

Clinical Sensitivity and Specificity Study Report

The “COVID-19 IgG/IgM Rapid Test,” by TM Testing, Inc. (“TMT”) is designed for qualitative detection of SARS-CoV-2 virus antibodies in humans. Examining statistical coincident rate, we were able to validate that the test can be used for detection of SARS- CoV-2 virus antibodies (both IgG and IgM), using human whole blood / serum / plasma.

1. Method

Regarding the study, testing was performed on approximately 271 COVID-19-infection suspected case from professional point of care sites. For confirmed cases, we choose clinical specimens with three disease periods, and the result was compared to RT-PCR.

2. Material

COVID-19 IgG/IgM Rapid Test

3. Results

3.1 COVID-19 IgM Postive results of three disease periods from symptom onset

| Disease period (days) | Sample number of PCR positive | Number of Positive results by TMT | Clinical Sensitivity | 95%CI |
|-----------------------|-------------------------------|-----------------------------------|----------------------|---------------|
| ≤7 | 32 | 21 | 65.63% | 46.81%~81.43% |
| 8~14 | 41 | 38 | 92.68% | 80.08%~98.47% |
| ≥15 | 44 | 42 | 95.45% | 84.53%~99.44% |

3.2 COVID-19 IgG Postive results of three disease periods from symptom onset

| Disease period (days) | Sample number of PCR positive | Number of Positive results by TMT | Clinical Sensitivity | 95%CI |
|-----------------------|-------------------------------|-----------------------------------|----------------------|----------------|
| ≤7 | 32 | 19 | 59.38% | 40.65%~76.30% |
| 8~14 | 41 | 40 | 97.56% | 87.14%~99.94% |
| ≥15 | 44 | 44 | 100.00% | 91.96%~100.00% |

3.3 Results of COVID-19 IgM Clinical Sensitivity and Specificity—for all time periods from symptom onset

| COVID-19 IgM | | RT-PCR | | Total |
|--------------|----------|----------|----------|-------|
| | | Positive | Negative | |
| TMT, Inc. | Positive | 101 | 1 | 102 |
| | Negative | 16 | 153 | 169 |
| Total | | 117 | 154 | 271 |

Clinical Sensitivity (%) = $101 / (101 + 16) * 100\% = 86.32\%$ (95% CI: 78.74%~91.98%)

Clinical Specificity (%) = $153 / (1 + 153) * 100\% = 99.35\%$ (95% CI: 96.44%~99.98%)

Total Coincidence Rate (%) = $[(101 + 153) / (101 + 16 + 1 + 153)] = 93.73\%$ (95% CI: 90.15%~96.30%)

3.4 Results of COVID-19 IgG Clinical Sensitivity and Specificity-for all time periods from symptom onset

| COVID-19 IgG | | RT-PCR | | Total |
|--------------|--|----------|----------|-------|
| | | Positive | Negative | |

| | | | | |
|-----------|----------|-----|-----|-----|
| TMT, Inc. | Positive | 103 | 2 | 105 |
| | Negative | 14 | 152 | 166 |
| Total | | 117 | 154 | 271 |

Clinical Sensitivity (%) = $103 / (103 + 14) * 100\% = 88.03\%$ (95% CI: 80.74%~93.30%)

Clinical Specificity (%) = $152 / (2 + 152) * 100\% = 98.70\%$ (95% CI: 95.39%~99.84%)

Total Coincidence Rate (%) = $[(103 + 152) / (103 + 14 + 2 + 152)] = 94.10\%$ (95% CI: 90.59%~96.59%)

4. Conclusion

The clinical research is a qualitative test comparison to evaluate the clinical use validity and group professional test applicability of *TMT's COVID-19 IgG/IgM Rapid Test*.

For COVID-19 IgM, when compared to RT-PCR, a statistical comparison was made between the results yielding a sensitivity of 86.32%, a specificity of 99.35% and an accuracy of 93.73%. For COVID-19 IgG, when compared to RT-PCR, a statistical comparison was made between the results yielding a sensitivity of 88.03%, a specificity of 98.70% and an accuracy of 94.10%.

From the test of three disease periods from symptom onset, COVID-19 IgM has better sensitivity than COVID-19 IgG in the early periods, but for middle and later period, COVID-19 IgG has better sensitivity than COVID-19 IgM. Therefore, the combined detection of COVID-19 IgM and COVID-19 IgG is beneficial to improve the sensitivity of the product to all time periods.