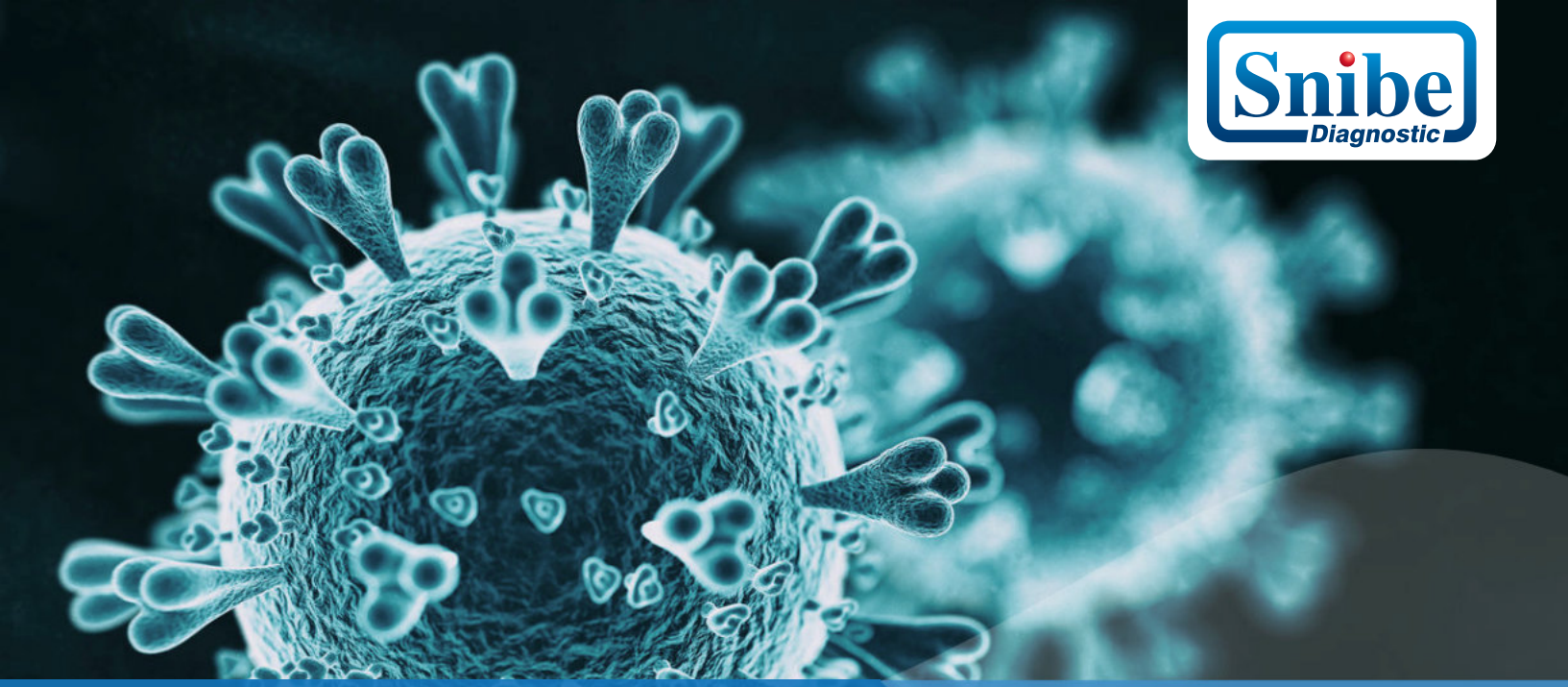

MAGLUMI 2019-nCoV IgG/IgM CLIA Assays

Product Benefit

- Fully automated CLIA solution (High Sensitivity Method)
- Qualitative determination of **2019-nCoV(Novel Coronavirus) IgG/IgM antibody**
- **Assist early detection** of 2019-nCoV suspicious cases with nucleic acid negative
- High sensitivity and high specificity for COVID-19 by joint detection of **2019-nCoV IgG and IgM**
- Sample type: **Human Serum, Plasma**
- Rapid detection **within 30 mins**
- Accurate test result with **ONLY 10μL** sample volume
- Free Calibrators & control (FOC) included
- High throughput analyzer with **Lab Automation Connection** (Thermo Fisher Scientific/Inpeco Track)

Clinical Background

The novel coronavirus (2019-nCov, official name SARS-CoV-2), which belongs to the genus Beta-coronavirus, causes an epidemic of acute respiratory syndrome in human population in Wuhan, Hubei China. It has an envelope, particles are round or oval, often polymorphic, and the diameter is 60 ~ 140nm. By gene sequence alignment, 2019-nCoV is approximately 79% similar to SARS-CoV and 50% similar to MERS--CoV3. [1]

2019-nCoV (SARS-CoV-2) is mainly transmitted through respiratory droplets and can also be transmitted through contact. The sources of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus.

Figure.1 The Novel Coronavirus From World Health Organization Website

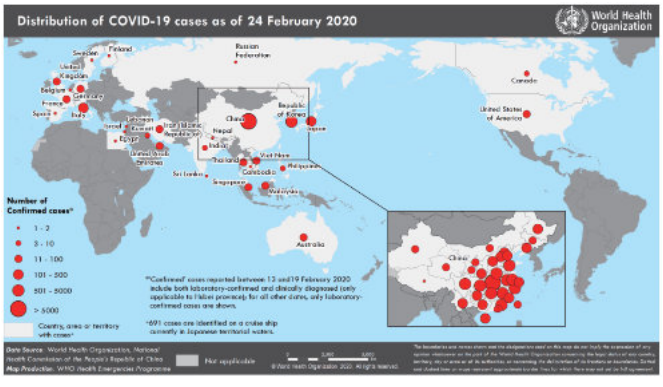

Figure.2 Distribution of COVID-19 cases as of 24 February 2020 [4]

2019-nCoV (SARS-CoV-2) has infected tens of thousands of people in the world and threatens to trigger a global outbreak. The high affinity of 2019-nCoV for human ACE2 may contribute to the apparent ease with which 2019-nCoV can spread from human-to-human. [2] World Health Organization has declared the crisis of 2019-nCov as a Public Health Emergency of International Concern. [3] With the increasing infected number of Novel Coronavirus, early diagnosis and early treatment to minimize the spread of the coronavirus has became a priority.

Clinical Application

- Assist **early detection** of 2019-nCoV infection
- Assist **diagnosis** of 2019-nCoV suspicious cases
- Assist **reducing the false negative case** of 2019-nCoV nucleic acid assay (Recommended by National Center of Clinical Laboratories of China)
- Preliminarily **determinate** the different stage of coronavirus infection

Note:

MAGLUMI 2019-nCoV IgG/IgM kits cannot be used as the only basis to diagnose and eliminate 2019-nCoV suspicious cases, and cannot be used in 2019-nCoV infection screening in general population. MAGLUMI 2019-nCoV IgG/IgM kits, as a supplement for the 2019-nCoV detection, are recommended to be used in combined with nucleic acid assay to improve the clinical detection rate.

If the test result is in a gray zone or positive, follow-up tests should be performed. If the antibody level does not change significantly, patient's viral nucleic acid results and imaging features such as CT (Computed Tomography) should be combined for confirmed diagnoisis.

MAGLUMI TEST PANEL-Total solution for 2019-nCoV infection-related disease[5]

Application	Parameter
Inflammatory Cytokine Storm	hs-CRP, PCT (Procalcitonin), IL- 6
Acute Cardiac Injury	CK-MB, Troponin I, Myoglobin, hs-cTnI, H-FABP, NT-proBNP, BNP
Acute Kidney Injury	β2-MG, Albumin, *NGAL
Coagulation Disorder	D-Dimer

*Available soon
Above information released by China General Office of the National Health Commission

Clinical Verification

Clinical Sensitivity

The clinical sensitivity was determined in China by confirmed novel coronavirus infected specimens. A total of 91 clinical confirmed positive specimens were tested by using Snibe MAGLUMI 2019-nCoV IgG/IgM CLIA Assays in China.

Specimen Category	2019-nCoV IgG (CLIA)			2019-nCoV IgM (CLIA)			2019-nCoV IgM (CLIA)+2019-nCoV IgG (CLIA)		
	N	Positive	%Sensitivity	N	Positive	%Sensitivity	N	Positive	%Sensitivity
Clinical Confirmed Positive Samples	91	83	91.21%	91	42	48.28%	91	87	95.6%

Note: 4 of the 91 samples had 2019-nCoV IgM test results in the gray zone and were not used for sensitivity data analysis. **The positive rate of IgG and IgM antibodies may be affected by the infection period of the test subject (when blood sampling) in different studies.**

Clinical Specificity

The clinical specificity was determined by non- novel coronavirus infected specimens, normal samples and interference samples. A total of 750 negative specimens were tested by using Snibe MAGLUMI 2019-nCoV IgG/IgM CLIA Assays in China.

Specimen Category	2019-nCoV IgG (CLIA)			2019-nCoV IgM (CLIA)			2019-nCoV IgM (CLIA)+2019-nCoV IgG (CLIA)		
	N	Negative	%Specificity	N	Negative	%Specificity	N	Negative	%Specificity
Negative Specimens	750	730	97.33%	750	722	96.27%	750	722	96%

Assay Specification

	2019-nCoV IgG and IgM
Test Principle	Chemiluminescence immunoassay (CLIA)
Sample Type	Human Serum, Plasma
First Result Time	Within 30 mins (Analyzers model dependent)
Sample Volume	10 µL
Repeatability	1.62%-6.08%

Ordering Information

Reagent pack:

2019-nCoV IgG	100 T (Catalog No: 130219015M)
2019-nCoVIgM	100 T (Catalog No: 130219016M)

Calibrators & internal quality controls (FOC) included

References:
[1] Roujian Lu
□XiangZhao,JuanLi, et al, Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Published online January 29, 2020
[2] Wrapp D, Wang N, Corbett K S, et al. Cryo-EM Structure of the 2019-nCoV Spike in the Prefusion Conformation[J]. bioRxiv, 2020.
[3] https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)
[4] https://reliefweb.int/sites/reliefweb.int/files/resources/20200224-sitrep-35-covid-19.pdf
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