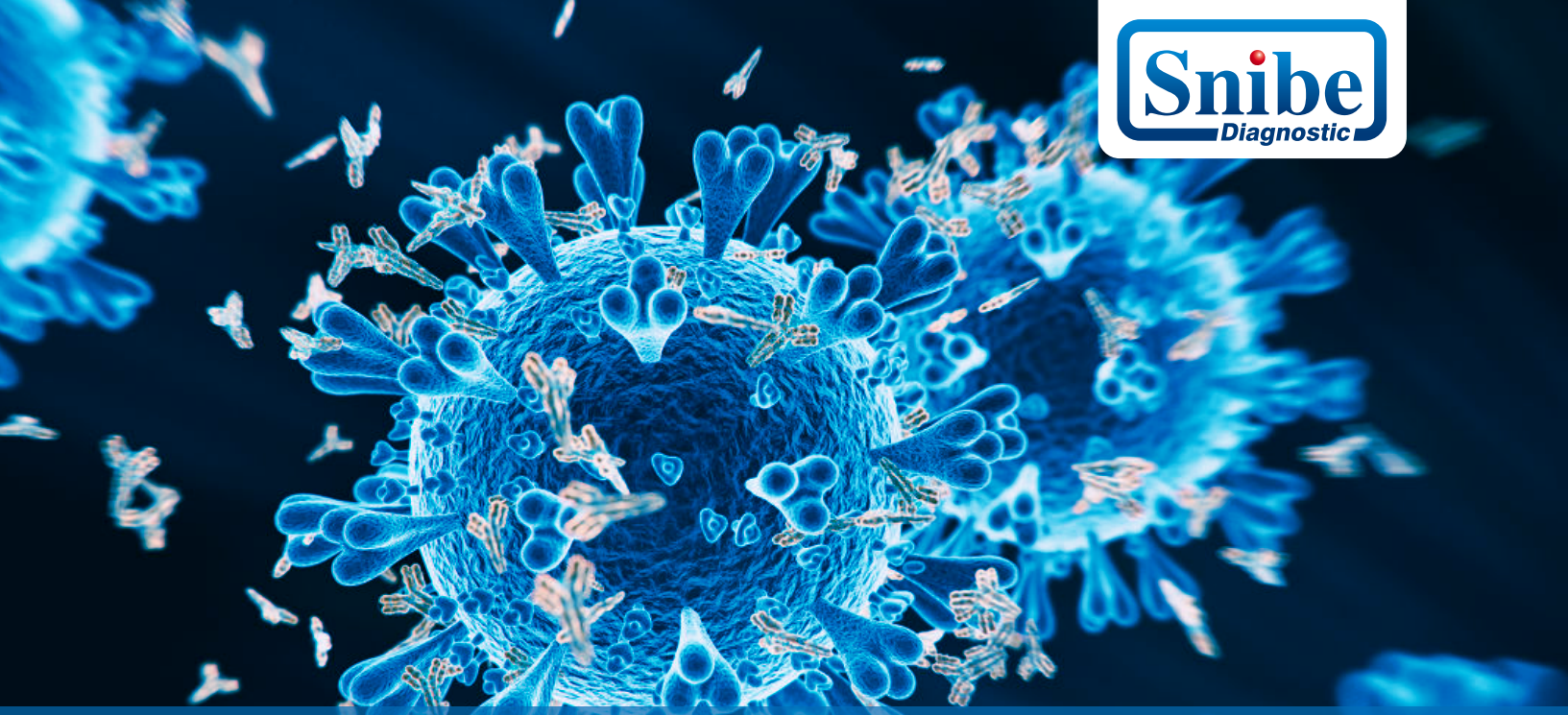


MAGLUMI® SARS-CoV-2 Neutralizing Antibody (CLIA)

Addressing the urgent need of assessing immunity during the COVID-19 pandemic

The fully automatic quantitative determination of MAGLUMI® SARS-CoV-2 Neutralizing Antibody Assay specializes in:

- Highly sensitive and specific detection of neutralizing antibodies-an important link to vaccine development and convalescent plasma screening in the COVID-19.
- 100% positive agreement to gold standard Virus Neutralization Test (VNT) ensures accurate results.☆

Clinical platform base with **15000** analyzers worldwide

First result available within **20 mins**▲

High throughput of **14400 tests/day**▲

Clinical value of neutralizing antibodies against SARS-CoV-2

- Assessing immunity in individuals and community.
- Evaluating the immunity response of receiver when the vaccines are available.
- Screening convalescent plasma for immunotherapy.
- Providing immunity 'certification' of individuals for returning to society.
- Offering seroepidemiological evidence for the policymakers.

▲ Depending on samples and assays configuration on MAGLUMI® X8 analyzer.
☆ Quoted from the clinical sensitivity study in MAGLUMI® SARS-CoV-2 Neutralizing Antibody IFU.

MAGLUMI® SARS-CoV-2 Neutralizing Antibody Assay is coated with ACE2 antigen and labeled with S-RBD antigen, which is designed to mimic the virus-host interaction to detect neutralizing antibodies. This RBD-ACE2 interaction can be neutralized (that is, blocked) by specific neutralizing antibodies in the patient, in the same manner as in cVNT or pVNT.

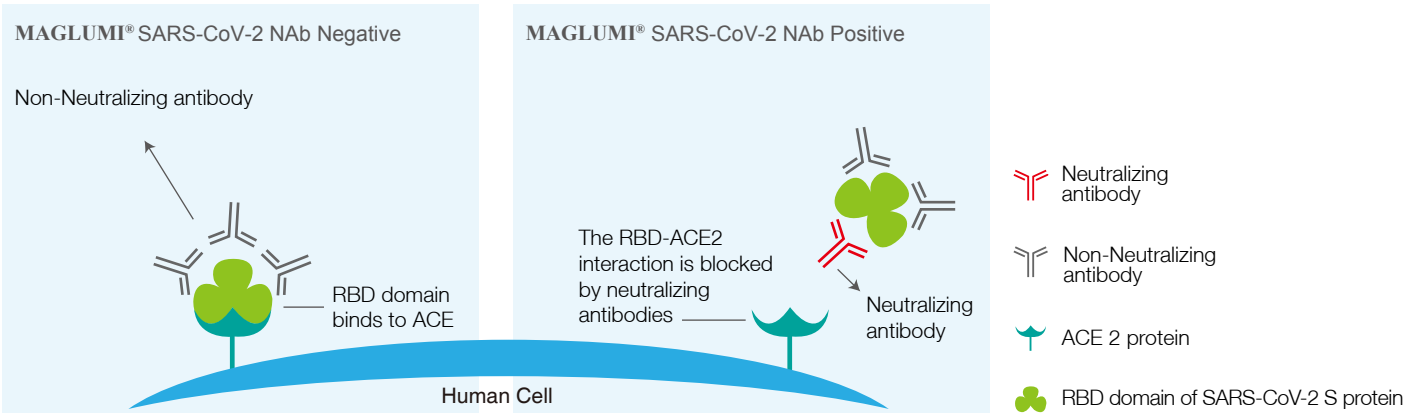


Figure 1. **MAGLUMI®** SARS-CoV-2 Neutralizing Antibody Detection

SARS-CoV-2 and the COVID-19 Pandemic

SARS-CoV-2 belongs to the genus Beta-coronavirus, which causes an epidemic of acute respiratory syndrome in the human population globally since December 2019. In February 2020, the World Health Organization (WHO) announced the official name of pneumonia caused by SARS-CoV-2 as "COVID-19", and acknowledged that COVID-19 had become a pandemic . [1]

Neutralizing antibodies against SARS-CoV-2

The antibody-mediated humoral response is crucial for preventing viral infections. Neutralizing antibodies are a subset of these antibodies, which reduce viral infectivity by binding to the surface epitopes of viral particles and blocking the entry of the virus to an infected cell. [2]

SARS-CoV-2 recognizes ACE2 as its host receptor binding to viral S protein. In antibody-mediated viral neutralization, neutralizing antibodies binding to the receptor-binding domain (RBD) of the viral spike protein, as well as other domains, prevent the virus from docking onto its entry receptor, ACE2. [3]

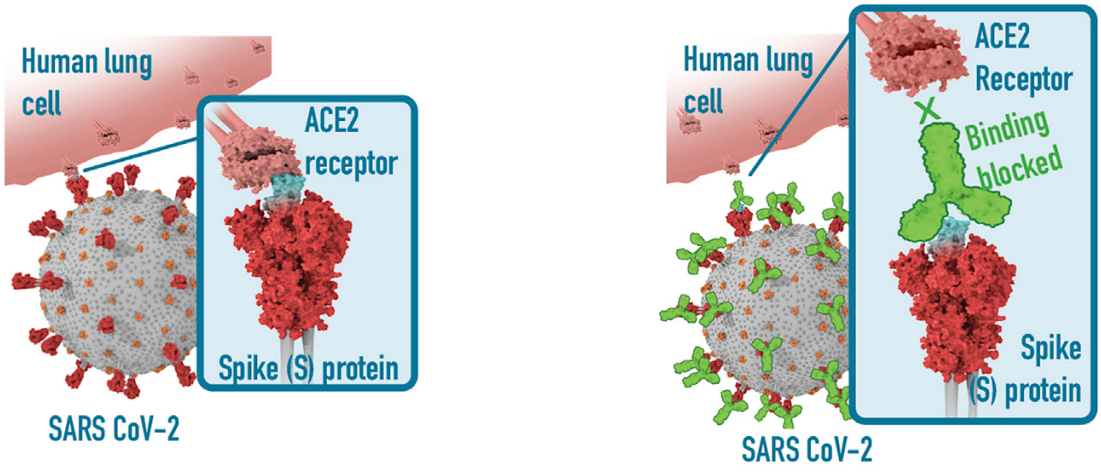


Figure 2. The model of antibody-mediated viral neutralization [4]

Neutralizing antibodies are critical in the fight against COVID-19 because they provide important specific immune defense against viral infections in patients. Neutralizing antibodies elicit their protective activities in three main steps:

- Preventing the attachment of the virion to its receptors on targeted cells.
- Causing aggregation of virus particles.
- Inducing viruses lysis through the constant (C) region of the antibody-mediated opsonization or complement activation. [2]

Clinical Verification

Comparison between the gold standard Virus Neutralization Test (VNT) and **MAGLUMI®** SARS-CoV-2 neutralizing antibody assay.

Clinical Sensitivity

The clinical sensitivity of the SARS-CoV-2 Neutralizing Antibody assay was determined by testing 57 samples confirmed SARS-CoV-2 VNT50 ≥ 20.

N of samples	Reactive	Sensitivity	95%CI
57	57	100%	93.69%-100.00%

Clinical Specificity

The clinical specificity of the SARS-CoV-2 Neutralizing Antibody assay was determined by testing 120 samples from subjects neither SARS-CoV-2 infection nor vaccination.

N of samples	Non-reactive	Specificity	95%CI
120	120	100%	96.90%-100.00%

Virus neutralization tests (VNT), such as the plaque-reduction neutralization test (PRNT) and microneutralization, use a SARS-CoV-2 virus from a clinical isolate or recombinant SARS-CoV-2 expressing reporter proteins. This testing requires BSL-3 laboratories and may take up to 5 days to complete.

Assay specification

	MAGLUMI® SARS-CoV-2 Neutralizing Antibody
Test Principle	Chemiluminescence Immunoassay (CLIA)
Sample Type	Human Serum, Plasma
First Result Time	20 mins* (**MAGLUMI®** X8)
Sample Volume	40 µL
Repeatability	2.02%-2.53 % (0.079µg/mL-21.192 µg/mL)
Reproducibility	4.71%-6.74 % (0.079µg/mL-21.192 µg/mL)
Limit of Blank (LoB)	0.030 µg/mL
Limit of Detection (LoD)	0.045 µg/mL
Linear Range	0.050-30 µg/mL
Cross-Reactivity	High Specificity: No cross-reaction to Human Coronavirus (HKU1, OC43, NL63, 229E), Influenza A virus, Influenza B virus, Respiratory syncytial virus, Adenovirus, EB virus, CMV, Human immunodeficiency virus, Hepatitis C virus , Hepatitis B virus , M.Pneumonia, ANA

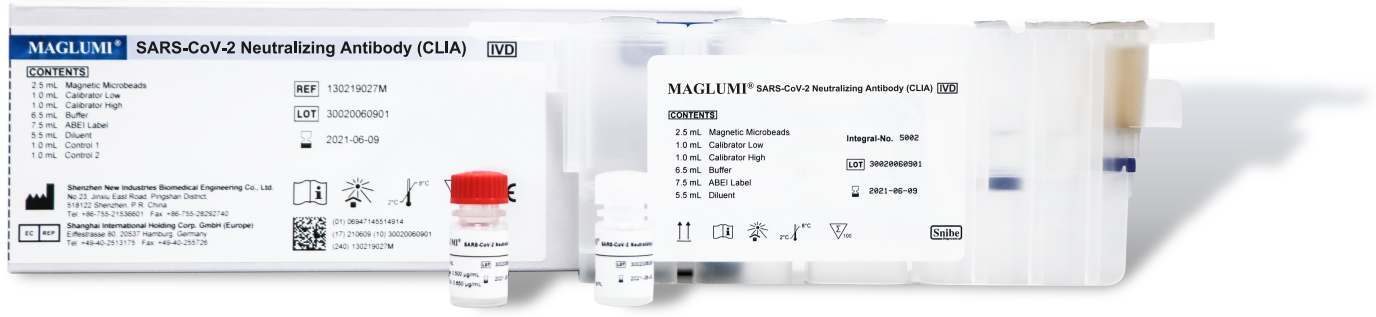
*Analyzer and Configuration dependent

Ordering information

Snibe Diagnostics Portfolio for SARS-CoV-2

Related Products	Number of tests	Catalog No
MAGLUMI® SARS-CoV-2 Neutralizing Antibody (CLIA)	100T	130219027M
	50T	130619027M
MAGLUMI® SARS-CoV-2 S-RBD IgG (CLIA)	100T	130219017M
	50T	130619017M
MAGLUMI® 2019-nCoV IgM (CLIA)	100T	130219016M
MAGLUMI® 2019-nCoV IgG (CLIA)	100T	130219015M
MAGLUMI® SARS-CoV-2 Ag (CLIA)★	50T	130619026M
	100T	130219026M
Molecision™ Nucleic Acid Extraction Kit★	32T	132131001HC
Molecision™ SARS-CoV-2 RT-PCR Assay	50T	132101002HB
Molecision™ SARS-CoV-2 & Flu A/B Assay	50T	132101003HB
Molecision™ SARS-CoV-2, Flu & RSV RT-PCR Assay★	50T	132101004HB

★Available soon



MAGLUMI® SARS-CoV-2 Neutralizing Antibody (CLIA)

References:

[1] https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[2] Guangyu Zhou, Qi Zhao. Perspectives on therapeutic neutralizing antibodies against the Novel Coronavirus SARS-CoV-2. Int. J. Biol. Sci. 2020, Vol. 16.

[3] Akiko Iwasaki, Yexin Yang. The potential danger of suboptimal antibody responses in COVID-19 nature Reviews Immunology. Volume 20 June 2020 339-341.

[4] Mehul S. Suthar, Matthew G. Zimmerman. Rapid Generation of Neutralizing Antibody Responses in COVID-19 Patients. Cell Reports Medicine 1, 100040, June 23, 2020.

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China

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