



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

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Clinical Study (internal clinical assessment) Report

COVID-19 Antigen Rapid Test (Colloidal Gold)

Prepared By: Ruixue XIE Date: 30/09/2020

Reviewed By: Qian XU Date: 30/09/2020

Approval By: Zhong WANG Date: 30/09/2020

1 Purpose:

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

2 Operation Information

Materials:

COVID-19 Antigen Rapid (Colloidal Gold)

Lot: COV2008003G-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:

76 samples of the novel coronavirus SARS-CoV-2 and 215 samples of healthy people were included in the testing plan. A total of 215 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 | + | + |



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| | | |
|---|---|---|
| Positive 17# 14 days post symptom onset | + | + |
| Positive 18# 15 days post symptom onset | + | + |
| 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 | + | + |



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| | | |
|---|---|---|
| Positive 57# 2 days post symptom onset | + | + |
| Positive 58# 6 days post symptom onset | + | + |
| Positive 59# 13 days post symptom onset | + | + |
| 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 | + | + |

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# | - | - |
| Negative 16# | - | - |



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| | | |
|--------------|---|---|
| Negative 17# | - | - |
| Negative 18# | - | - |
| Negative 19# | - | - |
| Negative 20# | - | - |
| Negative 21# | - | - |
| Negative 22# | - | - |
| Negative 23# | - | - |
| Negative 24# | - | - |
| Negative 25# | - | - |
| Negative 26# | - | - |
| Negative 27# | - | - |
| Negative 28# | - | - |
| Negative 29# | - | - |
| Negative 30# | - | - |
| Negative 31# | - | - |
| Negative 32# | - | - |
| Negative 33# | - | - |
| Negative 34# | - | - |
| Negative 35# | - | - |
| Negative 36# | - | - |
| Negative 37# | - | - |
| Negative 38# | - | - |
| Negative 39# | - | - |
| Negative 40# | - | - |
| Negative 41# | - | - |
| Negative 42# | - | - |
| Negative 43# | - | - |
| Negative 44# | - | - |
| Negative 45# | - | - |
| Negative 46# | - | - |
| Negative 47# | - | - |
| Negative 48# | - | - |
| Negative 49# | - | - |
| Negative 50# | - | - |
| Negative 51# | - | - |
| Negative 52# | - | - |
| Negative 53# | - | + |
| Negative 54# | - | - |
| Negative 55# | - | - |
| Negative 56# | - | - |



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



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| | | |
|---------------|---|---|
| Negative 97# | - | - |
| Negative 98# | - | - |
| Negative 99# | - | - |
| Negative 100# | - | - |
| Negative 101# | - | - |
| Negative 102# | - | - |
| Negative 103# | - | - |
| Negative 104# | - | - |
| Negative 105# | - | - |
| Negative 106# | - | - |
| Negative 107# | - | - |
| Negative 108# | - | - |
| Negative 109# | - | - |
| Negative 110# | - | - |
| Negative 111# | - | - |
| Negative 112# | - | - |
| Negative 113# | - | - |
| Negative 114# | - | - |
| Negative 115# | - | - |
| Negative 116# | - | - |
| Negative 117# | - | - |
| Negative 118# | - | - |
| Negative 119# | - | - |
| Negative 120# | - | - |
| Negative 121# | - | - |
| Negative 122# | - | - |
| Negative 123# | - | - |
| Negative 124# | - | - |
| Negative 125# | - | - |
| Negative 126# | - | - |
| Negative 127# | - | - |
| Negative 128# | - | - |
| Negative 129# | - | - |
| Negative 130# | - | - |
| Negative 131# | - | - |
| Negative 132# | - | - |
| Negative 133# | - | - |
| Negative 134# | - | - |
| Negative 135# | - | - |
| Negative 136# | - | - |



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| | | |
|---------------|---|---|
| Negative 137# | - | - |
| Negative 138# | - | - |
| Negative 139# | - | - |
| Negative 140# | - | - |
| Negative 141# | - | - |
| Negative 142# | - | - |
| Negative 143# | - | - |
| Negative 144# | - | - |
| Negative 145# | - | - |
| Negative 146# | - | - |
| Negative 147# | - | - |
| Negative 148# | - | - |
| Negative 149# | - | - |
| Negative 150# | - | - |
| Negative 151# | - | - |
| Negative 152# | - | - |
| Negative 153# | - | - |
| Negative 154# | - | - |
| Negative 155# | - | - |
| Negative 156# | - | - |
| Negative 157# | - | - |
| Negative 158# | - | - |
| Negative 159# | - | - |
| Negative 160# | - | - |
| Negative 161# | - | - |
| Negative 162# | - | - |
| Negative 163# | - | - |
| Negative 164# | - | - |
| Negative 165# | - | - |
| Negative 166# | - | - |
| Negative 167# | - | - |
| Negative 168# | - | - |
| Negative 169# | - | - |
| Negative 170# | - | - |
| Negative 171# | - | - |
| Negative 172# | - | - |
| Negative 173# | - | - |
| Negative 174# | - | - |
| Negative 175# | - | - |
| Negative 176# | - | - |



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| | | |
|---------------|---|---|
| Negative 177# | - | + |
| Negative 178# | - | - |
| Negative 179# | - | - |
| Negative 180# | - | - |
| Negative 181# | - | - |
| Negative 182# | - | - |
| Negative 183# | - | - |
| Negative 184# | - | - |
| Negative 185# | - | - |
| Negative 186# | - | - |
| Negative 187# | - | - |
| Negative 188# | - | - |
| Negative 189# | - | - |
| Negative 190# | - | - |
| Negative 191# | - | - |
| Negative 192# | - | - |
| Negative 193# | - | - |
| Negative 194# | - | + |
| Negative 195# | - | - |
| Negative 196# | - | - |
| Negative 197# | - | - |
| Negative 198# | - | - |
| Negative 199# | - | - |
| Negative 200# | - | - |
| Negative 201# | - | - |
| Negative 202# | - | - |
| Negative 203# | - | - |
| Negative 204# | - | - |
| Negative 205# | - | - |
| Negative 206# | - | - |
| Negative 207# | - | - |
| Negative 208# | - | - |
| Negative 209# | - | - |
| Negative 210# | - | - |
| Negative 211# | - | - |
| Negative 212# | - | - |
| Negative 213# | - | - |
| Negative 214# | - | - |
| Negative 215# | - | - |

4.2 The above results are summarized as follows:

| Method | | RT-PCR | | Total |
|--------------|----------|----------|----------|-------|
| | | Positive | Negative | |
| Test reagent | Positive | 73 | 4 | 77 |
| | Negative | 3 | 211 | 214 |
| Total | | 76 | 215 | 291 |

COVID-19 Antigen Rapid Test (Colloidal Gold) showed 96.1% sensitivity and 98.1% specificity.

Clinical sensitivity (%) = $[73 / (73 + 3)] \times 100\% = 96.1\%$

Clinical specificity (%) = $[211 / (211 + 4)] \times 100\% = 98.1\%$

Total agreement rate (%) = $[(73 + 211) / (73 + 3 + 4 + 211)] \times 100\% = 97.6\%$

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 | 9 | 9 | 8/9=88.9% |
| 4~7 | 33 | 33 | 32/33=97.0% |
| 8~14 | 25 | 25 | 24/25=96% |
| > 14 | 9 | 9 | 9/9=100% |
| Total | 76 | 76 | 73/76=96.1% 95% CI: (88.9% ~99.2%) |

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.