

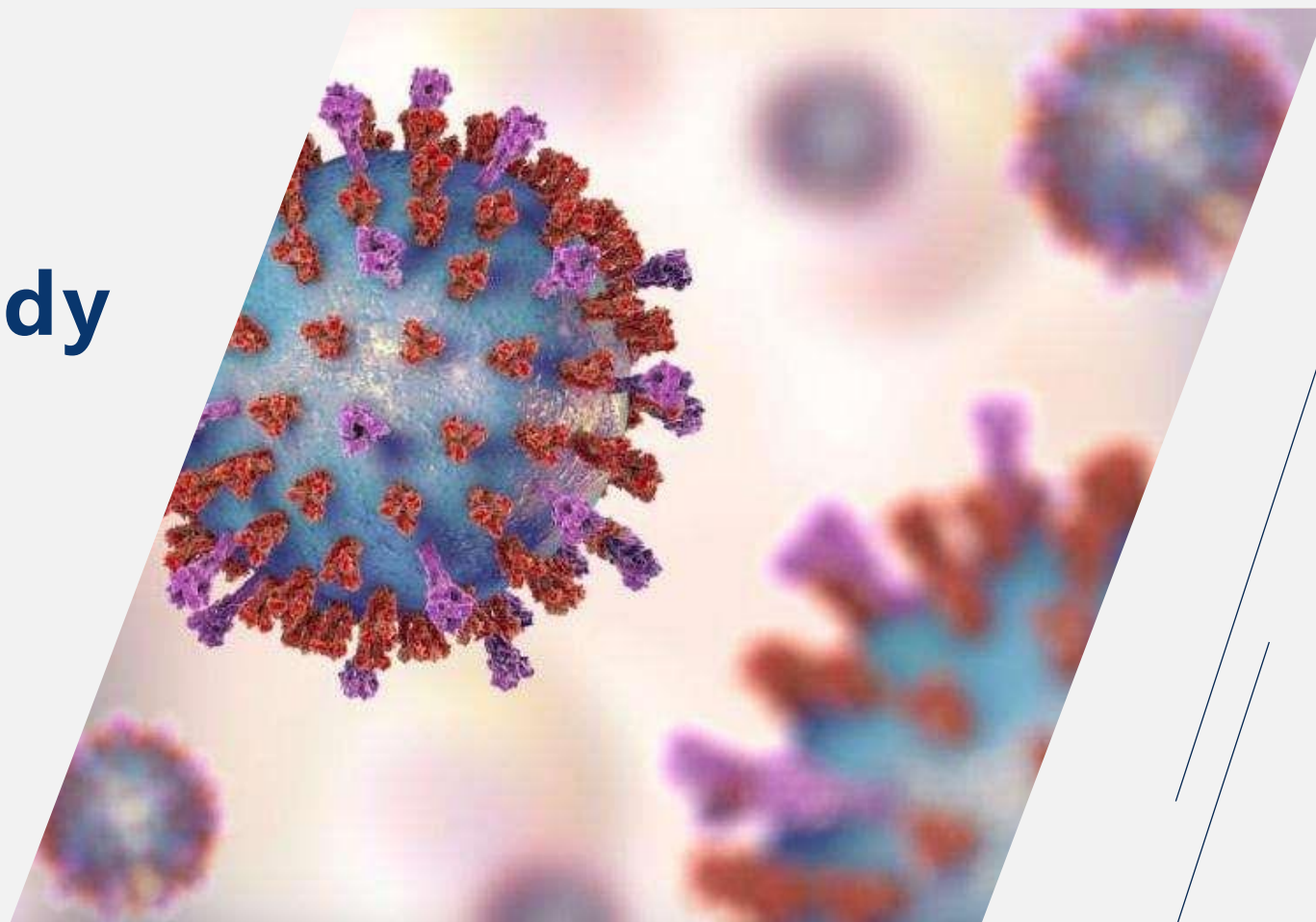
**Hecin** | 广东和信健康科技有限公司

Hecin Scientific, Inc.

# COVID-19 IgM Antibody Rapid Test Kit

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# COVID-19 IgM Antibody Rapid Test Kit

SFDA Number:

国械注准20203400199



Hecin COVID-19 IgM Antibody Rapid Test Kit is an immunochromatographic assay for rapid, qualitative detection of COVID-19 IgM Antibody in human whole blood, serum, plasma and fingertip blood sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV.



Storage	2°C ~ 30°C	Validity	6 months
Specimen	human whole blood, serum, plasma and fingertip blood sample		
Reaction conditions	Room temperature for 15min.		
Equipment needed	Not necessary		
Pack size	For 50 tests per box		
Components	Test cassette, Sample diluent		

## Specimen Requirement

Whole blood samples should be tested as soon as possible after collection. If blood samples cannot be tested within 2 hours, they should be stored at 2 ~ 8°C for no more than 2 days.

Serum and plasma samples may be stored for up to 7 days at 2 ~ 8°C or 3 months at -20°C prior to testing. Fingertip blood samples should be tested immediately after collection.

The samples should be restored to room temperature (10 ~ 30°C) before testing. The frozen samples should be completely thawed, rewarmed, and mixed before use. Avoid repeated freeze-thaw cycles.

# ▶ TEST PROCEDURE

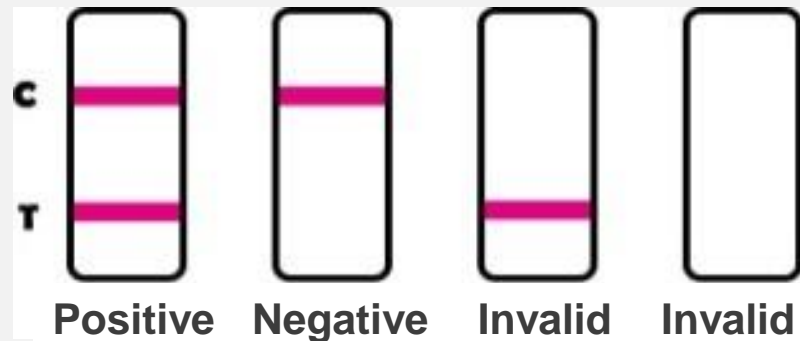
**Venous blood collection**



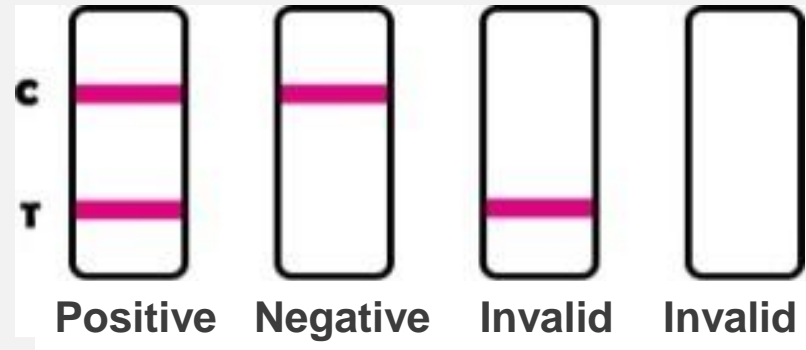
**10 $\mu$ l to the  
sample well**



**2 drops of  
sample diluent**



**Wait for 15 minutes  
and read the results**



Positive	Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the COVID-19 IgM antibodies in the specimen.
Negative	Colored band appear at control line (C) only. It indicates that the concentration of the COVID-19 IgM antibodies is zero or below the detection limit of the test.
Invalid	No visible colored band appear 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.

Reagents	Clinical cases		Total
	Confirmed	Excluded	
Positive	283	4	287
Negative	27	237	264
Total	310	241	551

551 clinical case samples which include 310 confirmed case samples and 241 confirmed excluded case samples, were obtained for testing, and then compared the test results between Hecin COVID-19 IgM Antibody Rapid Test Kit and the confirmed case samples.

## Sensitivity

91.29%

95% CI 【87.58%-94.18%】

## Specificity

98.34%

95% CI 【95.81%-99.55%】

## Total consistent

94.37%

95% CI 【92.11%-96.15%】

# THANKS !

Hecin Scientific, Inc.

