

Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19

LIONRUN Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19 is a CE-IVD test for the qualitative and differential detection of IgM and IgG antibodies against the 2019 novel Coronavirus (2019-nCoV) also known as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human whole blood, serum or plasma, capable of providing test results within 10 minutes. Veredus Laboratories is authorized to provide distribution and marketing of this product globally excluding China.

Benefits

- Differential detection of IgM and IgG antibodies covering different stages of 2019-nCoV infection
- Fast time to result: **10 Minutes**
- Product clinical performance: **Sensitivity 90.43%** (170/188, 65 IgM positive, 97 IgG positive, 8 positive for both IgM and IgG); **Specificity 100%** (182/182) using 188 blood specimens obtained from patients with clinically confirmed COVID-19 and 182 blood specimens from non-infected (2019-nCoV negative) patients; **Accuracy 95.14%**.

Analytical Performance

- **Reactivity: 100% positive coincidence rate** (15-600 U/mL, using 3 lots of kit tested in triplicate)
- **Specificity: 100% negative coincidence rate** (using 3 lots of kit tested in triplicate)
- **Limit of Detection (LOD): 10U/mL (2019-nCoV IgM) and 90U/mL (2019-nCoV IgG)** quantified by ELISA, with 90-95% probability of detection
- **Reproducibility: 100% positive coincidence rate** (15-30U/mL for 2019-nCoV IgM, 100-200U/mL for 2019-nCoV IgG using 3 lots of kit tested in 10 replicates)
- **Lot-to-lot Variation: 100% positive coincidence rate** (15-30U/mL for 2019-nCoV IgM, 100-200U/mL for 2019-nCoV IgG, using 3 lots of kit tested in 10 replicates)



LIONRUN Rapid Antibody Detection Test

- The Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19 has **no interference with infections that are non-COVID-19** based on validated tests performed on sera that are positive for IgM or IgG of the following pathogens; non-2019-nCoV strains (HKU1, OC43, NL63, and 229E), Influenza (A/H1N1-2009, A/seasonal H1N1, A/H3N2, A/H5N1, A/H7N9, B/Yamagata, B/Victoria), Respiratory Syncytial Virus (RSV), Rhinovirus (Group A, B, C), Adenovirus (Type 1, 2, 3, 4, 5, 7, 55), Enterovirus (Group A, B, C, D), Epstein-Barr virus (EBV), Rubella Virus, Human Cytomegalovirus (HCMV), Rotavirus, Norovirus, Mumps Virus, Varicella-zoster Virus (VZV) and Mycoplasma Pneumoniae.
- The Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19 has **no interference with endogenous analytes**; bilirubin, hemoglobin, triglyceride, heme, cholesterol, unspecific human IgM (4.5mg/mL), unspecific human IgG (45mg/mL), **other human antibodies** against Rheumatoid Factor (RF), Antinuclear Antibody (ANA), and Antimitochondrial Antibody (AMA) and **anticoagulants** (6.2mg/mL trisodium citrate, 1.5mg/mL EDTA, 5mg/mL Heparin).

Materials Provided Per Kit

- Detection Cassette
- Diluent
- Hemostix
- Disposable Micropipette
- Alcohol Swab
- User Manual

Specifications

Testing Principle	Colloidal Gold-based Immunochromatography Assay
Testing Time	10 Minutes
Specimen	Whole Blood, Serum, Plasma, Capillary Blood
Specimen Quantity	Whole Blood (Capillary Blood) 20µL; Serum (Plasma) 10µL
Package	20 Tests / Box
Storage	2 - 30°C
Warranty Period	12 months

Test Procedure

Step 1. Add Sample

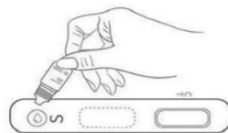
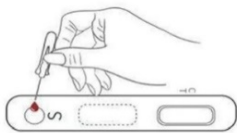
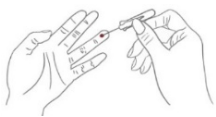
Dispense serum/plasma (10 µl) or whole blood (20 µl) into the specimen well

Step 2. Add Diluent

Dispense 2-3 drops of the assay diluent

Step 3. Read Results (Red Band)

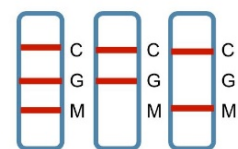
C = Control positive
G = IgG positive
M = IgM positive



Wait 10-20 mins



Positive



Ordering Information

Product	Catalogue No.	Specimen	Pack Size	Min. Order Qty.
Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19	LION-CA020	Serum/ Plasma/ Whole Blood	20 Tests/ Kit	25 Kits

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