

# COVID-19

## IgG and IgM ELISA Kits

### COVID-2019

Epitope Diagnostics has proudly introduced immunoassay kits exclusively for the qualitative detection of COVID-19. With **proven results** from clinical testing in China, Epitope Diagnostics, Inc. is eager to cooperate and collaborate to combat the current COVID-19 situation.

### COVID-19 IgG

IgG is most abundantly produced in response to an antigen and will be maintained in the body after initial exposure for long term response. Antibody titer is 4 times or higher than that of the acute phase\*.

Principle	Indirect Method
Sample Type	Serum
Sample Volume	10 µL
Assay Incubation	80 minutes, RT
Total Wash Steps	2
Limit of Detection	5IU/mL
Repeatability	CV < 15%
Reproducibility	CV < 20%

### COVID-19 IgM

IgM is first to be produced in response to an antigen and will be primarily detectable during the early onset of the disease. IgM antibodies begin to show positive after 3-5 days of onset\*.

Principle	Capture Method
Sample Type	Serum or Plasma
Sample Volume	20 µL
Assay Incubation	80 minutes, RT
Total Wash Steps	2
Limit of Detection	5IU/mL
Repeatability	CV < 15%
Reproducibility	CV < 20%

### Clinical Testing

At a local CDC Laboratory in China, 20 RT-PCR confirmed cases and 43 normal healthy donor specimen were tested. 75% (15 out of 20) of the positive cases show a 3x higher OD value than the positive cut off value and 90% (18 out of 20) have a 2x higher OD value than the positive cut off value.

*Additional data available upon request*

N = 63	COVID-19 IgG	
	Confirmed Positive	Confirmed Negative
IgG Test Positive	20	0
IgG Test Negative	0	43

**Sensitivity = 100%, Specificity = 100%, PPV = 100%, NPV = 100%**

### Ordering Information

#### Product Information

KT- 1032: EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit

KT-1033: EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit

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EPITOPE DIAGNOSTICS, INC.