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## **Clinical Study**

### **COVID-19 Antigen Rapid Test (Colloidal Gold) For use with anterior nasal swab specimens**

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**Reviewed By: Qian XU                         Date: 23/03/2021**

**Approval By: Zhong WANG                  Date: 23/03/2021**

## 1. Purpose:

The main purpose of this study is to determine the performance of COVID-19 Antigen Rapid Test compared to a commercially available competitor assay. The COVID-19 Antigen Rapid Test is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from anterior nasal swabs, without viral transport media. The Test kit contains all components required to carry out an assay for SARS-CoV-2.

## 2. Operation Information

Materials:

COVID-19 Antigen Rapid Test (Colloidal Gold)

Lot: COV20210330G

Competitor: Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd., a commercial SARS-COV-2 kit approved by CFDA, is used as the "gold standard" reagent.

Depending on the specification of the test kit:

1 test/kit, 5tests/kit, 10tests/kit, 25tests/kit

Components include:

- 1.test cassette (1/5/10/25 pieces)
- 2.extraction buffer (1/5/10/25 pieces)
- 3.sterile swab (1/5/10/25 pieces)
- 4.Instructions for use

### Testing Procedure

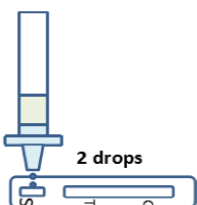
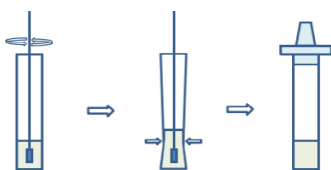
#### 1. Collection of samples

- Please disinfect your hands thoroughly before use!
- Gently insert the entire soft end of the swab about 2 cm into one nostril.
- Using medium pressure, slowly rub the swab in a circular motion around the inside of your nostril 4 times for a total of 15 seconds.
- Repeat the same procedure with the same swab in the other nostril.



#### 2. Sample handling

The swab is dipped below the liquid level of the sample extraction buffer after sampling. Turn and press it three times. The swab soak time is at least 15 seconds. Press firmly into the swab head area, then remove the swab and screw the test tube back on.



### 3. Getting the result

- Bring the test and sample to room temperature (15°C- 30°C) before testing.
- Remove the test cassette from the sealed pouch and place the test cassette on a flat surface.
- Place 2 drops of the sample vertically into the sample hole.



### 4. Waiting for the result

Wait for 15 minutes to read the results. It may happen that the control line appears earlier. Do not read the result before 15 minutes or after 30 minutes.

## INTERPRETATION OF THE RESULT

Positive (+): Two lines appear. One line should always appear in the control line area (C) and another line, in a different colour, should appear in the test line area (see Result 1). NOTE: The intensity of the colour in the test line area may vary depending on the concentration of SARSCoV-2 in the sample. Therefore, any colour shading in the test line area should be considered positive.

Negative (-): A coloured line appears in the control area (C). No coloured line appears in the test line area (T) (see Result 2).

Invalid: The control line could not be displayed (see Result 3). Insufficient sample volume or an inappropriate procedure are the most likely causes of error. Check the procedure and repeat the test with a new kit. If the problem persists, stop using the test kit immediately and contact your local distributor.

### Method:

102 samples of the novel coronavirus SARS-CoV-2 from 102 COVID-19-positive patients and 500 samples of 500 healthy people were included in the testing plan. A total of 602 samples were collected. Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

## 5. Clinical research results and analysis

### 5.1 Clinical research results

Positive results:

NO.	RT-PCR (nasopharyngeal swab)		COVID-19 Antigen Rapid Test (Colloidal Gold) with anterior nasal swab
	Ct	Result	
Positive 1#10 days post symptom onset	35	+	+
Positive 2# 2 days post symptom onset	23	+	+
Positive 3# 7 days post symptom onset	33	+	+
Positive 4# 9 days post symptom onset	28	+	+
Positive 5# 11 days post symptom onset	37	+	+
Positive 6# 14 days post symptom onset	36	+	+
Positive 7# 15 days post symptom onset	35	+	+
Positive 8# 16 days post symptom onset	36	+	+
Positive 9# 15 days post symptom onset	39	+	+
Positive 10# 16 days post symptom onset	37	+	+
Positive 11# 13 days post symptom onset	37	+	+

Positive 12# 15 days post symptom onset	35	+	+
Positive 13# 16 days post symptom onset	36	+	+
Positive 14# 9 days post symptom onset	38	+	-
Positive 15# 7 days post symptom onset	31	+	+
Positive 16# 8 days post symptom onset	28	+	+
Positive 17# 14 days post symptom onset	39	+	+
Positive 18# 15 days post symptom onset	38	+	+
Positive 19# 17 days post symptom onset	35	+	+
Positive 20# 16 days post symptom onset	39	+	+
Positive 21# 10 days post symptom onset	36	+	+
Positive 22# 13 days post symptom onset	34	+	+
Positive 23# 15 days post symptom onset	37	+	+
Positive 24# 16 days post symptom onset	38	+	+
Positive 25# 9 days post symptom onset	28	+	+
Positive 26# 14 days post symptom onset	35	+	+
Positive 27# 17 days post symptom onset	39	+	+
Positive 28# 15 days post symptom onset	36	+	+
Positive 29# 11 days post symptom onset	33	+	+
Positive 30# 8 days post symptom onset	35	+	+
Positive 31# 2 days post symptom onset	24	+	+
Positive 32# 3 days post symptom onset	24	+	+
Positive 33# 11 days post symptom onset	30	+	+
Positive 34# 5 days post symptom onset	39	+	-
Positive 35# 4 days post symptom onset	23	+	+
Positive 36# 6 days post symptom onset	25	+	+
Positive 37# 13 days post symptom onset	36	+	+
Positive 38# 7 days post symptom onset	24	+	+
Positive 39# 9 days post symptom onset	39	+	+
Positive 40# 4 days post symptom onset	27	+	+
Positive 41# 1 days post symptom onset	35	+	-
Positive 42# 2 days post symptom onset	21	+	+
Positive 43# 3 days post symptom onset	25	+	+
Positive 44# 2 days post symptom onset	23	+	+
Positive 45# 5 days post symptom onset	24	+	+
Positive 46# 6 days post symptom onset	28	+	+
Positive 47# 13 days post symptom onset	35	+	+
Positive 48# 6 days post symptom onset	27	+	+
Positive 49# 3 days post symptom onset	18	+	+
Positive 50# 10 days post symptom onset	37	+	+
Positive 51# 5 days post symptom onset	25	+	+
Positive 52# 4 days post symptom onset	24	+	+
Positive 53# 2 days post symptom onset	18	+	+
Positive 54# 9 days post symptom onset	35	+	+
Positive 55# 5 days post symptom onset	26	+	+
Positive 56# 11 days post symptom onset	37	+	+
Positive 57# 2 days post symptom onset	23	+	+
Positive 58# 6 days post symptom onset	26	+	+
Positive 59# 13 days post symptom onset	29	+	+
Positive 60# 12 days post symptom onset	30	+	+
Positive 61# 7 days post symptom onset	29	+	+
Positive 62# 11 days post symptom onset	31	+	+
Positive 63# 9 days post symptom onset	35	+	+
Positive 64# 5 days post symptom onset	27	+	+
Positive 65# 6 days post symptom onset	34	+	+
Positive 66# 4 days post symptom onset	23	+	+
Positive 67# 7 days post symptom onset	30	+	+

Positive 68# 10 days post symptom onset	35	+	+
Positive 69# 4 days post symptom onset	30	+	+
Positive 70# 5 days post symptom onset	29	+	+
Positive 71# 7 days post symptom onset	29	+	+
Positive 72# 5 days post symptom onset	25	+	+
Positive 73# 6 days post symptom onset	24	+	+
Positive 74# 4 days post symptom onset	25	+	+
Positive 75# 4 days post symptom onset	22	+	+
Positive 76# 5 days post symptom onset	28	+	+
Positive 77# 3 days post symptom onset	23	+	+
Positive 78# 2 days post symptom onset	23	+	+
Positive 79# 1 days post symptom onset	23	+	+
Positive 80# 7 days post symptom onset	32	+	+
Positive 81# 6 days post symptom onset	28	+	+
Positive 82# 5 days post symptom onset	30	+	+
Positive 83# 2 days post symptom onset	21	+	+
Positive 84# 3 days post symptom onset	19	+	+
Positive 85# 3 days post symptom onset	25	+	+
Positive 86# 5 days post symptom onset	22	+	+
Positive 87# 6 days post symptom onset	28	+	+
Positive 88# 4 days post symptom onset	25	+	+
Positive 89# 7 days post symptom onset	31	+	+
Positive 90# 6 days post symptom onset	23	+	+
Positive 91# 1 days post symptom onset	25	+	+
Positive 92# 5 days post symptom onset	28	+	+
Positive 93# 3 days post symptom onset	24	+	+
Positive 94# 2 days post symptom onset	25	+	+
Positive 95# 5 days post symptom onset	32	+	+
Positive 96# 6 days post symptom onset	27	+	+
Positive 97# 7 days post symptom onset	29	+	+
Positive 98# 5 days post symptom onset	24	+	+
Positive 99# 4 days post symptom onset	27	+	+
Positive 100# 7 days post symptom onset	26	+	+
Positive 101# 6 days post symptom onset	25	+	+
Positive 102# 3 days post symptom onset	21	+	+

Negative results:

<b>NO.</b>	<b>RT-PCR (nasopharyngeal swab)</b>	<b>COVID-19 Antigen Rapid Test (Colloidal Gold) with anterior nasal swab</b>
Negative 1#	-	-
Negative 2#	-	-
Negative 3#	-	-
Negative 4#	-	-
Negative 5#	-	-
Negative 6#	-	-
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5.2 The above results are summarized as follows :

Method		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	98	4	102
	Negative	4	496	500
Total		102	500	602

COVID-19 Antigen Rapid Test (Colloidal Gold) showed 96.1% sensitivity and 99.2% specificity.

Clinical sensitivity (%) =  $[98 / (98 + 4)] \times 100\% = 96.1\%$

Clinical specificity (%) =  $[496 / (496 + 4)] \times 100\% = 99.2\%$

Total agreement rate (%) =  $[(98 + 496) / (98 + 4 + 4 + 496)] \times 100\% = 98.7\%$

COVID-19 Antigen Rapid Test Positive Results by time from symptom onset:

Days post symptom onset	Number of samples	PCR positive	COVID-19 Antigen Test
≤3	20	20	19/20=95.0%
4~7	43	43	42/43=97.7%
8~14	25	25	24/25=96.0%
> 14	14	14	14/14=100.0%
Total	102	102	99/102=97.1% 95% CI: (91.64% ~ 99.39%)

The performance of COVID-19 Antigen Rapid Test (Colloidal Gold) with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the COVID-19 Antigen Rapid Test (Colloidal Gold) is higher with samples of a Ct count <35.

COVID-19 Antigen Rapid Test (Colloidal Gold) performance against the Comparator Method – by Cycle Threshold Counts.

COVID-19 Antigen Rapid Test (Colloidal Gold)	RT-PCR(Positive by Ct Category)	
	Positive(Ct < 35 )	Positive(Ct ≥ 35 )
Positive	70	29
Negative	0	3
Total	70	32
Positive Agreement (95% CI)	100.0%(94.87% ~ 100.00%)	90.6%(74.98% ~ 98.02%)

## 6. Discussion and Conclusion

The overall clinical performance of the Joinstar COVID-19 Antigen Rapid Test was comparable with the data obtained in the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR assay and supports the use of the Joinstar assay in the detection of SARS-CoV-2. The COVID-19 Antigen Rapid Test (Colloidal Gold) showed 96.1% sensitivity and 99.2% specificity.