

## **Clinical Study (internal clinical assessment) Report**

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

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## 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

Competitor assay: 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 referred herein as the "gold standard" reagent.

## 3 Method:

180 samples of the novel coronavirus SARS-CoV-2 and 90 samples of healthy people were included in the testing plan. A total of 90 saliva samples, 90 sputum samples and 90 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 The Test results were as follows:

| Novel Coronavirus | Covid 19 antigen Rapid Test |       |        | RT-PCR      |
|-------------------|-----------------------------|-------|--------|-------------|
|                   | Saliva                      | Stool | Sputum | throat swab |
| Healthy 1         | -                           | -     | -      | -           |
| Healthy 2         | -                           | -     | -      | -           |
| Healthy 3         | -                           | -     | -      | -           |
| Healthy 4         | -                           | -     | -      | -           |
| Healthy 5         | -                           | -     | -      | -           |
| Healthy 6         | -                           | -     | -      | -           |
| Healthy 7         | -                           | -     | -      | -           |
| Healthy 8         | -                           | -     | -      | -           |
| Healthy 9         | -                           | -     | -      | -           |
| Healthy 10        | -                           | -     | -      | -           |
| Healthy 11        | -                           | -     | -      | -           |
| Healthy 12        | -                           | -     | -      | -           |
| Healthy 13        | -                           | -     | -      | -           |
| Healthy 14        | -                           | -     | -      | -           |



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|            |   |   |   |   |
|------------|---|---|---|---|
| Healthy 15 | - | - | - | - |
| Healthy 16 | - | - | - | - |
| Healthy 17 | - | - | - | - |
| Healthy 18 | - | - | - | - |
| Healthy 19 | - | - | - | - |
| Healthy 20 | - | - | - | - |
| Healthy 21 | - | - | - | - |
| Healthy 22 | - | - | - | - |
| Healthy 23 | - | - | - | - |
| Healthy 24 | - | - | - | - |
| Healthy 25 | - | - | - | - |
| Healthy 26 | - | - | - | - |
| Healthy 27 | - | - | - | - |
| Healthy 28 | - | - | - | - |
| Healthy 29 | - | - | - | - |
| Healthy 30 | - | - | - | - |

|                        | Covid 19 antigen Rapid Test |       |        | RT-PCR      |                     |
|------------------------|-----------------------------|-------|--------|-------------|---------------------|
| DAY                    | Saliva                      | Stool | Sputum | throat swab | throat swab (notes) |
| Day 1 of disease onset | +                           | +     | +      | +           |                     |
| Day 9 of disease onset | +                           | +     | +      | +           |                     |
| Day 3 of disease onset | +                           | +     | +      | +           |                     |
| Day 6 of disease onset | +                           | +     | +      | +           |                     |
| Day 2 of disease onset | +                           | +     | -      | +           |                     |
| Day 5 of disease onset | +                           | +     | +      | +           |                     |
| Day 8 of disease onset | +                           | +     | +      | +           |                     |
| Day 4 of disease onset | +                           | +     | +      | +           |                     |
| Day 7 of disease onset | +                           | +     | +      | +           |                     |
| Day 7 of disease onset | +                           | +     | +      | +           |                     |
| Day 2 of disease onset | +                           | +     | +      | +           |                     |
| Day 2 of disease onset | -                           | -     | +      | +           | confirm by retest   |
| Day 2 of disease onset | +                           | +     | +      | +           |                     |
| Day 1 of disease onset | +                           | +     | +      | +           |                     |
| Day 1 of disease onset | +                           | +     | +      | +           |                     |
| Day 6 of disease onset | +                           | +     | +      | +           |                     |



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|                        |   |   |   |   |                   |
|------------------------|---|---|---|---|-------------------|
| Day 4 of disease onset | + | + | + | + |                   |
| Day 4 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 1 of disease onset | + | + | + | + |                   |
| Day 2 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | - | + | + | + |                   |
| Day 2 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 6 of disease onset | + | + | + | + |                   |
| Day 1 of disease onset | - | - | + | + | confirm by retest |
| Day 6 of disease onset | + | + | + | + |                   |
| Day 8 of disease onset | + | + | + | + |                   |
| Day 4 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 2 of disease onset | + | + | + | + |                   |
| Day 5 of disease onset | + | + | + | + |                   |
| Day 7 of disease onset | + | + | + | + |                   |
| Day 9 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 1 of disease onset | - | - | + | + | confirm by retest |
| Day 2 of disease onset | + | + | + | + |                   |
| Day 5 of disease onset | + | + | + | + |                   |
| Day 4 of disease onset | + | + | - | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 5 of disease onset | + | + | + | + |                   |
| Day 5 of disease onset | + | + | + | + |                   |
| Day 9 of disease onset | + | + | + | + |                   |
| Day 7 of disease onset | + | + | + | + |                   |
| Day 2 of disease onset | - | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 1 of disease onset | - | + | - | + |                   |
| Day 1 of disease onset | + | + | + | + |                   |
| Day 2 of disease onset | + | + | + | + |                   |
| Day 4 of disease onset | + | + | + | + |                   |
| Day 3 of disease onset | + | + | + | + |                   |
| Day 7 of disease onset | + | + | + | + |                   |

|                        |   |   |   |   |  |
|------------------------|---|---|---|---|--|
| Day 5 of disease onset | + | + | + | + |  |
| Day 6 of disease onset | + | + | + | + |  |
| Day 4 of disease onset | + | + | + | + |  |
| Day 6 of disease onset | + | + | + | + |  |
| Day 1 of disease onset | + | + | + | + |  |
| Day 2 of disease onset | + | + | + | + |  |

4.2 The above results are summarized as follows:

| Saliva Sample |          | Gold standard reagent |          | Total |
|---------------|----------|-----------------------|----------|-------|
|               |          | Positive              | Negative |       |
| Test reagent  | Positive | 54                    | 0        | 54    |
|               | Negative | 6                     | 30       | 36    |
| Total         |          | 60                    | 30       | 90    |

| Sputum Sample |          | Gold standard reagent |          | Total |
|---------------|----------|-----------------------|----------|-------|
|               |          | Positive              | Negative |       |
| Test reagent  | Positive | 57                    | 0        | 57    |
|               | Negative | 3                     | 30       | 33    |
| Total         |          | 60                    | 30       | 90    |

| Stool Sample |          | Gold standard reagent |          | Total |
|--------------|----------|-----------------------|----------|-------|
|              |          | Positive              | Negative |       |
| Test reagent | Positive | 57                    | 0        | 57    |
|              | Negative | 3                     | 30       | 33    |
| Total        |          | 60                    | 30       | 90    |

### Result analysis

**Saliva samples:** The Novel Coronavirus Spike Glycoprotein Detection Kit showed 90% sensitivity and 100% specificity in saliva samples.

Clinical sensitivity (%) =  $[54 / (54 + 6)] \times 100\% = 90\%$

Clinical specificity (%) =  $[30 / (0 + 30)] \times 100\% = 100\%$

Total agreement rate (%) =  $[(54 + 30) / (54 + 6 + 0 + 30)] \times 100\% = 93.3\%$

**Sputum samples:** The Novel Coronavirus Spike Glycoprotein Detection Kit showed 95%

sensitivity and 100% specificity in sputum samples.

Clinical sensitivity (%) =  $[57 / (57 + 3)] \times 100\% = 95\%$

Clinical specificity (%) =  $[30 / (0 + 30)] \times 100\% = 100\%$

Total agreement rate (%) =  $[(57 + 30) / (57 + 3 + 0 + 30)] \times 100\% = 96.7\%$

**Stool samples:** The Novel Coronavirus Spike Glycoprotein Detection Kit showed 95% sensitivity and 100% specificity in stool samples.

Clinical sensitivity (%) =  $[57 / (57 + 3)] \times 100\% = 95\%$

Clinical specificity (%) =  $[30 / (0 + 30)] \times 100\% = 100\%$

Total agreement rate (%) =  $[(57 + 30) / (57 + 3 + 0 + 30)] \times 100\% = 96.7\%$

## 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.