2019-nCoV IgG/IgM Rapid Single Use Test
(Fingerstick Whole Blood) Instruction For Use

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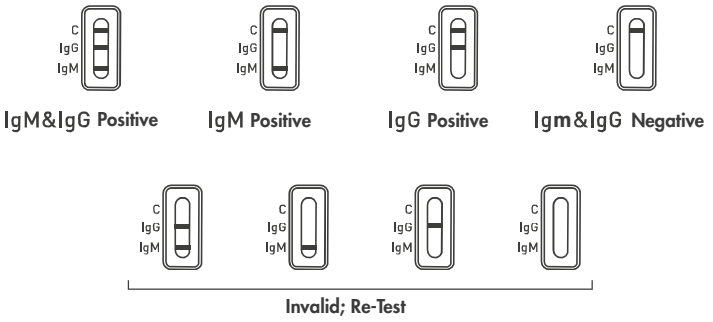
CORONA ANTIBODY RAPID TEST

RESULT INTERPRETATION
Positive Results: Colored bands appear at both test line (IgG/IgM) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.
•Both IgG/IgM Positive: Control line and both test lines appear.
•IgM Positive/IgG Negative: Both control line and the second test line (the lower test line which is closer to the sample well) appears. It indicates the possibility of primary infection.
•IgM Negative/IgG Positive: Both control line and the second test line (the higher test line) appears. It indicates the possibility of secondary infection or past infection.

Negative Result
Colored band appears at control line (C) only. It indicates that the concentration of the SARS CoV-2 antibodies is zero or below the detection limit of the test.
Invalid Result
No visible colored band appears at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



QUALITY CONTROL
A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS
1.This test has not been reviewed by the FDA
2.Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3.Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
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5.Not for the screening of donated blood
6.This reagent is designed to detect antibodies against SARS-CoV-2 in human whole blood, plasma, serum sample.
7.This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.
8.The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test results.
9.The test results of this test are for clinical reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
10.Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
11.In the early stage of infection, if IgM and IgG antibodies are not produced or the titer is very low, false negative results will occur.
12.Positive test results do not rule out co-infections with other pathogens. A negative result of this test can be caused by:

-Improper sample collection, improper sample transfer or handing, too low IgM/IgG titer in the sample;
-The level of SARS-CoV-2 antibodies is below the detection limit of the test.
-Variations in viral genes may cause changes in antibody determinants.

PERFORMANCE CHARACTERISTICS
Analytical Sensitivity and Precision Study
1. With 100% agreement, performance on all control levels, which meets the acceptance criteria, study results demonstrate that the 2019-nCoV IgG/IgM Rapid Single Use Test sensitivity is accurate and determined properly.
2. Based on the precision and reproducibility study, the results indicate high agreements of within-day, between-day, between lots and between human visual effects.
3. With the fact that no invalid result was reported, human error has been minimized so that 2019-nCoV IgG/IgM Rapid Single Use Test can be used easily.

Accuracy
A total of 74 specimens from confirmed patients were tested, the results showed that 65 specimens were IgM positive and/or IgG positive, and the clinical sensitivity was 87.8%. A total of 305 specimens from healthy persons were tested, the results showed that 302 specimens were both IgM and IgG negative, 1 specimen was IgM positive, 2 specimens were IgG positive, and the clinical specificity was 99.0%. The accuracy was 96.8%.

Assay Specificity

1.Other infectious diseases
Rapid 2019-nCoV IgG/IgM Rapid Single Use Test has tested samples that were infected by the following diseases: Influenza A Virus, Influenza B Virus, Adenovirus, Rotavirus and Mycoplasma Pneumoniae. All the samples showed no effect on the specificity of the assay.

2.Blood compounds
2019-nCoV IgG/IgM Rapid Single Use Test has tested samples with high Rheumatoid Factor (RF), Bilirubin, Triglyceride and Hemoglobin. The results showed that these compounds had no effect on the specificity of the assay up to the listed concentration.
Rheumatoid Factor: 80 IU/mL
Bilirubin: 342 μmol/L
Triglyceride: 37 mmol/L
Hemoglobin : 10 mg/mL

3.Common drugs
2019-nCoV IgG/IgM Rapid Single Use Test has tested samples with common drugs. The results showed that these drugs had no effect on the specificity of the assay.
Histamine Hydrochloride, Interferon-α, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin.

SYMBOL INDEX

IVD	In Vitro Diagnostic Use		See Instruction for Use
Σ	Tests per Kit		Manufacturing Date
LOT	Batch Number		Manufacturer
30°C 2°C	Store between 2~30°C		Do not reuse
EC REP	Authorized Representative		Keep away from Sunlight
	Expiry Date	REF	Catalog#
	Keep Dry		

CE