Correlation to Virus Neutralization Test

Mindray SARS-CoV-2 S-RBD IgG assay was compared to plaque reduction neutralization tests (PRNT). The PRNT titer was calculated based on a 50% reduction in plaque counts ($PRNT_{50}$). The results for 40 clinical samples from individual patients are summarized in the following table

Mindray SARS-CoV-2 Neutralizing Antibody assay	$PRNT_{50}$	
	Positive (≥1:20)	**Negative** (<1:20)
Positive	40	0
Positive Percent Agreement (95% CI)	100% (91.24%-100%)	

Clinical specificity

A total of 3113 specimens were tested with Mindray SARS-CoV-2 S-RBD IgG assay and 3102 were detected as negative. All specimens were collected before October 2019 and were assumed to be negative. The clinical specificity is 99.65% (95% CI: 99.37%-99.80%).

N	Negative	Specificity (95% CI)
3113	3102	99.65% (99.37%-99.80%)

*Please note that these are representative data. Sensitivity, specificity, and correlation to virus neutralization test may vary due to differences in demography, individual response to the pathogen, subject's infection phase of sample collection, and other conditions.

**CI: confidence interval

Order information

Name	P/N	Package
Severe Acute Respiratory Syndrome Coronavirus 2 S-RBD IgG (CLIA)	105-020773-00	2×50 tests (calibrators included)
	105-020774-00	2×100 tests (calibrators included)
SARS-CoV-2 S-RBD IgG Antibody Control（L）	105-020848-00	3×0.5 mL
	105-020849-00	6×0.5 mL
SARS-CoV-2 S-RBD IgG Antibody Control（H）	105-020850-00	3×0.5 mL
	105-020851-00	6×0.5 mL

References:

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3. Coronavirus Disease 2019 (COVID-19) – Symptoms. Centers for Disease Control and Prevention. (2021). Retrieved 23 February 2021, from https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
4. Wang, M. Y., Zhao, R., Gao, L. J., Gao, X. F., Wang, D. P., & Cao, J. M. (2020). SARS-CoV-2: structure, biology, and structure-based therapeutics development. Frontiers in cellular and infection microbiology, 10.
5. Banu, N., Panikar, S. S., Leal, L. R., & Leal, A. R. (2020). Protective role of ACE2 and its downregulation in SARS-CoV-2 infection leading to Macrophage Activation Syndrome: Therapeutic implications. Life sciences, 117905.
6. Huang, Y., Yang, C., Xu, X. F., Xu, W., & Liu, S. W. (2020). Structural and functional properties of SARS-CoV-2 spike protein: potential antivirus drug development for COVID-19. Acta Pharmacologica Sinica, 41(9), 1141-1149.
7. Wu, F., Wang, A., Liu, M., Wang, Q., Chen, J., Xia, S., ... & Huang, J. (2020). Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications.

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P/N:EN-SARS-CoV-2 S-RBD IgG-210285X6P-20210306

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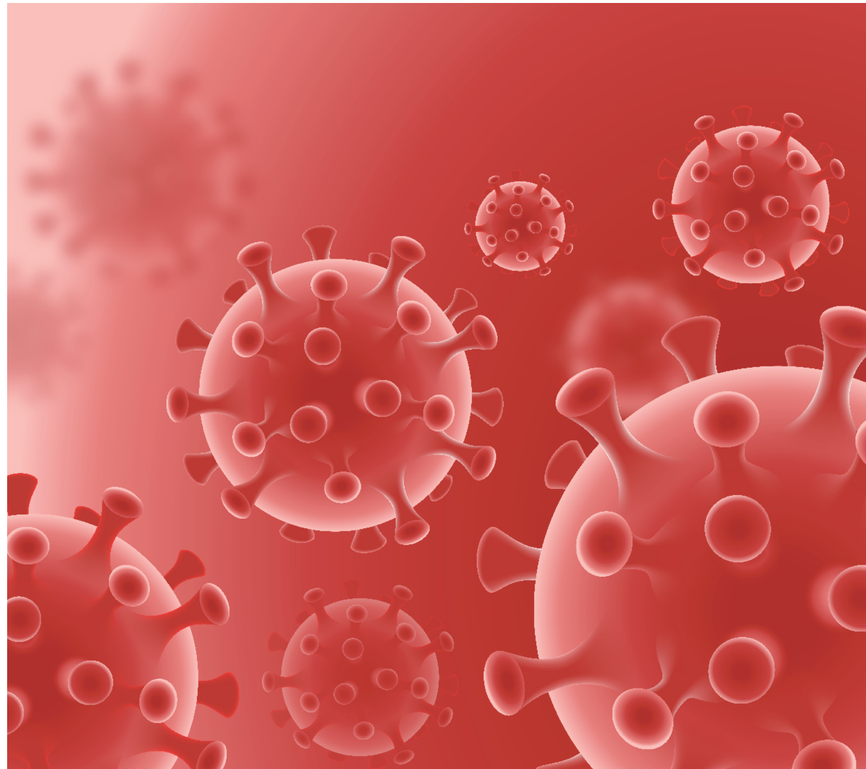
SARS-CoV-2 S-RBD IgG

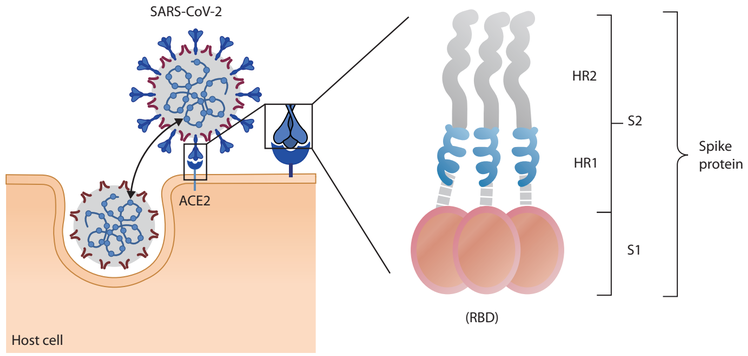


Severe acute respiratory syndrome coronavirus (SARS-COV-2), which causes COVID-19, belongs to β-coronaviruses and is a spherical positive single-stranded RNA virus [1]. It spreads mainly through direct, indirect, or close contact with infected people via secretions such as saliva and respiratory secretions, or through respiratory droplets expelled during coughs, sneezes, talks or sings [2]. People with COVID-19 manifest symptoms such as fever and/or acute respiratory illness (such as cough, difficulty breathing, etc.), which may appear 2 to 14 days after viral exposure. [3]

SARS-CoV-2 virus

Similar to other coronaviruses, the structural proteins of SARS-CoV-2 include S (spike) glycoproteins, E (envelope) glycoproteins, M (membrane) glycoproteins, and N (nucleocapsid) glycoproteins. The S protein is formed by 2 main functional units, S1 and S2. The N-terminal of S1 is responsible for virus attachment and contains the receptor-binding domain (RBD), which interacts and directly binds to the angiotensin-converting enzyme 2 (ACE2) receptor on the host cell. The S2 subunit is involved in the fusion of viruses with the host-cell membrane. [4]

Structure of S protein and SARS-CoV-2 viral entry [5, 6]

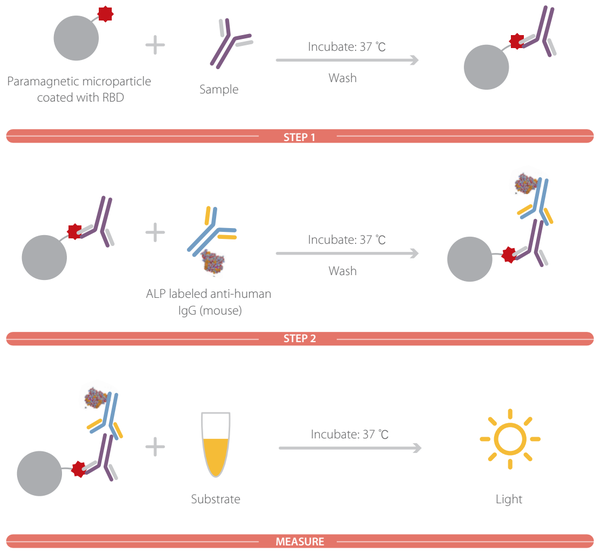


Multiple vaccines under development are designed to target or include the S1 RBD, as initial data indicated that antibodies to this region can be neutralizing [7]. The ability to identify specific antibodies associated with neutralization can provide valuable information to the immune response to the SARS CoV 2 virus.

SARS-CoV-2 S-RBD IgG assay

The Mindray SARS-CoV-2 S-RBD IgG assay is a chemiluminescence immunoassay for the quantitative determination of SARS-CoV-2RBD IgG in human serum or plasma.

Test principle



It is intended as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long that antibodies persist following infection and if the presence of antibodies confers protective immunity. Results from the test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

Features

Mindray provides SARS-CoV-2 S-RBD IgG assay that features:

Quantitative:
monitor the level of SARS-CoV-2 S-RBD IgG

Simple sampling:
intravenous serum or plasma (heparin), easy to operate

Small sample consumption:
10 μL

Flexible package choice:
2 x 50T and 2 x 100T

High throughput:
fully automatic, up to 480 tests/hour depending on analyzer models used

Performance

To assess the performance, clinical sensitivity, clinical specificity and correlation to virus neutralization test are evaluated*.

Clinical sensitivity

A total of 1093 specimens from confirmed COVID-19 cases (RT-PCR positive) were tested with Mindray SARS-CoV-2 S-RBD IgG assay. Results were classified by the time from symptom onset to sample collection. Data from this study are summarized in the table below. The sensitivity can reach up to 99.64% (95% CI**: 98.94%-99.88%) for samples collected > 14 days post-symptom onset.

Days post-symptom onset	N	Positive	Sensitivity (95% CI)
≤7	59	22	37.29% (26.08%~50.05%)
8~14	208	178	85.58% (80.16%~89.71%)
>14	826	823	99.64% (98.94%~99.88%)