



JOINSTAR BIOMEDICAL TECHNOLOGY CO.,LTD  
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## **Clinical Study (internal clinical assessment) Report**

**COVID-19 Antigen Rapid Test ( Latex )**

**Prepared By: Yanhua ZHANG Date: 18/12/2020**

**Reviewed By: Qian XU Date: 18/12/2020**

**Approval By: Zhong WANG Date: 18/12/2020**

**1 Purpose:**

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

**2 Operation Information**

## 2.3 Materials:

COVID-19 Antigen Rapid

Lot: COV2008003L-T

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 CFDA, is used as the "gold standard" reagent.

**3 Method:**

309 samples of the novel coronavirus SARS-CoV-2 from 103 COVID-19 patients and 318 samples from 106 healthy peoples were included in the testing plan. A total of 209 saliva samples, 209 sputum samples and 209 stool 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

## 4.1.1 Test results are as follows:

Novel Coronavirus	Test reagent			RT-PCR
	Saliva	Stool	Sputum	throat swab
Health 1	-	-	-	-
Health 2	-	-	-	-
Health 3	-	-	-	-
Health 4	-	-	-	-
Health 5	-	-	-	-
Health 6	-	-	-	-
Health 7	-	-	-	-
Health 8	-	-	-	-
Health 9	-	-	-	-
Health 10	-	-	-	-
Health 11	-	-	-	-
Health 12	-	-	-	-
Health 13	-	-	-	-
Health 14	-	-	-	-



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Health 15	-	-	-	-
Health 16	-	-	-	-
Health 17	-	-	-	-
Health 18	-	-	-	-
Health 19	-	-	-	-
Health 20	-	-	-	-
Health 21	-	-	-	-
Health 22	-	-	-	-
Health 23	-	-	-	-
Health 24	-	-	-	-
Health 25	-	-	-	-
Health 26	-	-	-	-
Health 27	-	-	-	-
Health 28	-	-	-	-
Health 29	-	-	-	-
Health 30	-	-	-	-
Health 31	-	-	-	-
Health 32	-	-	-	-
Health 33	-	-	-	-
Health 34	-	-	-	-
Health 35	-	-	-	-
Health 36	-	-	-	-
Health 37	-	-	-	-
Health 38	-	-	-	-
Health 39	-	-	-	-
Health 40	-	-	-	-
Health 41	-	-	-	-
Health 42	-	-	-	-
Health 43	-	-	-	-
Health 44	-	-	-	-
Health 45	-	-	-	-
Health 46	-	-	-	-
Health 47	-	-	-	-
Health 48	-	-	-	-
Health 49	-	-	-	-
Health 50	-	-	-	-
Health 51	-	-	-	-
Health 52	-	-	-	-
Health 53	-	-	-	-
Health 54	-	-	-	-
Health 55	-	-	-	-



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Health 56	-	-	-	-
Health 57	-	-	-	-
Health 58	-	-	-	-
Health 59	-	-	-	-
Health 60	-	-	-	-
Health 61	-	-	-	-
Health 62	-	-	-	-
Health 63	-	-	-	-
Health 64	-	-	-	-
Health 65	-	-	-	-
Health 66	-	-	-	-
Health 67	-	-	-	-
Health 68	-	-	-	-
Health 69	-	-	-	-
Health 70	-	-	-	-
Health 71	-	-	-	-
Health 72	-	-	-	-
Health 73	-	-	-	-
Health 74	-	-	-	-
Health 75	-	-	-	-
Health 76	-	-	-	-
Health 77	-	-	-	-
Health 78	-	-	-	-
Health 79	-	-	-	-
Health 80	-	-	-	-
Health 81	-	-	-	-
Health 82	-	-	-	-
Health 83	-	-	-	-
Health 84	-	-	-	-
Health 85	-	-	-	-
Health 86	-	-	-	-
Health 87	-	-	-	-
Health 88	-	-	-	-
Health 89	-	-	-	-
Health 90	-	-	-	-
Health 91	-	-	-	-
Health 92	-	-	-	-
Health 93	-	-	-	-
Health 94	-	-	-	-
Health 95	-	-	-	-
Health 96	-	-	-	-



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Health 97	-	-	-	-
Health 98	-	-	-	-
Health 99	-	-	-	-
Health 100	-	-	-	-
Health 101	-	-	-	-
Health 102	-	-	-	-
Health 103	-	-	-	-
Health 104	-	-	-	-
Health 105	-	-	-	-
Health 106	-	-	-	-
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 9 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	-	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 8 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 2 day	-	-	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 3 day	-	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 1 day	-	-	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 8 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+



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A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 9 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 1 day	-	-	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	-	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 9 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 2 day	-	-	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 1 day	-	+	-	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 4 day	-	+	-	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 2 day	+	-	-	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	-	-	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	-	+	+	+



A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	-	+	-	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 6 day	-	+	-	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	-	-	-	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 8 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+

4.2 The above results are summarized as follows:

Saliva Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	91	0	91
	Negative	12	106	118
Total		103	106	209

Sputum Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	95	0	95
	Negative	8	106	114
Total		103	106	209

Stool Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	96	0	96
	Negative	7	106	113
Total		103	106	209

### Result analysis

**Saliva samples:** The COVID-19 Antigen Rapid Test ( Latex ) showed 88.4% sensitivity and 100% specificity in saliva samples.

$$\text{Clinical sensitivity (\%)} = [ 91 / (91 + 12) ] \times 100\% = 88.4\%$$

$$\text{Clinical specificity (\%)} = [ 106 / (0 + 106) ] \times 100\% = 100\%$$

$$\text{Total agreement rate (\%)} = [ (91 + 106) / ( 91 + 12 + 0 + 106) ] \times 100\% = 94.3\%$$

**Sputum samples:** The COVID-19 Antigen Rapid Test ( Latex ) showed 92.2% sensitivity and 100% specificity in sputum samples.

$$\text{Clinical sensitivity (\%)} = [ 95 / (95 + 8) ] \times 100\% = 92.2\%$$

$$\text{Clinical specificity (\%)} = [ 106 / (0 + 106) ] \times 100\% = 100\%$$

$$\text{Total agreement rate (\%)} = [ (95 + 106) / ( 95 + 8 + 0 + 106) ] \times 100\% = 96.2\%$$

**Stool samples:** The COVID-19 Antigen Rapid Test ( Latex ) showed 93.2% sensitivity and 100% specificity in stool samples.

$$\text{Clinical sensitivity (\%)} = [ 96 / (96 + 7) ] \times 100\% = 93.2\%$$

$$\text{Clinical specificity (\%)} = [ 106 / (0 + 106) ] \times 100\% = 100\%$$

$$\text{Total agreement rate (\%)} = [ (96 + 106) / ( 96 + 7 + 0 + 106) ] \times 100\% = 96.7\%$$

### 5 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.