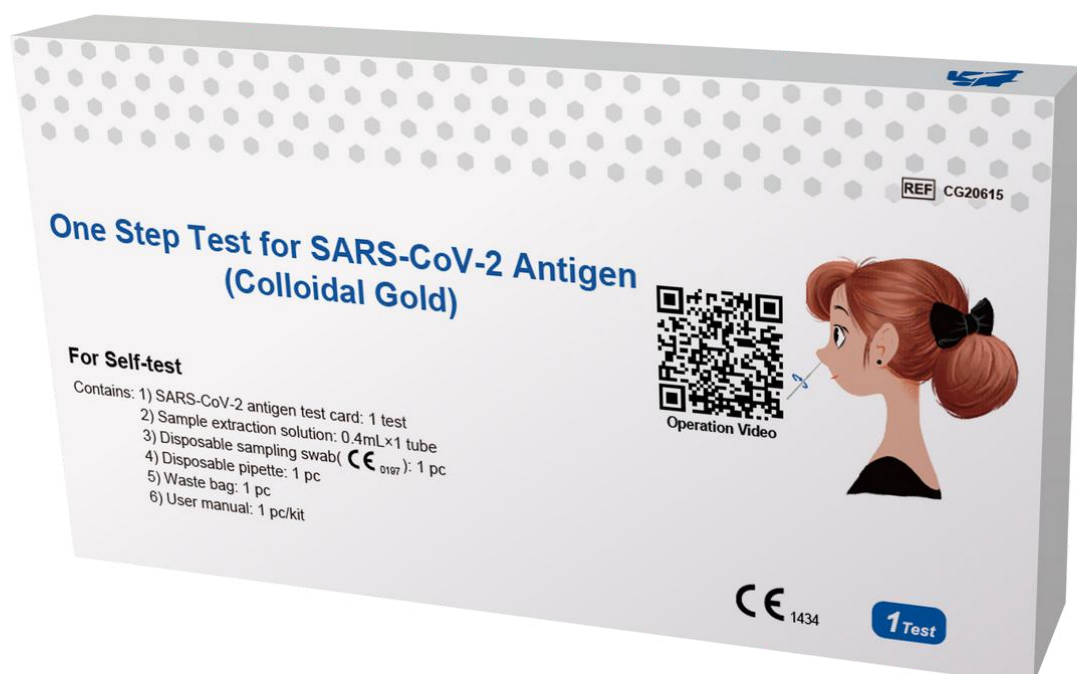


COVID-19 Ag SELF TEST

Eligible for use for 'Fit to Fly' and 'Test to Release'



GETEIN BIOTECH SARS-COV-2 ANTIGEN RAPID TEST KIT IS A SINGLE PACKED RAPID DIAGNOSTIC TEST BASED DELIVERING RELIABLE RESULTS IN 10-15 MINUTES. IT DETECTS THE NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 AND HAS A SENSITIVITY OF 97.01% AND SPECIFICITY OF 98.87%

Features

- Non-invasive sampling (Sample type: nasal swab)
- Rapid test. Test result available in 10-15 min.
- Read test results visually. Do not require test equipment.
- Simple operation, easy to learn and use
- Early detection of SARS-CoV-2 infection
- Room temperature storage (4-30°C)

| | |
|------------------------------|---|
| Product Name | One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) |
| Test Item | SARS-CoV-2 Antigen |
| Package | 1 T/kit, 5 T/kit, 7 T/kit, 25 T/kit |
| Test Time | 10-15 min |
| Storage Condition | 4-30°C |
| Shelf Life | 24 months |
| Recommended Test Temperature | 23-25°C |

Method of Sterilisation: Radiation



FIT-TO-FLY TEST REQUIREMENTS

| | REQUIREMENTS | GETEIN TEST |
|---|---|-------------|
| 1 | Specificity > 97% | |
| 2 | CE Certificate for self-test from notified body | |
| 3 | Unique QR code for easy test identification | |

| Brand | Sensitivity | Specificity | Accuracy |
|-------|-------------|-------------|----------|
| 1 | 97.01% | 98.87% | 97.94% |
| 2 | 96.70% | 97.50% | 97.10% |
| 3 | 97.10% | 98.80% | 97.95% |

1. Getein Biotech Inc: Clinical Validation Report of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) for Self-Testing
 2. Healgen - <https://www.healgen.com/if-respiratory-covid-19>
 3. FlowFlex - <https://www.flowflexrapidtest.com/wp-content/uploads/2021/03/Clinical-Study-Report.pdf> (go to page 5)





Ling Cheng
No.9 Bofu Road, Luhe District
Nanjing (211505)
China.

15 February 2022

Bcc. Medicines & Healthcare products Regulatory Agency (enforcement authority)

Dear Stakeholder,

Re: Notification of result – CTDA desktop review – One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) Test (Oral Fluid)

Thank you for your application for approval of a coronavirus test under the requirements that came into force on 28 July 2021 via [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021](#).

I can confirm the desktop review for your product has now been completed. I can inform you that based on the information and evidence provided your application has been successful.

Your product details will be published on the register of products that have been approved under regulation 38A(5) of the Medical Devices Regulations 2002: [COVID-19 test validation approved products - GOV.UK \(www.gov.uk\)](#). The details published on the register will include the name and address of the registered place of business of the applicant and manufacturer; the country in which the manufacturer is established; and if there is one, the name and address of a UK Responsible Person or Authorised Representative of the manufacturer.

The approval is valid for a period of 5 years from the date of this letter.

If your test is listed on the temporary protocol ([Medical Devices Regulations 2002: protocol](#)), please be advised your test will be removed from the temporary protocol as it is added to the CTDA register of approved tests.

The MHRA, in its capacity as an enforcing authority for medical device legislation in the UK, is in copy to this letter.

Yours sincerely

Angela Douglas MBE
BSc, CSci, MIHM, MHSCcert, FAHCS(Hon), FIPEM(Hon), FRCPath
Deputy Chief Scientific Officer
Chief Scientific Officer for England's Portfolio
Testing Operations
UKHSA



CERTIFICATE

EC Certificate No. 1434-IVDD-447/2021

**EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

GETEIN Biotech, Inc.

Nanjing, ul. Bofu Road, Luhe District 9, China

in vitro diagnostic medical devices
for self-testing

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

*Ref. codes: CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159,
CG2061510, CG2061512, CG2061515, CG2061520, CG2061525*

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021



Issued under the Contract No. [MD-66/2021](#)

Application No: [142/2021](#)

Certificate bears the qualified signature.

Warsaw, 30.07.2021

Module [A1](#)

Vice-President



Medicines & Healthcare products
Regulatory Agency



**Medicines & Healthcare products
Regulatory Agency**

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

**UKOS Ltd
Unit 6 Boundary Way
Hertfordshire
Hemel Hempstead
HP2 7TE
England, United Kingdom**

22 April 2021

Dear **Emily Tee**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **22 April 2021** has been reviewed:

Application reference: **2021042201199869**

Manufacturer organisation: **Getein Biotech Inc**
Address:
**No 9 Bofu Road
Luhe District
Nanjing
211505
China**

Manufacturer registration status: **Registered**

Device(s):

| GMDN term | Status | MHRA comment |
|---|------------|--------------|
| SARS-CoV-2 antigen IVD, kit, fluorescent immunoassay, rapid | Registered | |

Please note this letter **does not** represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- 1. company/organisation information e.g. name and address**
- 2. additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our [Public Access Registration Database](#) (PARAD). This applies to non-in vitro diagnostic devices only.

The account number for your company/organisation is **0000013682**.

Yours sincerely,



Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Getein Biotech, Inc.**
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay).

研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂。

研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂配套使用的分析仪。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-29

Latest Revision Date: 2020-07-22

Effective Date: 2020-07-26

Expiry Date: 2023-07-25

Page: 1 of 1



...making excellence a habit.™

Clinical Validation Report of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) for Self-Testing

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1 Purpose

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was developed by Getein Biotech, Inc., which was intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples. The aim of the clinical evaluation study was to compare and evaluate the clinical performance of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) with an RT-PCR test. The clinical performance characteristics of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated in a multi-site prospective study in Germany on March 2021 in which nasal swabs from patients are tested. Self-test sampling detection sites and performing RT-PCR assay sites in Germany participate in the study. Reagent Testing is performed by operators themselves and RT-PCR assay is performed in professional testing institution. An RT-PCR assay for the detection of SARS-CoV-2 is utilized as the comparator method for the study.

2 Experimental Materials

2.1 Trial reagent

Name: One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)
Specification: 25 tests per box
Lot no.: 6SC20003W (manufacturing date: March 22th, 2020)
Manufacturer: Getein Biotech, Inc.

2.2 Comparator reagent

Name: Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2
Specifications: 50 reactions per kit
Manufacturer: BGI Genomics Co. Ltd.
PCR System: ABI 7500 Fast Real-Time PCR System with software v2.0.6
Viral RNA extraction kit: QIAamp Viral RNA Mini Kit (cat. #52904)

3 Experimental sample

3.1 Sample source and amount

A total of 400 human nasal swab samples were selected from 400 patients from the European population in Germany. Self-user sampling detection sites were homes and performing RT-PCR assay sites were Media Concepts GmbH laboratory in Germany. Sample selection conformed to the Inclusion and Exclusion criteria as follows. The samples source and amount information is shown in table 1.

- Inclusion criteria

- Subject is suspected case of COVID-19 by clinical criteria a patient with acute respiratory tract infection (sudden onset of at least one of the following: cough, fever, shortness of breath, fatigue, decreased appetite, myalgia)
- No other etiology that fully explains the clinical presentation
- With or without a history of close contact with a confirmed or probable COVID-19 case in the last 14 days prior to onset of symptoms.
- Subject is an appropriate candidate for nasopharyngeal sample collection
- Subject is willing to provide nasal and nasopharyngeal swab samples

- Exclusion criteria

- Individuals who present to ER with 10 or greater days of COVID-19 related symptoms, (fever, cough, fatigue, decreased appetite, shortness of breath, myalgia) or post-defervescence and/or convalescence

The self-test operators performed sampling and detection by themselves and were collected nasopharyngeal swab samples at the same time from the same patients by professional staffs in Media Concepts GmbH. The self-test results (the self-test process was not supervised) were recorded by the professional staffs and the nasopharyngeal swab samples were collected by the professional staffs and then tested by RT-PCR in Media Concepts GmbH laboratory to verify the accuracy of the self-test kits.

The self-test sampling and detection steps are as follows.

1. Gently insert the entire collection tip of the swab into one nostril, but do not insert the swab more than 1.5 cm into your nose. Using medium pressure, rotate the swab slowly in a circular motion around the inside wall of your nostril at least 4 times for a total time of 15 seconds. Repeat the same process with the same swab in the other nostril.
2. Pour one tube of sample extraction solution into the disposable pipette, insert the swab after sampling to the disposable pipette and rotate the swab 10 times in the solution to make the sample dissolve in the sample extraction solution as much as possible.
Squeeze the swab tip along the inner wall of the disposable pipette 3 times to keep the liquid in the disposable pipette as much as possible before

taking it out.

Discard the swab and tighten the disposable pipette.

3. Place the test card horizontally on a clean surface. Add 2~3 drops of sample by disposable pipette to test card 2 min later. Nasal swab sample should be processed with sample extraction solution after collection. If testing is delayed, the sample should be strictly sealed, it can be stored up to 8 h at 2~8°C before testing.

4. Read the result visually in 10~15 min, don't read results after 20 min.

A total of 400 clinical samples (RT-PCR result: 134 positive, 266 negative) from 400 patients: All these samples were numbered and recorded the sample information.

Table 1 Sample source and amount

| Sample types | Self-test samples | | Total |
|-------------------|-------------------|----------|-------|
| | Positive | Negative | |
| Nasal swab sample | 134 | 266 | 400 |

3.2 Sample information

Table 2 The positive patient sample information of clinical evaluation study

| Testing sites | Home base | | | | | | | | |
|---------------|-----------|-----|------------|----------------------|-------------------------------|------------------------------|----------|-------|------------|
| No. | Gender | Age | Occupation | Education background | Clinical symptoms | Days since onset of symptoms | Ct value | | PCR result |
| | | | | | | | VIC/HEX | FAM | |
| 1 | male | 39 | Teacher | Bachelor | Fever, fatigue | 1 | 23.37 | 27.86 | + |
| 2 | male | 37 | Doctor | Master | Fever, cough | 7 | 19.36 | 29.24 | + |
| 3 | male | 34 | Lawyer | Doctor | Diarrhea | 1 | 22.65 | 30.90 | + |
| 4 | male | 43 | Lawyer | Master | Fever, fatigue | 3 | 21.65 | 26.82 | + |
| 5 | female | 44 | Programmer | Doctor | Dry cough | 2 | 21.58 | 37.86 | + |
| 6 | male | 62 | Designer | Master | Nasal congestion, sore throat | 5 | 22.61 | 31.93 | + |
| 7 | female | 57 | Programmer | Doctor | Dry cough | 3 | 19.81 | 27.10 | + |
| 8 | male | 37 | Programmer | Master | Fever, fatigue | 7 | 21.70 | 31.25 | + |
| 9 | female | 63 | Teacher | Doctor | Dry cough | 3 | 23.09 | 25.95 | + |

| | | | | | | | | | |
|----|--------|----|------------|------------------------------|-----------------------------------|---|-------|-------|---|
| 10 | male | 46 | Doctor | Master | Diarrhea | 1 | 22.39 | 34.98 | + |
| 11 | male | 25 | Lawyer | Master | Nasal congestion, sore throat | 6 | 23.79 | 30.11 | + |
| 12 | male | 59 | Lawyer | Master | Nasal congestion, sore throat | 1 | 23.63 | 33.40 | + |
| 13 | female | 57 | Programmer | Doctor | Nasal congestion, sore throat | 2 | 23.05 | 28.59 | + |
| 14 | female | 51 | Designer | Master | Nasal congestion, myalgia | 7 | 21.48 | 31.00 | + |
| 15 | male | 49 | Programmer | Doctor | Fever | 6 | 21.27 | 34.44 | + |
| 16 | male | 19 | Student | High school degree and below | Nasal congestion, myalgia | 6 | 21.83 | 37.14 | + |
| 17 | female | 58 | Teacher | Bachelor | High fever | 1 | 22.83 | 35.81 | + |
| 18 | male | 29 | Other | Bachelor | Fever, fatigue | 4 | 23.17 | 29.15 | + |
| 19 | female | 61 | Programmer | Bachelor | Nasal congestion, sore throat | 1 | 20.68 | 28.25 | + |
| 20 | male | 36 | Designer | Bachelor | Diarrhea | 5 | 19.35 | 30.08 | + |
| 21 | male | 40 | Programmer | Bachelor | High fever | 4 | 19.34 | 31.80 | + |
| 22 | female | 23 | Teacher | Bachelor | Diarrhea | 7 | 21.85 | 26.42 | + |
| 23 | female | 25 | Doctor | Bachelor | Fever, cough | 6 | 19.70 | 36.80 | + |
| 24 | female | 32 | Lawyer | Bachelor | Fever, acute respiratory distress | 3 | 22.55 | 34.80 | + |

| | | | | | | | | | |
|----|--------|----|------------|----------|------------------------------|---|-------|-------|---|
| 25 | female | 49 | Other | Bachelor | Acute respiratory distress | 2 | 20.57 | 31.37 | + |
| 26 | male | 34 | Other | Master | Fever | 7 | 19.28 | 33.95 | + |
| 27 | male | 35 | Other | Doctor | Fever | 7 | 20.87 | 26.32 | + |
| 28 | female | 65 | Other | Bachelor | Fever | 5 | 21.99 | 32.19 | + |
| 29 | male | 51 | Other | Master | Fever, cough | 5 | 22.20 | 32.31 | + |
| 30 | male | 41 | Other | Doctor | Nasal congestion, runny nose | 3 | 19.81 | 28.15 | + |
| 31 | male | 40 | Other | Bachelor | Fever | 6 | 20.61 | 36.26 | + |
| 32 | male | 57 | Programmer | Master | Fever | 6 | 22.29 | 26.96 | + |
| 33 | female | 58 | Teacher | Master | Fever | 5 | 19.35 | 25.44 | + |
| 34 | male | 44 | Doctor | Master | Fever, cough | 7 | 19.05 | 35.05 | + |
| 35 | male | 47 | Lawyer | Master | Nasal congestion, runny nose | 7 | 20.76 | 32.52 | + |
| 36 | male | 32 | Programmer | Master | Fever | 4 | 23.01 | 35.85 | + |
| 37 | male | 51 | Teacher | Master | Fever | 6 | 19.41 | 36.11 | + |
| 38 | male | 45 | Doctor | Master | Nasal congestion, myalgia | 4 | 20.07 | 32.64 | + |
| 39 | male | 63 | Lawyer | Master | High fever | 1 | 21.22 | 26.44 | + |

| | | | | | | | | | |
|----|--------|----|------------|------------------------------|-----------------------------------|---|-------|-------|---|
| 40 | male | 44 | Programmer | Master | Fever, fatigue | 7 | 19.93 | 31.32 | + |
| 41 | female | 49 | Programmer | Master | Nasal congestion, sore throat | 5 | 19.37 | 31.42 | + |
| 42 | male | 18 | Student | High school degree and below | Diarrhea | 7 | 23.75 | 27.47 | + |
| 43 | male | 18 | Student | High school degree and below | High fever | 1 | 21.13 | 26.61 | + |
| 44 | male | 49 | Peasantry | High school degree and below | Diarrhea | 3 | 22.54 | 33.02 | + |
| 45 | male | 41 | Peasantry | High school degree and below | Fever, cough | 5 | 23.10 | 32.19 | + |
| 46 | male | 62 | Peasantry | High school degree and below | Fever, acute respiratory distress | 5 | 20.12 | 35.37 | + |
| 47 | female | 56 | Programmer | Doctor | Acute respiratory distress | 7 | 23.19 | 33.28 | + |
| 48 | male | 52 | Peasantry | High school degree and below | Fever | 5 | 20.57 | 27.33 | + |
| 49 | male | 33 | Teacher | Master | Fever | 2 | 19.09 | 31.57 | + |
| 50 | male | 62 | Doctor | Bachelor | Fever | 6 | 19.73 | 25.29 | + |
| 51 | male | 30 | Lawyer | Doctor | Fever, cough | 2 | 21.34 | 34.62 | + |
| 52 | female | 50 | Other | High school degree and below | Nasal congestion, runny nose | 7 | 23.17 | 32.82 | + |
| 53 | male | 54 | Doctor | Master | Fever | 4 | 19.84 | 33.92 | + |
| 54 | male | 43 | Lawyer | Bachelor | Fever | 7 | 21.58 | 30.44 | + |

| | | | | | | | | | |
|----|--------|----|------------|------------------------------|-----------------------------------|---|-------|-------|---|
| 55 | male | 28 | Teacher | Doctor | Fever | 2 | 22.98 | 27.85 | + |
| 56 | female | 20 | Student | High school degree and below | Fever, fatigue | 4 | 21.15 | 28.97 | + |
| 57 | male | 19 | Student | High school degree and below | Nasal congestion, sore throat | 6 | 23.71 | 25.87 | + |
| 58 | male | 36 | Other | Doctor | High fever | 7 | 19.32 | 27.20 | + |
| 59 | male | 28 | Peasantry | High school degree and below | Fever, fatigue | 7 | 19.83 | 33.19 | + |
| 60 | male | 26 | Other | Master | Nasal congestion, sore throat | 4 | 20.37 | 28.02 | + |
| 61 | female | 61 | Other | Bachelor | Diarrhea | 4 | 19.36 | 36.30 | + |
| 62 | male | 63 | Other | High school degree and below | High fever | 1 | 23.33 | 36.75 | + |
| 63 | male | 63 | Peasantry | High school degree and below | Diarrhea | 6 | 23.06 | 29.01 | + |
| 64 | male | 21 | Other | High school degree and below | Fever, cough | 1 | 22.91 | 32.56 | + |
| 65 | male | 24 | Other | Bachelor | Fever, acute respiratory distress | 4 | 19.55 | 26.31 | + |
| 66 | male | 65 | Other | Doctor | Acute respiratory distress | 4 | 22.09 | 32.94 | + |
| 67 | female | 50 | Other | High school degree and below | Fever | 1 | 21.12 | 35.22 | + |
| 68 | male | 49 | Programmer | Master | Fever | 4 | 19.30 | 36.84 | + |
| 69 | male | 40 | Teacher | Bachelor | Fever | 6 | 23.00 | 31.24 | + |

| | | | | | | | | | |
|----|--------|----|------------|------------------------------|-----------------------------------|---|-------|-------|---|
| 70 | male | 37 | Doctor | Doctor | Fever, cough | 1 | 19.65 | 37.29 | + |
| 71 | male | 45 | Lawyer | High school degree and below | Nasal congestion, runny nose | 7 | 23.87 | 27.38 | + |
| 72 | female | 53 | Other | Master | Fever | 6 | 22.24 | 34.29 | + |
| 73 | male | 34 | Designer | Bachelor | Fever | 1 | 22.30 | 30.78 | + |
| 74 | male | 58 | Programmer | Doctor | Fever | 7 | 21.51 | 34.81 | + |
| 75 | male | 55 | Teacher | High school degree and below | Fever, fatigue | 6 | 21.00 | 31.74 | + |
| 76 | male | 40 | Doctor | Master | High fever | 3 | 22.55 | 35.01 | + |
| 77 | male | 64 | Lawyer | Bachelor | Diarrhea | 1 | 22.48 | 27.83 | + |
| 78 | male | 31 | Other | Doctor | Fever, cough | 3 | 18.21 | 30.39 | + |
| 79 | female | 32 | Other | High school degree and below | Fever, acute respiratory distress | 2 | 23.56 | 29.78 | + |
| 80 | male | 49 | Programmer | Master | Acute respiratory distress | 6 | 20.36 | 32.99 | + |
| 81 | male | 38 | Teacher | Bachelor | Fever | 6 | 18.94 | 28.78 | + |
| 82 | male | 53 | Doctor | Doctor | Fever | 7 | 18.33 | 37.44 | + |
| 83 | male | 22 | Other | High school degree and below | Fever | 3 | 18.06 | 32.39 | + |
| 84 | male | 22 | Other | High school degree and below | Fever, cough | 7 | 19.8 | 27.59 | + |

| | | | | | | | | | |
|----|--------|----|------------|------------------------------|-----------------------------------|---|-------|-------|---|
| 85 | male | 41 | Designer | Doctor | Nasal congestion, runny nose | 3 | 18.12 | 31.79 | + |
| 86 | female | 46 | Programmer | High school degree and below | Fever | 7 | 21.65 | 37.49 | + |
| 87 | male | 42 | Teacher | Master | High fever | 4 | 19.1 | 30.23 | + |
| 88 | male | 61 | Doctor | Bachelor | Diarrhea | 2 | 24.58 | 36.05 | + |
| 89 | male | 57 | Lawyer | Doctor | Fever, cough | 3 | 23.97 | 28.08 | + |
| 90 | male | 22 | Other | Bachelor | Fever, acute respiratory distress | 3 | 18.5 | 35.85 | + |
| 91 | male | 30 | Designer | Doctor | Acute respiratory distress | 5 | 21.23 | 29.69 | + |
| 92 | male | 62 | Programmer | High school degree and below | Fever | 2 | 24.24 | 30.99 | + |
| 93 | female | 58 | Teacher | Master | Fever | 3 | 18.46 | 30.05 | + |
| 94 | male | 34 | Doctor | Bachelor | Fever | 6 | 18.6 | 28.56 | + |
| 95 | male | 45 | Lawyer | Doctor | Fever, cough | 4 | 19.53 | 27.9 | + |
| 96 | male | 45 | Other | High school degree and below | Nasal congestion, runny nose | 4 | 24.85 | 32.07 | + |
| 97 | male | 63 | Programmer | Master | Fever | 4 | 24.52 | 29.1 | + |
| 98 | male | 28 | Teacher | Bachelor | High fever | 1 | 20.81 | 26.42 | + |
| 99 | male | 50 | Doctor | Doctor | Diarrhea | 2 | 22.6 | 36.93 | + |

| | | | | | | | | | |
|-----|--------|----|----------|------------------------------|-----------------------------------|---|-------|-------|---|
| 100 | female | 49 | Other | High school degree and below | Fever, cough | 6 | 18.68 | 37.99 | + |
| 101 | male | 61 | Other | Master | Fever, acute respiratory distress | 2 | 22.51 | 36.87 | + |
| 102 | male | 30 | Other | Bachelor | Acute respiratory distress | 3 | 21.47 | 34.42 | + |
| 103 | male | 35 | Other | Doctor | Fever | 1 | 22.48 | 28.58 | + |
| 104 | male | 18 | Student | High school degree and below | Fever | 4 | 24.87 | 27.11 | + |
| 105 | male | 27 | Other | Doctor | Fever | 6 | 20.74 | 31.68 | + |
| 106 | male | 25 | Other | High school degree and below | Fever, cough | 4 | 21.23 | 28.71 | + |
| 107 | female | 41 | Other | Master | Nasal congestion, runny nose | 1 | 18.85 | 29.85 | + |
| 108 | male | 53 | Designer | Bachelor | Fever | 2 | 23.36 | 33.57 | + |
| 109 | male | 23 | Other | Doctor | High fever | 1 | 20.54 | 32.47 | + |
| 110 | male | 63 | Other | High school degree and below | Diarrhea | 6 | 18.58 | 33.1 | + |
| 111 | male | 37 | Doctor | Bachelor | Fever, cough | 4 | 23.58 | 33.58 | + |
| 112 | male | 57 | Lawyer | Bachelor | Fever, acute respiratory distress | 3 | 23.14 | 26.52 | + |
| 113 | male | 20 | Student | High school degree and below | Acute respiratory distress | 6 | 24.85 | 29.01 | + |
| 114 | female | 55 | Teacher | Master | Fever | 7 | 22.18 | 25.81 | + |

| | | | | | | | | | |
|-----|--------|----|------------|------------------------------|-----------------------------------|---|-------|-------|---|
| 115 | male | 36 | Doctor | Master | Fever | 7 | 21.31 | 32.3 | + |
| 116 | male | 23 | Other | Master | Fever | 5 | 23.69 | 32.74 | + |
| 117 | male | 22 | Other | High school degree and below | Fever, cough | 4 | 18.91 | 27.26 | + |
| 118 | male | 44 | Other | Bachelor | Nasal congestion, runny nose | 3 | 22.72 | 30.28 | + |
| 119 | male | 46 | Other | Bachelor | Fever | 5 | 18.21 | 26.89 | + |
| 120 | male | 29 | Other | Bachelor | High fever | 3 | 19.48 | 31.76 | + |
| 121 | female | 32 | Designer | Bachelor | Diarrhea | 6 | 24.15 | 33.38 | + |
| 122 | male | 31 | Programmer | Bachelor | Fever, cough | 5 | 18.89 | 29.38 | + |
| 123 | male | 35 | Teacher | Bachelor | Fever, acute respiratory distress | 1 | 24.59 | 32.42 | + |
| 124 | male | 57 | Doctor | Bachelor | Acute respiratory distress | 1 | 19.56 | 31.52 | + |
| 125 | male | 36 | Lawyer | Bachelor | Fever | 4 | 21.87 | 27.4 | + |
| 126 | male | 18 | Student | High school degree and below | Fever | 3 | 23.82 | 27.51 | + |
| 127 | male | 37 | Lawyer | Doctor | Fever | 3 | 21.07 | 26.22 | + |
| 128 | female | 19 | Student | High school degree and below | Fever, cough | 6 | 22.86 | 33.71 | + |
| 129 | male | 20 | Student | High school degree and below | Nasal congestion, runny nose | 4 | 19.52 | 29.41 | + |

| | | | | | | | | | |
|-----|------|----|---------|--------|-----------------------------------|---|-------|-------|---|
| 130 | male | 34 | Lawyer | Doctor | Fever | 3 | 18.8 | 27.67 | + |
| 131 | male | 40 | Teacher | Master | High fever | 3 | 23.84 | 25.7 | + |
| 132 | male | 41 | Doctor | Master | Diarrhea | 7 | 19.08 | 27.85 | + |
| 133 | male | 44 | Lawyer | Master | Fever, cough | 4 | 22.79 | 25.61 | + |
| 134 | male | 60 | Teacher | Master | Fever, acute respiratory distress | 7 | 18.62 | 27.52 | + |

Table 3 The negative patient sample information of clinical evaluation study

| Testing sites | Home base | | | | | | | | |
|---------------|-----------|--------|-----|------------|------------------------------|-------------------|--------------------------|------------------------------|------------|
| | No. | Gender | Age | Occupation | Education background | Clinical symptoms | Samples for nucleic acid | Days since onset of symptoms | PCR result |
| | 135 | male | 62 | Teacher | Doctor | High fever | 3 | | - |
| | 136 | male | 63 | Doctor | High school degree and below | Fever | 2 | | - |
| | 137 | female | 30 | Lawyer | Master | Fever, fatigue | 4 | | - |

| | | | | | | | |
|-----|--------|----|-----------|------------------------------|------------------------------|---|---|
| 138 | female | 65 | Teacher | Bachelor | Fever | 5 | - |
| 139 | male | 40 | Doctor | Doctor | Fever, mild fatigue | 1 | - |
| 140 | male | 52 | Other | High school degree and below | Nasal congestion, runny nose | 7 | - |
| 141 | male | 39 | Teacher | Master | Fever, fatigue | 3 | - |
| 142 | male | 28 | Other | Bachelor | Nasal congestion, runny nose | 7 | - |
| 143 | female | 39 | Other | Doctor | Fever | 4 | - |
| 144 | female | 46 | Other | High school degree and below | High fever | 7 | - |
| 145 | male | 55 | Other | Master | Fever | 3 | - |
| 146 | male | 44 | Other | Bachelor | High fever | 4 | - |
| 147 | female | 35 | Other | Doctor | Fever, mild fatigue | 7 | - |
| 148 | female | 35 | Other | High school degree and below | Fever | 5 | - |
| 149 | male | 27 | Other | Master | Fever, fatigue | 4 | - |
| 150 | male | 36 | Other | Bachelor | Nasal congestion, myalgia | 5 | - |
| 151 | female | 30 | Other | Doctor | Fever, mild fatigue | 7 | - |
| 152 | female | 28 | Peasantry | High school degree and below | Nasal congestion, runny nose | 2 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 153 | male | 64 | Other | Master | Nasal congestion, runny nose | 1 | - |
| 154 | male | 64 | Other | Bachelor | Fever, mild fatigue | 2 | - |
| 155 | female | 53 | Other | Doctor | Nasal congestion, myalgia | 2 | - |
| 156 | female | 64 | Other | High school degree and below | Fever | 6 | - |
| 157 | male | 59 | Doctor | Master | High fever | 2 | - |
| 158 | male | 48 | Doctor | Bachelor | High fever | 7 | - |
| 159 | female | 34 | Teacher | Doctor | High fever | 5 | - |
| 160 | female | 65 | Other | High school degree and below | Fever | 3 | - |
| 161 | male | 55 | Programmer | Master | High fever | 1 | - |
| 162 | male | 42 | Programmer | Bachelor | High fever | 6 | - |
| 163 | female | 31 | Programmer | Doctor | Nasal congestion, myalgia | 1 | - |
| 164 | female | 43 | Other | High school degree and below | Fever, mild fatigue | 2 | - |
| 165 | male | 53 | Programmer | Bachelor | Nasal congestion, myalgia | 4 | - |
| 166 | male | 35 | Programmer | Bachelor | Fever | 4 | - |
| 167 | female | 50 | Programmer | Bachelor | Nasal congestion, myalgia | 5 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 168 | female | 21 | Other | High school degree and below | Nasal congestion, runny nose | 6 | - |
| 169 | male | 26 | Designer | Master | Fever | 2 | - |
| 170 | male | 47 | Programmer | Master | Nasal congestion, myalgia | 5 | - |
| 171 | female | 50 | Teacher | Master | Fever, fatigue | 2 | - |
| 172 | female | 29 | Doctor | Master | Fever, mild fatigue | 2 | - |
| 173 | male | 23 | Lawyer | Master | Nasal congestion, myalgia | 4 | - |
| 174 | male | 18 | Student | High school degree and below | High fever | 1 | - |
| 175 | female | 30 | Designer | Master | Nasal congestion, runny nose | 2 | - |
| 176 | female | 65 | Programmer | Bachelor | Nasal congestion, myalgia | 4 | - |
| 177 | male | 33 | Teacher | Master | Fever | 4 | - |
| 178 | male | 19 | Student | High school degree and below | Fever | 5 | - |
| 179 | female | 31 | Designer | Master | Nasal congestion, myalgia | 7 | - |
| 180 | female | 28 | Programmer | Bachelor | Nasal congestion, myalgia | 6 | - |
| 181 | male | 42 | Teacher | Master | Nasal congestion, myalgia | 5 | - |
| 182 | male | 50 | Doctor | Bachelor | Fever, fatigue | 7 | - |

| | | | | | | | |
|-----|--------|----|----------|------------------------------|------------------------------|---|---|
| 183 | female | 65 | Lawyer | Master | Fever, fatigue | 3 | - |
| 184 | female | 58 | Designer | Bachelor | Fever, fatigue | 5 | - |
| 185 | male | 29 | Teacher | Master | Nasal congestion, runny nose | 7 | - |
| 186 | male | 65 | Doctor | Bachelor | Fever | 4 | - |
| 187 | female | 39 | Lawyer | Master | High fever | 1 | - |
| 188 | female | 62 | Teacher | Bachelor | Fever, mild fatigue | 1 | - |
| 189 | male | 60 | Doctor | Master | Fever | 6 | - |
| 190 | male | 55 | Lawyer | Bachelor | Fever | 3 | - |
| 191 | female | 56 | Teacher | Master | Nasal congestion, runny nose | 4 | - |
| 192 | female | 38 | Doctor | Bachelor | Fever, mild fatigue | 3 | - |
| 193 | male | 54 | Lawyer | Master | Fever, fatigue | 5 | - |
| 194 | male | 42 | Teacher | Bachelor | Nasal congestion, runny nose | 3 | - |
| 195 | female | 41 | Doctor | Master | High fever | 3 | - |
| 196 | female | 45 | Lawyer | Bachelor | Nasal congestion, runny nose | 1 | - |
| 197 | male | 18 | Student | High school degree and below | Fever, mild fatigue | 2 | - |

| | | | | | | | |
|-----|--------|----|---------|----------|---------------------------|---|---|
| 198 | male | 37 | Lawyer | Master | Fever | 1 | - |
| 199 | female | 59 | Lawyer | Master | Nasal congestion, myalgia | 7 | - |
| 200 | female | 44 | Lawyer | Master | Fever, fatigue | 7 | - |
| 201 | male | 52 | Lawyer | Master | Fever, mild fatigue | 3 | - |
| 202 | male | 33 | Lawyer | Master | Fever, mild fatigue | 5 | - |
| 203 | female | 55 | Lawyer | Master | Fever, fatigue | 2 | - |
| 204 | female | 36 | Lawyer | Master | Fever | 7 | - |
| 205 | male | 48 | Lawyer | Master | Fever, fatigue | 3 | - |
| 206 | male | 23 | Other | Bachelor | Fever | 3 | - |
| 207 | female | 24 | Other | Bachelor | Nasal congestion, myalgia | 3 | - |
| 208 | female | 22 | Other | Bachelor | High fever | 6 | - |
| 209 | male | 25 | Other | Master | Nasal congestion, myalgia | 7 | - |
| 210 | male | 53 | Teacher | Master | Fever | 6 | - |
| 211 | female | 33 | Doctor | Master | High fever | 3 | - |
| 212 | female | 31 | Lawyer | Master | Fever, mild fatigue | 5 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|--|---|---|
| 213 | male | 41 | Teacher | Master | Fever, mild fatigue | 5 | - |
| 214 | male | 52 | Doctor | Doctor | Fever | 7 | - |
| 215 | female | 59 | Other | High school degree and below | Fever, mild fatigue | 2 | - |
| 216 | female | 57 | Other | Master | Fever | 4 | - |
| 217 | male | 61 | Other | Bachelor | Nasal congestion, runny nose | 3 | - |
| 218 | male | 63 | Other | Doctor | Fever | 2 | - |
| 219 | female | 60 | Other | Doctor | Acute respiratory distress syndrome | 3 | - |
| 220 | female | 44 | Other | High school degree and below | Fever | 2 | - |
| 221 | male | 60 | Other | Master | Nasal congestion, myalgia | 2 | - |
| 222 | male | 38 | Designer | Bachelor | Nasal congestion, runny nose | 4 | - |
| 223 | female | 57 | Programmer | Doctor | Nasal congestion, myalgia | 3 | - |
| 224 | female | 51 | Other | High school degree and below | Fever | 7 | - |
| 225 | male | 40 | Doctor | Master | High fever | 7 | - |
| 226 | male | 55 | Lawyer | Bachelor | Fever, acute respiratory distress syndrome | 6 | - |
| 227 | female | 33 | Designer | Doctor | High fever | 1 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 228 | female | 37 | Other | High school degree and below | High fever | 3 | - |
| 229 | male | 52 | Teacher | Master | Nasal congestion, runny nose | 1 | - |
| 230 | male | 23 | Peasantry | High school degree and below | Fever | 5 | - |
| 231 | female | 41 | Designer | Doctor | High fever | 1 | - |
| 232 | female | 28 | Other | High school degree and below | Fever | 7 | - |
| 233 | male | 53 | Teacher | Master | High fever | 4 | - |
| 234 | male | 60 | Doctor | Bachelor | Nasal congestion, runny nose | 3 | - |
| 235 | female | 36 | Lawyer | Doctor | Fever | 4 | - |
| 236 | female | 59 | Other | High school degree and below | Nasal congestion, runny nose | 1 | - |
| 237 | male | 61 | Programmer | Master | Nasal congestion, runny nose | 7 | - |
| 238 | male | 43 | Teacher | Bachelor | High fever | 2 | - |
| 239 | female | 52 | Doctor | Doctor | Nasal congestion, myalgia | 3 | - |
| 240 | female | 40 | Other | High school degree and below | High fever | 3 | - |
| 241 | male | 21 | Other | High school degree and below | Fever | 4 | - |
| 242 | male | 35 | Other | High school degree and below | Fever, fatigue | 5 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 243 | female | 29 | Other | Master | Fever | 6 | - |
| 244 | female | 37 | Other | Bachelor | Fever, mild fatigue | 5 | - |
| 245 | male | 61 | Other | Doctor | Nasal congestion, runny nose | 3 | - |
| 246 | male | 43 | Other | High school degree and below | High fever | 2 | - |
| 247 | female | 49 | Other | Master | Fever | 4 | - |
| 248 | female | 54 | Other | Doctor | Nasal congestion, runny nose | 6 | - |
| 249 | male | 27 | Other | High school degree and below | High fever | 2 | - |
| 250 | male | 49 | Other | Master | Nasal congestion, myalgia | 3 | - |
| 251 | female | 32 | Programmer | Bachelor | High fever | 4 | - |
| 252 | female | 46 | Teacher | Doctor | Fever | 1 | - |
| 253 | male | 39 | Other | High school degree and below | Fever, fatigue | 2 | - |
| 254 | male | 57 | Teacher | Master | Fever | 3 | - |
| 255 | female | 57 | Designer | Bachelor | Fever, mild fatigue | 1 | - |
| 256 | female | 58 | Programmer | Doctor | Nasal congestion, runny nose | 1 | - |
| 257 | male | 41 | Other | High school degree and below | High fever | 6 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 258 | male | 22 | Other | Master | Fever | 2 | - |
| 259 | female | 53 | Designer | Bachelor | Nasal congestion, runny nose | 2 | - |
| 260 | female | 50 | Programmer | Bachelor | High fever | 5 | - |
| 261 | male | 35 | Teacher | Bachelor | Nasal congestion, myalgia | 7 | - |
| 262 | male | 64 | Doctor | Bachelor | High fever | 3 | - |
| 263 | female | 44 | Lawyer | Bachelor | Fever | 6 | - |
| 264 | female | 21 | Student | High school degree and below | Fever, fatigue | 5 | - |
| 265 | male | 46 | Programmer | Doctor | Fever | 7 | - |
| 266 | male | 36 | Other | High school degree and below | Fever, mild fatigue | 6 | - |
| 267 | female | 54 | Doctor | Master | Nasal congestion, runny nose | 4 | - |
| 268 | female | 41 | Lawyer | Bachelor | High fever | 7 | - |
| 269 | male | 32 | Designer | Doctor | Fever | 2 | - |
| 270 | male | 62 | Other | High school degree and below | Nasal congestion, runny nose | 1 | - |
| 271 | female | 52 | Teacher | Master | High fever | 3 | - |
| 272 | female | 46 | Doctor | Bachelor | Nasal congestion, myalgia | 6 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 273 | male | 60 | Lawyer | Doctor | High fever | 3 | - |
| 274 | male | 29 | Peasantry | High school degree and below | Fever | 3 | - |
| 275 | female | 38 | Teacher | Master | Fever, fatigue | 2 | - |
| 276 | female | 58 | Doctor | Bachelor | Fever | 3 | - |
| 277 | male | 38 | Lawyer | Doctor | Fever, mild fatigue | 7 | - |
| 278 | male | 28 | Peasantry | High school degree and below | Nasal congestion, runny nose | 7 | - |
| 279 | female | 54 | Designer | Master | High fever | 5 | - |
| 280 | female | 24 | Programmer | Bachelor | Fever | 1 | - |
| 281 | male | 51 | Teacher | Doctor | Nasal congestion, runny nose | 2 | - |
| 282 | male | 26 | Peasantry | High school degree and below | High fever | 2 | - |
| 283 | female | 37 | Designer | Master | Nasal congestion, myalgia | 1 | - |
| 284 | female | 29 | Programmer | Bachelor | High fever | 2 | - |
| 285 | male | 19 | Other | High school degree and below | Fever | 1 | - |
| 286 | male | 19 | Other | High school degree and below | Fever, fatigue | 1 | - |
| 287 | female | 65 | Other | High school degree and below | Fever | 1 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 288 | female | 20 | Other | High school degree and below | Fever, mild fatigue | 7 | - |
| 289 | male | 38 | Other | Doctor | Nasal congestion, runny nose | 1 | - |
| 290 | male | 39 | Other | High school degree and below | High fever | 4 | - |
| 291 | female | 48 | Programmer | Master | Fever | 4 | - |
| 292 | female | 35 | Teacher | Bachelor | Nasal congestion, runny nose | 1 | - |
| 293 | male | 34 | Doctor | Doctor | High fever | 1 | - |
| 294 | male | 25 | Other | High school degree and below | Nasal congestion, myalgia | 4 | - |
| 295 | female | 43 | Programmer | Doctor | High fever | 2 | - |
| 296 | female | 23 | Other | High school degree and below | Fever | 6 | - |
| 297 | male | 52 | Programmer | Master | Fever, fatigue | 7 | - |
| 298 | male | 22 | Other | High school degree and below | Fever | 7 | - |
| 299 | female | 38 | Other | High school degree and below | Fever, mild fatigue | 7 | - |
| 300 | female | 60 | Other | High school degree and below | Nasal congestion, runny nose | 2 | - |
| 301 | male | 64 | Other | High school degree and below | High fever | 7 | - |
| 302 | male | 63 | Other | High school degree and below | Fever | 1 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 303 | female | 65 | Programmer | Doctor | Nasal congestion, runny nose | 2 | - |
| 304 | female | 43 | Peasantry | High school degree and below | High fever | 6 | - |
| 305 | male | 46 | Programmer | Master | Nasal congestion, myalgia | 2 | - |
| 306 | male | 48 | Teacher | Bachelor | High fever | 6 | - |
| 307 | female | 47 | Doctor | Doctor | Fever | 5 | - |
| 308 | female | 50 | Peasantry | High school degree and below | Fever, fatigue | 2 | - |
| 309 | male | 50 | Teacher | Master | Fever | 4 | - |
| 310 | male | 50 | Doctor | Bachelor | Fever, mild fatigue | 4 | - |
| 311 | female | 26 | Teacher | Doctor | Nasal congestion, runny nose | 2 | - |
| 312 | female | 19 | Student | High school degree and below | High fever | 1 | - |
| 313 | male | 61 | Designer | Master | Fever | 5 | - |
| 314 | male | 21 | Workman | High school degree and below | Nasal congestion, runny nose | 1 | - |
| 315 | female | 31 | Workman | High school degree and below | High fever | 2 | - |
| 316 | female | 39 | Workman | High school degree and below | Nasal congestion, myalgia | 2 | - |
| 317 | male | 29 | Workman | High school degree and below | High fever | 3 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 318 | male | 42 | Designer | Doctor | Fever | 5 | - |
| 319 | female | 34 | Workman | High school degree and below | Fever, fatigue | 6 | - |
| 320 | female | 54 | Designer | Master | Fever | 2 | - |
| 321 | male | 63 | Programmer | Bachelor | Fever, mild fatigue | 2 | - |
| 322 | male | 29 | Designer | Doctor | Nasal congestion, runny nose | 1 | - |
| 323 | female | 38 | Other | High school degree and below | High fever | 4 | - |
| 324 | female | 43 | Teacher | Master | Fever | 3 | - |
| 325 | male | 43 | Doctor | Bachelor | Nasal congestion, runny nose | 4 | - |
| 326 | male | 19 | Student | High school degree and below | High fever | 6 | - |
| 327 | female | 28 | Other | High school degree and below | Nasal congestion, myalgia | 5 | - |
| 328 | female | 23 | Other | High school degree and below | High fever | 7 | - |
| 329 | male | 19 | Student | High school degree and below | Fever | 5 | - |
| 330 | male | 63 | Teacher | Master | Fever, fatigue | 4 | - |
| 331 | female | 43 | Doctor | Master | Fever | 5 | - |
| 332 | female | 26 | Lawyer | Master | Fever, mild fatigue | 4 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 333 | male | 52 | Teacher | Master | Nasal congestion, runny nose | 6 | - |
| 334 | male | 32 | Other | Master | High fever | 4 | - |
| 335 | female | 19 | Student | High school degree and below | Fever | 3 | - |
| 336 | female | 25 | Other | Master | Nasal congestion, runny nose | 1 | - |
| 337 | male | 58 | Other | Master | High fever | 1 | - |
| 338 | male | 38 | Other | Master | Nasal congestion, myalgia | 6 | - |
| 339 | female | 43 | Other | Master | High fever | 7 | - |
| 340 | female | 28 | Designer | Master | Fever | 7 | - |
| 341 | male | 63 | Programmer | Doctor | Fever, fatigue | 6 | - |
| 342 | male | 56 | Workman | High school degree and below | Fever | 6 | - |
| 343 | female | 47 | Doctor | Master | Fever, mild fatigue | 2 | - |
| 344 | female | 59 | Lawyer | Bachelor | Nasal congestion, runny nose | 3 | - |
| 345 | male | 43 | Designer | Doctor | High fever | 6 | - |
| 346 | male | 62 | Workman | High school degree and below | Fever | 6 | - |
| 347 | female | 63 | Teacher | Master | Nasal congestion, runny nose | 4 | - |

| | | | | | | | |
|-----|--------|----|---------|------------------------------|------------------------------|---|---|
| 348 | female | 40 | Doctor | Bachelor | High fever | 5 | - |
| 349 | male | 28 | Lawyer | Doctor | Nasal congestion, myalgia | 6 | - |
| 350 | male | 29 | Teacher | Doctor | High fever | 6 | - |
| 351 | female | 27 | Workman | High school degree and below | Fever | 4 | - |
| 352 | female | 40 | Teacher | Master | Fever, fatigue | 7 | - |
| 353 | male | 37 | Doctor | Bachelor | Fever | 2 | - |
| 354 | male | 56 | Lawyer | Doctor | Fever, mild fatigue | 1 | - |
| 355 | female | 26 | Workman | High school degree and below | Nasal congestion, runny nose | 5 | - |
| 356 | female | 39 | Other | Master | High fever | 4 | - |
| 357 | male | 36 | Other | Bachelor | Fever | 7 | - |
| 358 | male | 51 | Other | Doctor | Nasal congestion, runny nose | 4 | - |
| 359 | female | 32 | Other | Doctor | High fever | 4 | - |
| 360 | female | 21 | Workman | High school degree and below | Nasal congestion, myalgia | 6 | - |
| 361 | male | 28 | Other | Doctor | High fever | 2 | - |
| 362 | male | 58 | Workman | High school degree and below | Fever | 3 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 363 | female | 20 | Workman | High school degree and below | Fever, fatigue | 5 | - |
| 364 | female | 28 | Other | Bachelor | Fever | 1 | - |
| 365 | male | 34 | Other | Bachelor | Fever, mild fatigue | 3 | - |
| 366 | male | 54 | Other | Bachelor | Nasal congestion, runny nose | 4 | - |
| 367 | female | 36 | Other | Bachelor | High fever | 4 | - |
| 368 | female | 30 | Other | Bachelor | Fever | 1 | - |
| 369 | male | 58 | Designer | Bachelor | Nasal congestion, runny nose | 7 | - |
| 370 | male | 33 | Programmer | Bachelor | High fever | 1 | - |
| 371 | female | 36 | Teacher | Bachelor | Nasal congestion, myalgia | 6 | - |
| 372 | female | 45 | Doctor | Bachelor | High fever | 7 | - |
| 373 | male | 38 | Lawyer | Bachelor | Fever | 5 | - |
| 374 | male | 61 | Designer | Bachelor | Fever, fatigue | 1 | - |
| 375 | female | 48 | Programmer | Bachelor | Fever | 1 | - |
| 376 | female | 43 | Teacher | Bachelor | Fever, mild fatigue | 1 | - |
| 377 | male | 29 | Doctor | Bachelor | Nasal congestion, runny nose | 1 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 378 | male | 20 | Student | High school degree and below | High fever | 2 | - |
| 379 | female | 29 | Teacher | Bachelor | Fever | 5 | - |
| 380 | female | 35 | Doctor | Doctor | Nasal congestion, runny nose | 6 | - |
| 381 | male | 56 | Peasantry | High school degree and below | High fever | 7 | - |
| 382 | male | 64 | Teacher | Master | Nasal congestion, myalgia | 1 | - |
| 383 | female | 31 | Doctor | Bachelor | High fever | 5 | - |
| 384 | female | 51 | Teacher | Doctor | Fever | 2 | - |
| 385 | male | 31 | Peasantry | High school degree and below | Fever, fatigue | 3 | - |
| 386 | male | 43 | Programmer | Master | Fever | 5 | - |
| 387 | female | 24 | Teacher | Bachelor | Fever, mild fatigue | 3 | - |
| 388 | female | 53 | Doctor | Doctor | Nasal congestion, runny nose | 1 | - |
| 389 | male | 42 | Peasantry | High school degree and below | High fever | 1 | - |
| 390 | male | 63 | Programmer | Master | Fever | 1 | - |
| 391 | female | 31 | Teacher | Bachelor | Nasal congestion, runny nose | 3 | - |
| 392 | female | 57 | Doctor | Doctor | High fever | 3 | - |

| | | | | | | | |
|-----|--------|----|------------|------------------------------|------------------------------|---|---|
| 393 | male | 34 | Peasantry | High school degree and below | Nasal congestion, myalgia | 3 | - |
| 394 | male | 47 | Programmer | Master | High fever | 2 | - |
| 395 | female | 54 | Teacher | Bachelor | Fever | 4 | - |
| 396 | female | 19 | Other | High school degree and below | Fever, fatigue | 5 | - |
| 397 | male | 41 | Other | High school degree and below | Fever | 5 | - |
| 398 | male | 46 | Other | High school degree and below | Fever, mild fatigue | 4 | - |
| 399 | female | 22 | Other | High school degree and below | Nasal congestion, runny nose | 2 | - |
| 400 | female | 43 | Other | Doctor | High fever | 4 | - |

4 Test process

The clinical evaluation study of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated by testing a total of 400 clinical samples. The samples were collected from patients in Germany in Europe. Testing was performed on March 2021.

The clinical evaluation study of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was a double-blind and randomization experiment. The test was performed by A, B, C. A is responsible for the test by One Step Test for SARS-CoV-2 Antigen (Colloidal Gold). B is responsible for the numbering of samples and the test by comparator reagent (PCR) (Note: A and B should keep the test results confidential to ensure double-blind testing). C is responsible for unblinding the test results and the statistical analysis of the data.

400 clinical samples were tested separately, the results were recorded and statistically analyzed. The clinical agreement was studied by comparing the test results of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) with BGI's test kit.

5 Statistical methods

5.1 Calculation method of positive, negative and total percent agreement

Table 4 The test results of trial reagent and comparator reagent

| Experiment | | comparator reagent | |
|---------------|----------|--------------------|----------|
| | | positive | negative |
| trial reagent | positive | a | b |
| | negative | c | d |

Calculation with the following formula:

Positive percent agreement = $a / (a+c) \times 100\%$

Negative percent agreement = $d / (b+d) \times 100\%$

Total percent agreement = $(a+d) / (a+b+c+d) \times 100\%$

5.2 Calculation method of 95% confidence interval

(1) The formula for calculating 95% confidence interval of total percent agreement

$$[100\% (Q1 - Q2) / Q3, 100\% (Q1 + Q2) / Q3]$$

$$Q1 = 2(a+d) + 1.96^2$$

$$Q2 = 1.96 \sqrt{1.96^2 + 4(a+d)(b+c)/n}$$

$$Q3 = 2(n + 1.96^2)$$

(2) The formula for calculating 95% confidence interval of positive percent agreement

$$[100\% (Q1, ppa - Q2, ppa) / Q3, 100\% (Q1, ppa + Q2, ppa) / Q3, ppa]$$

$$Q1, ppa = 2a + 1.96^2$$

$$Q2, ppa = 1.96 \sqrt{1.96^2 + 4ac/(a+c)}$$

$$Q3, ppa = 2(a+c + 1.96^2)$$

(3) The formula for calculating 95% confidence interval of negative percent agreement

$$[100\% * (Q1, npa - Q2, npa) / Q3, npa, 100\% * (Q1, npa + Q2, npa) / Q3, npa]$$

$$Q1, npa = 2d + 1.96^2$$

$$Q2, npa = 1.96 \sqrt{1.96^2 + 4bd/(b+d)}$$

$$Q3, npa = 2(b+d + 1.96^2)$$

6 Test results

The test results are as follows.

1) Valid Test

Positive (+):

Two bands appear, one at the control area (C) and the other at the test line (T). The result indicates the presence of SARS-CoV-2 antigen.

Negative (-):

A single band appears at the control area (C) and no other band at test line. The result indicates that the sample does not contain SARS-CoV-2 antigen or the concentration is below the limit of detection of the kit.



2) Invalid Test

If no band appears in the control area (C), the test result is invalid. The test should be repeated with a new test card and if the same situation reappears, please stop using this batch of products and contact your supplier.



Across all study sites, 134 samples with PCR positive and 266 samples with PCR negative were tested with the One Step Test for SARS-CoV-2 Antigen (Colloidal Gold). Overall study results are shown in Table 5 below.

Table 5 The test results of clinical evaluation study

| No. | Getein self-test results | PCR result | No. | Getein self-test results | PCR result |
|-----|--------------------------|------------|-----|--------------------------|------------|
| 1 | + | + | 201 | - | - |
| 2 | + | + | 202 | - | - |
| 3 | + | + | 203 | - | - |
| 4 | + | + | 204 | - | - |
| 5 | + | + | 205 | - | - |
| 6 | + | + | 206 | - | - |
| 7 | + | + | 207 | - | - |
| 8 | + | + | 208 | - | - |
| 9 | + | + | 209 | - | - |
| 10 | + | + | 210 | - | - |
| 11 | + | + | 211 | - | - |
| 12 | + | + | 212 | - | - |
| 13 | + | + | 213 | - | - |

| | | | | | |
|----|---|---|-----|---|---|
| 14 | + | + | 214 | - | - |
| 15 | + | + | 215 | - | - |
| 16 | + | + | 216 | - | - |
| 17 | + | + | 217 | - | - |
| 18 | + | + | 218 | - | - |
| 19 | + | + | 219 | - | - |
| 20 | + | + | 220 | - | - |
| 21 | + | + | 221 | - | - |
| 22 | + | + | 222 | - | - |
| 23 | + | + | 223 | - | - |
| 24 | + | + | 224 | - | - |
| 25 | + | + | 225 | - | - |
| 26 | + | + | 226 | - | - |
| 27 | + | + | 227 | - | - |
| 28 | + | + | 228 | - | - |

| | | | | | |
|----|---|---|-----|---|---|
| 29 | + | + | 229 | - | - |
| 30 | + | + | 230 | - | - |
| 31 | + | + | 231 | - | - |
| 32 | + | + | 232 | - | - |
| 33 | + | + | 233 | - | - |
| 34 | + | + | 234 | - | - |
| 35 | + | + | 235 | - | - |
| 36 | + | + | 236 | - | - |
| 37 | + | + | 237 | - | - |
| 38 | + | + | 238 | - | - |
| 39 | + | + | 239 | - | - |
| 40 | + | + | 240 | - | - |
| 41 | + | + | 241 | - | - |
| 42 | + | + | 242 | - | - |
| 43 | + | + | 243 | - | - |

| | | | | | |
|----|---|---|-----|---|---|
| 44 | + | + | 244 | - | - |
| 45 | + | + | 245 | - | - |
| 46 | + | + | 246 | - | - |
| 47 | + | + | 247 | - | - |
| 48 | + | + | 248 | - | - |
| 49 | + | + | 249 | - | - |
| 50 | + | + | 250 | - | - |
| 51 | + | + | 251 | - | - |
| 52 | + | + | 252 | - | - |
| 53 | + | + | 253 | - | - |
| 54 | + | + | 254 | - | - |
| 55 | + | + | 255 | - | - |
| 56 | + | + | 256 | - | - |
| 57 | + | + | 257 | - | - |
| 58 | + | + | 258 | - | - |

| | | | | | |
|----|---|---|-----|---|---|
| 59 | + | + | 259 | - | - |
| 60 | + | + | 260 | - | - |
| 61 | + | + | 261 | - | - |
| 62 | + | + | 262 | - | - |
| 63 | + | + | 263 | - | - |
| 64 | + | + | 264 | - | - |
| 65 | + | + | 265 | - | - |
| 66 | + | + | 266 | - | - |
| 67 | + | + | 267 | - | - |
| 68 | + | + | 268 | - | - |
| 69 | + | + | 269 | - | - |
| 70 | + | + | 270 | - | - |
| 71 | + | + | 271 | - | - |
| 72 | + | + | 272 | - | - |
| 73 | + | + | 273 | - | - |

| | | | | | |
|----|---|---|-----|---|---|
| 74 | + | + | 274 | - | - |
| 75 | - | + | 275 | - | - |
| 76 | + | + | 276 | - | - |
| 77 | + | + | 277 | - | - |
| 78 | + | + | 278 | - | - |
| 79 | + | + | 279 | - | - |
| 80 | - | + | 280 | - | - |
| 81 | + | + | 281 | - | - |
| 82 | + | + | 282 | - | - |
| 83 | + | + | 283 | - | - |
| 84 | + | + | 284 | - | - |
| 85 | + | + | 285 | - | - |
| 86 | + | + | 286 | - | - |
| 87 | + | + | 287 | - | - |
| 88 | + | + | 288 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 89 | + | + | 289 | - | - |
| 90 | + | + | 290 | - | - |
| 91 | + | + | 291 | - | - |
| 92 | + | + | 292 | - | - |
| 93 | + | + | 293 | - | - |
| 94 | + | + | 294 | - | - |
| 95 | + | + | 295 | - | - |
| 96 | + | + | 296 | - | - |
| 97 | + | + | 297 | - | - |
| 98 | + | + | 298 | - | - |
| 99 | + | + | 299 | + | - |
| 100 | + | + | 300 | - | - |
| 101 | + | + | 301 | - | - |
| 102 | + | + | 302 | - | - |
| 103 | + | + | 303 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 104 | + | + | 304 | - | - |
| 105 | + | + | 305 | - | - |
| 106 | + | + | 306 | - | - |
| 107 | + | + | 307 | - | - |
| 108 | + | + | 308 | - | - |
| 109 | + | + | 309 | - | - |
| 110 | + | + | 310 | - | - |
| 111 | + | + | 311 | - | - |
| 112 | + | + | 312 | - | - |
| 113 | + | + | 313 | - | - |
| 114 | + | + | 314 | - | - |
| 115 | - | + | 315 | - | - |
| 116 | + | + | 316 | - | - |
| 117 | + | + | 317 | - | - |
| 118 | + | + | 318 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 119 | + | + | 319 | - | - |
| 120 | + | + | 320 | - | - |
| 121 | + | + | 321 | - | - |
| 122 | + | + | 322 | - | - |
| 123 | + | + | 323 | - | - |
| 124 | + | + | 324 | - | - |
| 125 | + | + | 325 | - | - |
| 126 | + | + | 326 | - | - |
| 127 | + | + | 327 | - | - |
| 128 | + | + | 328 | - | - |
| 129 | + | + | 329 | - | - |
| 130 | + | + | 330 | - | - |
| 131 | + | + | 331 | - | - |
| 132 | + | + | 332 | - | - |
| 133 | + | + | 333 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 134 | - | + | 334 | - | - |
| 135 | - | - | 335 | - | - |
| 136 | - | - | 336 | - | - |
| 137 | - | - | 337 | - | - |
| 138 | - | - | 338 | - | - |
| 139 | - | - | 339 | - | - |
| 140 | + | - | 340 | - | - |
| 141 | - | - | 341 | - | - |
| 142 | - | - | 342 | - | - |
| 143 | - | - | 343 | - | - |
| 144 | - | - | 344 | - | - |
| 145 | - | - | 345 | - | - |
| 146 | - | - | 346 | - | - |
| 147 | - | - | 347 | - | - |
| 148 | - | - | 348 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 149 | - | - | 349 | - | - |
| 150 | - | - | 350 | - | - |
| 151 | - | - | 351 | - | - |
| 152 | - | - | 352 | - | - |
| 153 | - | - | 353 | - | - |
| 154 | - | - | 354 | - | - |
| 155 | - | - | 355 | - | - |
| 156 | - | - | 356 | - | - |
| 157 | - | - | 357 | - | - |
| 158 | - | - | 358 | - | - |
| 159 | - | - | 359 | - | - |
| 160 | - | - | 360 | - | - |
| 161 | - | - | 361 | - | - |
| 162 | - | - | 362 | - | - |
| 163 | - | - | 363 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 164 | - | - | 364 | - | - |
| 165 | - | - | 365 | - | - |
| 166 | - | - | 366 | - | - |
| 167 | - | - | 367 | - | - |
| 168 | - | - | 368 | - | - |
| 169 | - | - | 369 | - | - |
| 170 | - | - | 370 | - | - |
| 171 | - | - | 371 | - | - |
| 172 | - | - | 372 | - | - |
| 173 | - | - | 373 | - | - |
| 174 | - | - | 374 | - | - |
| 175 | - | - | 375 | - | - |
| 176 | - | - | 376 | - | - |
| 177 | - | - | 377 | - | - |
| 178 | - | - | 378 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 179 | - | - | 379 | - | - |
| 180 | - | - | 380 | - | - |
| 181 | - | - | 381 | - | - |
| 182 | - | - | 382 | - | - |
| 183 | - | - | 383 | - | - |
| 184 | - | - | 384 | - | - |
| 185 | - | - | 385 | - | - |
| 186 | - | - | 386 | - | - |
| 187 | - | - | 387 | - | - |
| 188 | - | - | 388 | - | - |
| 189 | - | - | 389 | - | - |
| 190 | - | - | 390 | - | - |
| 191 | - | - | 391 | - | - |
| 192 | - | - | 392 | - | - |
| 193 | - | - | 393 | - | - |

| | | | | | |
|-----|---|---|-----|---|---|
| 194 | - | - | 394 | - | - |
| 195 | - | - | 395 | - | - |
| 196 | - | - | 396 | - | - |
| 197 | - | - | 397 | + | - |
| 198 | - | - | 398 | - | - |
| 199 | - | - | 399 | - | - |
| 200 | - | - | 400 | - | - |

7 Statistical analysis

According to the statistical methods, the results of clinical evaluation study were as follows.

(1) Correlation analysis of SARS-CoV-2 Antigen reagents

The test results were summarized as follows.

Table 6 Trail reagent and comparator reagent results of SARS-CoV-2 Antigen

| SARS-CoV-2 Antigen | | Comparator reagent | |
|--------------------|----------|--------------------|----------|
| | | positive | negative |
| Trial reagent | positive | 130 | 3 |
| | negative | 4 | 263 |

SARS-CoV-2 Antigen positive percent agreement= $130/(130+4) \times 100\% = 97.01\%$

SARS-CoV-2 Antigen negative percent agreement= $263/(263+3) \times 100\% = 98.87\%$

SARS-CoV-2 Antigen total percent agreement= $(130+263)/400 \times 100\% = 98.25\%$

Table 7 The 95% CI and percent agreement of SARS-CoV-2 Antigen trail reagent

| SARS-CoV-2 Antigen trail reagent | Getein | | | |
|----------------------------------|----------|---------|----------|---------------|
| | Q1 | Q2 | Q3 | 95% CI |
| Total percent agreement | 789.8416 | 10.9745 | 807.6832 | 96.43%~99.15% |
| | Q1,ppa | Q2,ppa | Q3,ppa | 95% CI |
| Positive percent agreement | 263.8416 | 8.6249 | 275.6832 | 92.58%~98.83% |
| | Q1,npa | Q2,npa | Q3,npa | 95% CI |
| Negative percent agreement | 529.8416 | 7.7677 | 539.6832 | 96.74%~99.62% |

(2) Patient Demographics

Patient demographics (days since onset of symptoms) are available for the 400 samples used in the analysis.

Table 8 The specimen positivity based on days since onset of symptoms

| Days since | RT-PCR | SARS-CoV-2 | PPA | 95 % Confidence |
|------------|--------|------------|-----|-----------------|
|------------|--------|------------|-----|-----------------|

| onset of symptoms | Positive (+) | Antigen trail reagent Positive (+) | | Interval |
|-------------------|--------------|------------------------------------|---------|----------------|
| 1 | 20 | 20 | 100.00% | 83.89%~100.00% |
| 2 | 12 | 12 | 100.00% | 75.75%~100.00% |
| 3 | 21 | 21 | 100.00% | 84.54%~100.00% |
| 4 | 22 | 22 | 100.00% | 85.13%~100.00% |
| 5 | 13 | 13 | 100.00% | 77.19%~100.00% |
| 6 | 22 | 20 | 90.91% | 72.18%~97.47% |
| 7 | 24 | 22 | 91.67% | 74.15%~97.68% |

8 Conclusion

In this study, *One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)* developed by the Getein Biotech, Inc., is the trial reagent. Real-Time Fluorescent RT-PCR Kit for detecting SARS-CoV-2 Antigen developed by BGI Genomics Co. Ltd., is the comparator reagent. 400 clinical samples from 400 patients, including 134 patients with positive PCR results and 266 patients with negative PCR results, were tested with the trial reagent to evaluate the clinical agreement.

According to the results of clinical validation study, 400 clinical patients were tested for SARS-CoV-2 Antigen. For SARS-CoV-2 Antigen tested by trial reagents, the positive percent agreement was 97.01%, the 95% confidence interval of the positive percent agreement (diagnostic sensitivity) was [92.58%,98.83%], the negative percent agreement (diagnostic specificity) was 98.87%, the 95% confidence interval of the negative percent agreement was [96.74%,99.62%], the total percent agreement was 98.25%, the 95% confidence interval of the total percent agreement was [96.43%,99.15%].