



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: 25/08/2021

Reviewed By: Qian XU Date: 25/08/2021

Approval By: Zhong WANG Date: 25/08/2021

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:

103 samples of the novel coronavirus SARS-CoV-2 from 103 COVID-19 patients and 106 samples from 106 healthy peoples were included in the testing plan. A total of 209 nasopharyngeal swab 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 |
|-------------------|---------------------|-------------|
| | nasopharyngeal swab | 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 | - | - |



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| | | |
|-----------|---|---|
| Health 14 | - | - |
| 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 | - | - |



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| | | |
|-----------|---|---|
| Health 55 | - | - |
| 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 | - | - |



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| | | |
|---------------------------------|---|---|
| Health 96 | - | - |
| 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 | + | + |



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| | | |
|---------------------------------|---|---|
| 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 | + | + |
| 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 | + | + |



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| | | |
|---------------------------------|---|---|
| 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 | + | + |



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| | | |
|---------------------------------|---|---|
| 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 | + | + |



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| | | |
|---------------------------------|---|---|
| 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:

| Nasopharyngeal Swab Sample | | Gold standard reagent | | Total |
|----------------------------|----------|-----------------------|----------|-------|
| | | Positive | Negative | |
| Test reagent | Positive | 98 | 0 | 98 |
| | Negative | 5 | 106 | 111 |
| Total | | 103 | 106 | 209 |

Result analysis

Nasopharyngeal swab sample: The COVID-19 Antigen Rapid Test (Latex) showed 95.2% sensitivity and 100% specificity in stool samples.

Clinical sensitivity (%) = $[98 / (98 + 5)] \times 100\% = 95.2\%$

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

Total agreement rate (%) = $[(98 + 106) / (98 + 5 + 0 + 106)] \times 100\% = 97.6\%$

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.

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