

TM TESTING, INC

# COVID-19 IgM/IgG Rapid Test

ASSAY AND FACT SHEET

Single-use, point-of-care and home-use diagnostic test designed for qualitative detection of immunoglobulin antibodies to COVID-19 virus. Statistical coincident rate validates that the test can be used for detection of 2019-nCoV-SARS virus antibodies (both IgG and IgM), using human whole blood, serum or plasma.



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## COVID-19 test results in 15 minutes

### Diagnostic Kit for IgM/IgG Antibody of COVID-19-SARS-CoV-2 Assay

- Uses finger prick whole blood or plasma samples (<20  $\mu$ L)
- Provides rapid results: 15 minutes, no more than 20 minutes
- Intuitive visual interpretation
- Detects IgM and IgG antibodies for COVID-19
- Failure rate: less than 1%
- FDA approved
- No other equipment required

## Tiny fingertip blood sample: <20 $\mu$ L

### Clinical Sensitivity and Specificity Study Report

A clinical study was performed on approximately 271 COVID-19-infection suspected cases from professional point-of-care sites. The clinical research served as a qualitative test comparison, evaluating the clinical use validity and group professional test applicability of *TMRS's COVID-19 IgG/IgM Rapid Test*.

For COVID-19 IgM, when compared to RT-PCR (nasal swab), 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%.



# Usage Instructions

*Convenient, rapid and reliable results*



1. Constant temperature and static position



2. Massage fingertip



3. Disinfect with alcohol swab



4. Prick fingertip with safety lancet



5. Wipe off the first drop of blood with dry cotton balls



6. Use disposable dropper to collect two drops of blood



7. Add blood drops to test cassette



8. Add diluent and start timer



9. Review results after 15 minutes and not more than 20 minutes