



## LIVZON Diagnostics

# COVID-19 IgM and IgG antibody Rapid Test (One Step Immunochromatography Colloidal Gold Assay)

*\*Forward looking leaflet does not represent any offers, subject to final release version*

### A Much Easier and Faster Way to Diagnose COVID-19

**Serology test such as immunochromatography rapid test is highly recommended in combination use of nucleic acid test in COVID-19 because:**

1. The COVID-19 coronavirus misdiagnosis is a huge concern due to many reasons and more likely happens if only rely on single PCR test result.
2. The PCR/molecular tests require much higher standard and facilities to perform from both safety and quality perspectives. It becomes the major bottleneck to test suspected cases (can be large in some countries) in time. Shortage of test performed will lead to potential mass infection events in terms of COVID-19.
3. Serology test may also function as markers for prognosis, virus tracing and epidemiology study.



COVID-19 IgM Antibody Rapid Diagnostic Test Kit (Colloidal Gold)



COVID-19 IgG Antibody Rapid Diagnostic Test Kit (Colloidal Gold)

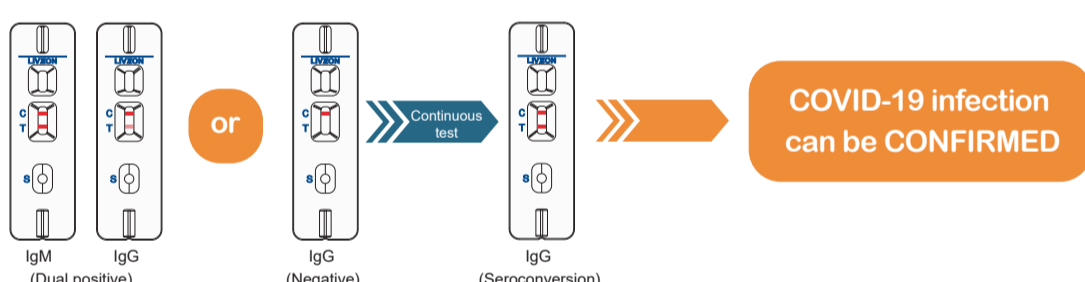
<b>Whole blood sample supported</b>
<b>One step, result viewed in 15 minutes</b>
<b>Independent IgM and IgG results</b>
<b>Validated by hundreds in China from January</b>
<b>Optional 12-Channel Reader for batching</b>
<b>First admitted in the process of EUA (China)</b>
<b>Commercial Launch and CE label Soon</b>

### IgM & IgG tests as lab confirmation method newly adopted in China from March

Serology tests have been adopted as one of the lab confirmation tests (molecular PCR, sequencing and serology) of COVID-19, published on the **Guideline for COVID-19 Diagnosis and Treatment, 7th Edition** by the **National Health Commission of P.R.China** dated March 3rd, 2020. "Seroconversion of COVID-19 specific IgM antibodies usually can be detected in 3-5 days after symptoms"

"Confirm suspected infection cases when:

1. COVID-19 specific IgM AND IgG antibody together show positive in serum; or
2. COVID-19 specific IgG antibody seroconverts or 4 times higher titer changes measured."



### Performance Studies Overview

#### 1. Specificity Study:

No cross-reactions showed in below validation process.

- a. Internal enterprise controls including negatives and cross-reaction samples (other frequent respiratory infectious disease patients' serum)
- b. Official sampling validation performed by National Institutes for Food and Drug Control (China) and achieved PASS

#### 2. Sensitivity Study:

	Total Combined (IgM+IgG)	Early Stage (IgM+IgG)	Mid-late Stage (IgM+IgG)	IgM	IgG
Total Confirmed Cases (by PCR)	203	58	143	203	203
Positive	185	44	140	165	170
Negative	18	14	3	38	33
Sensitivity	91.1%	75.9%	97.9%	81.3%	83.7%

#### 3. Advanced Confirmed (before positive PCR result) Cases Study:

8 antibody positive cases (symptomatic/asymptomatic) found before PCR confirmation (one even with 11 negative results in a row) then confirmed within days. Such indication is not priority study in China therefore no clinical enrollment carried out.

\*Unpublished data for research purpose only  
\*Officially approved product data shall prevail



Optional 12-Channel Reader

Product Name	Packing Size	Storage Temperature	Sample Type and Volume Needed	Test Time
COVID-19 IgM Antibody Rapid Diagnostic Test Kit (Colloidal Gold)	20 tests/box, 40 tests/box	2-30°C	Plasma/Serum: 10µL Whole Blood: 20µL	15 minutes after loading
COVID-19 IgG Antibody Rapid Diagnostic Test Kit (Colloidal Gold)	20 tests/box, 40 tests/box	2-30°C	Plasma/Serum: 10µL Whole Blood: 20µL	15 minutes after loading

\*Research Use Only product information  
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### ELISA test to COVID-19 IgM and IgG (RUO)

### Advanced PCR test to COVID-19 RNA (RUO)



Economic and Efficient Batch Automation with hundreds of samples  
More Repeatable Lab Test Quality based on the most established ELISA

Quantitative Tests In Research, can be used for:

- Detail study to course of disease and prognosis (e.g. IgG level)
- Evaluate determination of recovery period and hospital discharge
- Evaluate antibodies from the serum of cured patients for treatment

- All-in-one Lyophilized Kit, super stable in ambient temperature
- Large volume reaction system to ensure high sensitivity
- Optimized extraction system assures high quality result
- Full range mineral oil cover, safe and free of contamination
- Automation equipment for high throughput when shorthanded