/3/20	NA	NA	28.07	Negative	Ruled-out Case	
463	WZFY122	Female	74	Oropharyngeal swab	Lung infection	N/A	N/A	26.00	24.00	Negative	3/3/20	NA	NA	33.72	Negative	Ruled-out Case	
464	WZFY123	Female	66	Oropharyngeal swab	Lung infection(Retest)	N/A	N/A	11.83	15.00	Negative	3/3/20	NA	NA	26.38	Negative	Ruled-out Case	
465	ZJK001	Female	40	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	18.33	25.16	Negative	26/2/20	NA	NA	26.2	Negative	Ruled-out Case	
466	ZJK002	Female	31	Sputum	Suspected infection coronavirus	N/A	N/A	19.66	18.33	Negative	26/2/20	NA	NA	25.681	Negative	Ruled-out Case	
467	ZJK003	Female	56	Sputum	Suspected infection coronavirus	N/A	N/A	25	25.83	Negative	26/2/20	NA	NA	26.241	Negative	Ruled-out Case	
468	ZJK004	Female	43	Oropharyngeal swab	Close contacts	N/A	N/A	25	23	Negative	26/2/20	NA	NA	28.323	Negative	Ruled-out Case	
469	ZJK005	Female	26	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	21.33	34.33	Negative	26/2/20	NA	NA	26.163	Negative	Ruled-out Case	
470	ZJK006	Female	24	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	25.33	22.5	Negative	26/2/20	NA	NA	20.855	Negative	Ruled-out Case	
471	ZJK007	Male	29	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	25.66	28	Negative	26/2/20	NA	NA	22.562	Negative	Ruled-out Case	
472	ZJK008	Male	37	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	27.33	23	Negative	26/2/20	NA	NA	24.459	Negative	Ruled-out Case	
473	ZJK009	Male	26	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	24.5	20.83	Negative	26/2/20	NA	NA	26.032	Negative	Ruled-out Case	ZJK009 and ZJK061 are the same patient
474	ZJK010	Male	59	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	21.5	20.33	Negative	26/2/20	NA	NA	25.167	Negative	Ruled-out Case	
475	ZJK011	Female	29	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	21.83	12.33	Negative	26/2/20	NA	NA	22.66	Negative	Ruled-out Case	
476	ZJK012	Female	26	Oropharyngeal swab	Close contacts	N/A	N/A	24.83	28.66	Negative	26/2/20	NA	NA	25.83	Negative	Ruled-out Case	
477	ZJK013	Male	32	Sputum	Close contacts	N/A	N/A	19.5	21	Negative	26/2/20	NA	NA	26.14	Negative	Ruled-out Case	
478	ZJK014	Female	7	Sputum	Suspected infection coronavirus	N/A	N/A	23.66	25	Negative	26/2/20	NA	NA	26.131	Negative	Ruled-out Case	
479	ZJK015	Female	36	Oropharyngeal swab	Close contacts	N/A	N/A	25.5	23.13	Negative	26/2/20	NA	NA	26.564	Negative	Ruled-out Case	
480	ZJK016	Male	27	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	26	19.5	Negative	26/2/20	NA	NA	22.821	Negative	Ruled-out Case	
481	ZJK017	Female	不详	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	25.16	22.83	Negative	26/2/20	NA	NA	25.665	Negative	Ruled-out Case	
482	ZJK018	Female	不详	Sputum	Suspected infection coronavirus	N/A	N/A	33.83	19.33	Negative	26/2/20	NA	NA	25.187	Negative	Ruled-out Case	
483	ZJK019	Female	不详	Sputum	Suspected infection coronavirus	N/A	N/A	21.33	23.66	Negative	26/2/20	NA	NA	22.573	Negative	Ruled-out Case	
484	ZJK020	Female	不详	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	20	20.16	Negative	26/2/20	NA	NA	25.462	Negative	Ruled-out Case	
485	ZJK021	Male	不详	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	27.66	24.33	Negative	26/2/20	NA	NA	29.517	Negative	Ruled-out Case	
486	ZJK022	Male	不详	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	25.16	24	Negative	26/2/20	NA	NA	25.22	Negative	Ruled-out Case	

487	ZJK023	Male	35	Oropharyngeal swab	Close contacts	N/A	N/A	21.33	30.83	Negative	26/2/20	NA	NA	26.187	Negative	Ruled-out Case	
488	ZJK024	Male	48	Sputum	Suspected infection coronavirus	N/A	N/A	26.83	28.5	Negative	26/2/20	NA	NA	26.012	Negative	Ruled-out Case	
489	ZJK025	Male	39	Sputum	Suspected infection coronavirus	N/A	N/A	21.33	21.83	Negative	26/2/20	NA	NA	22.825	Negative	Ruled-out Case	
490	ZJK026	Male	62	Oropharyngeal swab	Close contacts	N/A	N/A	21.5	16.66	Negative	26/2/20	NA	NA	23.322	Negative	Ruled-out Case	
491	ZJK027	Female	33	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	23.16	27.66	Negative	26/2/20	NA	NA	25.842	Negative	Ruled-out Case	
492	ZJK028	Male	59	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	27.83	25.33	Negative	26/2/20	NA	NA	22.736	Negative	Ruled-out Case	
493	ZJK029	Female	48	Sputum	Suspected infection coronavirus	N/A	N/A	19.16	20.5	Negative	26/2/20	NA	NA	28.33	Negative	Ruled-out Case	
494	ZJK030	Female	14	Sputum	Suspected infection coronavirus	N/A	N/A	21.66	23.16	Negative	26/2/20	NA	NA	26.267	Negative	Ruled-out Case	
495	ZJK031	Male	35	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	19.83	21.33	Negative	26/2/20	NA	NA	23.653	Negative	Ruled-out Case	
496	ZJK032	Female	64	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	24.5	20.83	Negative	26/2/20	NA	NA	22.901	Negative	Ruled-out Case	
497	ZJK033	Female	12	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	27	25.66	Negative	26/2/20	NA	NA	25.566	Negative	Ruled-out Case	
498	ZJK034	Male	24	Sputum	Suspected infection coronavirus	N/A	N/A	23.66	18.66	Negative	26/2/20	NA	NA	26.866	Negative	Ruled-out Case	
499	ZJK035	Female	53	Oropharyngeal swab	Close contacts	N/A	N/A	18.16	24.16	Negative	26/2/20	NA	NA	23.748	Negative	Ruled-out Case	
500	ZJK036	Male	29	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	22.33	23	Negative	26/2/20	NA	NA	22.78	Negative	Ruled-out Case	
501	ZJK037	Male	22	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	24.66	24.16	Negative	26/2/20	NA	NA	22.095	Negative	Ruled-out Case	
502	ZJK038	Male	40	Oropharyngeal swab	Close contacts	N/A	N/A	26.16	25.33	Negative	26/2/20	NA	NA	24.185	Negative	Ruled-out Case	
503	ZJK039	Female	23	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	12.83	22.83	Negative	26/2/20	NA	NA	24.893	Negative	Ruled-out Case	
504	ZJK040	Female	54	Sputum	Close contacts	N/A	N/A	18	20.83	Negative	27/2/20	NA	NA	26.195	Negative	Ruled-out Case	
505	ZJK041	Male	36	Sputum	Suspected infection coronavirus	N/A	N/A	23.5	26.33	Negative	27/2/20	NA	NA	27.7	Negative	Ruled-out Case	
506	ZJK042	Female	不详	Sputum	Suspected infection coronavirus	N/A	N/A	25.33	24	Negative	27/2/20	NA	NA	26.64	Negative	Ruled-out Case	
507	ZJK043	Female	28	Sputum	Suspected infection coronavirus	N/A	N/A	25.33	24	Negative	27/2/20	NA	NA	25.816	Negative	Ruled-out Case	
508	ZJK044	Male	8	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	24.33	21.5	Negative	27/2/20	NA	NA	24.84	Negative	Ruled-out Case	
509	ZJK045	Female	40	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	19.33	20.5	Negative	27/2/20	NA	NA	25.879	Negative	Ruled-out Case	
510	ZJK046	Female	28	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	24.33	17.5	Negative	27/2/20	NA	NA	24.032	Negative	Ruled-out Case	
511	ZJK047	Male	24	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	22.16	27.83	Negative	27/2/20	NA	NA	25.7	Negative	Ruled-out Case	
512	ZJK048	Female	25	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	24.16	27.33	Negative	27/2/20	NA	NA	23.481	Negative	Ruled-out Case	
513	ZJK049	Female	54	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	31.5	28.66	Negative	27/2/20	NA	NA	24.523	Negative	Ruled-out Case	
514	ZJK050	Male	27	Sputum	Suspected infection coronavirus	N/A	N/A	23	25.84	Negative	27/2/20	NA	NA	23.99	Negative	Ruled-out Case	
515	ZJK051	Female	41	Sputum	Suspected infection coronavirus	N/A	N/A	16	17	Negative	27/2/20	NA	NA	26.448	Negative	Ruled-out Case	

516	ZJK052	Male	41	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	26.33	28	Negative	27/2/20	NA	NA	26.067	Negative	Ruled-out Case	
517	ZJK053	Male	11	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	20.16	19.83	Negative	27/2/20	NA	NA	24.096	Negative	Ruled-out Case	
518	ZJK054	不详	不详	Sputum	Suspected infection coronavirus	N/A	N/A	17.5	19.83	Negative	27/2/20	NA	NA	22.969	Negative	Ruled-out Case	
519	ZJK055	不详	不详	Sputum	Suspected infection coronavirus	N/A	N/A	21.33	23.16	Negative	27/2/20	NA	NA	26.293	Negative	Ruled-out Case	
520	ZJK056	Female	29	Sputum	Suspected infection coronavirus	N/A	N/A	21.33	24.33	Negative	27/2/20	NA	NA	25.394	Negative	Ruled-out Case	
521	ZJK057	Male	33	Sputum	Suspected infection coronavirus	N/A	N/A	18.83	16.16	Negative	27/2/20	NA	NA	22.015	Negative	Ruled-out Case	
522	ZJK058	Female	27	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	23.16	32.66	Negative	27/2/20	NA	NA	21.673	Negative	Ruled-out Case	
523	ZJK059	Male	25	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	28.16	21.83	Negative	27/2/20	NA	NA	24.164	Negative	Ruled-out Case	
524	ZJK060	Male	58	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	21.16	17.5	Negative	27/2/20	NA	NA	21.54	Negative	Ruled-out Case	
525	ZJK061	Male	26	Sputum	Suspected infection coronavirus	N/A	N/A	20.83	19.16	Negative	27/2/20	NA	NA	25.972	Negative	Ruled-out Case	ZJK061 and ZJK0091 are the same patient
526	ZJK062	Male	21	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	18.16	21.5	Negative	27/2/20	NA	NA	23.972	Negative	Ruled-out Case	
527	ZJK063	Female	26	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	25.83	22.33	Negative	27/2/20	NA	NA	25.402	Negative	Ruled-out Case	
528	ZJK064	Male	32	Sputum	Suspected infection coronavirus	N/A	N/A	22.16	24.83	Negative	27/2/20	NA	NA	22.113	Negative	Ruled-out Case	
529	ZJK065	Male	23	Sputum	Suspected infection coronavirus	N/A	N/A	21.83	24.03	Negative	27/2/20	NA	NA	27.102	Negative	Ruled-out Case	
530	ZJK066	Female	24	Sputum	Suspected infection coronavirus	N/A	N/A	16.33	20.83	Negative	27/2/20	NA	NA	21.052	Negative	Ruled-out Case	
531	ZJK067	Male	26	Sputum	Suspected infection coronavirus	N/A	N/A	18.5	18.16	Negative	27/2/20	NA	NA	25.684	Negative	Ruled-out Case	
532	ZJK068	Male	33	Sputum	Suspected infection coronavirus	N/A	N/A	25.16	19.33	Negative	27/2/20	NA	NA	24.484	Negative	Ruled-out Case	
533	ZJK069	Female	59	Sputum	Suspected infection coronavirus	N/A	N/A	23.33	24.16	Negative	27/2/20	NA	NA	23.772	Negative	Ruled-out Case	
534	ZJK070	Female	52	Sputum	Suspected infection coronavirus	N/A	N/A	17	18.16	Negative	27/2/20	NA	NA	22.882	Negative	Ruled-out Case	
535	ZJK071	Male	61	Sputum	Suspected infection coronavirus	N/A	N/A	29	16.83	Negative	27/2/20	NA	NA	24.005	Negative	Ruled-out Case	
536	ZJK072	Female	4	Sputum	Suspected infection coronavirus	N/A	N/A	16.66	24.83	Negative	27/2/20	NA	NA	28.085	Negative	Ruled-out Case	
537	ZJK073	Male	28	Sputum	Close contacts	N/A	N/A	17.33	22.83	Negative	27/2/20	NA	NA	25.402	Negative	Ruled-out Case	
538	ZJK074	Male	不详	Sputum	Suspected infection coronavirus	N/A	N/A	23.33	24.16	Negative	27/2/20	NA	NA	25.924	Negative	Ruled-out Case	
539	ZJK075	Female	25	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	22.5	24.33	Negative	27/2/20	NA	NA	26.149	Negative	Ruled-out Case	
540	ZJK076	Female	48	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	20.66	21.66	Negative	27/2/20	NA	NA	24.796	Negative	Ruled-out Case	
541	ZJK077	Female	19	Oropharyngeal swab	Suspected infection coronavirus	N/A	N/A	19.33	18.66	Negative	27/2/20	NA	NA	25.373	Negative	Ruled-out Case	
542	ZJK078	Female	24	Sputum	Suspected infection coronavirus	N/A	N/A	21.5	23.66	Negative	27/2/20	NA	NA	24.574	Negative	Ruled-out Case	
543	ZJK079	Female	48	Sputum	Close contacts	N/A	N/A	26.83	28.16	Negative	27/2/20	NA	NA	23.168	Negative	Ruled-out Case	
544	ZJK080	Male	11	Sputum	Suspected infection coronavirus	N/A	N/A	19.83	22.16	Negative	27/2/20	NA	NA	25.45	Negative	Ruled-out Case	
545	ZJK081	Female	68	Sputum	Suspected infection coronavirus	N/A	N/A	26.66	22.00	Negative	27/2/20	NA	NA	21.05	Negative	Ruled-out Case	
546	ZJK082	Male	70	Sputum	Confirmed Case	7.33	10.00	N/A	N/A	Positive	28/2/20	NA	NA	36.20	Negative	Confirmed Case	
547	ZJK083	Female	40	Sputum	Confirmed Case	N/A	N/A	37.66	39.50	Negative	28/2/20	35.80	37.50	35.60	Positive	Confirmed Case	
548	ZJK084	Male	38	Sputum	Confirmed Case	14.83	10.33	N/A	N/A	Positive	28/2/20	26.90	28.40	21.70	Positive	Confirmed Case	
549	ZJK085	Male	41	Sputum	Confirmed Case	8.00	6.83	N/A	34.16	Positive	28/2/20	26.70	27.60	28.80	Positive	Confirmed Case	
550	ZJK086	Female	15	Oropharyngeal swab	Confirmed Case	9.66	8.83	N/A	N/A	Positive	28/2/20	23.40	24.30	28.30	Positive	Confirmed Case	
551	ZJK087	Female	不详	Oropharyngeal swab	Confirmed Case	6.00	8.66	N/A	N/A	Positive	28/2/20	24.30	26.30	25.80	Positive	Confirmed Case	
552	ZJK088	Male	53	Sputum	Confirmed Case	8.00	9.00	N/A	N/A	Positive	28/2/20	25.10	26.30	25.80	Positive	Confirmed Case	
553	ZJK089	Male	51	Sputum	Confirmed Case	12.16	9.00	N/A	N/A	Positive	28/2/20	23.40	24.20	28.80	Positive	Confirmed Case	

554	ZJK090	Female	68	Oropharyngeal swab	Confirmed Case	11.00	10.33	N/A	N/A	Positive	28/2/20	22.80	24.60	11.10	Positive	Confirmed Case	
555	ZJK091	Female	29	Sputum	Confirmed Case	8.33	8.50	N/A	N/A	Positive	28/2/20	24.00	26.00	25.80	Positive	Confirmed Case	
556	ZJK092	Female	65	Sputum	Confirmed Case	7.66	9.16	38.33	N/A	Positive	28/2/20	21.4 (21.69)	22.8 (22.83)	NA (24.45)	Retest (Positive)	Confirmed Case	Retest
557	ZJK093	Female	37	Sputum	Confirmed Case	9.66	12.50	N/A	34.66	Positive	28/2/20	24.00	24.90	32.70	Positive	Confirmed Case	
558	ZJK094	Female	47	Oropharyngeal swab	Confirmed Case	5.50	7.00	26.00	N/A	Positive	28/2/20	22.40	24.30	32.50	Positive	Confirmed Case	
559	ZJK095	Female	47	Sputum	Confirmed Case	7.00	7.66	N/A	N/A	Positive	28/2/20	22.00	23.90	25.00	Positive	Confirmed Case	
560	ZJK096	Female	65	Sputum	Confirmed Case	9.33	9.66	18.66	34.00	Positive	28/2/20	26.70	27.90	29.00	Positive	Confirmed Case	
561	ZJK097	Female	36	Oropharyngeal swab	Confirmed Case	6.00	8.83	33.00	33.83	Positive	28/2/20	25.90	27.70	31.40	Positive	Confirmed Case	
562	ZJK098	Female	不详	Sputum	Confirmed Case	9.83	10.50	34.00	N/A	Positive	28/2/20	23.60	24.40	30.20	Positive	Confirmed Case	
563	ZJK099	Female	35	Sputum	Confirmed Case	11.00	7.83	N/A	39.00	Positive	28/2/20	24.10	25.60	35.10	Positive	Confirmed Case	
564	ZJK100	Male	26	Oropharyngeal swab	Confirmed Case	8.00	12.66	N/A	N/A	Positive	28/2/20	27.70	29.50	13.30	Positive	Confirmed Case	
565	ZJK101	Male	78	Oropharyngeal swab	Confirmed Case	9.83	6.66	21.50	23.50	Positive	28/2/20	26.20	28.40	38.10	Positive	Confirmed Case	
566	ZJK102	Female	不详	Sputum	Confirmed Case	9.00	9.50	34.66	N/A	Positive	28/2/20	24.50	25.80	30.30	Positive	Confirmed Case	
567	ZJK103	Male	28	Sputum	Confirmed Case	10.00	7.83	N/A	N/A	Positive	28/2/20	24.40	26.10	29.00	Positive	Confirmed Case	
568	ZJK104	Female	不详	Sputum	Confirmed Case	16.83	19.33	28.00	29.66	Positive	28/2/20	25.50	26.20	25.80	Positive	Confirmed Case	
569	ZJK105	Female	不详	Sputum	Confirmed Case	12.50	9.83	26.00	N/A	Positive	28/2/20	27.80	28.60	26.20	Positive	Confirmed Case	
570	ZJK106	Male	不详	Sputum	Confirmed Case	16.16	29.50	15.66	24.16	Positive	28/2/20	25.80	26.00	28.00	Positive	Confirmed Case	
571	ZJK107	Female	不详	Sputum	Confirmed Case	10.16	11.83	N/A	N/A	Positive	28/2/20	27.80	27.20	29.00	Positive	Confirmed Case	
572	ZJK108	Male	67	Sputum	Confirmed Case	11.16	10.00	33.50	N/A	Positive	28/2/20	25.00	26.60	28.20	Positive	Confirmed Case	
573	ZJK109	Female	30	Sputum	Confirmed Case	19.83	14.33	N/A	18.16	Positive	28/2/20	26.80	28.40	30.40	Positive	Confirmed Case	
574	ZJK110	Female	66	Sputum	Confirmed Case	26.83	27.50	19.33	18.66	Positive	28/2/20	27.80	29.00	27.60	Positive	Confirmed Case	
575	ZJK111	Male	63	Oropharyngeal swab	Confirmed Case	N/A	N/A	19.16	36.33	Negative	28/2/20	37.3 (35.87)	38.5 (36.6)	NA (30.64)	Retest (Positive)	Confirmed Case	Retest
576	ZJK112	Male	32	Oropharyngeal swab	Confirmed Case	11.50	18.50	N/A	N/A	Positive	28/2/20	26.80	27.80	30.10	Positive	Confirmed Case	
577	ZJK113	Female	30	Oropharyngeal swab	Confirmed Case	19.83	14.33	N/A	N/A	Positive	28/2/20	27.70	28.70	27.10	Positive	Confirmed Case	
578	ZJK114	Female	30	Oropharyngeal swab	Confirmed Case	N/A	N/A	31.16	28.83	Negative	28/2/20	37.40	36.40	32.00	Positive	Confirmed Case	
579	ZJK115	Female	69	Oropharyngeal swab	Confirmed Case	10.33	9.50	18.66	16.16	Positive	28/2/20	27.20	27.30	31.50	Positive	Confirmed Case	
580	ZJK116	Male	#####	Sputum	Confirmed Case	22.50	23.83	20.00	26.00	Positive	43889.00	NA (NA)	37.3 (36.78)	31.5 (30.89)	Retest (Negative)	Confirmed Case	Retest
581	ZJK117	Female	45	Oropharyngeal swab	Confirmed Case	7.16	9.33	N/A	N/A	Positive	28/2/20	26.70	28.50	32.90	Positive	Confirmed Case	
582	ZJK118	Female	58	Oropharyngeal swab	Confirmed Case	9.66	8.33	22.50	36.83	Positive	28/2/20	22.50	29.00	32.60	Positive	Confirmed Case	
583	ZJK119	Male	33	Sputum	Confirmed Case	7.66	7.33	N/A	N/A	Positive	28/2/20	29.30	31.00	36.70	Positive	Confirmed Case	
584	ZJK120	Male	11	Oropharyngeal swab	Confirmed Case	6.83	7.33	N/A	N/A	Positive	28/2/20	29.30	31.40	32.20	Positive	Confirmed Case	
585	ZJK121	Female	37	Oropharyngeal swab	Confirmed Case	8.33	9.16	N/A	N/A	Positive	28/2/20	26.90	29.50	38.30	Positive	Confirmed Case	
586	ZJK122	Female	28	Sputum	Confirmed Case	11.83	8.66	38.66	N/A	Positive	28/2/20	26.80	29.00	29.80	Positive	Confirmed Case	

587	ZJK123	Male	47	Oropharyngeal swab	Confirmed Case	20.33	8.66	N/A	22.50	Positive	28/2/20	28.80	30.20	30.90	Positive	Confirmed Case	
588	ZJK124	Male	65	Sputum	Confirmed Case	10.16	14.16	N/A	N/A	Positive	28/2/20	28.10	29.80	28.60	Positive	Confirmed Case	
589	ZJK125	Female	53	Oropharyngeal swab	Confirmed Case	10.00	13.00	N/A	27.33	Positive	28/2/20	26.80	28.80	32.60	Positive	Confirmed Case	
590	ZJK126	Female	62	Oropharyngeal swab	Confirmed Case	9.83	7.33	N/A	N/A	Positive	28/2/20	28.10	29.80	28.60	Positive	Confirmed Case	
591	ZJK127	Female	49	Oropharyngeal swab	Confirmed Case	8.66	8.66	N/A	N/A	Positive	28/2/20	26.10	27.60	32.90	Positive	Confirmed Case	
592	ZJK128	Female	62	Sputum	Confirmed Case	8.33	8.33	N/A	N/A	Positive	28/2/20	30.60	30.60	30.00	Positive	Confirmed Case	
593	ZJK129	Female	63	Oropharyngeal swab	Confirmed Case	8.16	8.33	26.83	15.33	Positive	28/2/20	29.60	31.10	31.70	Positive	Confirmed Case	
594	ZJK130	Male	23	Sputum	Confirmed Case	11.83	8.33	N/A	25.33	Positive	28/2/20	27.70	29.20	31.90	Positive	Confirmed Case	
595	ZJK131	Male	65	Sputum	Confirmed Case	12.66	6.66	27.33	21.33	Positive	28/2/20	19.80	21.10	28.40	Positive	Confirmed Case	
596	ZJK132	Male	56	Oropharyngeal swab	Confirmed Case	8.50	12.66	28.66	20.83	Positive	28/2/20	26.00	26.80	28.70	Positive	Confirmed Case	
597	ZJK133	Male	49	Sputum	Confirmed Case	7.50	9.50	N/A	N/A	Positive	28/2/20	27.70	28.60	29.70	Positive	Confirmed Case	
598	ZJK134	Female	65	Sputum	Confirmed Case	9.83	11.66	N/A	24.66	Positive	28/2/20	28.00	29.20	27.20	Positive	Confirmed Case	
599	ZJK135	Male	70	Oropharyngeal swab	Confirmed Case	10.00	9.50	N/A	N/A	Positive	28/2/20	28.40	29.80	31.00	Positive	Confirmed Case	
600	ZJK136	Male	66	Sputum	Confirmed Case	8.50	9.33	27.33	N/A	Positive	28/2/20	27.20	29.10	32.20	Positive	Confirmed Case	
601	ZJK137	Female	63	Oropharyngeal swab	Confirmed Case	7.83	8.00	30.50	32.33	Positive	28/2/20	27.50	28.50	29.40	Positive	Confirmed Case	
602	ZJK138	Female	46	Oropharyngeal swab	Confirmed Case	21.66	18.00	N/A	N/A	Positive	28/2/20	22.40	23.50	23.90	Positive	Confirmed Case	
603	ZJK139	Female	10	Oropharyngeal swab	contracting the novel coronavirus.	16.16	11.83	31.66	27.83	Positive	2/3/20	30.90	28.20	28.90	Positive	Confirmed Case	
604	ZJK140	Female	31	Oropharyngeal swab	contracting the novel coronavirus.	13.00	9.16	N/A	35.66	Positive	2/3/20	27.60	26.70	28.00	Positive	Confirmed Case	
605	ZJK141	Female	51	Oropharyngeal swab	contracting the novel coronavirus.	9.83	17.83	N/A	N/A	Positive	2/3/20	28.00	24.90	27.90	Positive	Confirmed Case	
606	ZJK142	Female	33	Oropharyngeal swab	contracting the novel coronavirus.	11.66	10.16	N/A	N/A	Positive	2/3/20	NA (35.95)	36.3 (36.95)	28.9 (31.49)	Retest (Positive)	Confirmed Case	Retest
607	ZJK143	Female	27	Oropharyngeal swab	contracting the novel coronavirus.	7.66	8.00	23.66	29.16	Positive	2/3/20	27.70	27.50	27.90	Positive	Confirmed Case	
608	ZJK144	Male	61	Sputum	contracting the novel coronavirus.	7.66	8.16	33.00	N/A	Positive	2/3/20	26.00	25.30	28.50	Positive	Confirmed Case	
609	ZJK145	Male	7	Oropharyngeal swab	contracting the novel coronavirus.	8.16	8.16	N/A	N/A	Positive	2/3/20	35.20	31.60	28.70	Positive	Confirmed Case	
610	ZJK146	Male	44	Oropharyngeal swab	contracting the novel coronavirus.	6.50	9.83	N/A	29.83	Positive	2/3/20	34.70	33.20	28.50	Positive	Confirmed Case	
611	ZJK147	Male	24	Oropharyngeal swab	contracting the novel coronavirus.	6.66	6.66	14.00	11.66	Positive	2/3/20	31.40	27.40	28.30	Positive	Confirmed Case	
612	ZJK148	Male	35	Oropharyngeal swab	contracting the novel coronavirus.	8.83	7.16	37.16	19.66	Positive	2/3/20	27.60	27.40	28.30	Positive	Confirmed Case	
613	ZJK149	Female	62	Oropharyngeal swab	contracting the novel coronavirus.	9.00	8.00	24.16	22.33	Positive	2/3/20	28.30	25.80	28.20	Positive	Confirmed Case	

614	ZJK150	Male	34	Oropharyngeal swab	contracting the novel coronavirus.	7.00	13.50	N/A	28.16	Positive	2/3/20	NA	NA	28.90	Negative	Confirmed Case	
615	ZJK151	Male	64	Oropharyngeal swab	contracting the novel coronavirus.	14.00	10.00	N/A	N/A	Positive	2/3/20	34.00	32.60	28.60	Positive	Confirmed Case	
616	ZJK152	Female	4	Oropharyngeal swab	contracting the novel coronavirus.	11.33	9.00	N/A	N/A	Positive	2/3/20	33.50	31.90	27.90	Positive	Confirmed Case	
617	ZJK153	Male	19	Oropharyngeal swab	contracting the novel coronavirus.	10.00	8.50	30.83	17.83	Positive	2/3/20	28.70	25.70	28.20	Positive	Confirmed Case	
618	ZJK154	Female	29	Oropharyngeal swab	contracting the novel coronavirus.	7.33	7.33	24.66	18.83	Positive	2/3/20	26.40	25.80	27.90	Positive	Confirmed Case	
619	ZJK155	Male	7	Oropharyngeal swab	contracting the novel coronavirus.	N/A	7.83	22.83	N/A	Positive	2/3/20	35.90	33.30	30.00	Positive	Confirmed Case	
620	ZJK156	Male	34	Oropharyngeal swab	contracting the novel coronavirus.	10.16	11.83	20.00	29.66	Positive	2/3/20	30.40	29.70	28.50	Positive	Confirmed Case	
621	ZJK157	Male	31	Oropharyngeal swab	contracting the novel coronavirus.	9.16	6.66	14.00	15.83	Positive	2/3/20	28.50	27.80	28.50	Positive	Confirmed Case	
622	ZJK158	Male	49	Oropharyngeal swab	contracting the novel coronavirus.	9.00	10.00	13.83	15.33	Positive	2/3/20	24.20	23.20	28.10	Positive	Confirmed Case	
623	ZJK159	Female	36	Oropharyngeal swab	contracting the novel coronavirus.	8.83	9.83	20.83	N/A	Positive	2/3/20	30.30	26.70	28.30	Positive	Confirmed Case	
624	ZJK160	Female	48	Oropharyngeal swab	contracting the novel coronavirus.	12.16	8.16	20.83	21.16	Positive	2/3/20	28.20	26.40	28.50	Positive	Confirmed Case	
625	ZJK161	Male	37	Oropharyngeal swab	contracting the novel coronavirus.	13.16	11.16	N/A	N/A	Positive	2/3/20	29.50	27.30	29.60	Positive	Confirmed Case	
626	ZJK162	Male	51	Oropharyngeal swab	contracting the novel coronavirus.	10.66	10.00	N/A	N/A	Positive	2/3/20	29.40	26.30	28.40	Positive	Confirmed Case	
627	ZJK163	Male	10	Oropharyngeal swab	contracting the novel coronavirus.	11.66	12.00	26.50	N/A	Positive	2/3/20	30.90	28.80	29.20	Positive	Confirmed Case	
628	ZJK164	Male	44	Oropharyngeal swab	contracting the novel coronavirus.	10.66	11.00	23.50	22.83	Positive	2/3/20	27.60	27.70	28.40	Positive	Confirmed Case	Cough
629	ZJK165	Female	39	Sputum	contracting the novel coronavirus.	9.50	9.66	24.66	26.16	Positive	2/3/20	29.80	26.30	29.00	Positive	Confirmed Case	
630	ZJK166	Female	70	Oropharyngeal swab	contracting the novel coronavirus.	10.50	9.00	24.83	27.83	Positive	2/3/20	NA	NA	29.00	Negative	Confirmed Case	

In vitro diagnostic reagent clinical trial report

Product name : Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA
(Isothermal amplification-real time fluorescence assay)

Specifications: 20 tests/box

Clinical trials categories:

- New diagnostic reagents product research
- existing clinical research with varieties approved products
- Products in the clinical research on the alteration application

Version and release date: V1.0, February 13, 2020

Test period: from February to March in 2020

Clinical test units: The First Affiliated Hospital, Zhejiang University School of Medicine (Lead Unit's seal)

Peking Union Medical College Hospital, Chinese academy of medical sciences

The first affiliated hospital of Wenzhou medical University

Zhejiang provincial center for disease control and prevention

Shenzhen Center for disease control and prevention

Clinical trial Lead Unit (signature) :

Statistics analysis unit (seal) : The First Affiliated Hospital, Zhejiang University School of Medicine

Statistical head (signature) :

Registered applicant (seal): Ustar Biotechnology (Hangzhou) Co., Ltd

Contact information (mobile or office phone):

Report date: March 2019

Original data is reserved by the clinical institutions individually.

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Summary of the clinical trial

Summary :

We accepted the clinical evaluation of Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA (Isothermal amplification-real time fluorescence assay) developed by Ustar Biotechnology (Hangzhou) Co. Ltd for the laboratory study, pilot-scale production, quality testing and preclinical study has been completed according to the < Administrative measures for registration of in vitro diagnostic reagents > promulgated by National medical products administration (NMPA).

The evaluation kit using Isothermal amplification-real time fluorescence technology, is suitable for detect the new coronavirus (2019-nCoV) ORF1ab and N gene from the pharynx and sputum samples of new coronavirus infection pneumonia suspected cases, suspected of assembly or other needs of 2019-nCoV diagnosis or differential diagnosis qualitatively in vitro. According to the guiding principle of clinical trials in vitro diagnostic reagent technology request, the total sample size should be not less than 500 cases, and blinded, controlled trial was adopted to design, sample types are pharyngeal swab samples and sputum samples, the 2019-nCoV diagnosis kit of Shanghai BioGerm Medical Biotechnology Co., Ltd was taken as the comparison kit. Both the subject and the comparison kits had been evaluated synchronously. The epidemiological background of the patients, clinical symptoms and disease outcome information fully analyzed if there were inconsistent test results between the both kits. In addition, according to the registration technical review of 2019-nCoV nucleic acid detection reagents(2020,4th), the sample quantity was not less than 500 in total. The pharynx was above 270 in total including above 100 positive cases and 170 negative cases. The total sputum samples were not less than 230 cases including >100 positives and >130 negatives. According to the bid requests, we tested not less than 125 cases, at the same time considering examination and clinical diagnosis reagent test result/exclude the results were compared., and analyzed the test results of subject kit with the clinical diagnosis or elimination results.

In this clinical trial, there were 627 suspected patients with 630 samples enrolled in 5 institutions, of which 0 cases with scheme deviation / violation did not meet the inclusion

criteria or exclusion criteria; 37 cases were repeatedly sampled in different days, belonging to repeated enrollment, and 1 case had operational errors or other errors in the detection process, resulting in results missing, they were eliminated according to the elimination standard and not be included in the statistical analysis. Conclusively, there were 589 qualified cases and 592 samples, including 266 sputum samples and 326 Oropharyngeal swabs samples.

Among 589 qualified cases, 219 were clinically diagnosed as confirmed cases, of which 2 were previously negative; 370 were excluded, of which 1 was released from isolation and qualified for discharge.

Among 589 eligible cases, 277 were male, 310 were female, and 2 were not recorded. The average age is 45.2 years old with the minimum, 0, and the maximum ,93 years old (17 patients' age were not recorded and not included in the statistics).

The accuracy analysis of the tested kit, the comparison kit and the clinical diagnosis / exclusion results are summarized as follows:

(1) Consistency analysis with the comparison Kit: there were 592 samples of qualified cases in this clinical trial, 212 were positive and 380 were negative by the test kit; 198 were positive and 394 were negative by the comparison kit. The results showed that the positive coincidence rate was 98.0%, 95% CI (94.9%, 99.4%); the negative coincidence rate was 95.4%, 95% CI (92.9%, 97.3%); the total coincidence rate was 96.3%, 95% CI (94.4%, 97.7%); the kappa value was 0.918, $P < 0.001$. The consistency between these two kits is good.

(2) Consistency analysis with the clinical diagnosis / exclusion results: 589 cases were qualified in this clinical trial, 211 cases were positive and 378 cases were negative by the test kit; 219 cases were confirmed and 370 cases were excluded by the clinical diagnosis / exclusion results. The results showed that the clinical sensitivity of test kit was 96.3%, 95% CI (92.9%, 98.4%); its clinical specificity was 100%, 95% CI (99.0%, 100%); the total coincidence rate was 98.6%, 95% CI (97.3%, 99.4%); the kappa value was 0.971, $P < 0.001$. The consistency between them is good.

Novel coronavirus novel coronavirus 2019-nCoV nucleic acid detection kit (isothermal

amplification real-time fluorescence method) developed by Hangzhou excellent Biochemical Technology Co., Ltd., which is accurate, stable and reliable, has good consistency with the contrast kit. The negative samples for the early diagnosis of new coronavirus 2019-nCoV negative test are negative. 33.3% of the samples were in accordance with the discharge standard, and the overall consistency with the clinical diagnosis / exclusion results was good.

	s 47F		
Abbreviation: None			
Opinions of the clinical trial management department of the medical institution in charge of the clinical trial:			
Agree!			
(Seal)			
Date: yy-mm-dd			

USTAR

Clinical trial report (text)

1. Introduction

Coronaviruses belong to coronaviridae and coronavirus. Coronavirus is a single plus strand RNA virus with envelope, with a diameter of 80-120nm. Its genetic material is the largest of all RNA viruses, only infecting human, mouse, pig, cat, dog and poultry vertebrates. A variant of coronavirus is the pathogen of SARS, which belongs to RNA virus. The coronavirus was first isolated from chickens in 1937. The diameter of the virus particles is 60-200nm, and the average diameter is 100nm. It is spherical or elliptical and has polymorphosis. The whole virus is like the corona, and the spines of different coronaviruses are obviously different. Sometimes tubular inclusions can be seen in the cells infected with coronavirus.

In December 2019, pneumonia of unknown cause was found in Wuhan. In January 2020, the novel coronavirus 2019-nCoV^[1] was initially identified by the group of experts.

According to the World Health Organization (WHO)^[2], the incubation period of the disease is about 10 days, and there are mild patients. In the early stage, there were significant respiratory diseases, such as acute and severe respiratory diseases, fever, cough, shortness of breath and dyspnea. Some cases were accompanied with renal failure.

No treatment method of 2019-nCoV induced disease is currently available. However, many of the symptoms can be dealt with, so it needs to be treated according to the clinical situation of patients. In addition, supplementary care for infected people may be very effective.

Standard recommendations for reducing exposure and the spread of a range of diseases include maintaining basic hand and respiratory hygiene, adhering to safe eating habits, and, as far as possible, avoiding close contact with anyone who shows symptoms of respiratory disease (such as coughing and sneezing).

At present, 2019-nCoV infection is routinely detected by real-time fluorescence RT-PCR^[3]. Any 2019-nCoV detection must be conducted in laboratory with appropriate conditions by trained personnel with relevant technical safety. Nucleic

acid detection methods novel coronavirus genome is mainly designed with the 1a/b (open reading frame 1ab, ORF1ab) and core shell protein (nucleocapsid protein, N). To confirm a novel coronavirus infection in laboratory, both targets should be reported as positive.

Nucleic acid detection is an approved technology for 2019-nCoV detection, with high specificity, sensitivity and shortened detection time. It is an important means of early diagnosis. .

Products on the market in China: Diagnostic kit for novel-Coronavirus (2019-nCOV) (fluorescent PCR assay) (Shanghai Berger Medical Technology Co., Ltd., No. 20203400065); Diagnostic kit for novel-Coronavirus (2019-nCOV) (fluorescent PCR assay) (Hua Da Biotechnology (Wuhan) Co., Ltd., No. 20203400060); Diagnostic kit for novel-Coronavirus (2019-nCOV) (fluorescent PCR assay) (Shanghai Zhijiang Biotechnology Co., Ltd., No. 20203400057); Diagnostic kit for novel-Coronavirus (2019-nCOV) (fluorescent PCR assay) (Hunan Shengxiang Biotechnology Co., Ltd., No. 20203400064) ,et.

RT-PCR technology is the most widely used molecular diagnostic technology in clinical practice. It has high specificity and requires only one round of reaction. It avoids the scattered pollution of amplified products and can quantify unknown samples, especially in epidemiology and clinical strategies. It has a wide range of uses and effects. The disadvantage is that special PCR laboratories and PCR instruments are required. Generally, only large and medium-sized hospitals have the conditions to carry out this test, and grassroots hospitals do not have the capacity to do so.

Therefore, the development of sensitive, specific, simple, fast and suitable inspection methods for primary medical care and disease prevention and control institutions is expected by the majority of medical workers. Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA (Isothermal amplification-real time fluorescence assay) (hereinafter referred to as the "the tested kit") developed and produced by Ustar Biotechnology (Hangzhou) Co., Ltd has just met this market demand.

Compared with the current products on the market, Hangzhou Ustar

Biotechnology Co, Ltd independently developed the tested kits have the following significant clinical application value:

- (1) Cross Primer Amplification (CPA) with independent innovation and exclusive global intellectual property rights;
- (2) Design of cartridge with independent innovation and global exclusive intellectual property rights: Adopting multi-layer liquid phase movement technology of magnetic beads under the traction of external magnetic body and liquid layering technology under the control of thermally denatured materials (paraffin) The external magnetic is used as a power source to control the thermally denatured material in the kit by heating, so that the liquid phase reagent can pass through the isolation layer and reach the liquid phase regions while maintaining the separated state of the liquid phase reagent. This design enables multiple processing steps of sample lysis, nucleic acid extraction, purification, elution, amplification and detection to occur in the same cartridge, which are performed consecutively in sequence and improves the detection efficiency and avoids sample cross-contamination and amplification products pollution.
- (3) Simple and stable operation: The operator only needs to add samples in one step and then "one-click" completes the entire detection process, which is very convenient for operator, especially at the grassroots level;
- (4) Internal Quality control: Internal control and sample go through the whole process from extraction to detection, which can monitor nucleic acid extraction efficiency, amplification reagent failure, amplification instrument failure or inhibitors in the sample;
- (5) There are no special requirements for the use environment: Because the tested kit is completely closed for testing, there are no special requirements for the use environment of the instrument.

Entrusted by Ustar Biotechnology (Hangzhou) Co., Ltd, We select five of the clinical institution. After completing laboratory research, pilot production, quality inspection, and preclinical research on the tested kits for evaluation of clinical application. The goal is to obtain relevant test data, relevant evaluation and conduct

appropriate statistical analysis through trials, and provide scientific basis for the clinical application value of the kit.

2. Overall design

2.1. Trial Purpose

Compare the clinical performance of Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA (Isothermal amplification-real time fluorescence assay)^[3] with Diagnostic kit for novel-Coronavirus(2019-NCOV) (fluorescent PCR assay) that has been marketed in China and clinical diagnosis / exclusion results. The clinical performance (including sensitivity, specificity, and accuracy) between different sample types was compared to verify the consistency with the comparison kits and clinical diagnosis / exclusion results, and the effectiveness and safety of clinical tests were evaluated.

2.2. Trial Management

The clinical trial is planned to be conducted in three or more clinical trial institutions. According to the characteristics of the clinical trial, a head of institution was set up in the clinical trial, and the head of clinical trial institution coordinated the institutions to conduct clinical trials in accordance with the same clinical trial protocol.

During the entire test, the tested kit and comparison kit should be under effective quality control; the researcher responsible for the test operation should strictly perform the operation in accordance with the instructions and / or operating procedures to ensure the accuracy and repeatability of the test data. The instruments, consumables and reagents, etc. used in the clinical trial should be consistent in each institutions.

In the process of data collection, samples with inconsistent results between the tested kit and the comparison kit should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, and disease outcomes.

The ethics committees of each institutions independently conduct ethical review of clinical trial protocols and data summary tables. During the clinical trial, if ethical

approval documents are modified, and ethical review needs to be re-performed and approve then continue to conduct clinical trials.

The sponsor of the clinical trial is Ustar Biotechnology (Hangzhou) Co., Ltd, which is responsible for providing the required tested kits, supplies, reagents and other related costs required by the clinical trial institute.

2.3. Trial Design

This clinical trial was designed using blind and controlled method.

After the sample is collected, inactivated, and packed, it should be coded. The blinded code is kept by a special person. The tested kit and the comparison kit shall be used for testing respectively. After the test, the blindness is uncovered and the test data is aggregated. The tested kits are compared with the comparison kits and the clinical diagnosis / exclusion results. All inconsistent results in clinical trials should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, and disease outcomes and other information.

2.4. Trial Method

The tested kits and adaptive instruments are provided by Ustar Biotechnology (Hangzhou) Co., Ltd. The sample preservation solution, comparison kit, nucleic acid extraction kit, and adaptive instruments——Real-Time PCR Instrument provided by the corresponding clinical institutions.

2.4.1. Sample preservation solution

Product Name: Virus sampling kit

Specification: 20 tests / box

Registration Certificate No: 京械注准 20182400236

Manufacturer: Youkang Hengye Biotechnology (Beijing) Co., Ltd

Storage conditions/expiration date: Store at 5°C-25°C, expiration date is 12 months. Please refer to the outer box for production date and expiration date

The batch number of reagents: 01200101, 01200205, 01200101, 01191203, 01101202, 01190904, The expiration date of reagents: 2020.12.30, 2021.02.05,

2020.12.30, 2020.12.03, 2020.12.01, 2020.09.03.

2.4.2. The tested kits and adaptive instruments

2.4.2.1. The tested kits

Product name: Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA (Isothermal amplification-real time fluorescence assay)

Specifications: 20 tests/box

Manufacturer: Ustar Biotechnology (Hangzhou) Co., Ltd

Storage conditions/expiration date: Store at 2°C-8°C, expiration date is 6months.

Please refer to the label for production date and expiration date

The batch number of reagents: 20200222, The expiration date of reagents: 20200821.

2.4.2.2. The adaptive instruments with tested kits

Product name: Nucleic acid amplification detection analyzer

Model Specifications: UC0102

Registration Certificate No: 国械注准 20193221026

Manufacturer: Ustar Biotechnology (Hangzhou) Co., Ltd

The number and expiration date of the instrument used in the clinical trial are as follows:

Instrument Number	Expiration date
210218050001A	2023.07.01
210218050003A	2023.07.01
210219070017A	2024.12.19
210218050006A	2023.07.01
210218030004A	2023.03.22
210218050009A	2023.07.06
210218070004A	2023.08.18
210218100002A	2023.11.15
210219070009A	2025.01.30
210219070013A	2025.01.27

210218050008A	2023.07.06
210218030001A	2023.03.13
210218030002A	2023.03.13
210218030006A	2023.04.19
210218080003A	2023.08.09
210218100004A	2023.09.27
210218030003A	2023.03.22
210218050005A	2023.07.06
210218080001A	2023.09.26
210218080002A	2023.09.26
210219070009A	2023.11.15
210218070003A	2023.08.10
210218050010A	2023.07.19
210218050004A	2023.07.01
210218070005A	2023.07.06

2.4.3. The comparison kits and adaptive nucleic acid extraction kits and instruments

2.4.3.1. The comparison kits

Product name: Diagnostic kit for novel-Coronavirus (2019-NCOV) RNA (fluorescent PCR assay)

Specifications: 50 tests/box

Registration Certificate No: 国械注准 20203400065

Manufacturer: Shanghai Berger Medical Technology Co., Ltd.

Storage conditions and expiration date: Store in the dark at -20 ± 5 °C, the expiration date is tentatively set for 6 months. Avoid repeated freezing and thawing 6 times without affecting the detection effect. Production date and expiration date: see outer box.

The batch number of reagents: 20200221A, 20200202A, 20200212A, 20200218A, 20200204A; The expiration date of reagents: 2020.08.20, 20200801,

20200811, 2020.08.17, 2020.08.03。

2.4.3.2. The adaptive nucleic acid extraction kits with comparison kits

Product name: Nucleic acid extraction kits

Specifications: 100 tests/box

Registration Certificate No:沪奉械备 20180202 号

Manufacturer: Shanghai Berger Medical Technology Co., Ltd.

Storage conditions and expiration date: The reagents are transported at room temperature and stored at room temperature. The expiration date is 6 months. The date of production and use period: see the outer box.

The batch number of reagents: 20200125E, The expiration date of reagents: 2021.01.24,

2.4.3.3. The adaptive instruments with comparison kits

Product name: Real-Time PCR Instrument

Specifications: Applied Biosystems™ 7500

Registration Certificate No: 国械注进 20163400767

Manufacturer: Life Technologies Holdings Pte Ltd

2.5. Subject selection

2.5.1. Selection criteria

All the following criteria must be met:

- (1) No restriction on age and gender;
- (2) Cases diagnosed with suspected novel coronavirus infection according to the "Diagnosis and Treatment Program for Pneumonitis of Novel Coronavirus Infection" (trial version 5) issued by the General Office of the National Health and Health Commission; or suspected clustered cases; Other cases where novel coronaviruses need to be identified or cases for release isolation and discharge standards;
- (3) According to the different stages of the " Diagnosis and Treatment Program for Pneumonitis of Novel Coronavirus Infection" issued by the General Office of the National Health and Health Commission, some pre-negative confirmed cases of Novel Coronavirus 2019-nCoV were used for retrospective research.

2.5.2. Exclusion criteria

Excludes criteria as follow:

- (1) The sample has not been collected, inactivated, packing, extracted, stored, tested and determined according to the requirements of the tested kit and the comparison kit;
- (2) Contamination of sample caused by any reason;
- (3) Subject information cannot be traced in the hospital's medical records;

2.5.3. Elimination criteria

Elimination criteria as follow:

- (1) Using products with quality issues;
- (2) Operation errors or other errors occurred during the test, which resulted in the lack of results;

2.6. Sample size and rationale

According to the requirements of the "Technical Guiding Principles for Clinical Tests of In vitro Diagnostic Reagents", the product belongs to the third category of diagnostic products, of which two (two) 1. Clause: "Applicants for third category of in vitro diagnostic reagents shall select no less than three (including 3). Applicants for the second type of in vitro diagnostic reagents should select no less than 2 (including 2) clinical trial institutions to conduct clinical trials in accordance with relevant regulations ", and Article 3 (3) 2.1: " Using nucleic acid amplification Methods In vitro diagnostic reagents for pathogen detection: the total number of clinical trial samples is at least 500. ". According to the notes of the "Technical Review of Registration of Novel Coronavirus Nucleic Acid Detection Reagents for 2019" (No. 4, 2020), the novel coronavirus 2019-nCoV nucleic acid detection reagent is a qualitative product, and the sample size of the clinical trial process should be able to meet clinical evaluation requirements, such as clinical sensitivity, clinical specificity, negative coincidence rate and positive coincidence rate, etc., are recommended to include no less than 200 confirmed cases, exclude cases no less than 300, and at the same time enroll in partially de-isolated and eligible discharge cases. There should be a certain

number of patients with different clinical severity and different stages of disease. If the declared reagent contains different sample types, it is recommended that each sample type be counted separately to meet the statistical requirements.

Refer to the "Guidelines for In vitro Diagnostic Reagents for Clinical Trials (Draft for Comment)" section III (Seven) 2.1 "For the parameter estimation of clinical trials, only the width of the confidence interval of the evaluation index is guaranteed to meet the expected value, and there is no target value, you can use The following formula ", the evaluation indicators of this clinical trial are mainly positive compliance rate and negative compliance rate. Positive compliance rate is used to calculate Positive sample size, and negative compliance rate is used to calculate Negative sample size.

The formula for estimating the Positive / Negative sample size is:

$$n = \frac{Z_{1-\alpha/2}^2 P(1 - P)}{\Delta^2}$$

In the formula, n is the Positive / Negative sample size, $Z_{1-\alpha/2}$ is the quantile of the standard normal distribution, P is the expected value of the positive coincidence rate or negative coincidence rate, and Δ is the allowable error size of P . Generally, P is the half of the width of the 95% confidence interval, commonly used values are 0.05-0.10.

Take $P_{\text{positive coincidence rate}} = 90\%$, $P_{\text{negative coincidence rate}} = 90\%$, $\alpha = 0.05$, $\Delta_{\text{positive coincidence rate}} = 0.05$, $\Delta_{\text{negative coincidence rate}} = 0.05$, and calculate and consult relevant statistical tables to obtain Positive sample size is 139 cases, the sample size of Negative is 139 cases, and the total sample size of clinical trials is 278 cases.

Combining statistical methods and referring to the requirements of the above two guiding principles, it was determined that the total sample size of this clinical trial was not less than 500 cases, and the total number of oropharyngeal swabs samples was not less than 270 cases. Positive oropharyngeal swabs samples were Less than 100 cases, Negative oropharyngeal swabs samples were no less than 170 cases, total sputum samples was not less than 230 cases, of which no less than 100 cases of sputum positive cases and no less than 130 cases of sputum negative cases (see Table 1)), The

allocation number of sample type is shown in Table 2; and it is carried out in three or more clinical trial institutions, and the specific number of distribution cases is determined according to the case collection capacity of each clinical trial institution.

Table 1 Clinical trial sample size

Sample Types Clinical diagnosis	oropharyngeal swabs	sputum
Confirmed Cases	≥ 100	≥ 100
Excluded Cases	≥ 170	≥ 130

2.7. Research Sample

2.7.1. Sample types

Remaining oropharyngeal swabs and sputum samples collected during the clinical diagnosis and treatment of the subjects.

2.7.2. Collection, inactivation, packing, extraction, storage, detection and result determination of samples ^[4]

After the subjects are selected, the researcher should complete the collection, packing, extraction, storage, testing and result determination as soon as possible. The specific requirements are shown in the table below:

Table 2. Methods for collection, inactivation, packing, extraction, storage, detection and result determination of oropharyngeal swabs samples

	01 tube	02 tube																									
Application	For the tested kits	For the comparison kits																									
Sample collection and inactivation	Gently wipe the bilateral pharyngeal tonsils and the posterior pharyngeal wall simultaneously with two plastic rod swabs of polypropylene fiber head, immerse the swab head in a tube containing 3ml of sampling solution, discard the tail, and tighten the tube cap tightly. After sampling, the sample was placed in a 56 ° C water bath for 30 minutes to inactivate. After inactivation, the sampling solution was dispensed.																										
Sample packing	Take 500µL of swab sampling solution into 1.5mL centrifuge tube.	Take at least 200µL of swab sampling solution into 1.5 mL centrifuge tube.																									
Sample extraction	Implementation according to the product instructions respectively.	Implementation according to the product instructions respectively.																									
Sample storage	Implementation according to the product instructions respectively.																										
Sample detection and result determination	When ORF1ab and / or N genes were positive, novel coronavirus (2019-nCoV) RNA was detected in the samples. The test result is "positive"; When ORF1ab and N genes were negative and ICl or ICr were positive, no novel coronavirus (2019-nCoV) RNA was detected in the samples. The test result is "negative"; When ICl and ICr are negative, no human GAPDH mRNA is detected in the sample, and it is uncertain whether there is novel coronavirus (2019-nCoV) RNA in the sample or not. The test result is "invalid"; When the detection system does not	<table border="1"> <thead> <tr> <th colspan="3">Test Chanel</th> <th rowspan="2">Results</th> </tr> <tr> <th>FAM Chanel</th> <th>HEX/VIC Chanel</th> <th>ROX Chanel</th> </tr> </thead> <tbody> <tr> <td>Ct Value≤38</td> <td>Ct Value≤38</td> <td>Ct Value≤38</td> <td>Positive</td> </tr> <tr> <td>No Ct Value or Ct Value>38</td> <td>No Ct Value or Ct Value>38</td> <td>Ct Value≤38</td> <td>Negative</td> </tr> <tr> <td>No Ct Value or Ct Value>38</td> <td>Ct Value≤38</td> <td>Ct Value≤38</td> <td rowspan="3">Retest*</td> </tr> <tr> <td>Ct Value≤38</td> <td>No Ct Value or Ct Value>38</td> <td>Ct Value≤38</td> </tr> </tbody> </table>			Test Chanel			Results	FAM Chanel	HEX/VIC Chanel	ROX Chanel	Ct Value≤38	Ct Value≤38	Ct Value≤38	Positive	No Ct Value or Ct Value>38	No Ct Value or Ct Value>38	Ct Value≤38	Negative	No Ct Value or Ct Value>38	Ct Value≤38	Ct Value≤38	Retest*	Ct Value≤38	No Ct Value or Ct Value>38	Ct Value≤38	Retest*
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	collect enough data. Report "No Results"	
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Table 3. Methods for collect, inactivation, packing, extraction, storage, detection and result determination of sputum samples

	01 tube	02 tube																								
Application	For the tested kits	For the comparison kits																								
Sample collection and inactivation	After the patient is asked to have a deep cough, collect the coughed sputum in a screw mouth plastic tube containing 3ml of sampling solution, and screw the tube cap tightly. Add an equal volume of proteinase K buffer (0.4mg / mL) to the sputum sample, shake for 15s, and place the sample in a 56 ° C water bath for 30 minutes to inactivate. After inactivation, the sampling solution is divided into aliquots.																									
Sample packing	Take 200µL of swab sampling solution into 1.5mL centrifuge tube.	Take at least 200µL of swab sampling solution into 1.5 mL centrifuge tube.																								
Sample extraction	Implementation according to the product instructions respectively.	Implementation according to the product instructions respectively.																								
Sample storage	Implementation according to the product instructions respectively.																									
Sample detection and result determination	When ORF1ab and / or N genes were positive, novel coronavirus (2019-nCoV) RNA was detected in the samples. The test result is "positive"; When ORF1ab and N genes were negative and ICl or ICr were positive, no novel coronavirus (2019-nCoV) RNA was detected in the samples. The test result is "negative"; When ICl and ICr are negative, no human GAPDH mRNA is detected in the sample, and it is uncertain whether there is novel coronavirus (2019-nCoV) RNA in the sample or not. The test result is "invalid";	<table border="1"> <thead> <tr> <th colspan="3">Test Chanel</th> <th rowspan="2">Results</th> </tr> <tr> <th>FAM Chanel</th> <th>HEX/VIC Chanel</th> <th>ROX Chanel</th> </tr> </thead> <tbody> <tr> <td>Ct Value≤38</td> <td>Ct Value≤38</td> <td>Ct Value≤38</td> <td>Positive</td> </tr> <tr> <td>Undetermined or Ct Value>38</td> <td>Undetermined or Ct Value>38</td> <td>Ct Value≤38</td> <td>Negative</td> </tr> <tr> <td>Undetermined or Ct Value>38</td> <td>Ct Value≤38</td> <td>Ct Value≤38</td> <td rowspan="2">Retest*</td> </tr> <tr> <td>Ct Value≤38</td> <td>Undetermined or Ct Value>38</td> <td>Ct Value≤38</td> </tr> </tbody> </table>			Test Chanel			Results	FAM Chanel	HEX/VIC Chanel	ROX Chanel	Ct Value≤38	Ct Value≤38	Ct Value≤38	Positive	Undetermined or Ct Value>38	Undetermined or Ct Value>38	Ct Value≤38	Negative	Undetermined or Ct Value>38	Ct Value≤38	Ct Value≤38	Retest*	Ct Value≤38	Undetermined or Ct Value>38	Ct Value≤38
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2.7.3. Sample coding and blinding

After the samples are collected, inactivated and repacked, they should be coded. The codes should be kept by a special person and blinded at the same time, then the tested kits and comparison kits should be test respectively. After the test is completed, the blindness will be uncovered and the data will be aggregated. The results of tested kits are compared with the comparison kit and the clinical diagnosis / exclusion results. All inconsistent results in clinical trials should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, and disease outcomes.

3. Clinical evaluation criteria

3.1. Accuracy Evaluation Criteria

(1) Positive coincidence rate refers to the proportion of positive samples detected simultaneously by the tested kits and the comparison kits to the total number of positive samples detected by the comparison kits: $\geq 90\%$;

(2) Negative coincidence rate refers to the proportion of negative samples detected simultaneously by the tested kits and the comparison kits to the total number of negative samples detected by the comparison kits: $\geq 90\%$;

(3) The total coincidence rate refers to the ratio of true positives and true negatives to the total number of samples compared with the comparison kit: $\geq 90\%$. Compared with clinically confirmed/excluded results, the proportion of true positives and true negatives in total samples: $\geq 90\%$.

(4) Clinical sensitivity refers to the proportion of positive samples detected by the tested kit to the total number of clinically confirmed samples: $\geq 90\%$.

(5) Clinical specificity refers to the proportion of negative samples detected by the tested kit to the total number of clinically excluded samples: $\geq 90\%$.

(6) 95% confidence intervals for positive coincidence rates, negative coincidence rates and total coincidence rates.

(7) Kappa value is used to evaluate the consistency of the tested kit and the comparison kit, also known as the coefficient of fit: it is meaningful to judge the consistency between 0 and +1. The larger the Kappa value, the better the consistency. It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved. If the Kappa value is less than 0.4,

the degree of agreement is not satisfactory.

(8) Detection rate: According to the notice of the "Technical Review of Novel Coronavirus Nucleic Acid Detection Reagent Registration Techniques in 2019" (No. 4 of 2020), No. 5, "For confirmed cases of novel coronavirus 2019-nCoV sample test negative, and case samples that are released from isolation and meet discharge standards, should calculate the detection rate of the test reagents for the novel coronavirus 2019-nCoV".

3.2. Reliability Evaluation Criteria

Internal control results: When the result of tested kit is positive, the internal test result of standard is not required; when the test result is negative, the internal control must be positive ($IC\ Tt \leq 40$), otherwise the test result is invalid.

4. Statistical analysis

The statistical analysis of the clinical trial was completed by statisticians. After the data analysis is completed, the clinical trial report output by the report writer.

4.1. Statistical Analysis Software

The analysis of the data set was implemented on genuine SPSS 25.0 statistical analysis software.

4.2. Statistical Analysis of Population

4.2.1. The definition of case type:

(1) Selected case samples: Case samples that meet the selection criteria and do not meet the exclusion criteria and are included in clinical trials;

(2) Excluded case samples: Selected case samples meet the exclusion criteria;

(3) Scenario Deviation / Violation Cases: Samples of misconduct or other violations of the protocol.

4.2.2. The Statistical Analysis of Data Set

The statistical analysis select clinical data of qualified case samples as the full analysis set. In short, excluding case samples and protocol deviation / violating case samples are not included in statistics.

Full analysis set = sample of selected cases—sample of excluded cases—sample of protocol deviation / violation of cases.

5. Clinical evaluation and statistical methods

5.1. Accuracy

5.1.1. Accuracy evaluation methods

(1) After the samples were collected and packed, they were coded and blinded. After the blind test was performed on the tested kit and the comparison kit, the blindness was uncovered. The comparison kit is used as a reference to calculate the accuracy of the test result of sample. According to the degree of agreement between the tested kit and the comparison kit, the accuracy of the kit is evaluated.

(2) In addition, according to the Notice of "Technical Review of Registration of New Coronavirus Nucleic Acid Detection Reagents in 2019" (No. 4 of 2020), the accuracy of the results will be calculated based on the clinical diagnosis / exclusion results. The accuracy of the tested kit is evaluated according to the degree of compliance between the tested kit and the clinical diagnosis / exclusion results.

5.1.2. Accuracy statistical method

(1) Compare the results of the tested kits with the comparison kit and clinical diagnosis / exclusion results, calculate the positive coincidence rate, negative coincidence rate, total coincidence rate and its 95% confidence interval, and Kappa value. Among them, Kappa value was statistically analyzed using SPSS statistical software.

a. Register the background information of each sample, and record the results of the tested kit and comparison kit for each sample.

b. Establish a data summary table in EXCEL, input all data into the computer for data analysis and statistical analysis.

c. Statistical analysis will select the data that conforms to the protocol, that is, the sample data of all subjects that meet the requirements of the clinical trial protocol for statistical analysis. The Kappa consistency test is used for the tested kit and the comparison kit. The P value less than or equal to 0.01 will be considered as a statistically significant difference.

Positive coincidence rate, negative coincidence rate, total coincidence rate and its 95% confidence interval. The statistical of Kappa value is as follows.

Table 1. Four-compartment table compared to comparison kit

Test Results	The comparison kit	Total
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		Positive	Negative	
The tested kit	Positive	A	B	A+B
	Negative	C	D	C+D
Total		A+C		A+B+C+D

Using the following formula:

$$\text{Positive coincidence rate} = A / (A + C) \times 100\%$$

$$\text{Negative compliance rate} = D / (B + D) \times 100\%$$

$$\text{Total compliance rate} = (A + D) / (A + B + C + D) \times 100\%$$

95% confidence intervals for positive, negative, and total coincidence rates

Kappa value was statistically analyzed using SPSS statistical software.

(2) Compare the tested kit with the clinical diagnosis / exclusion results, and calculate the clinical sensitivity and clinical specificity. The clinical sensitivity and clinical specificity statistical method is as follows.

Table 2. Four-compartment table compared to clinical diagnosis / exclusion results

Test Results	Clinical diagnosis / exclusion				Total	
	Confirmed	results		Clinical		
		diagnosis case	excluded case			
The tested kit	Positive	A	B		A+B	
	Negative	C	D		C+D	
Total		A+C	B+D		A+B+C+D	

Using the following formula:

$$\text{Clinical sensitivity} = A / (A + C) \times 100\%$$

$$\text{Clinical specificity} = D / (B + D) \times 100\%$$

$$\text{Total compliance rate} = (A + D) / (A + B + C + D) \times 100\%$$

95% confidence interval for clinical sensitivity, clinical specificity, and overall compliance

Kappa value was statistically analyzed using SPSS statistical software.

This clinical trial is stratified statistics for different populations, such as confirmed /excluded cases, confirmed cases of novel coronavirus 2019-nCoV tests negative, and cases of release from isolation and meeting discharge standards. Based on the pre-negative samples of confirmed cases and for the samples that were released

from isolation and met the discharge standard, the detection rate of the novel coronavirus 2019-nCoV by the tested kit was analyzed. At the same time, based on the statistical analysis of the total sample number (the sum of each sample type) for different sample types, each sample type is statistically analyzed separately.

All inconsistent results in clinical trials should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, and disease outcomes.

5.2. Reliability

5.2.1. Reliability evaluation methods

According to the internal control results of the tested kit, the reliability of the test kit is evaluated.

6. Data Analysis

6.1. Case Inclusion/Exclusion Summary

A collection of 627 cases with 630 samples were included in the trial, without any cases of protocol violation or protocol deviation. Of the 627 cases, 37 were excluded because of duplicated sampling during the treatment, and 1 case was also excluded due to misoperations. As a result, a valid collection of 589 cases with 592 samples, including 266 sputum samples and 326 oropharyngeal swab samples, were submitted to further analysis.

Among the 589 cases, 219 were diagnosed as 2019-NCOV, and 2 of them showed negative test results in the beginning but positive test results in subsequent disease progression. The other 370 cases had been ruled out the diagnosis of 2019-NCOV, of which 1 case had met the criteria for quarantine release and hospital discharge.

A summary of case inclusion/exclusion is listed in Table 6-9.

Table 6 Sample inclusion/exclusion summary

Medical Facilities	No. of Included Samples	No. of Valid Samples	No. of Samples with Protocol Violation or Protocol Deviation	No. of Excluded samples
The First Affiliated Hospital of Medical School of Zhejiang University	178	178	0	0
Peking Union Medical College Hospital	88	88	0	0
The First Affiliated Hospital of Wenzhou Medical University	123	85	0	38
Zhejiang Provincial Center for Disease Control and Prevention	166	166	0	0
Shenzhen Center for Disease Control and Prevention	75	75	0	0
Total	630	592	0	38

Table 7 Composition of valid cases

Classification	The First Affiliated Hospital of Medical School of Zhejiang University	Peking Union Medical College Hospital	The First Affiliated Hospital of Wenzhou Medical University	Zhejiang Provincial Center for Disease Control and Prevention	Shenzhen Center for Disease Control and Prevention	Total
Confirmed Cases						
(including cases with negative test results in the beginning)	76 (2)	10	17	85	31	589
Ruled Out Cases						
(including cases meeting the criteria for quarantine release and hospital discharge)	100	78	68 (1)	80	44	

Table 8 Valid cases with multiple sampling and test results

Sample ID	Test Results	Sample Type	Memo
ZJK009	Negative	Oropharyngeal swab	The Same Case
ZJK061	Negative	Sputum	

ZJFY017	Negative	Sputum	
ZJFY177	Positive	Sputum	The Same Case
ZJFY036	Positive	Sputum	
ZJFY178	Negative	Sputum	The Same Case

Table 9 Information of excluded cases

Medical Facilities	Sample ID	Memo
The First Affiliated Hospital of Wenzhou Medical University	WZFY029	The same case as sample WZFY001; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY072	The same case as sample WZFY001; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY105	The same case as sample WZFY001; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY020	The same case as sample WZFY002; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY021	The same case as sample WZFY003; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY030	The same case as sample WZFY003; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY035	The same case as sample WZFY003; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY068	The same case as sample WZFY003; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY032	The same case as sample WZFY005; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY060	The same case as sample WZFY005; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY086	The same case as sample WZFY005; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY018	The same case as sample WZFY006; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY016	The same case as sample WZFY011; Sampling on different days
The First Affiliated Hospital of WZFY031		The same case as sample WZFY011;

Wenzhou Medical University	Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	The same case as sample WZFY011; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	The same case as sample WZFY011; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	The same case as sample WZFY012; Sampling on different days
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The First Affiliated Hospital of Wenzhou Medical University	The same case as sample WZFY015; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	The same case as sample WZFY017; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	The same case as sample WZFY019; Sampling on different days

The First Affiliated Hospital of Wenzhou Medical University	WZFY073	The same case as sample WZFY034; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY050	The same case as sample WZFY038; Sampling on the same days
The First Affiliated Hospital of Wenzhou Medical University	WZFY049	The same case as sample WZFY039; Sampling on the same days
The First Affiliated Hospital of Wenzhou Medical University	WZFY066	The same case as sample WZFY041; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY063	The same case as sample WZFY042; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY061	The same case as sample WZFY046; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY096	The same case as sample WZFY056; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY103	The same case as sample WZFY079; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY112	The same case as sample WZFY092; Sampling on different days
The First Affiliated Hospital of Wenzhou Medical University	WZFY027	Traceability information unavailable

6.1.1. Demographic characteristics

Of the 589 qualify cases, 277 were male, 310 were female, and 2 of them were unknown. The average age was 45.2 years, the minimum age was 17 days, and the maximum age was 93 years (the age of 17 people were unknown, not included in statistics).

Table 1. Age characteristics of clinical diagnosis of novel coronaviruses [Case (%)]

Age (Years)	Confirmed diagnosis (n=219)	case Clinical excluded (n=370)	case Total (n=589)

≤4	2 (0.3%)	4 (0.7%)	6 (1.0%)
5~17	9 (1.5%)	17 (2.9%)	26 (4.4%)
18~64	160 (27.2%)	282 (47.9%)	442 (75.0%)
≥65	41 (7.0%)	57 (9.7%)	98 (16.6%)
Unknown	7 (1.2%)	10 (1.7%)	17 (2.9%)
Total	219 (37.2%)	370 (62.8%)	589 (100%)

Table 2. Gender characteristics of clinical diagnosis of novel coronaviruses
[Case (%)]

Gender	Confirmed diagnosis case (n=219)	Clinical excluded case (n=370)	Total (n=589)
Male	116 (19.7%)	161 (27.3%)	277 (47.0%)
Female	103 (17.5%)	207 (35.1%)	310 (52.6%)
Unknown	0 (0%)	2 (0.3%)	2 (0.3%)
Total	219 (37.2%)	370 (62.8%)	589 (100%)

Table 3. Characteristics of clinical diagnosis of novel coronaviruses [Case (%)]

The information of clinical diagnosis	Confirmed case (n=219)	Clinical diagnosis (n=370)	excluded case (n=589)	Total
Suspected infection (fever, cough, lung infection, etc.)	217 (36.8%)	320 (54.3%)	537 (91.2%)	
Other symptoms	2 (0.3%)	50 (8.5%)	52 (8.8%)	
Total	219 (37.2%)	370 (62.8%)	589 (100%)	

6.1.2. Consistency analysis with comparison kits:

A total of 592 qualified cases were tested in the clinical trial, and 212 were Positive, and 380 were Negative, and 198 were Positive, and 394 were Negative. Consistency analysis was performed between the tested kit and the comparison kit. The analysis results are as follows.

Table 4.The Consistency analysis with comparison kits

Test Results	The comparison kits		Total
	Positive	Negative	
The tested kits	Positive	194	18
	Negative	4	376
Total		198	394
			592

Calculation results:

Positive compliance rate = 98.0%, 95% CI (94.9%, 99.4%)

Negative compliance rate = 95.4%, 95% CI (92.9%, 97.3%)

Total compliance rate = 96.3%, 95% CI (94.4%, 97.7%)

Kappa value = 0.918, P < 0.001

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 5. Kappa value table

	value	asymptotic	approximate	asymptotic
		standard error ^a	T ^b	significance
Protocol measurement	0.918	0.017	22.366	0.000
Number of valid cases	592			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.1.3. Consistency Analysis with Clinical Diagnosed Results:

A total of 589 qualified cases in this clinical trial were tested, 211 were Positive, and 378 were Negative by the tested kits. According to the clinical diagnosis/exclusion results, 219 were confirmed diagnosis case and 370 were clinical excluded case. Consistent analysis was performed between the tested kit and the clinical diagnosis / exclusion results. The analysis results are as follows.

Table 6. The Consistency analysis between the tested kits and Clinical Diagnosed/ excluded results

Test Results	Clinical	Diagnosed/	Excluded	Total
	Results	Confirmed	Clinical	
	diagnosis case	excluded case		
The tested kits	Positive	211	0	211
	Negative	8	370	378
	Total	219	370	589

Calculation results:

Clinical sensitivity = 96.3%, 95% CI (92.9%, 98.4%)

Clinical specificity = 100%, 95% CI (99.0%, 100%)

Total compliance rate = 98.6%, 95% CI (97.3%, 99.4%)

Kappa value = 0.971, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 7. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	Kappa	0.971	0.010	23.568
Number of valid cases		589		0.000

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.1.4. Consistency analysis between comparison kit and clinical diagnosis / exclusion results:

A total of 589 qualified cases were tested in the clinical trial, and 197 were Positive and 392 were Negative test by the comparison kit, and 219 were Confirmed diagnosis case and 370 were clinical excluded case. Consistency analysis was performed between the comparison kit and the clinical diagnosis / exclusion results. The analysis results are as follows.

Table 8. The Consistency analysis between the comparison kits and Clinical Diagnosed/ excluded results

Test Results		Clinical	Diagnosed/	Excluded	Total	
		Results				
			Confirmed	Clinical		
			diagnosis case	excluded case		
The tested kit	Positive	197	0	197	197	
	Negative	22	370	392	392	
	Total	219	370	589	589	

Calculation results:

Clinical sensitivity = 90.0%, 95% CI (85.2%, 93.6%)

Clinical specificity = 100%, 95% CI (99.0%, 100%)

Total compliance rate = 96.3%, 95% CI (94.4%, 97.6%)

Kappa value = 0.918, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 9. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	Kappa	0.918	0.017	22.363 0.000
Number of valid cases	589			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2. Hierarchical statistics

6.2.1. Analysis of different sample types

6.2.1.1. Consistency analysis of sputum samples by tested reagents and comparison kits

A total of 266 sputum samples were tested in the clinical trial, and 106 were Positive and 160 Negative test by the tested kits, and 104 were Positive and 162 were Negative tested by the comparison kits. Consistency analysis of sputum samples was performed on the tested kit and the comparison kits. The analysis results are as follows.

Table 10. Consistency analysis of sputum samples by tested reagents and comparison kits

Test Results	The comparison kits		Total
	Positive	Negative	
The tested kits	Positive	102	106
	Negative	2	158
Total	104	162	266

Calculation results:

Positive compliance rate = 98.1%, 95% CI (93.2%, 99.8%)

Negative compliance rate = 97.5%, 95% CI (93.8%, 99.3%)

Total compliance rate = 97.7%, 95% CI (95.2%, 99.2%)

Kappa value = 0.953, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 11. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	0.953	0.019	15.542	0.000
Number of valid cases	266			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.1.2. Consistency analysis of oropharyngeal swabs samples by tested kits and comparison kits

A total of 326 Oropharyngeal swabs samples were tested in the clinical trial, and 106 were Positive and 220 Negative test by the tested kits, and 94 were Positive and 232 were Negative tested by the comparison kits. Consistency analysis of oropharyngeal swabs samples was performed on the tested kit and the comparison kits. The analysis results are as follows.

Table 12. Consistency analysis of oropharyngeal swabs samples by tested kits and comparison kits

Test Results	The comparison kits		Total
	Positive	Negative	
The kits	Positive	92	106
	Negative	2	220
Total	94	232	326

Calculation results:

Positive compliance rate = 97.9%, 95% CI (92.5%, 99.7%)

Negative compliance rate = 94.0%, 95% CI (90.1%, 96.7%)

Total compliance rate = 95.1%, 95% CI (92.2%, 97.2%)

Kappa value = 0.885, P < 0.001

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 13. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	0.885 Kappa	0.028	16.035	0.000
Number of valid cases	326			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.1.3. Consistency analysis of sputum samples by tested kits and clinical diagnosed/excluded Results

A total of 264 sputum samples were tested in the clinical trial, and 105 were Positive and 159 Negative test by the tested kits, and 110 were confirmed diagnosis case and 154 were clinical excluded case. Consistency analysis of sputum samples was performed between the tested kit and clinical diagnosed/excluded results. The analysis results are as follows.

Table 14. Consistency analysis of sputum samples by tested kits and clinical diagnosed/excluded Results

Test Results	Clinical Results			Total
	Diagnosed/ Confirmed		Excluded	
	diagnosis case	Clinical excluded case		
The tested kits	Positive 5	105 154	0 154	105 159
Total		110	154	264

Calculation results:

Clinical sensitivity = 95.5%, 95% CI (89.7%, 98.5%)

Clinical specificity = 100%, 95% CI (97.6%, 100%)

Total compliance rate = 98.1%, 95% CI (95.6%, 99.4%)

Kappa value = 0.961, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 15. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	0.961 Kappa	0.017	15.623	0.000
Number of valid cases	264			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.1.4. Consistency analysis of sputum samples by comparison kits and clinical diagnosed/excluded Results

A total of 264 sputum samples were tested in the clinical trial, and 105 were Positive and 159 Negative test by the comparison kits, and 110 were confirmed diagnosis case and 154 were clinical excluded case. Consistency analysis of sputum samples was performed between the comparison kits and clinical diagnosed/excluded results. The analysis results are as follows.

Table 16 Consistency analysis of sputum samples by comparison kits and clinical diagnosed/excluded Results

Test Results	Clinical Diagnosed/ Excluded		Total	
	Results			
	Confirmed	Clinical		
	diagnosis case	excluded case		
The	Positive	103	0	
			103	

comparison kits	Negative	7	154	161
Total		110	154	264

Calculation results:

Clinical sensitivity = 93.6%, 95% CI (87.3%, 97.4%)

Clinical specificity = 100%, 95% CI (97.6%, 100%)

Total compliance rate = 97.3%, 95% CI (94.6%, 98.9%)

Kappa value = 0.945, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 17. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	0.945	0.020	15.377	0.000
Number of valid cases	264			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.1.5. Consistency analysis of oropharyngeal swabs samples by tested kits and clinical diagnosed/excluded Results

A total of 326 Oropharyngeal swabs samples were tested in the clinical trial, and 106 were Positive and 220 Negative test by the tested kits, and 109 were confirmed diagnosis case and 217 were clinical excluded case. Consistency analysis of oropharyngeal swabs samples was performed between the tested kit and clinical diagnosed/excluded results. The analysis results are as follows.

Table 18. Consistency analysis of oropharyngeal swabs samples by comparison kits and clinical diagnosed/excluded Results

Test Results	Clinical Diagnosed/ Excluded			Total	
	Results		Clinical		
	Confirmed	diagnosis case			
The tested Positive	106	0		106	
kits Negative	3	217		220	
Total	109	217		326	

Calculation results:

Clinical sensitivity = 97.2%, 95% CI (92.2%, 99.4%)

Clinical specificity = 100%, 95% CI (98.3%, 100%)

Total compliance rate = 99.1%, 95% CI (97.3%, 99.8%)

Kappa value = 0.979, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 19. Kappa value table

	value	asymptotic	approximate	asymptotic
		standard error ^a	T ^b	significance
Protocol measurement	Kappa	0.979	0.012	17.683 0.000
Number of valid cases		326		

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.1.6. Consistency analysis of oropharyngeal swabs samples by comparison kits and clinical diagnosed/excluded Results

A total of 326 Oropharyngeal swabs samples were tested in the clinical trial, and 94 were Positive and 232 Negative test by the comparison kits, and 109 were confirmed diagnosis case and 217 were clinical excluded case. Consistency analysis of

oropharyngeal swabs samples was performed between the comparison kits and clinical diagnosed/excluded results. The analysis results are as follows.

Table 20.Consistency analysis of oropharyngeal swabs samples by comparison kits and clinical diagnosed /excluded Results

Test Results	Clinical Diagnosed/ Excluded			Total	
	Results		Clinical		
	Confirmed	Clinical			
	diagnosis case	excluded case			
The comparison kits	Positive	94	0	94	
	Negative	15	217	232	
Total		109	217	326	

Calculation results:

Clinical sensitivity = 86.2%, 95% CI (78.3%, 92.1%)

Clinical specificity = 100%, 95% CI (98.3%, 100%)

Total compliance rate = 95.4%, 95% CI (92.5%, 97.4%)

Kappa value = 0.893, P < 0.001

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 21. Kappa value table

	value	asymptotic standard error ^a	T ^b	approximate asymptotic significance
Protocol measurement	Kappa	0.027	16.216	0.000
Number of valid cases	326			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.2. Analysis of different populations

6.2.2.1. For 2019-nCoV suspected cases, the consistency analysis of the tested kits and the comparison kits, Test results from all samples of the analysis population were included..

A total of 540 suspected case of 2019-nCoV were tested in the clinical trial.210 cases were Positive, 330 cases were Negative tested by the tested kit, 196 cases were Positive, and 344 cases Negative tested by the comparison kit. Consistency analysis was performed on the tested kits and the comparison kits. The analysis results are as follows:

Table 22. For 2019-nCoV suspected cases, the consistency analysis of the tested kits and the comparison kits

Test Results		The comparison kits		Total
		Positive	Negative	
The tested kits	Positive	192	18	210
	Negative	4	326	330
Total		196	344	540

Calculation results:

Positive compliance rate = 98.0%, 95% CI (94.9%, 99.4%)

Negative compliance rate = 94.8%, 95% CI (91.9%, 96.9%)

Total compliance rate = 95.9%, 95% CI (93.9%, 97.4%)

Kappa value = 0.913, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 23. Kappa value table

	value	asymptotic standard error ^a	approximate T ^b	asymptotic significance
Protocol measurement	Kappa	0.913	0.018	21.254 0.000

Number of valid cases 540

- a. No null hypothesis is assumed.
- b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.2.2. For confirmed diagnosed cases of Negative test in the early stage, the consistency analysis of the tested kits and the comparison kits, Test results from all samples of the analysis population were included.

In this clinical trial, 4 of confirmed diagnosed cases of Negative were detected in the early stage, and 3 cases of Positive and 1 case of Negative were detected by the tested kit; 3 cases of Positive and 1 case of Negative were detected by the comparison kit. Consistency analysis was performed on the tested kits and the comparison kit. The analysis results are as follows:

Table 24. For confirmed diagnosed cases of Negative test in the early stage, the consistency analysis of the tested kits and the comparison kits

Test Results	The comparison kits		Total
	Positive	Negative	
The tested kits	Positive 3	0	3
	Negative 0	1	1
Total	3	1	4

Calculation results:

Positive compliance rate = 100%

Negative compliance rate = 100%

Total compliance rate = 100%

6.2.2.3. For the release of quarantine and cases that meet the discharge standards, the consistency analysis of the tested kits and the comparison kits. Test results from all samples of the analysis population were included.

In this clinical trial, 1 case was released and met the discharge standard. 0 cases were Positive, 1 case was Negative were tested by the tested kit, and 0 cases were

Positive, and 1 case was Negative were tested by the comparison kit. Consistency analysis was performed on the tested kits and the comparison kits. The analysis results are as follows:

Table 25. For the release of quarantine and cases that meet the discharge standards, the consistency analysis of the tested kits and the comparison kits

Test Results	The comparison kits		Total
	Positive	Negative	
The tested kits	Positive	0	0
	Negative	0	1
Total		0	1

Calculation results:

Negative compliance rate = 100%

6.2.2.4. For 2019-nCoV suspected cases, the consistency analysis of the tested kits and clinical diagnosed /excluded Results.

A total of 537 suspected case of 2019-nCoV were tested in the clinical trial.209 cases were Positive, 328 cases were Negative tested by the tested kit, 217 were confirmed diagnosis case, and 320 were clinical excluded cases Consistency analysis was performed on the tested kits and clinical diagnosed /excluded results. The analysis results are as follows:

Table 26. For 2019-nCoV suspected cases, the consistency analysis of the tested kits and clinical diagnosed /excluded results

Test Results	Clinical Diagnosed/ Excluded			Total	
	Results		Clinical		
	Confirmed	diagnosis case			
The tested kits	Positive	209	0	209	
	Negative	8	320	328	
Total		217	320	537	

Calculation results:

Clinical sensitivity = 96.3%, 95% CI (92.9%, 98.4%)

Clinical specificity = 100%, 95% CI (98.9%, 100%)

Total compliance rate = 98.5%, 95% CI (97.1%, 99.4%)

Kappa value = 0.969, $P < 0.001$

It is generally believed that the Kappa value is ≥ 0.75 , indicating that a fairly satisfactory degree of agreement has been achieved, and that the difference tested has statistical significance.

Table 27. Kappa value table

	value	asymptotic standard error ^a	approximate T^b	asymptotic significance
Protocol measurement	0.969	0.011	22.463	0.000
Number of valid cases	537			

a. No null hypothesis is assumed.

b. Use asymptotic standard error under the assumption of null hypothesis.

6.2.3. The detection rate of confirmed cases with negative test in the early stage and the test for the samples of cases with de isolation and discharge standards

There were 589 qualified cases in this clinical trial, of which 2 were confirmed cases with negative test in the early stage, and 1 was samples of cases with de isolation and discharge standards. The detection rate analysis results of the above cases by the tested kit are as follows:

Table 32. Statistical method of detection rate

Test Results		The results of Clinical diagnosis / exclusion			
Tested Kits	Positive	confirmed cases with negative test in the early stage	the samples of cases with de isolation and discharge standards	and	
Tested Kits	Positive	1	0		
	Negative	1	1		

Totals	2	1
--------	---	---

The tested kits of detection rate of confirmed cases with negative test in the early stage and the test for the samples of cases with de isolation and discharge standards=33.3%

6.3.4. The consistency analyze between the tested kit and the comparison Kit for weakly positive samples

Based on the CT value of the comparison kit, the weakly positive samples were screened according to the following criteria: the CT value of FAM Channel is more than 35 or HEX/VIC Channel is less than 40, and the CT value of ROX Channel is less than 38. The data summary is shown as below:

Table 33. Detection of weakly positive sample between tested kit and comparison kit

Enrollment Numbers	The results of tested kits					The results of comparison kit				The results of clinical diagnosis / exclusion
	ORF1 ab Tt	N Tt	ICl	ICr	Results	ORF1ab Ct	N Ct	ROX	Results	
ZJK145	8.16	8.16	N/A	N/A	Positive	35.20	31.60	28.70	Positive	Confirmed Case
ZJK155	N/A	7.83	22.83	N/A	Positive	35.90	33.30	30.00	Positive	Confirmed Case
ZJK114	N/A	N/A	31.16	28.83	Negative	37.40	36.40	32.00	Positive	Confirmed Case
ZJK142	11.66	10.16	N/A	N/A	Positive	Undetermined (35.95)	36.3 (36.95)	28.9 (31.49)	Retest (Positive)	Confirmed Case
ZJK116	22.50	23.83	20.00	26.00	Positive	Undetermined (Undetermined)	37.3 (36.78)	31.5 (30.89)	Retest Negative	Confirmed Case
ZJK083	N/A	N/A	37.66	39.50	Negative	35.80	37.50	35.60	Positive	Confirmed Case
ZJK111	N/A	N/A	19.16	36.33	Negative	37.3 (35.87)	38.5 (36.6)	Undetermined (30.64)	Retest (Positive)	Confirmed Case
WZFY001	7.00	7.00	N/A	N/A	Positive	Undetermined (Undetermined)	35.97 (37.89)	30.33 (26.94)	Retest (Negative)	Confirmed Case

WZFY004	9.16	13.83	N/A	30.50	Positive	Undetermined (Undetermined)	35.43 (37.61)	28.39 (28.66)	Retest (Negative)	Confirmed Case
WZFY005	9.00	10.83	32.16	N/A	Positive	Undetermined (Undetermined)	36.10 (35.01)	28.76 (34.96)	Retest (Negative)	Confirmed Case
WZFY006	17.60	16.33	N/A	N/A	Positive	37.76	37.82	31.90	Positive	Confirmed Case
WZFY009	12.66	13.00	N/A	N/A	Positive	Undetermined (Undetermined)	38.59 (37.97)	27.53 (28.47)	Negative	Confirmed Case
WZFY010	9.66	10.50	25.83	N/A	Positive	36.16	37.86	28.61	Positive	Confirmed Case
WZFY017	12.16	12.00	N/A	N/A	Positive	36.64	33.88	26.84	Positive	Confirmed Case
WZFY019	15.50	17.16	36.00	N/A	Positive	34.93	37.56	33.18	Positive	Confirmed Case
ZJFY016	14.33	16.16	N/A	N/A	Positive	Undetermined (Undetermined)	37.71 (27.05)	26.25 (25.62)	Retest (Negative)	Confirmed Case
ZJFY050	15.00	13.83	N/A	N/A	Positive	35.76	34.29	23.47	Positive	Confirmed Case
ZJFY059	19.33	21.66	N/A	N/A	Positive	35.94	35.13	25.70	Positive	Confirmed Case
ZJFY116	15.66	12.16	N/A	N/A	Positive	35.88	36.31	29.98	Positive	Confirmed Case

ZJFY117	15.33	15.16	N/A	N/A	Positive	36.54	25.31	25.24	Positive	Confirmed Case
ZJFY131	9.83	15.50	N/A	N/A	Positive	Undetermined (35.64)	36.52 (39.23)	27.09 (31.58)	Retest (Negative)	Confirmed Case
ZJFY159	15.66	14.83	N/A	N/A	Positive	Undetermined (37.89)	38.46 (36.97)	29.56 (30.56)	Retest (Positive)	Confirmed Case
ZJFY161	16.83	14.00	N/A	N/A	Positive	34.97 (31.93)	35.97 (35.61)	Undetermined (29.32)	Retest (Positive)	Confirmed Case
ZJFY165	N/A	N/A	24.66	30.83	Negative	Undetermined (37.22)	36.11 (37.44)	31.80 (31.67)	Retest (Positive)	Confirmed Case
ZJFY169	9.50	9.00	N/A	N/A	Positive	Undetermined (34.47)	35.72 (36.27)	31.09 (28.00)	Retest (Positive)	Confirmed Case
SZJK001	25.66	24.83	N/A	N/A	Positive	37.80	37.01	29.63	Positive	Confirmed Case
SZJK002	10.66	9.83	N/A	N/A	Positive	37.97	35.70	29.21	Positive	Confirmed Case
SZJK003	12.00	10.83	N/A	N/A	Positive	34.37	35.69	32.96	Positive	Confirmed Case
SZJK004	21.33	18.00	N/A	N/A	Positive	34.02	35.30	31.01	Positive	Confirmed Case
SZJK006	20.66	22.83	N/A	N/A	Positive	Undetermined (Undetermined)	37.96 (37.76)	29.04 (26.80)	Retest Negative	Confirmed Case

SZJK024	10.83	11.33	N/A	N/A	Positive	35.40	31.44	27.48	Positive	Confirmed Case
SZJK027	16.66	21.83	N/A	N/A	Positive	Undetermined (Undetermined)	35.21 (36.69)	25.99 (23.26)	Retest Negative	Confirmed Case
SZJK029	17.33	18.16	N/A	N/A	Positive	Undetermined (Undetermined)	30.09 (31.24)	22.62 (20.35)	Retest Negative	Confirmed Case
BJXH069	16.00	14.33	N/A	N/A	Positive	34.8	36.5	25.5	Positive	Confirmed Case

The results showed that:

Among 592 qualified cases, 34 cases were identified as weakly positive sample by comparison kit, and which were clinically confirm diagnosed cases. 30 positive and 4 negative samples were detected by the tested kit; but 24 positive and 10 negative samples were detected by the comparison kit.

Table 34. Consistency analysis of weakly positive samples compared with the comparison Kit

The results of test	The comparison kit		Totals
	Positive	Negative	
The tested kit	Positive	20	10
	Negative	4	0
Totals		24	10
			34

Calculation results:

Positive compliance rate = 83.3%

Clinical sensitivity of the tested kit = 88.2%

Clinical sensitivity of the comparison kit = 70.6%

6.3. The Analysis of inconsistent samples

The analysis of inconsistency among the tested kit and the comparison kit, clinical diagnosis/ excluded results are summarized as follows:

(1) The analysis of inconsistency between the tested kit and the comparison kit: Among 592 qualified case, there were 22 samples with inconformity results between the tested kit and the comparison kit. The analysis of inconsistent samples show as below;

Table 35. The Analysis of Inconsistency with the comparison kit

Group Number	The results of tested kits				Results	The results of comparison kit			Results	The results of clinical diagnosis / exclusion
	ORF1ab Tt	N Tt	ICL Tt	ICR Tt		ORF1ab Ct	N Ct	ROX		
ZJK082	7.33	10.00	N/A	N/A	Positive	Undetermined	Undetermined	36.20	Negative	Confirmed Case
ZJK083	N/A	N/A	37.66	39.50	Negative	35.80	37.50	35.60	Positive	Confirmed Case
ZJK111	N/A	N/A	19.16	36.33	Negative	37.3 (35.87)	38.5 (36.6)	Undetermi ned (30.64)	Retest (Positive)	Confirmed Case
ZJK114	N/A	N/A	31.16	28.83	Negative	37.40	36.40	32.00	Positive	Confirmed Case
ZJK116	22.50	23.83	20.00	26.00	Positive	Undetermined (Undetermined)	37.3 (36.78)	31.5 (30.89)	Retest (Negative)	Confirmed Case
ZJK150	7.00	13.50	N/A	28.16	Positive	Undetermined	Undetermined	28.90	Negative	Confirmed Case
ZJK166	10.50	9.00	24.83	27.83	Positive	Undetermined	Undetermined	29.00	Negative	Confirmed Case
WZFY001	7.00	7.00	N/A	N/A	Positive	Undetermined (Undetermined)	35.97 (37.89)	30.33 (26.94)	Retest (Negative)	Confirmed Case
WZFY004	9.16	13.83	N/A	30.50	Positive	Undetermined (Undetermined)	35.43 (37.61)	28.39 (28.66)	Retest (Negative)	Confirmed Case
WZFY005	9.00	10.83	32.16	N/A	Positive	Undetermined (Undetermined)	36.10 (35.01)	28.76 (34.96)	Retest (Negative)	Confirmed Case
WZFY009	12.66	13.00	N/A	N/A	Positive	Undetermined (Undetermined)	38.59 (37.97)	27.53 (28.47)	Retest (Negative)	Confirmed Case

ZJFY016	14.33	16.16	N/A	N/A	Positive	Undetermined (Undetermined)	37.71 (27.05)	26.25 (25.62)	Retest (Negative)	Confirmed Case
ZJFY131	9.83	15.50	N/A	N/A	Positive	Undetermined (35.64)	36.52 (39.23)	27.09 (31.58)	Retest (Negative)	Confirmed Case
ZJFY165	N/A	N/A	24.66	30.83	Negative	Undetermined (37.22)	36.11 (37.44)	31.80 (31.67)	Retest (Positive)	Confirmed Case
SZJK006	20.66	22.83	N/A	N/A	Positive	Undetermined (Undetermined)	37.96 (37.76)	29.04 (26.80)	Retest (Negative)	Confirmed Case
SZJK012	20.33	18.00	34.16	N/A	Positive	Undetermined	Undetermined	31.13	Negative	Confirmed Case
SZJK027	16.66	21.83	N/A	N/A	Positive	Undetermined (Undetermined)	35.21 (36.69)	25.99 (23.26)	Retest (Negative)	Confirmed Case
SZJK028	21.00	19.50	N/A	30.83	Positive	Undetermined	Undetermined	31.27	Negative	Confirmed Case
SZJK029	17.33	18.16	N/A	N/A	Positive	Undetermined (Undetermined)	30.09 (31.24)	22.62 (20.35)	Retest (Negative)	Confirmed Case
SZJK032	20.16	22.00	N/A	N/A	Positive	Undetermined	Undetermined	24.98	Negative	Confirmed Case
SZJK037	21.66	22.83	29.83	30.66	Positive	Undetermined (Undetermined)	36.27 (Undetermined)	28.03 (27.14)	Retest (Negative)	Confirmed Case
BJXH088	13.33	10.33	N/A	32.66	Positive	Undetermined	Undetermined	34.04	Negative	Confirmed Case

The results showed that:

A total of 22 samples with inconsistent results between the test kit and the comparison kit: 18 were confirm diagnosed cases in the 22 inconsistent samples, the tested kits were Positive but the comparison kits were Negative. The virus concentration in the samples was very close to or lower sensitivity than the comparison kit, which maybe the possible causes.

Another 4 cases were clinically confirm diagnosed cases. The results of the tested kits were Negative but the comparison kits were Positive. The Possible causes: The virus concentration in the sample was very close to or lower sensitivity than the tested kit (The Ct value of the comparison kit approaching its cutoff value also suggests that the sample is weakly positive).

(2) Analysis of inconsistency with clinical Diagnosed / excluded results: Among the 589 quality cases, a total of 8 samples with inconsistent test results between the test kit and the comparison kit. The analysis of inconsistent samples were shown following table

Table 36. The Analysis of Inconsistency with clinical Diagnosed / excluded results

Group	The results of tested kits					The results of comparison kit			Results	The results of clinical diagnosis / exclusion
	ORF1ab Tt		N Tt	ICL Tt	ICR Tt	Results	ORF1ab Ct	N Ct	ROX	
Number	ORF1ab Tt	N Tt	ICL Tt	ICR Tt	Results	ORF1ab Ct	N Ct	ROX	Results	The results of clinical diagnosis / exclusion
ZJK083	N/A	N/A	37.66	39.50	Negative	35.80	37.50	35.60	Positive	Confirmed Case
ZJK111	N/A	N/A	19.16	36.33	Negative	37.3 (35.87)	38.5 (36.6)	Undetermined (30.64)	Retest (Positive)	Confirmed Case
ZJK114	N/A	N/A	31.16	28.83	Negative	37.40	36.40	32.00	Positive	Confirmed Case
WZFY110	N/A	N/A	36.16	24.00	Negative	Undetermined	Undetermined	26.97	Negative	Confirmed Case
ZJFY006	N/A	N/A	29.16	33.33	Negative	Undetermined	Undetermined	26.65	Negative	Confirmed Case
ZJFY024	N/A	N/A	33.83	35.50	Negative	Undetermined	Undetermined	26.88	Negative	Confirmed Case
ZJFY053	N/A	N/A	29.33	29.50	Negative	Undetermined	Undetermined	24.39	Negative	Confirmed Case
ZJFY165	N/A	N/A	24.66	30.83	Negative	Undetermined (37.22)	36.11 (37.44)	31.80 (31.67)	Retest (Positive)	Confirmed Case

The results show that:

A total of 8 samples that were inconsistent with the clinical diagnosis / exclusion results: 4 of the inconsistent samples were clinically confirm diagnosed cases, and the tested kit and comparison kit test results were Negative. Possible causes: Samples the medium concentration is very close to or lower sensitivity than the tested kit and the comparison kit.

Another 4 cases were clinically confirm diagnosed cases, The result of the tested kit was Negative, but the result of the comparison kit was Positive. Possible causes: The virus concentration in the sample was very close to or lower sensitivity than the test kit (The Ct value of the comparison kit approaching its cutoff value also indicates that the sample is weakly Positive).

6.4. Reliability Analysis

In this clinical trial, a total of 592 valid statistical samples were obtained. The results of tested kits were not appeared "invalid". The reliability of the tested kit was very perfect.

7. Quality control

7.1. Quality control of clinical trial sites

During the clinical trial, the clinical supervisor appointed by the sponsor regularly conducts on-site inspection visits to the clinical trial sites to ensure that all the contents of the clinical trial protocol are strictly followed and the research data is filled in correctly. All participating researchers have unified trained, include testing, recording methods and judgment standards. The entire clinical trial process is conducted under strict clinical trial protocol. Each sample should be summarized in a data form, which includes clear clinical data of the Subjects (contents include: Group number, ID number, test results, clinical diagnosis, etc.) to ensure that the contents of the registration form are complete, authentic, and reliable. All observations and findings in the clinical trial are verified to ensure the reliability of the data and to ensure that the conclusions in the clinical trial are derived from the original data. There are corresponding data management measures in clinical trials and data processing stages.

7.1.1. Quality control of clinical trial process

(1) Internal Control:

There were 592 samples were counted effectively in the clinical trial and the test

results was not appeared "invalid".

(2) External Control:

The researchers should be conduct external quality control once respectively when turn on the instrument every day, record the test results of positive control and 2019 negative control, and then start the formal test after confirming that the external quality control results are normal.

7.2. Quality assurance of clinical trials

7.2.1.Pre-clinical training

Before start of the formal clinical trial, the researchers of the hospital would be received the training of Ustar Biotechnology (Hangzhou) Co., Ltd and completed the pre-clinical training (referred to as "proficiency test"), to ensure that the test operation is skilled, correctly and then they became qualified test operators.

7.2.2.Clinical trial supervision

Ustar Biotechnology (Hangzhou) Co., Ltd is responsible for comprehensively tracking and monitoring the implementation of clinical trials, ensuring that the clinical trials conform to the "Technical Guidelines for Clinical Trials of In Vitro Diagnostic Reagents" and related regulations, and are implemented in accordance with clinical trial protocols.

The clinical supervisor conducts regularly visits to the progress and completion of the trial. The supervisor checks the completeness of the case records, the accuracy of the contents of the data summary table, verifies the test data, checks the compliance of researchers with the clinical trial protocol and the "Technical Guidelines for Clinical Trials of In vitro Diagnostic Reagents" to ensure the distribution of test supplies, Storage and counting accuracy.

8. Conclusions

In this clinical trial, there were 627 suspected patients with 630 samples enrolled in 5 clinical institutions, of which 0 cases with scheme deviation / violation did not meet the inclusion criteria or exclusion criteria; 37 cases were repeatedly sampled in different days, belonging to repeated enrollment, and 1 case had operational errors or other errors in the detection process, resulting in results missing, they were eliminated according to the elimination standard and not be included in the statistical analysis. Conclusively, there were 589 qualified cases and 592 samples, including 266 sputum samples and 326Oropharyngeal swabs samples.

Among 589 qualified cases, 219 were clinically diagnosed as confirmed cases, of which 2 were previously negative; 370 were excluded, of which 1 was released from isolation and qualified for discharge.

Among 589 eligible cases, 277 were male, 310 were female, and 2 were not recorded. The average age is 45.2 years old with the minimum, 0, and the maximum, 93 years old (17 patients' age were not recorded and not included in the statistics).

The accuracy analysis of the tested kit, the comparison kit and the clinical diagnosis / exclusion results are summarized as follows:

(1) Consistency analysis with the comparison Kit: there were 592 samples of qualified cases in this clinical trial, 212 were positive and 380 were negative by the test kit; 198 were positive and 394 were negative by the comparison kit. The results showed that the positive coincidence rate was 98.0%, 95% CI (94.9%, 99.4%); the negative coincidence rate was 95.4%, 95% CI (92.9%, 97.3%); the total coincidence rate was 96.3%, 95% CI (94.4%, 97.7%); the kappa value was 0.918, $P < 0.001$. The consistency between these two kits is good.

(2) Consistency analysis with the clinical diagnosis / exclusion results: 589 cases were qualified in this clinical trial, 211 cases were positive and 378 cases were negative by the test kit; 219 cases were confirmed and 370 cases were excluded by the clinical diagnosis / exclusion results. The results showed that the clinical sensitivity of test kit was 96.3%, 95% CI (92.9%, 98.4%); its clinical specificity was 100%, 95% CI (99.0%, 100%); the total coincidence rate was 98.6%, 95% CI (97.3%, 99.4%); the kappa value was 0.971, $P < 0.001$. The consistency between them is good.

Diagnostic kit for novel-Coronavirus (2019-nCoV) RNA (Isothermal amplification-real time fluorescence assay) developed by Ustar Biotechnology (Hangzhou) Co., Ltd, which is accurate, stable and reliable, has good consistency with the PCR kit. The negative samples for the early diagnosis of novel coronavirus 2019-nCoV negative test are negative. 33.3% of the samples were in accordance with the discharge standard, and the overall consistency with the clinical diagnosis / exclusion results was good.

9. Attachment

Attachment 1: Summary Table of Clinical Trial Data

Attachment 2: Instructions for The tested kit and comparison kit

10. Reference

- [1] National Health Commission. "Diagnosis and Treatment of Pneumonia Caused by Novel Coronavirus(2019-nCoV) Infection" (trial version 5). 2020
- [2] World Health Organization. Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected interim guidance. 2020.1.12.
- [3] Xu G, Hu L, Zhong H, etc. Cross priming amplification: mechanism and optimization for isothermal DNA amplification. *Sci. Rep.* 2012;2:246.
- [4] Technical Guide for Laboratory Testing of Pneumonia Infected by a Novel Coronavirus(2019-nCoV) (Second Edition). 2020