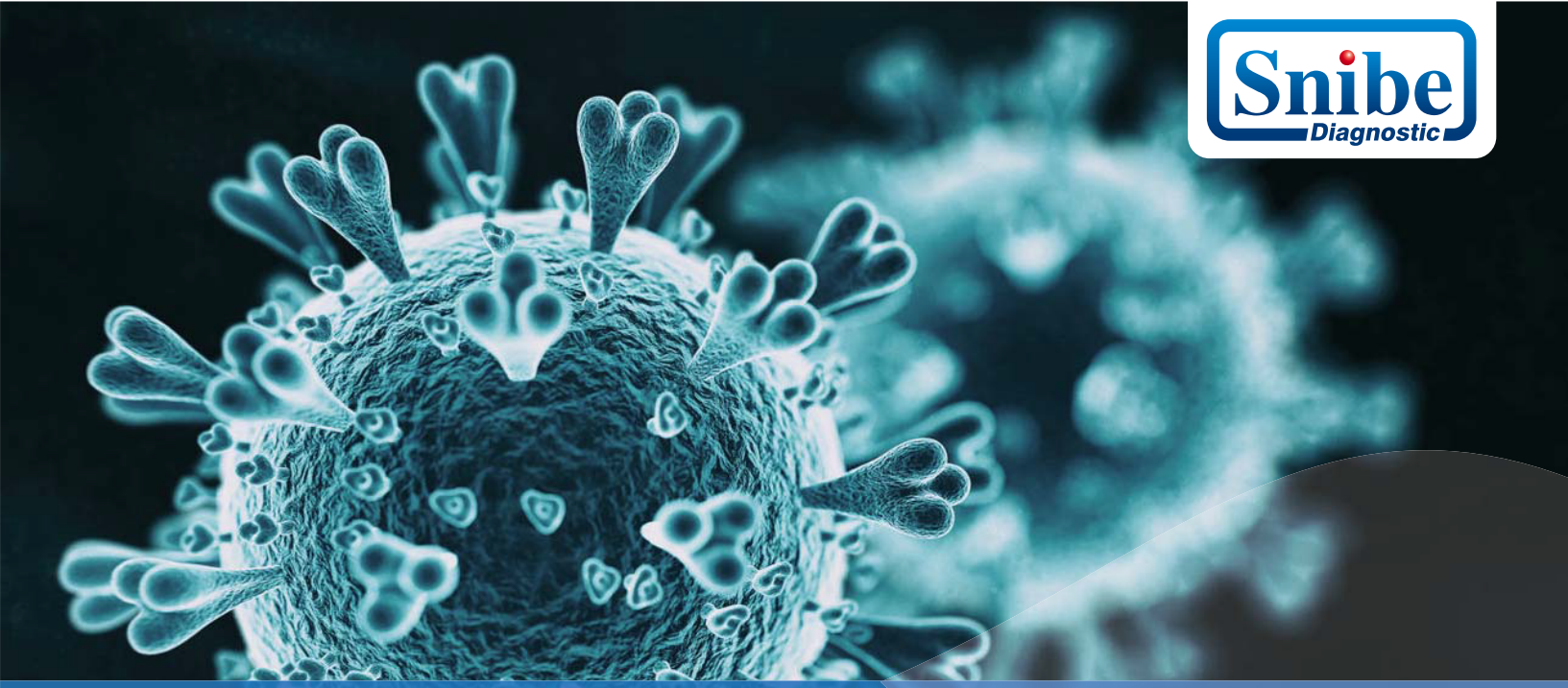

MAGLUMI® 2019-nCoV IgG/IgM CLIA Assays

Product Benefits

- 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 globally. 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. World Health Organization (WHO) announced that pneumonia infected with SARS-CoV-2 will be officially named "COVID-19".

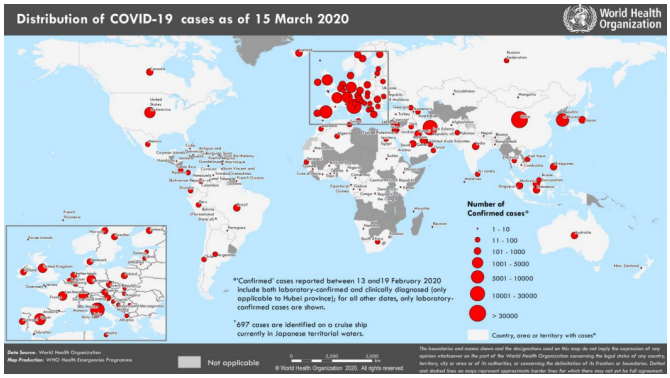

Figure.2 Distribution of COVID-19 cases as of 15 March 2020 [4]

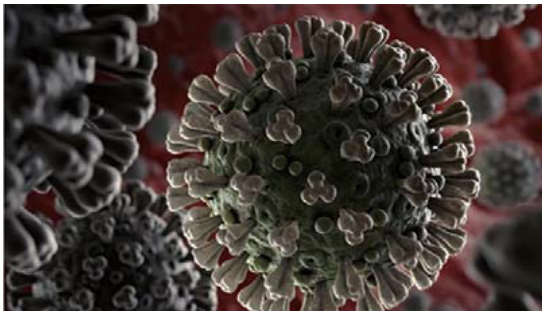

Figure.1 The Novel Coronavirus From World Health Organization Website

2019-nCoV (SARS-CoV-2) has infected more than 160,000 people in the world and has caused a serious global outbreak.The high affinity of 2019-nCoV S 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 (SARS-CoV-2) as a Public Health Emergency of International Concern and COVID-19 can be characterized as a pandemic [3]. With the increasing infected number of Novel Coronavirus, early diagnosis and early treatment to minimize the spreadof the coronavirus has become 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:

- "**Diagnosis and treatment program of novel coronavirus pneumonia** (Trial version 7)" issued by the National Health Commission of China has incorporated 2019-nCoV (SARS-CoV-2) IgG/IgM into the new criteria for **confirmed and ruled out COVID-19 suspicious cases** (not for general population):

  1) **Confirmed 2019-nCoV (SARS-CoV-2) infection:** when serology antibody tests show 2019-nCoV IgM and IgG are positive, or 2019-nCoV IgG change from negative to positive or was 4 times higher in the recovery period than in the acute phase.

  2) **Ruled out COVID-2019 suspicious cases:** test the suspected COVID-2019 case by using nucleic acid assays two times and both results are negative in a row (taken at least 24-hour apart), and the 2019-nCoV IgM and IgG were negative after 7 days of onset.
- MAGLUMI 2019-nCoV IgG/IgM kits 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.
- For samples with concentration near the cut-off 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 (Interleukin 6), *SAA (Serum Amyloid A)
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

The clinical sensitivity was determined in China by testing confirmed novel coronavirus infected specimens and the clinical specificity was determined in China by testing non-novel coronavirus infected specimens (including normal samples and interference samples).

Study 1	Specimen Category	2019-nCoV IgM (CLIA)			2019-nCoV IgM (CLIA)+2019-nCoV IgG (CLIA)		
Clinical Sensitivity	Clinically Confirmed Positive Samples	No.	Positive	%Sensitivity	No.	Positive	%Sensitivity
		89	70	78.65%	89	80	**89.89%**
Clinical Specificity	Negative Specimens	No.	Negative	%Specificity	No.	Negative	%Specificity
		200	195	97.50%	200	193	**96.5%**

Study 2	Specimen Category	2019-nCoV IgG (CLIA)			2019-nCoV IgM (CLIA)+2019-nCoV IgG (CLIA)		
Clinical Sensitivity	Clinically Confirmed Positive Samples	No.	Positive	%Sensitivity	No.	Positive	%Sensitivity
		91	83	91.21%	91	87	**95.6%**
Clinical Specificity	Negative Specimens	No.	Negative	%Specificity	No.	Negative	%Specificity
		750	730	97.33%	750	720	**96.0%**

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.

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 of 2019-nCoV IgM	2.06%-4.26%
Repeatability of 2019-nCoV IgG	1.62%-6.08%

Ordering Information

Reagent pack:

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

Calibrators & internal quality controls (FOC) included

References:
[1] Roujian Lu, Xiang Zhao, Juan Li, 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/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020
[4] https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200315-sitrep-55-covid-19.pdf?sfvrsn=33daa5cb_6
[5] Chaolin Huang, Yeming Wang. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Vol 395 February 15, 2020