



JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.

Add: NO.519 Xingguo RD. Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang, China

Tel: 0571-89028388 Fax: 0571-89028228

Web: <http://www.joinstar.cn> Email: info@joinstar.cn

Clinical Study (internal clinical assessment) Report

COVID-19 Antigen Rapid Test (Colloidal Gold)

Prepared By: Ruixue XIE Date: 30/11/2020

Reviewed By: Qian XU Date: 30/11/2020

Approval By: Zhong WANG Date: 30/11/2020

1 Purpose:

To determine the performance of COVID-19 Antigen Rapid Test (Colloidal Gold) compared to a commercially available competitor assay.

2 Operation Information

2.3 Materials:

COVID-19 Antigen Rapid (Colloidal Gold)

Competitors: 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 NMPA, is used as the "gold standard" reagent.

3 Method:

102 samples of the novel coronavirus SARS-CoV-2 from medical institution and 500 samples of healthy people were included in the testing plan. A total of 602 samples were tested in the COVID-19 Antigen Rapid assay and the Novel Coronavirus (SARS-COV-2) real-time multiplex RT-PCR kit, and the clinical sensitivity, specificity and overall agreement between the 2 assays calculated.

4. Clinical research results and analysis

4.1 Clinical research results

Positive results:

NO.	RT-PCR	COVID-19 Antigen Rapid Test (Colloidal Gold)
Positive 1# 10 days post symptom onset	+	+
Positive 2# 2 days post symptom onset	+	+
Positive 3# 7 days post symptom onset	+	+
Positive 4# 9 days post symptom onset	+	+
Positive 5# 11 days post symptom onset	+	-
Positive 6# 14 days post symptom onset	+	+
Positive 7# 15 days post symptom onset	+	+
Positive 8# 16 days post symptom onset	+	+
Positive 9# 15 days post symptom onset	+	+
Positive 10# 16 days post symptom onset	+	+
Positive 11# 13 days post symptom onset	+	+
Positive 12# 15 days post symptom onset	+	+
Positive 13# 16 days post symptom onset	+	+
Positive 14# 9 days post symptom onset	+	+
Positive 15# 7 days post symptom onset	+	+
Positive 16# 8 days post symptom onset	+	+
Positive 17# 14 days post symptom onset	+	+
Positive 18# 15 days post symptom onset	+	+



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



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Positive 60# 12 days post symptom onset	+	+
Positive 61# 7 days post symptom onset	+	+
Positive 62# 11 days post symptom onset	+	+
Positive 63# 9 days post symptom onset	+	+
Positive 64# 5 days post symptom onset	+	+
Positive 65# 6 days post symptom onset	+	+
Positive 66# 4 days post symptom onset	+	+
Positive 67# 7 days post symptom onset	+	+
Positive 68# 10 days post symptom onset	+	+
Positive 69# 4 days post symptom onset	+	+
Positive 70# 5 days post symptom onset	+	+
Positive 71# 7 days post symptom onset	+	+
Positive 72# 5 days post symptom onset	+	+
Positive 73# 6 days post symptom onset	+	+
Positive 74# 4 days post symptom onset	+	+
Positive 75# 4 days post symptom onset	+	+
Positive 76# 5 days post symptom onset	+	+
Positive 77# 3 days post symptom onset	+	+
Positive 78# 2 days post symptom onset	+	+
Positive 79# 1 days post symptom onset	+	+
Positive 80# 7 days post symptom onset	+	+
Positive 81# 6 days post symptom onset	+	+
Positive 82# 5 days post symptom onset	+	+
Positive 83# 2 days post symptom onset	+	+
Positive 84# 3 days post symptom onset	+	+
Positive 85# 3 days post symptom onset	+	+
Positive 86# 5 days post symptom onset	+	+
Positive 87# 6 days post symptom onset	+	-
Positive 88# 4 days post symptom onset	+	+
Positive 89# 7 days post symptom onset	+	+
Positive 90# 6 days post symptom onset	+	+
Positive 91# 1 days post symptom onset	+	+
Positive 92# 5 days post symptom onset	+	+
Positive 93# 3 days post symptom onset	+	+
Positive 94# 2 days post symptom onset	+	+
Positive 95# 5 days post symptom onset	+	+
Positive 96# 6 days post symptom onset	+	+
Positive 97# 7 days post symptom onset	+	+
Positive 98# 5 days post symptom onset	+	+
Positive 99# 4 days post symptom onset	+	+
Positive 100# 7 days post symptom onset	+	+



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Positive 101# 6 days post symptom onset	+	+
Positive 102# 3 days post symptom onset	+	+

Negative results:

NO.	RT-PCR	COVID-19 Antigen Rapid Test (Colloidal Gold)
Negative 1#	-	-
Negative 2#	-	-
Negative 3#	-	-
Negative 4#	-	-
Negative 5#	-	-
Negative 6#	-	-
Negative 7#	-	-
Negative 8#	-	-
Negative 9#	-	-
Negative 10#	-	-
Negative 11#	-	-
Negative 12#	-	-
Negative 13#	-	-
Negative 14#	-	-
Negative 15#	-	-
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Negative 17#	-	-
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Negative 19#	-	-
Negative 20#	-	-
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Negative 23#	-	-
Negative 24#	-	-
Negative 25#	-	-
Negative 26#	-	-
Negative 27#	-	-
Negative 28#	-	-
Negative 29#	-	-
Negative 30#	-	-
Negative 31#	-	-
Negative 32#	-	-



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Negative 33#	-	-
Negative 34#	-	-
Negative 35#	-	-
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Negative 39#	-	-
Negative 40#	-	-
Negative 41#	-	-
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Negative 495#	-	-
Negative 496#	-	-
Negative 497#	-	-
Negative 498#	-	-
Negative 499#	-	-
Negative 500#	-	-

4.2 The above results are summarized as follows:

Method		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	98	5	103
	Negative	4	495	499
Total		102	500	602

COVID-19 Antigen Rapid Test (Colloidal Gold) showed 96.1% sensitivity and 99.0% specificity.

Clinical sensitivity (%) = $[98 / (98 + 4)] \times 100\% = 96.1\%$; 95% CI: (90.26%~98.92%)

Clinical specificity (%) = $[495 / (495 + 5)] \times 100\% = 99.0\%$; 95% CI: (97.68%-99.67%)

Total agreement rate (%) = $[(98 + 495) / (98 + 4 + 5 + 495)] \times 100\% = 98.5\%$; 95% CI: (97.18%-99.31%)

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	20/20=100.0%
4~7	43	43	41/43=95.3%
8~14	26	26	25/26=96.2%
> 14	13	13	12/13=92.3%
Total	102	102	98/102=96.1% 95% CI: (90.26% ~ 98.92%)



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5 Discussion and conclusion

The overall clinical performance of the Joinstar COVID-19 Antigen Rapid Test (Colloidal Gold) 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.

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