EU CE Certification | **Emergency Use Authorization** | **WHO-Emergency Use Listing**

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

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Ons kenmerk:
CIBG-20204011

Bijlagen
-

Uw aanvraag
13 augustus 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 18 augustus 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 13 augustus 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam JOYSBIO (Tianjin) Biotechnology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

SARS-CoV-2 IgG/Neutralizing antibody Rapid Test Kit(Colloidal Gold) ,SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold),Immunochromatography analyzer
(geen merknaam) (NL-CA002-2020-53008)

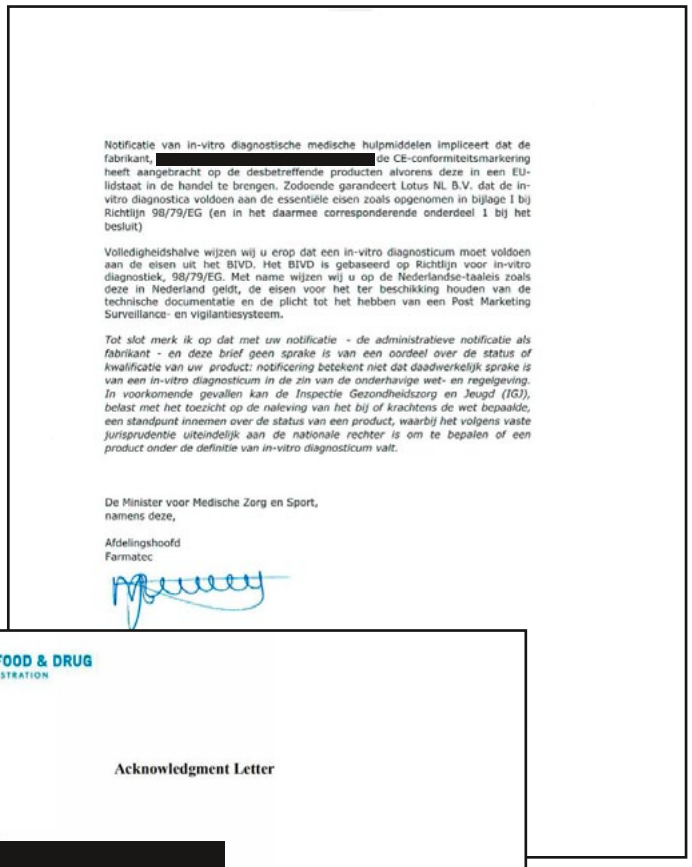
Tuberculosis Antibody Test Kit (Colloidal Gold) ,Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold),Treponema Pallidum Antibody Test Kit (Colloidal Gold),Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-53009)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Pagina 1 van 2



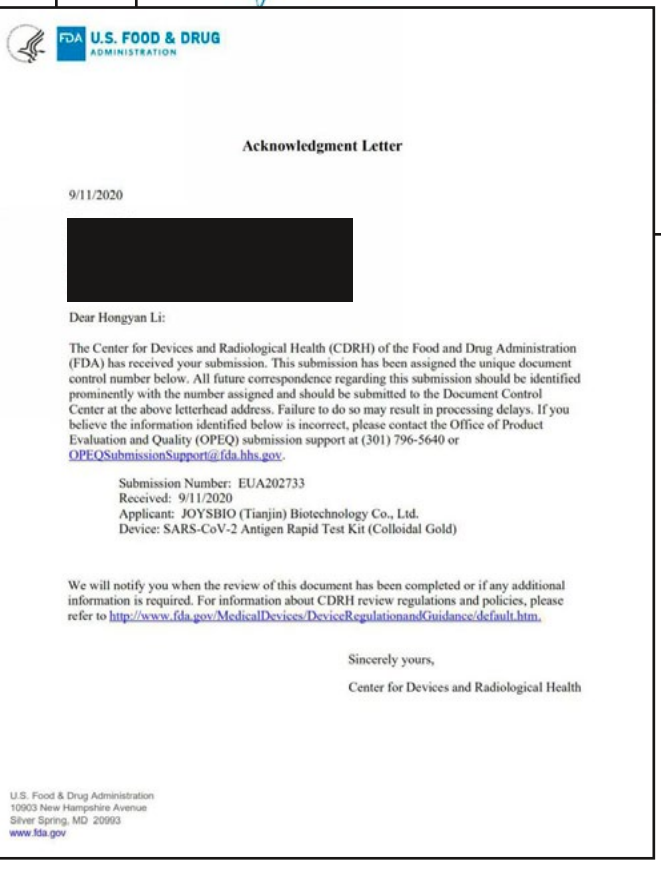
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, [redacted] de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

9/11/2020

[redacted]

Dear Hongyan Li:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA202733
Received: 9/11/2020
Applicant: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) Clinical

Evaluation Report

Product name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Packing specification: 20 tests/box

Clinical evaluation category: Comparison with Real-Time Fluorescent RT-PCR Kit for Detecting 2019-nCoV produced by [redacted]

Clinical evaluation place: Beijing Ditan Hospital Capital Medical University, China

Start date: June 13, 2020

End date : June 18, 2020

Operator (signature): Liu Minjuan, LiJing, Nian Yaxuan

Statistics (signature)：Tian Hui

Application company（seal）：[redacted]

Contact：Li Hongyan

Phone：-86-022-65378415

Report date: June 2l, 2020

3.2.1 Introduction:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N).

The antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

3.2.3 Detection principle:

The Kit uses an immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in oral fluid samples from patients with signs and symptoms of infection who are suspected of COVID-19..

Key components: the anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody, and goat anti-chicken IgY antibody.

When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to colloidal gold in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A color band will show up when antigen-conjugate is deposited at the Test “T” position and the Control “C” position on the device.

3.2.4 Purpose:

Evaluation the clinical performance of the SARS-CoV-2 Antigen Rapid Test Kit for accurately detection of SARS-CoV-2 antigen in human oral fluid.

3.2.5 Testing management:

During the trial, the main investigator is responsible for the coordination and management of the entire clinical trial, and the main participants are responsible for the main trial work. During the clinical trial, the main researcher supervises the quality control of the testing laboratory. Any problems found in the test must be contacted with the main researcher in time and appropriate measures should be taken. The final test results are statistically analyzed by the person in charge of statistics, and the main investigator confirmed and wrote the report.

3.2.6 Methods:

Synchronous blind test and methodological comparison design.

The oral fluid and throat swab samples were collected by hospital professional medical staff in accordance with the sampling methods of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and Real-Time Fluorescent RT-PCR Kit for Detecting 2019-nCoV. The oral fluid and throat swab samples are blindly numbered and grouped by the JOYSBIO editor. Oral fluid samples are divided into one group, throat swab samples are divided into another group, and then tested by JOYSBIO laboratory inspectors.

3.2.7 Discussion and Conclusion

Results:

In this clinical trial, oral fluid specimens were obtained from Beijing Ditan Hospital Capital Medical University and tested with the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and the comparator device Real-Time Fluorescent RT-PCR Kit for Detecting 2019-nCoV produced by [redacted] Statistical analysis was performed to calculate the positive agreement rate and negative agreement rate.

In this study, a total of 122 oral fluid samples were obtained for clinical performance evaluation by comparing the investigational device, the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold), and reference reagent [redacted] device. The oral fluids prospectively collected from individual symptomatic patients who were suspected of COVID-19. No duplicate samples were selected. The gender ratio was 76 males (62.30%) and 46 females (37.70%). The age of enrolled patients ranged from 10 to 80years. There were 82 negative SARS-CoV-2 antigen cases, total of 67.21% of the subjects and 40 positive samples, (32.79%). In June 2020, 520 PCR (Real-time fluorescent RT-PCR Kit for Detecting 2019-nCoV,) samples were collected prospectively from the Beijing Ditan Hospital Capital Medical University.

These 122 samples were tested both investigational device and comparator device and results were compared. The results showed that the clinical sensitivity and specificity 95.00% and the was 98.78%.

Conclusion:

This clinical trial by comparing the results obtained by testing potential SARS-CoV-2 positive samples with investigational device and EUL granted device demonstrated that the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) devices performs as it is claimed in the clinical. The

detection sensitivity for the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) of oral fluid was 95.00%, and the specificity was 98.78%. The results showed that the investigational device, the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold), meets the needs of clinical testing.

3.2.8 Main Content

General design

This test uses a synchronous blind test and methodological comparison design.

In order to eliminate the possible impact of the subjective biases and personal preferences of researchers on the test results during the clinical trial process, this test uses a blind test. That is, the test personnel in this test do not know the specific information of the sample, and the clinical information of the sample may not be released until the end of the test. After the samples were enrolled, the samples were coded by the blind editor authorized by the clinical trial, in which the blind editor was not involved in the test operation of the clinical trial. Testing personnel shall test the coded sample according to the reagent test specification. In the process of test operation, clinical test researchers should strictly follow the requirements of the product specification for test operation and interpretation check, and the results obtained in the test process should be truthfully recorded in the data collection table.

For the detection of SARS-CoV-2 Antigen, The oral fluid and throat swab samples were collected by hospital professional medical staff in accordance with the sampling methods of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2. The oral fluid and throat swab samples are blindly numbered and grouped by the JOYSBIO editor. Oral fluid samples are divided into one group, throat swab samples are divided into another group, and then tested by JOYSBIO laboratory inspectors. Among them, there are 3 JOYSBIO laboratory inspectors.

Measures to reduce and avoid bias

Subjects were screened strictly according to the blind grouping of the clinical trial protocol to reduce the selection bias.

Prior to the start of the trial, the sponsor trained the lab operators to correctly perform the tests and follow the trial protocol.

Clinical sample related requirements

1) DOs and DON'Ts of Sample Collection

• Do collect sample as soon as possible after onset of symptoms.

• Do test sample immediately.

2) Sample storage

- Specimen Transport and Storage
- Freshly collected specimens should be processed within 1 hour.
- It is essential that correct specimen collection and preparation methods be followed.

Clinical sample selection

1) Inclusion criteria

Sample inclusion criteria: the sample should be a sample with clearly recorded source, including different age, gender and other factors. The collection and treatment of samples are in accordance with the reagent specification or relevant regulations. Sample information should be complete, including age, sex, sample collection date, clinical diagnosis such as confirmation or exclusion of SARS-CoV-2 infection.

2) Exclusion criteria

- Samples that are unable to complete the test process human factors (sample contamination during operation).
- Samples were contaminated with bacteria or/and bleeding gums.
- Contains more food residue.
- Samples not kept at the requirement conditions.

3.2.9 Quality control

Definition

Quality control is defined as the operation of techniques and activities, such as monitoring, under the quality assurance system to verify that the research quality meets the requirements. Quality control must be applied at every stage of data processing to ensure that all data is trusted and properly located.

1）Study monitoring

During the outbreak, authorized and qualified inspectors will conduct regular remote primary data checks according to the monitoring plan to verify compliance with protocols and regulations and assist investigators.

2） Laboratory quality control

The laboratory of the testing shall establish a unified test index, standard operating procedures and quality control procedures.

3）Quality control of reagent testing process

In each test, the control line shall have red strip (qualified quality control). If the control line does not have red strip (unqualified quality control), the cause shall be found out and retested until the quality control result is qualified, so as to ensure the reliability and stability of the system.

4）Qualification of researchers

The researchers participating in the clinical trial must have the specialty, qualification and ability of the clinical trial, and pass the qualification examination. The personnel requirements should be relatively fixed.

3.2.10 Reagents and instruments for clinical research

The information of reagents for test is shown in Table 1:

Table 1 Reagent Information

	Assessment reagent	Reference reagent
Reagent Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Real-Time Fluorescent RT-PCR Kit for Detecting 2019-nCoV
Specification	20 tests/box	50 tests/box
Company	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	BGI BIOTECHNOLOGY (WUHAN) CO.,LTD
Lot Number	2020031204	20200502
Expiration	2021.03.11	2020.11.01
Preserrvation Condition	2~30℃	< -18℃
Registration Number	/	国械注准：20203400060

3.2.11 Statistical analysis method of clinical trial data

Use SPSS16.0 statistical software or the following formula for statistical analysis.

Table 2 Consistency data analysis

Experimental Reagent Group	Reference Reagent Group		Sum
	Positive	Negative	
Positive	a	b	a+b
Negative	c	d	c+d

Sum	a+c	b+d	a+b+c+d
Sensitivity	a/(a+c)		
Specificity	d/(b+d)		
Accuracy	ACC/OPA=(a+d)/(a+b+c+d)*100%		
Kappa	$\frac{2(ad-bc)}{(a+b)(b+d)+(a+c)(c+d)}$		
95%CI	Normal approximation		

3.2.12 Clinical Trial Results and Analysis

Overall distribution of samples

In this test, a total of 122 cases of oral fluid specimens were enrolled in the consistency comparison test of experimental reagent and reference reagent, and 0 cases of repeated samples were excluded for statistical analysis, including 82 negative samples (67.21%), 40 positive samples (32.79%).

Table 3 Proportion and number distribution of clinical trials

Sample	oral fluid specimens	
	Negative	Positive
Number of cases	82	40
Ratio	67.21%	32.79%
Number of total cases Positive	122	

Sex and age distribution of samples

A total of 122 oral fluid specimens were enrolled in the consistency comparison test of experimental reagent and reference reagent, including 76 males and 46 females.

The specific distribution of samples is shown in the following table:

Table 4 Sex and age distribution

Index	Sample type	Oral fluid specimens
Number of samples	Total	122
Sex	Male（N,%）	76 (62.30%)
	Female（N,%）	46 (37.70%)
Age（y）	X±SD	40.68±20.09
	Min-Max	10 ~80

Consistency analysis of test results

1) Consistency comparison of experimental reagent and reference reagent

Overall Clinical Study

In this study, 122 oral fluid specimens were obtained in the clinical performance study to compare SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) (evaluating device for antigen testing) and the Real-Time Fluorescent RT-PCR Kit for Detecting 2019-nCoV(BGI BIOTECHNOLOGY). The clinical performance data of the SARS-CoV-2 test results were analyzed, and 98 samples were tested positive by the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold). There were 4 samples in which the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was positive and the BGI device was negative. There were 10 samples in which the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was negative and the reference reagent was positive. There were 408 samples with negative test results in experimental reagent and 412 samples with negative test results in reference reagent. Hence, the sensitivity and specificity were 95.00% and 98.78% respectively.

Table 8 Overall Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	38	1	39
negative	2	81	83
Subtotal	40	82	122

Positive Percent Agreement (PPA)= 38/40(95.00%) （95%CI: 83.1%~99.4%）
Negative Percent Agreement (NPA)= 81/82(98.78%) （95%CI: 93.4%~100.0%）
Accuracy=(38+81)/122×100%=97.54%
Kappa=2×3076/ 6518=0.94＞0.5

2) Test Reliability

- The collection and preservation methods of all test samples are reliable.
- The operators have received special training throughout the test process to ensure the reliability of the test results.
- When conducting clinical trials, the tests shall be conducted in strict accordance with the requirements of laboratory quality control and clinical trial program in clinical hospitals. The results were analyzed by experienced researchers to ensure the reliability of clinical trials.

3) Discussion and Conclusion

In this test, a total of 122 oral fluid specimens samples were enrolled for the consistency comparison of experimental reagent and reference reagent, and no duplicate samples were selected. The sex ratio was distributed among 76 males (62.30%) and 46 females (37.70%). The age of enrolled patients ranged from 10 to 80 years. There were 82 cases with negative SARS-CoV-2 Ag, accounting for 67.21% and 40 positive samples, accounting for 32.79%. In June 2020, 122 PCR (Real-time fluorescent RT-PCR Kit for Detecting 2019-nCoV,) samples from the Beijing Ditan Hospital Capital Medical University.

According to the consistency analysis of 122 samples, clinical study results showed that the detection sensitivity was 95.00% and the specificity was 98.78% .

Conclusion:

This clinical trial has performed a full analysis of the experimental reagents through methodological comparisons, and the results all meet the criteria for clinical evaluation. All the results showed that SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) meet the needs of clinical test.

Basic information of positive and negative samples of SARS-CoV-2, 122 cases verified by PCR (Real-Time Fluorescent RT-PCR Kit for Detecting 2019-nCoV, BGI) were collected in June 2020 from the Beijing Ditan Hospital Capital Medical University.

Basic information on positive samples of SARS-CoV-2

NO.	Sample ID	Gender	Age	Physiological state	Number of days to collect samples after symptoms appear	Experimental reagent Assessment test results			PCR test results			
						Sample type	Collection date	Determination	Sample type	Collection date	Determination	CT
1	DT-S10036	male	42	cough	0	oral fluid	2020/6/18	+	throat swab (TS)	2020/6/18	+	22
2	DT-S 10035	male	54	myalgia	0	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	24
3	DT-S 10073	male	23	fever, fatigue	0	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	22
4	DT-S 10048	female	55	cough	0	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	23
5	DT-S 10182	male	39	fever	0	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	22
6	DT-S 10157	male	29	cough	0	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	23
7	DT-S 10159	female	40	fever	0	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	24
8	DT-S 10170	male	36	fever, runny nose	0	oral fluid	2020/6/16	+	throat swab (TS)	2020/6/16	+	22
9	DT-S 10037	female	20	cough	0	oral fluid	2020/6/17	+	throat swab (TS)	2020/6/17	+	23
10	DT-S 10063	female	31	cough	0	oral fluid	2020/6/17	+	throat swab (TS)	2020/6/17	+	24
11	DT-S 10141	female	33	myalgia	0	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	22
12	DT-S 10001	female	51	fever, fatigue	0	oral fluid	2020/6/16	+	throat swab (TS)	2020/6/16	+	23
13	DT-S 10190	male	52	cough	1	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	23
14	DT-S 10200	male	46	fever	1	oral fluid	2020/6/13	+	throat swab	2020/6/13	+	22

									(TS)			
15	DT-S 10155	male	60	fever	1	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	24
16	DT-S 10059	female	66	fever, fatigue	1	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	22
17	DT-S 10138	male	46	myalgia	1	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	23
18	DT-S 10187	female	60	fever, fatigue	1	oral fluid	2020/6/16	+	throat swab (TS)	2020/6/16	+	24
19	DT-S 10007	male	63	fever, runny nose	1	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	22
20	DT-S 10164	male	10	fever, fatigue	1	oral fluid	2020/6/17	+	throat swab (TS)	2020/6/17	+	24
21	DT-S 10040	female	42	fever, fatigue	1	oral fluid	2020/6/16	+	throat swab (TS)	2020/6/16	+	23
22	DT-S 10027	male	74	fever, fatigue	1	oral fluid	2020/6/18	+	throat swab (TS)	2020/6/18	+	24
23	DT-S 10023	male	65	fever	1	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	23
24	DT-S 10121	female	25	fever, runny nose	1	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	22
25	DT-S 10105	male	29	cough	1	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	24
26	DT-S 10046	male	33	myalgia	1	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	+	23
27	DT-S 10082	female	67	myalgia	1	oral fluid	2020/6/18	+	throat swab (TS)	2020/6/18	+	23
28	DT-S 10020	male	19	fever, fatigue	1	oral fluid	2020/6/17	+	throat swab (TS)	2020/6/17	+	24
29	DT-S 10101	female	25	myalgia	1	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	24
30	DT-S 10021	male	55	fever, cough	2	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	23
31	DT-S 10092	female	64	fever, cough	2	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	25
32	DT-S 10135	female	34	cough	2	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	23
33	DT-S 10011	male	30	cough	2	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	24
34	DT-S 10131	male	38	myalgia	2	oral fluid	2020/6/16	+	throat swab	2020/6/16	+	24

									(TS)			
35	DT-S 10026	female	49	cough	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	+	25
36	DT-S 10033	male	57	cough	2	oral fluid	2020/6/18	+	throat swab (TS)	2020/6/18	+	23
37	DT-S 10198	female	75	fever, cough	3	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	24
38	DT-S 10116	male	19	myalgia	3	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	+	25
39	DT-S 10167	male	18	myalgia	3	oral fluid	2020/6/14	+	throat swab (TS)	2020/6/14	+	25
40	DT-S 10142	male	53	cough	3	oral fluid	2020/6/13	+	throat swab (TS)	2020/6/13	+	24

Basic information on negative samples of SARS-CoV-2 AG

NO.	Sample ID	Gender	Age	Physiological state	Number of days to collect samples after symptoms appear	Experimental reagent Assessment test results			PCR test results			
						Sample type	Collection date	Determination	Sample type	Collection date	Determination	CT
1	DT-S 10075	male	16	fever	0	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
2	DT-S 10149	male	12	cough	0	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
3	DT-S 10192	male	30	cough	0	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
4	DT-S 10122	male	28	myalgia	0	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
5	DT-S 10083	male	31	fever, fatigue	0	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
6	DT-S 10071	male	40	cough	0	oral fluid	2020/6/15	+	throat swab (TS)	2020/6/15	-	N/A
7	DT-S 10049	female	59	fever	0	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
8	DT-S 10153	male	13	cough	0	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A

9	DT-S 10125	male	51	cough	0	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
10	DT-S 10069	female	28	myalgia	0	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
11	DT-S 10118	male	28	fever, fatigue	0	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
12	DT-S 10017	female	78	fever	0	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
13	DT-S 10186	male	71	fever	0	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
14	DT-S 10038	male	11	fever	0	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
15	DT-S 10084	female	38	fever	0	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
16	DT-S 10128	female	27	fever	0	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
17	DT-S 10024	male	23	fever	0	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
18	DT-S 10100	male	12	fever	0	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
19	DT-S 10231	male	22	fever	0	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
20	DT-S 10134	male	37	fever, fatigue	0	oral fluid	2020/6/18	-	throat swab (TS)	2020/6/18	-	N/A
21	DT-S 10189	male	16	fever, runny nose	0	oral fluid	2020/6/18	-	throat swab (TS)	2020/6/18	-	N/A
22	DT-S 10006	female	78	cough	1	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
23	DT-S 10193	male	74	fever	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
24	DT-S 10180	female	54	myalgia	1	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
25	DT-S 10161	male	44	cough	1	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
26	DT-S 10133	female	25	cough	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
27	DT-S 10096	female	39	cough	1	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
28	DT-S 10010	male	78	fever	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A

29	DT-S 10115	female	50	myalgia	1	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
30	DT-S 10041	female	21	cough	1	oral fluid	2020/6/18	-	throat swab (TS)	2020/6/18	-	N/A
31	DT-S 10175	male	80	cough	1	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
32	DT-S 10173	male	61	fever, fatigue	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
33	DT-S 10163	female	16	cough	1	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
34	DT-S 10123	male	26	fever, runny nose	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
35	DT-S 10067	male	79	cough	1	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
36	DT-S 10129	male	80	fever	1	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
37	DT-S 10022	male	44	cough	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
38	DT-S 10139	male	49	cough	1	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
39	DT-S 10098	male	24	cough	1	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
40	DT-S 10156	male	35	fever	1	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
41	DT-S 10099	female	61	fever, runny nose	1	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
42	DT-S 10102	female	79	cough	1	oral fluid	2020/6/18	-	throat swab (TS)	2020/6/18	-	N/A
43	DT-S 10030	male	12	fever, runny nose	1	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
44	DT-S 10108	female	32	fever, runny nose	2	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
45	DT-S 10104	female	60	fever, runny nose	2	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
46	DT-S 10005	male	16	fever	2	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
47	DT-S 10012	male	14	fever	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
48	DT-S 10112	female	14	fever, cough	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A

49	DT-S 10090	male	54	fever, cough	2	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
50	DT-S 10119	male	25	fever, runny nose	2	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
51	DT-S 10136	male	39	myalgia	2	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
52	DT-S 10054	female	59	cough	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
53	DT-S 10031	male	33	cough	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
54	DT-S 10126	female	34	fever, runny nose	2	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
55	DT-S 10168	female	74	myalgia	2	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
56	DT-S 10179	male	30	myalgia	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
57	DT-S 10188	female	73	fever, runny nose	2	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
58	DT-S 10080	male	76	fever, runny nose	2	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
59	DT-S 10109	male	21	fever, runny nose	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
60	DT-S 10177	male	19	cough	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
61	DT-S 10124	female	25	myalgia	2	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
62	DT-S 10114	male	42	fever, fatigue	2	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
63	DT-S 10029	female	20	cough	2	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
64	DT-S 10076	female	16	fever	2	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
65	DT-S 10094	male	57	fever	2	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
66	DT-S 10085	male	16	fever	2	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
67	DT-S 10151	male	37	cough	2	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
68	DT-S 10053	male	49	fever, cough	2	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A

69	DT-S 10165	female	79	cough	3	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
70	DT-S 10008	male	30	myalgia	3	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
71	DT-S 10148	female	56	fever, fatigue	3	oral fluid	2020/6/17	-	throat swab (TS)	2020/6/17	-	N/A
72	DT-S 10130	female	15	fever	3	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
73	DT-S 10111	male	45	fever	3	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
74	DT-S 10127	female	32	fever	3	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
75	DT-S 10025	male	67	fever	3	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
76	DT-S 10132	female	24	myalgia	4	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
77	DT-S 10154	male	52	cough	4	oral fluid	2020/6/15	-	throat swab (TS)	2020/6/15	-	N/A
78	DT-S 10197	female	28	myalgia	4	oral fluid	2020/6/18	-	throat swab (TS)	2020/6/18	-	N/A
79	DT-S 10062	male	24	fever	4	oral fluid	2020/6/16	-	throat swab (TS)	2020/6/16	-	N/A
80	DT-S 10103	male	23	myalgia	4	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A
81	DT-S 10176	male	18	fever	5	oral fluid	2020/6/13	-	throat swab (TS)	2020/6/13	-	N/A
82	DT-S 10196	male	28	fever	5	oral fluid	2020/6/14	-	throat swab (TS)	2020/6/14	-	N/A