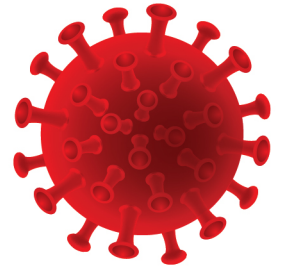


 MADE IN KOREA

# ADTech

## COVID-19 IgM/IgG RAPID KIT



May 2020



ADTech Co., LTD

에이디텍 주식회사

NOVEL IMMUNOASSAY

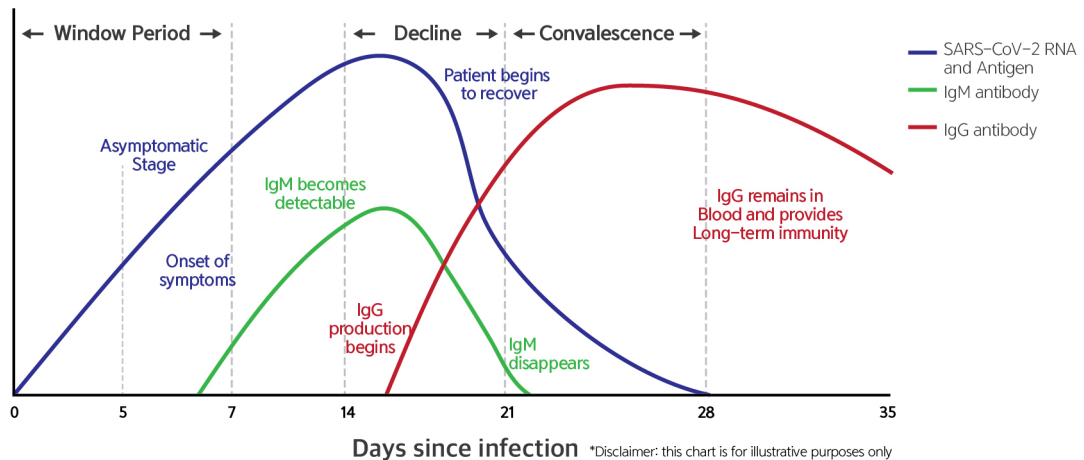
TOTAL IVD SOLUTION PROVIDER

[www.adtchip.com](http://www.adtchip.com)



### IgM/IgG Antibodies RAPID TEST

IgM/IgG serological tests offer some advantages over RT-qPCR. Firstly, serological tests detect human antibodies (proteins belonging to the immunoglobulin class) which are known to be much more stable than viral RNA. As a result, IgM/IgG serological specimens are less sensitive to spoilage during collection, transport, storage and testing than RT-qPCR specimens. Secondly, because antibodies are typically uniformly distributed in the blood, serological specimens have much less variations than nasopharyngeal viral RNA specimens and can be easily collected. Thirdly, unlike RT-qPCR, serological tests can detect past infection because virus-specific antibodies (unlike viral RNA) can persist in the blood for several weeks/months after onset of symptoms. And you get the clear answer with ADTech COVID-19 IgM/IgG RAPID KIT.



Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	-	-	Patient may be in the window period of infection.
+	+	-	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	-	+	Patient may be in the late or recurrent stage of infection.
-	+	-	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
-	-	+	Patient may have had a past infection, and has recovered.
-	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

#### Clinical Significance of an IgM/IgG Serological Test Result

Source: <http://www.diazyme.com/covid-19-antibody-tests>

## PRODUCT INTRODUCTION

Adtech COVID-19 IgM/IgG RAPID KIT is a gold nanoparticle based immunochromatography test kit that qualitatively measures IgM and IgG antibodies from COVID-19 in whole blood, serum or plasma.

The kit is accurate, easy to use, and results can be checked with the naked eye within 10–15 minutes.

### PRODUT DESCRIPTION

#### ADTech COVID-19 IgM/IgG RAPID KIT [HS CODE 3002.15]

- Model No. : C 0430-1
- Quantity : 20 Tests/KIT
- Sample : Venous/Finger blood, Plasma and serum
- Test time : Reading in 10–15 min
- Storage : 2°C–30 °C(35.6°F–86°F)
- Expiry : 18 months since manufactured



### HOW TO USE

#### 1. Collecting of Sample

For the test, 10 $\mu$ l of whole blood, plasma or serum is used  
Collect the blood sample obtained by venipuncture into blood collection tube or use fingertip blood.

#### 2. Adding of Sample

Add the collected sample into the sample inlet of the test cassette.

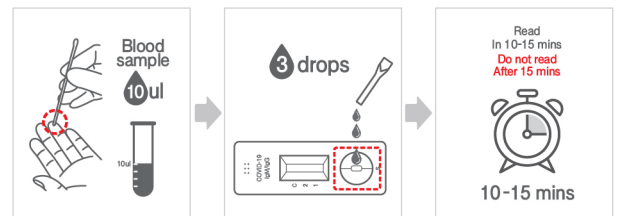
#### 3. Dropping of Sample Buffer

Add 3 drops(90  $\mu$ l) of sample into the inlet of the test cassette.

#### 4. Reading the Test Result

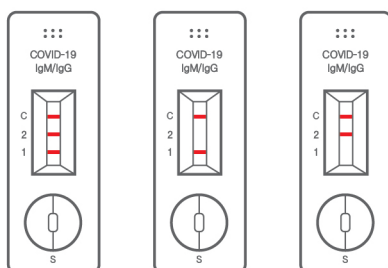
Read the test result at 10–15 minutes

※ Do not read after 15 minutes



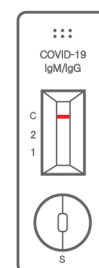
### TEST RESULT

#### Positive



When all the 3 lines are shown at Test 1, Test 2 and Control, then the test result is "POSITIVE", Even in case 2 lines are shown at 'control and Test 1' or 'Control and Test 2', the test result is "POSITIVE", too

#### Negative



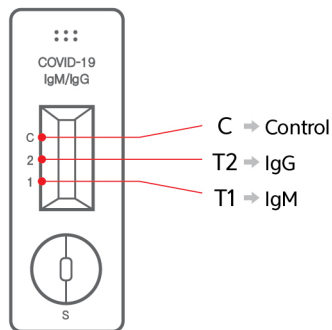
When the control line does not show up without 2 Test lines, the test result is "NEGATIVE"

※ If the line is not shown up at the control line though test is fulfilled, then that test cassette and test result are invalid, at that time, you have to re-test with new test cassette.

## PRODUCT INTRODUCTION



### 1 Cassette



### 2 Pouch

#### Test line

- T1 : IgM
- T2 : IgG
- C : control

#### Cassette

- Size : 69,5mm x 25 mm x 4 mm
- Weight : 4,8g

#### Pouch

- Size : 120 mm x 70 mm
- Weight : 7,9g
- Items : 1 test(cassette) & 1 silica gel

### 3 Outer box

- Size : 170 mm x 120 mm x 75 mm
- Weight : 203,6g
- Items : 20 (pouched) tests  
20 lancets  
1 buffer solution  
1 user manual

### 4 Carton box

- Size : 530 mm x 500 mm x 400 mm
- Weight : 15kg
- Items : 60 outer boxes(= 1,200 tests)

### 5 Palette

- Size : 1,100mm x 1,100mm x 2,120 mm
- Weight : 306kg
- Items : 120 carton boxes(= 24,000 tests)

### 6 Container

#### 20ft container

- 10 Pallettes(= 240,000 tests)

#### 40ft container

- 20 Pallettes(= 480,000 tests)

## PRE-CLINICAL TRIAL REPORT

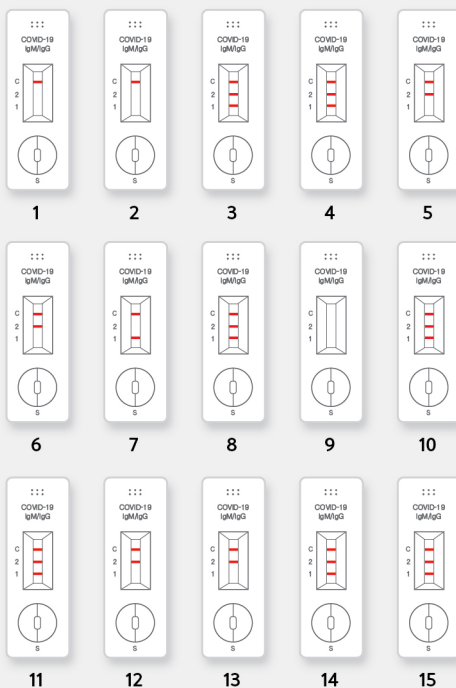
### Pre-Clinical Test summary

- 1) Pre-clinical test is fulfilled by Domestic large clinical laboratory with ADTech COVID-19 IgM/IgG RAPID KIT.
- 2) Tests are made by total 15 samples with 12 positive and 3 negative samples.
- 3) Clinical Laboratory tested the sample with Immunofluorescence Analysis if there remains the antibodies in the samples.  
(All the 'Positive' samples are verified that they contains IgM and/or IgG antibodies by Immunofluorescence Analysis)

### Pre-clinical test result

- 1) Samples were tested by ADTech COVID-19 IgM/IgG RAPID KIT
- 2) Test result by ADTech's RAPID KIT
  - 4 negatives and 11 positives results in 15 samples
- 3) Comparison between Immunofluorescence analysis and ADTech's RAPID KIT
  - 14 test results are same(including negative and positive results)
  - 1 sample's test result are different(Positive → Negative by ADTech)
- 4) Accuracy
  - In total samples → 93.3% (14/15)
  - In positive samples → 91.7% (11/12)

#### ADTech's RAPID KIT Test result



#### Immunofluorescence Analysis

No	Immunofluorescence		Remarks
	IgM	IgG	
1	Negative	Negative	Accurate
2	Negative	Negative	Accurate
3	Positive	Positive	Accurate
4	Positive	Positive	Accurate
5	Negative	Positive	Accurate
6	Negative	Positive	Accurate
7	Positive	Negative	Accurate
8	Positive	Positive	Accurate
9	Negative	Negative	Accurate
10	Positive	Positive	Accurate
11	Positive	Positive	Accurate
12	Negative	Positive	Inaccurate(ADTech: Negative)
13	Negative	Positive	Accurate
14	Positive	Positive	Accurate
15	Positive	Positive	Accurate

\* All the positive samples above are verified that the IgM and/ or IgG antibodies remain in the sample by Immunofluorescence analysis. Even though the sample comes from the infected patient, if there is no antibodies in the sample, then the test result shows 'NEGATIVE'.

## CLINICAL TRIAL REPORT

### 01. Test Institution & Test Period

Seoul Clinical Laboratories  
2020. 04. 13 – 2020. 05. 04

### 02. Specimens

33 positive samples, and 33 negative samples were used in this evaluation study.

### 03. Test Comparison

Tests were performed on the collected specimens using a test reagent (ADTech IgM / IgG RAPID KIT), and RT-qPCR (control reagent: Allplex™ 2019-nCoV Assay) was tested on the upper and lower respiratory tract specimens of the same patient. Test results were compared with the results of RT-qPCR.

### 04. Test Result

Test Results		Control Reagents (Allplex™ 2019-nCoV Assay)		Total
		Positive	Negative	
Test Reagents (ADTech IgM/IgG RAPID KIT)	Positive	28	0	28
	Negative	5	33	38
Total		33	33	66

### 05. Match rate

1) Positive match rate =  $a / (a+c) \times 100(\%) = 28 / (28+5) \times 100(\%) = 84.85\%$   
(95% confidence intervals 0.6908 – 0.9335)

2) Negative match rate =  $d / (b+d) \times 100(\%) = 33 / (0+33) \times 100(\%) = 100.0\%$   
(95% confidence intervals 0.8957 – 1.0000)

3) Total Match rate =  $(a+d) / (a+b+c+d) \times 100(\%) = (28+33) / (28+0+5+33) \times 100(\%) = 92.42\%$   
(95% confidence intervals 0.8349 – 0.9672)

### 06. Coincidence

Kappa =  $2(ad-bc) / \{(a+b)(b+d)+(a+c)(c+d)\} =$   
 $2(28 \times 33 - 0 \times 5) / \{(28+0)(0+33)+(28+5)(5+33)\} = 1848 / 2178 = 0.8485$   
(95% confidence intervals 0.8328 – 0.8629)

### 07. Clinical efficacy evaluation results

The clinical efficacy assessment for COVID-19 of ADTech IgM / IgG RAPID KIT was conducted for upper respiratory tract samples, whole blood, plasma, and serum samples of positive patients and normal persons which were previously tested with Allplex™ 2019-nCoV Assay (No. 20-119).

As a result of evaluating the overall matching rate, a positive matching rate was 84.85% (95% confidence interval 0.6908–0.9335), a negative matching rate was 100.0% (0.8957 – 1.0000), and an overall matching rate was 92.42% (0.8349 – 0.9672). The coincidence evaluation result was kappa 0.8485 which indicates good coincidence.