

# COVID-19 Neutralization Antibody FIA

## ■ CLUNGENE® COVID-19 Neutralization Antibody FIA

Clongene has developed the COVID-19 Neutralization Antibody FIA is a Fluorescence immunoassay intended for the qualitative detection of neutralizing antibodies to SARS-CoV-2 in human whole blood, serum and plasma.

The COVID-19 Neutralization Antibody FIA is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The COVID-19 Neutralization Antibody FIA should not be used to diagnose acute SARS-CoV-2 infection.



## ■ Product Features

High sensitivity

High specificity

Easy and fast operation

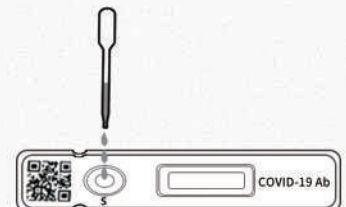
Whole blood, plasma and serum can be detected

## ■ Test Procedure

1. Remove the test cassette from the sealed pouch.



2. Hold the dropper vertically and transfer 3 drops of specimen (approximately 100µL) to the specimen well (S) of the test cassette.



3. Standard Test or Quick Test: Input the basic patient medical information, including sample number and sample type and etc.

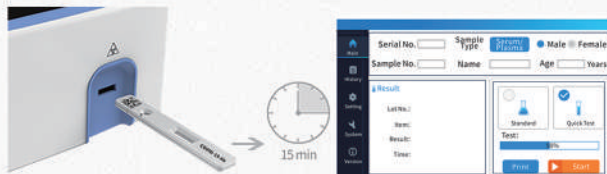
① Standard test:

After the sample is added, insert the test cassette into the instrument and click "standard". After the reaction countdown ends in 15 minutes, the instrument automatically performs the test.



② Quick test:

After adding the sample, insert the test cassette into the instrument in 15~20 minutes, and click "quick Test" as soon as possible. The instrument will automatically test the test cassette.



4. After the test is completed, the analyzer automatically displays the test results of the current sample shown under the result of the screen. Click Print to print the test result.

## ■ INTERPRETATION OF RESULTS

Result	Interpretation
Positive (+)	Positive for COVID-19 Neutralization Antibody
Negative (-)	Negative for COVID-19 Neutralization Antibody
No Sample	Test Invalid, Repeat the test

## ■ PERFORMANCE CHARACTERISTICS

### Clinical Performance

167 samples retrospectively collected from SARS-CoV-2 RT-PCR positive and negative individuals using the COVID-19 Neutralization Antibody FIA and the PRNT<sub>50</sub> comparator. Summary data of COVID-19 Neutralization Antibody FIA by serum as below:

COVID-19 Neutralization Antibody FIA		Plaque Reduction Neutralization Test (PRNT <sub>50</sub> )		Total
		Positive	Negative	
CLUNGENE®	Positive	62	0	62
	Negative	0	105	105
Total		62	105	167

Positive Percent Agreement (PPA): 100% (62/62) (95%CI: 94.17%~100%)

Negative Percent Agreement (NPA): 100% (105/105) (95%CI: 96.47% ~99.71%)

### Cross-Reactivity

115 other virus, bacteria or autoantibodies samples were evaluated and no cross-reactivity was observed.