MAGLUMI®
SARS-CoV-2 S-RBD IgG (CLIA)

A Better Choice in Post-pandemic Era

- The fully automated **quantitative** serology test to detect IgG antibodies against **S-RBD** (the receptor-binding domain of S protein)
- Strong correlation to neutralizing antibodies level, which reflects the COVID-19 patients' immunity, indicating its medical value of **assessing immunity** in individuals and community
- More than **13000** MAGLUMI® CLIA analyzer installations worldwide provide platform foundation for wide availability of MAGLUMI® SARS-CoV-2 S-RBD IgG
- Additional MAGLUMI® COVID-19 Antibody Assays offer **total solution**☆ for the COVID-19

14400 Tests/Day

- Run up to 600 Test/Hour▲ on the **MAGLUMI® X8** analyzer
- Multi **MAGLUMI® X8** can be connected to form modular system

100% Sensitivity*
99.6% Specificity

A total of 351 samples collected for sensitivity analysis according to study in **MAGLUMI®** SARS-CoV-2 S-RBD IgG IFU.

* ≥15 days post onset of symptom.

100% NPV▼
99.51% PPV▼

▼ Quoted from internal evaluation study collecting 431 samples, positive subjects are 15 days post of symptom onset.

The COVID-19 Pandemic and SARS-CoV-2

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].

A coronavirus contains four structural proteins, including spike (S), envelope (E), membrane (M), and nucleocapsid (N) proteins. The S protein mediates viral entry into host cells by first binding to a host receptor through the receptor-binding domain (RBD) in the S1 subunit and then fusing the viral and host membranes through the S2 subunit. SARS-CoV-2 recognizes ACE2 as its host receptor binding to viral S protein. Therefore, it is critical to define the RBD in SARS-CoV-2 S protein as the most likely target for the development of virus attachment inhibitors, neutralizing antibodies, and vaccines [2].

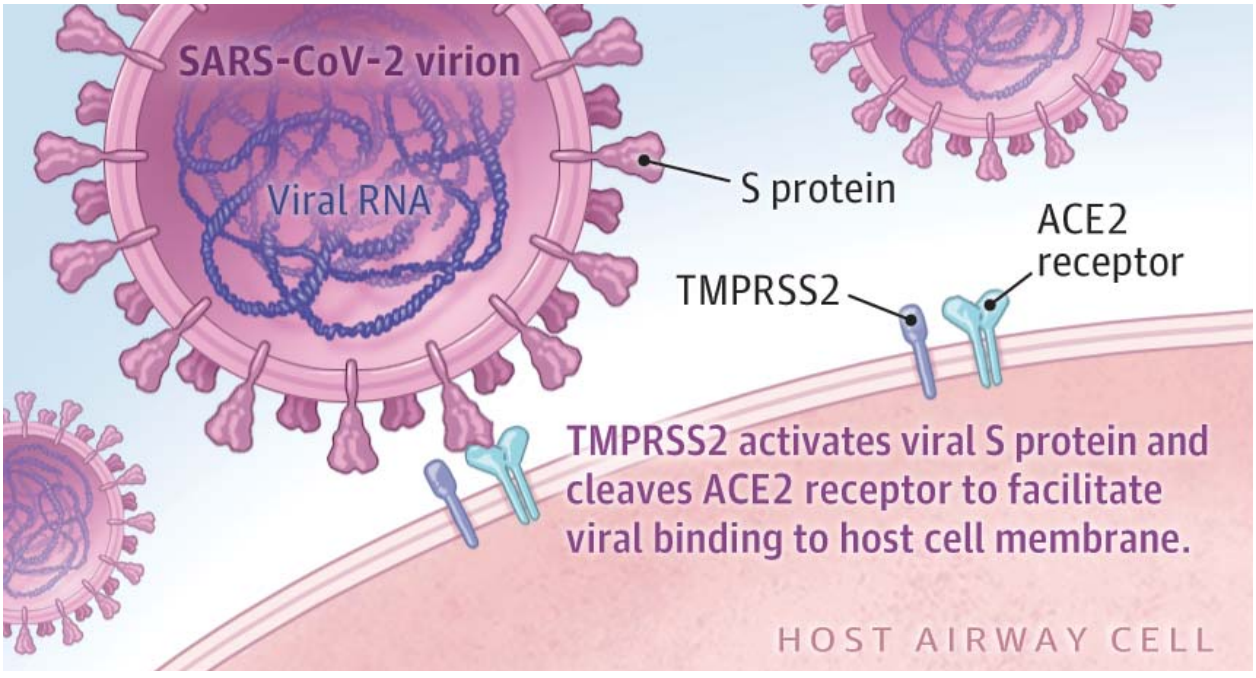

Fig. 1. SARS-CoV-2 viral infection of host airway cells [3]

Clinical value of targeting SARS-CoV-2 S-RBD protein

The level and duration of protective immunity in the population at large and in specific groups matters and help with the decision of patients' treatment [4]. MAGLUMI® SARS-CoV-2 S-RBD IgG coated with S-RBD recombinant antigen to detect RBD binding antibodies may be important in measuring immunity based on the current laboratory studies.

◆ Virus neutralizing antibodies induced by vaccines or infected viruses play crucial roles in controlling viral infection. The binding of RBDs to their respective receptors and interfering with S2-mediated membrane fusion or entry into the host cell, thus inhibiting viral infections. [5]

◆ Studies showed that antibodies directed against the S1 subunit of the SARS-CoV-2 spike protein and specifically to the receptor binding domain (RBD) within the S1 subunit strongly correlate with virus neutralization. [4]

◆ RBD-specific antibodies have greater potency to neutralize infection with divergent virus strains, suggesting that the RBD of SARS-CoV-2 can also serve as an important target for the development of potent and specific neutralizing antibodies [5].

◆ There is a strong correlation between levels of RBD-binding antibodies and SARS-CoV-2 neutralizing antibodies in patients, support using the RBD antigen in serological diagnostic assays, and RBD-specific antibody levels as a correlate of SARS-CoV-2 neutralizing antibodies in people [6].

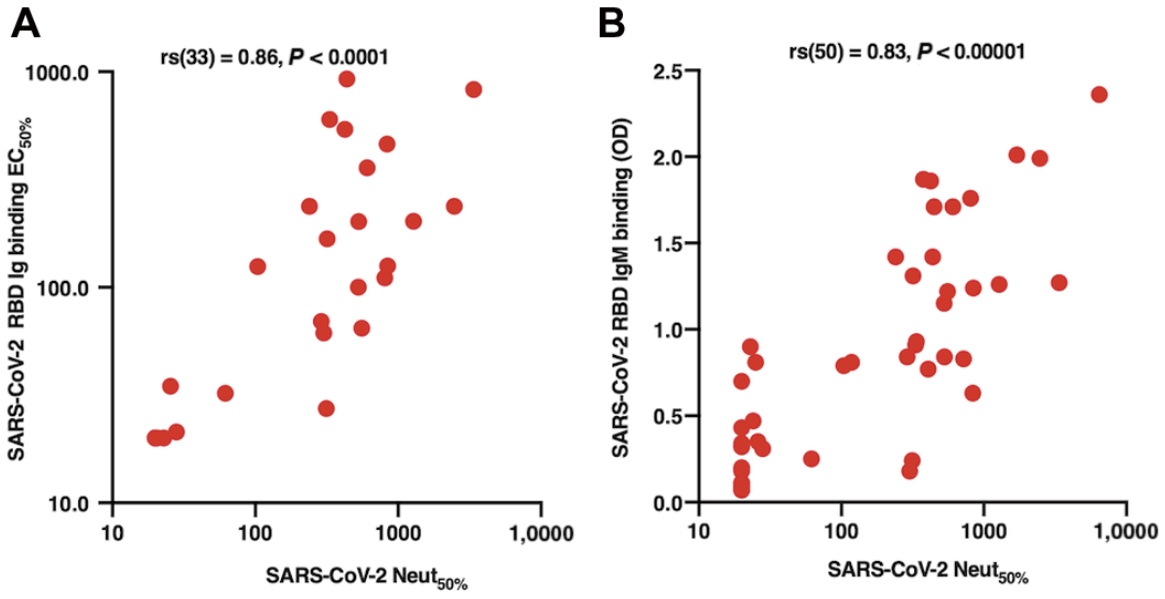

Fig. 2. Correlation between spike RBD antigen binding and SARS-CoV-2 neutralizing antibody titers [6].

Clinical Verification

Sensitivity

The clinical sensitivity of the SARS-CoV-2 S-RBD IgG assay was determined by testing 351 samples confirmed COVID-19 infected specimens.

Days Post Onset of Symptoms	N of samples	Reactive	Sensitivity	95% CI
0-7	55	41	74.5%	63.0%-86.1%
8-14	94	92	97.9%	95.0%-100.0%
≥ 15	202	202	100.0%	99.9%-100.0%

Specificity

The clinical specificity of the SARS-CoV-2 S-RBD IgG assay was determined by testing 229 samples from subjects assumed to be negative for SARS-CoV-2.

N of samples	Non-reactive	Specificity	95% CI
229	228	99.6%	98.7%-100.0%

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

	MAGLUMI® SARS-CoV-2 S-RBD IgG
Test Principle	Quantitative chemiluminescence immunoassay (CLIA)
Sample Type	Human serum or plasma
First Result Time	**29mins▲** (MAGLUMI® X8)
Sample Volume	10 μL
Repeatability	1.77%-7.64 % (0.396 AU/mL-5.109 AU/mL)
Reproducibility	4.89 %-12.37 % (0.396 AU/mL-5.109 AU/mL)
Limit of Blank (LoB)	0.100 AU/mL
Limit of Detection (LoD)	0.180 AU/mL
Linear Range	0.180-100 AU/mL
Cross-Reactivity	**High Specificity:** No cross-reaction to Human Coronavirus (HKU1, OC43, NL63, 229E), Measles virus, Influenza A virus, Influenza B virus, Respiratory syncytial virus antibodies, Rhinovirus, Adenovirus, Enterovirus,EB virus, CMV, Rotavirus, Norovirus, Mumps virus,Varicella zoster virus, M.Pneumoniae, Human immunodeficiency virus

Ordering information

MAGLUMI® Total Solution☆ for SARS-CoV-2 Antiboy Test	Test capacity	Catalog No
MAGLUMI® SARS-CoV-2 S-RBD IgG(CLIA)	100T	130219017M
MAGLUMI® SARS-CoV-2 S-RBD IgG(CLIA)	50T	130619017M
MAGLUMI® 2019-nCoV IgM (CLIA)	100T	130219016M
MAGLUMI® 2019-nCoV IgG (CLIA)	100T	130219015M

Calibrators & internal quality controls (FOC) included

References:

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

[2] Wanbo Tai1, Lei He2, Characterization of the receptor-binding domain (RBD) of 2019 novel coronavirus: implication for development of RBD protein as a viral attachment inhibitor and vaccine.Cellular & Molecular Immunology (2020) 17:613 – 620.

[3] W. Joost Wiersinga, Andrew Rhodes, Pathophysiology, Transmission, Diagnosis, and Treatment of Coronavirus Disease 2019 (COVID-19), JAMA published online July 10, 2020.

[4] Corine H. GeurtsvanKessel , Nisreen M. A. Okba, An evaluation of COVID-19 serological assays informs future diagnostics and exposure assessment, NATURE COMMUNICTIONS | (2020) 11:3436.

[5] Shibo Jiang,Christopher Hillyer, Neutralizing Antibodies against SARS-CoV-2 and Other Human Coronaviruses, Trends in Immunology, May 2020, Vol. 41, No. 5.

[6] Premkumar et al., Sci. Immunol. 5, eabc8413 (2020).

▲The first result time depends on samples and assays configuration on MAGLUMI X8 analyzer.

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