

EC Declaration of Conformity

Manufacturer:

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Whose Authorized Representative:

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We, the manufacturer, here with declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Specification	20Tests/box (1Test/bag ×20 Bags) , 40 Tests /box (1Test / bag ×40 Bags)
Intended Use	For in vitro qualitative detect of SARS-CoV-2 nucleocapsid antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015



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

We agree to develop, implement and maintain a documented post-production monitoring process.

Name of General Manager	王森
Signature	
Date	2020.08.28
Place	Tianjin, China.
Seal (Manufacturer)	

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 Bosphore Novel Coronavirus Detection kit produced by Anatolia Geneworks

Clinical evaluation place: Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALY.

Start date: October 5, 2020

End date: November 5, 2020

Laboratory (seal):



Application company (seal): JOYSBIO (Tianjin) Biotechnology Co., Ltd.

Phone: -86-022-65378415

Report date: November 6, 2020



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.

Detection principle:

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

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

Purpose:

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

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.

Methods:

Synchronous blind test and methodological comparison design.

The nasal swab and rino oropharyngeal 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 Bosphore novel coronavirus detection kit. The nasal swab and rino oropharyngeal swab samples are blindly numbered and grouped by the Centro Diagnostico Delta S.r.l. sito editor. Nasal swab samples are divided into one group, rino oropharyngeal swab samples are divided into another group, and then tested by Centro Diagnostico Delta S.r.l. sito laboratory inspectors.

Discussion and Conclusion**Results:**

In this clinical trial, nasal swab specimens were obtained from Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALIA and tested with the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and the comparator device Bosphore novel coronavirus detection kit produced by Anatolia Geneworks. Statistical analysis was performed to calculate the positive agreement rate and negative agreement rate.

In this study, a total of 190 nasal swab 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 Bosphore novel coronavirus detection kit. The nasal swabs prospectively collected from individual patients who were suspected of COVID-19. No duplicate samples were selected. The sex ratio was distributed among 136 males (71.58%) and 54 females (28.42%). The age of enrolled patients ranged from 6 to 90 years. There were 112 cases with negative SARS-CoV-2 AG, accounting for 58.95% and 78 positive samples, accounting for 41.05%. In October and November 2020, 190 PCR (Bosphore novel coronavirus detection kit) samples from the Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALIA.

According to the consistency analysis of 190 samples, clinical study results showed that the detection sensitivity was 98.72% and the specificity was 97.32%.

Conclusion:

This clinical trial by comparing the results obtained by testing potential SARS-CoV-2 positive samples with investigational device 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) was 98.72%, and the specificity was 97.32%. The results showed that the investigational device, the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold), meets the needs of clinical testing.

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 nasal swab and rino oropharyngeal 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 Bosphore novel coronavirus detection kit. The nasal swab and rino oropharyngeal swab samples are blindly numbered and grouped by the Centro Diagnostico Delta S.r.l. sito editor. Nasal swab samples are divided into one group, rino oropharyngeal swab samples are divided into another group, and then tested by Centro Diagnostico Delta S.r.l. sito laboratory inspectors. Among them, there are 3 Centro Diagnostico Delta S.r.l. sito 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 test sample immediately.
- Use only swabs provided with the kit.

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 nosebleed.
- Samples went through too many freeze-thaw cycles.
- Samples not kept at the requirement conditions.

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.

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)	Bosphore Novel Coronavirus (2019-nCov) Detection Kit
Specification	20 tests/box	100 reactions/box
Company	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Anatolia Geneworks
Lot Number	2020090804	SAG002
Expiration	2022.09.06	2021.12
Preservation Condition	2~30°C	< -20°C

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

Clinical Trial Results and Analysis

Overall distribution of samples

In this test, a total of 190 cases of nasal swab 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 112 negative samples (58.95%), 78 positive samples (41.05%).

Table 3 Proportion and number distribution of clinical trials

Sample	nasal swab specimens	
	Negative	Positive
Number of cases	112	78
Ratio	58.95%	41.05%
Number of total cases Positive	190	

Sex and age distribution of samples

A total of 190 nasal swab specimens were enrolled in the consistency comparison test of experimental reagent and reference reagent, including 136 males and 54 females.

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

Table 4 Sex and age distribution

Index	Sample type	Nasal swab specimens
Number of samples	Total	190
Sex	Male (N,%)	136 (71.58%)
	Female (N,%)	54 (28.42%)
Age (y)	X±SD	41.17±16.71
	Min-Max	6~90

Consistency analysis of test results

1) Consistency comparison of experimental reagent and reference reagent

Clinical sample stratification statistics

➤ Overall Clinical Study

In this study, 190 nasal swab 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 Bosphore novel coronavirus detection kit (Anatolia Geneworks). The clinical performance data of the SARS-CoV-2 test results were analyzed, and 77 samples were tested positive by the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold). There were 3 samples in which the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was positive and the Anatolia Geneworks device was negative. There was 1 sample in which the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was negative and the reference reagent was positive. There were 109 samples with negative test results in experimental reagent and 112 samples with negative test results in reference reagent. Hence, the sensitivity and specificity were 98.72% and 97.32% respectively.

Table 5 Overall Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	77	3	80
negative	1	109	110
Subtotal	78	112	190

Positive Percent Agreement (PPA)= $77/78(98.72\%)$ (95%CI: 93.0%~100.0%)

Negative Percent Agreement (NPA)= $109/112(97.32\%)$ (95%CI:92.4%~99.4%)

Accuracy= $(77+109)/190 \times 100\%=97.89\%$

$$\text{Kappa}=2 \times (77 \times 109 - 3 \times 1) / (80 \times 112 + 78 \times 110) = 0.96 > 0.5$$

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 190 nasal swab 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 136 males (71.58%) and 54 females (28.42%). The age of enrolled patients ranged from 6 to 90 years. There were 112 cases with negative SARS-CoV-2 AG, accounting for 58.95% and 78 positive samples, accounting for 41.05%. In October and November 2020, 190 PCR (Bosphore Novel Coronavirus Detection kit) samples from the Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati, 8-82030 Apollosa (Benevento) ITALIA.

According to the consistency analysis of 190 samples, clinical study results showed that the detection sensitivity was 98.72% and the specificity was 97.32%.

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.

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

Basic information of positive and negative samples of SARS-CoV-2, 190 cases verified by PCR (Bosphore Novel Coronavirus Detection kit) were collected in October and November 2020 from the Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALY.

Basic information on positive samples of SARS-CoV-2

N O	Sample ID	Gender	Age	Physiological state	Experimental reagent Assessment test results						PCR test results				
					Sample type	Collection date	Test date	test line apperaran	Determination	Sample type	Collection date	Test date	Determination	CT	
1	100800172	M	55	Fever > 37°C, Headache	nasal swab	2020/10/5	2020/10/5	< 5 min	Positive	Rino oropharyngeal swab	2020/10/5	2020/10/5	Positive	(N 19; E 21; RdRP 22)	
2	100800173	M	51		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 19; E 19; RdRP 20)	
3	100800174	M	50		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 21; E 21; RdRP 22)	
4	100800176	F	48		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 21; E 20; RdRP 20)	
5	100800180	M	24		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 20; E 19; RdRP 19)	
6	101300042	F	44	Headache	nasal swab	2020/10/13	2020/10/13	< 8 min	Positive	Rino oropharyngeal swab	2020/10/13	2020/10/13	Positive	(N 33; E 28; RdRP 29)	
7	101400211	M	87		nasal swab	2020/10/14	2020/10/14	/	Negative	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 42; E 30; RdRP 29)	
8	101400267	F	60		nasal swab	2020/10/14	2020/10/14	< 5 min	Positive	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 20; E 21; RdRP 22)	
9	101400269	M	64		nasal swab	2020/10/14	2020/10/14	< 8 min	Positive	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 22; E 22; RdRP 23)	
10	101400398	M	20		nasal swab	2020/10/14	2020/10/14	< 5 min	Positive	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 19; E 19; RdRP 18)	
11	102607178	M	57		nasal swab	2020/10/26	2020/10/26	< 5 min	Positive	Rino oropharyngeal swab	2020/10/26	2020/10/26	Positive	(N 20; E 21; RdRP 21)	
12	102607263	F	24		nasal swab	2020/10/26	2020/10/26	< 5 min	Positive	Rino oropharyngeal swab	2020/10/26	2020/10/26	Positive	(N 21; E 21; RdRP 22)	
13	102607262	F	32		nasal swab	2020/10/26	2020/10/26	< 8 min	Positive	Rino oropharyngeal swab	2020/10/26	2020/10/26	Positive	(N 31; E 27; RdRP 26)	

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

31	102907891	M	35		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/31	Positive	(N 22; E 21; RdRP 21)
32	103000014	F	36		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 21; RdRP 21)
33	103000086	F	64		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 23; E 24; RdRP 24)
34	103000087	M	70		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 20; RdRP 20)
35	103000035	M	15		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 20; E 19; RdRP 19)
36	103000094	M	52		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 19; E 19; RdRP 19)
37	103000066	M	38		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 15; E 15; RdRP 15)
38	103000115	F	74		nasal swab	2020/10/30	2020/10/30	< 10 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 27; E 26; RdRP 26)
39	103000072	F	52		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 18; E 18; RdRP 18)
40	103000081	M	20		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 24; E 30; RdRP N/A)
41	103000124	M	27		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 20; E 19; RdRP 20)
42	103000137	F	35		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 21; RdRP 21)
43	1030000210	M	68		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 20; RdRP 21)
44	103000177	M	31		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 23; E 22; RdRP 23)
45	103000172	M	40		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 31; E N/A; RdRP N/A)
46	103000220	F	42		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 22; E 21; RdRP 21)
47	103000343	M	20		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/11/2	Positive	(N 22; E 21; RdRP 21)
48	103000338	M	52		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/11/2	Positive	(N 20; E 21; RdRP 20)

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

66	110400043	M	29		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 23; E 24; RdRP 23)
67	110400076	M	56		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 19; E 19; RdRP 19)
68	110400089	M	58		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 20; E 20; RdRP 19)
69	110400086	M	46		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 20; E 19; RdRP 18)
70	110400088	F	51		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 19; E 20; RdRP 18)
71	110400143	M	62		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 24; E 26; RdRP 24)
72	110400184	M	53		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 20; E 22; RdRP 21)
73	110400205	F	55		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 24; E 26; RdRP 24)
74	110400180	F	26		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 34; E N/A; RdRP N/A)
75	110400181	M	58		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 19; E 19; RdRP 18)
76	110400188	M	68		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 25; E 29; RdRP 26)
77	110400144	M	24		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 32; E N/A; RdRP N/A)
78	110400142	M	28		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/5	Positive	(N 31; E N/A; RdRP N/A)

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

NO	Sample ID	Gender	Age	Physiological state	Experimental reagent Assessment test results						PCR test results				
					Sample type	Collection date	Test date	test line appearance	Determination	Sample type	Collection date	Test date	Determination	CT	
1	100800171	F	22		nasal swab	2020/10/8	2020/10/8		Negative	rino oropharyngeal swab	2020/10/8	2020/10/8	Negative	N/A	
2	100800179	F	59		nasal swab	2020/10/8	2020/10/8	< 12 min	Positive	rino oropharyngeal	2020/10/8	2020/10/8	Negative	N/A	

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

20	103000078	F	76		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
21	103000069	M	69		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
22	103000112	F	26		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
23	103000027	M	41		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
24	103000001	M	22		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
25	103000002	M	36		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
26	103000021	F	15		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
27	103000114	F	49		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
28	103000042 0	F	31		nasal swab	2020/10/29	2020/10/30		Negative	oropharyngeal rino swab	2020/10/29	2020/10/30	Negative	N/A
29	103000042 3	M	58		nasal swab	2020/10/29	2020/10/30		Negative	oropharyngeal rino swab	2020/10/29	2020/10/30	Negative	N/A
30	103000139	M	39		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
31	103000119	M	31		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
32	103000132	M	6		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
33	103000133	F	50		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
34	103000193	M	19		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
35	103000277	M	48		nasal swab	2020/10/30	2020/10/30		-	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
36	103000274	F	29		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A
37	103000276	F	63		nasal swab	2020/10/30	2020/10/30		Negative	oropharyngeal rino swab	2020/10/30	2020/10/30	Negative	N/A

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55	110400016	M	33		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/4	Negative	N/A
56	110400058	M	69		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/4	Negative	N/A
57	110500084	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
58	110500037	M	28		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
59	110500090	M	42		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
60	110500137	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
61	110500094	M	38		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
62	110500131	M	27		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
63	110500023	M	24		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
64	110500093	M	40		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
65	110500019	M	50		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
66	110500117	M	29		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
67	110500108	M	27		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
68	110500091	M	31		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
69	110500097	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
70	110500127	M	65		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
71	110500110	M	28		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A
72	110500095	M	51		nasal swab	2020/11/4	2020/11/4		Negative	rimo oropharyngeal swab	2020/11/4	2020/11/5	Negative	N/A

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90	110500116	M	30		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
91	110500099	M	17		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
92	110500130	M	38		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
93	110500113	M	32		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
94	110500100	M	18		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
95	110500119	M	24		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
96	110500118	M	24		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
97	110500159	M	35		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
98	110500087	M	43		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
99	110500104	M	19		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
100	110500017	M	45		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
101	110500092	M	56		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
102	110500085	M	47		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
103	110500106	M	19		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
104	110500022	M	45		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
105	110500115	M	33		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
106	110500129	M	33		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal swab	2020/1/4	2020/1/5	Negative	N/A
107	110500021	M	27		nasal swab	2020/1/4	2020/1/4		Negative	rimo oropharyngeal	2020/1/4	2020/1/5	Negative	N/A

