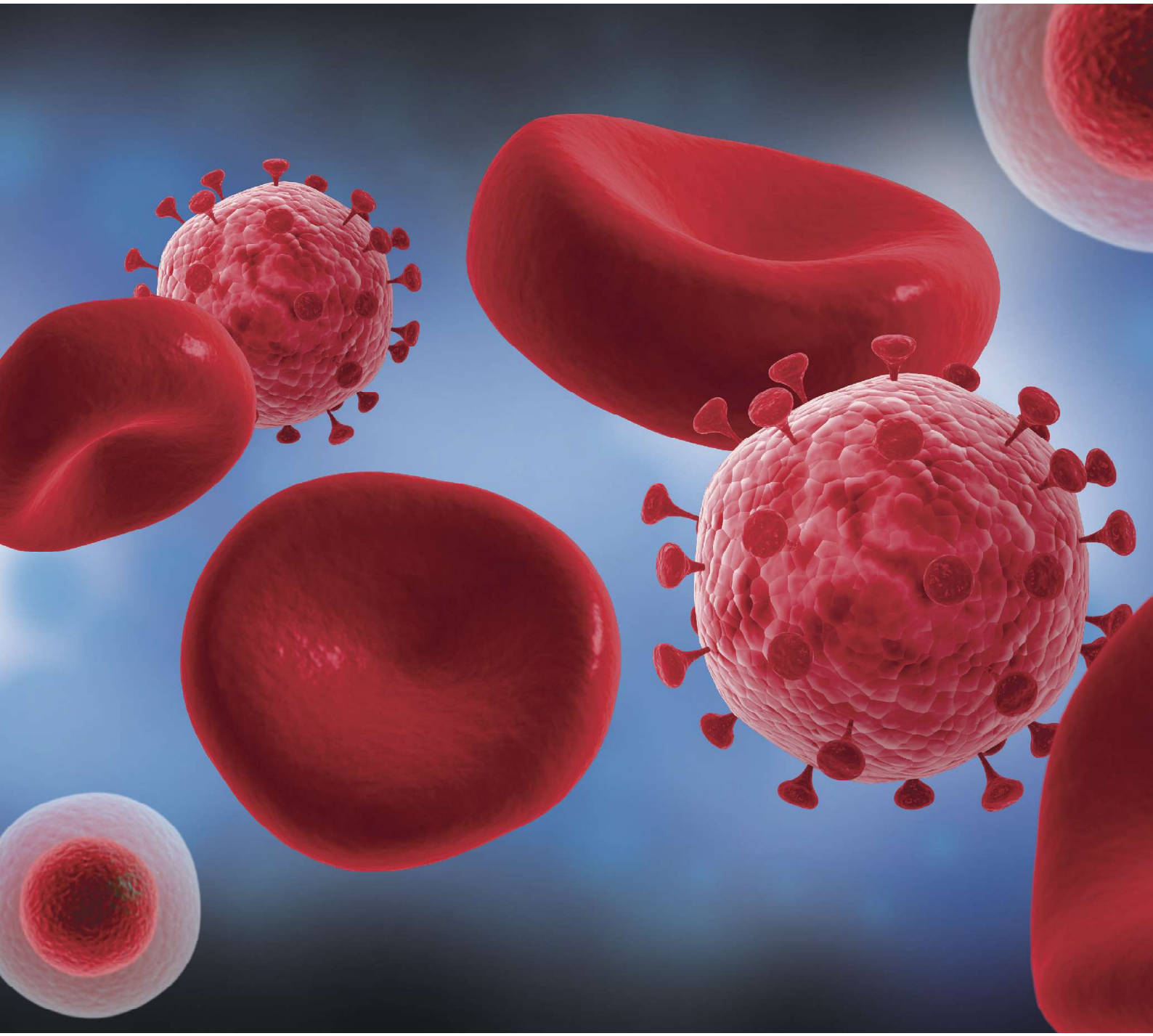
mindray

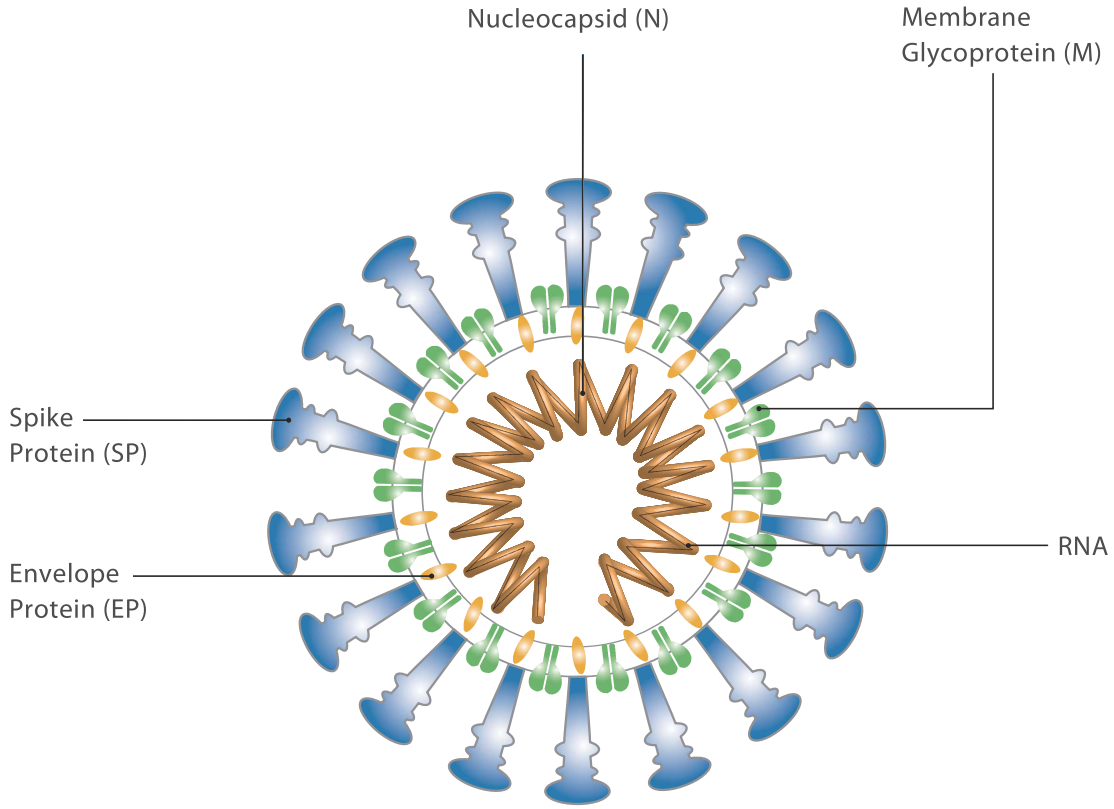
SARS-CoV-2 IgG
SARS-CoV-2 IgM

Useful diagnostic tools of COVID-19 disease



In December 2019, an acute respiratory disease caused by a novel coronavirus was first reported in China and has been detected in more than 140 countries and regions globally. The virus has been named SARS-CoV-2 by the International Committee of Taxonomy of Viruses and the disease it causes has been named coronavirus disease 2019 (abbreviated as COVID-19).

SARS-CoV-2 virus



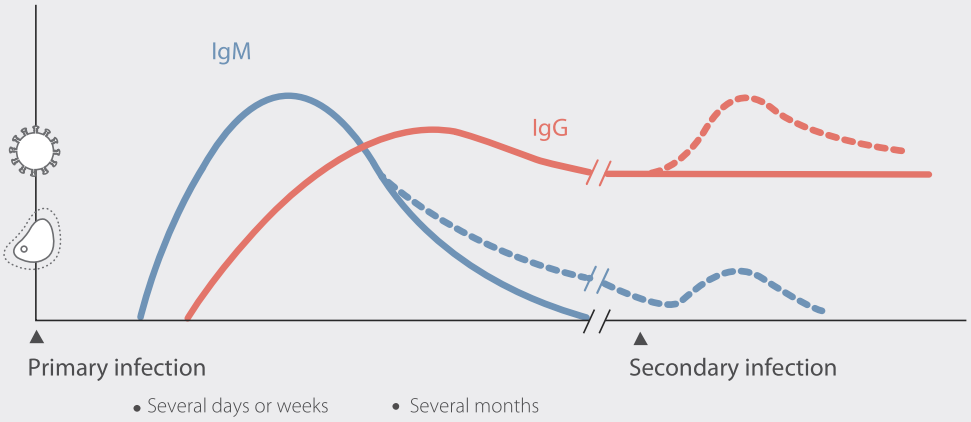
SARS-CoV-2 has a positive-sense single-stranded RNA (+ssRNA) genome. The virion is approximately 40-160 nanometers in diameter. Similar to other coronaviruses, SARS-CoV-2 has 4 structural proteins, i.e. the S (spike), E (envelope), M (membrane), and N (nucleocapsid).

SARS-CoV-2 IgG/IgM test

Currently, World Health Organization (WHO) recommends the detection of unique sequences of virus RNA by nucleic acid amplification tests (NAAT) for confirmation of COVID-19 disease. However, NAAT has several limitations: 1) It has longer turnaround time and is more demanding in terms of environment and operation. 2) Only certified laboratories are capable of performing these tests. 3) A number of cases of false negatives were also reported from NAAT in real practice. Therefore, serological tests, detecting the antigens or antibodies of a particular pathogen, can be provided as useful diagnostic tools.

3 to 5 days after infected with SARS-CoV-2 virus, specific IgM becomes reactive, indicating an acute or recent infection. Specific IgG is a marker indicating an individual's immune status to the virus. Its titer is usually 4 or more times higher in the convalescence phase than that in the acute phase.

In cases where NAAT assays are negative and a strong epidemiological link to COVID-19 is indicated, SARS-CoV-2 serological tests with paired samples (in the acute and convalescent phase) could support diagnosis. Besides, serological surveys can also be used to detect cases with few or no symptoms and to aid investigation of an ongoing outbreak and retrospective assessment of an outbreak.



Features

Mindray provides SARS-CoV-2 IgG assay and SARS-CoV-2 IgM assay that feature:

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

Less turnaround time:
time to first result is less than 30 minutes

High throughput:
up to 480 tests/hour depending on different analyzer models used

Small sample consumption:
10 μL

Safe:
fully automatic testing, minimizing infection risk

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

Performance

Clinical sensitivity, clinical specificity and early detection capacity are determined by using samples collected in China*.

Clinical sensitivity

To study the clinical sensitivity, samples from three categories are collected and tested with Mindray SARS-CoV-2 IgG and SARS-CoV-2 IgM assays.

Sample category	SARS-CoV-2 IgM reactive (%)	SARS-CoV-2 IgG reactive (%)	SARS-CoV-2 IgM or IgG reactive (%)**
Patients clinically diagnosed with COVID-19	86.13%	95.38%	97.11%
Patients with positive NAAT results	85.05%	96.26%	97.20%
Patients clinically diagnosed with COVID-19 but with negative NAAT results	83.87%	87.10%	93.55%

Clinical specificity

To study the clinical specificity, samples of patients without COVID-19 are collected and tested with Mindray SARS-CoV-2 IgG and SARS-CoV-2 IgM assays.

Sample category	SARS-CoV-2 IgM non-reactive (%)	SARS-CoV-2 IgG non-reactive (%)
Outpatient and inpatient without COVID-19 (With diabetes, hypertension, tumor, fever, pregnancy, autoimmune diseases, and other conditions)	93.41%	93.09%

Early detection

To study the early detection capacity, samples of patients who have known onset date of COVID-19 symptoms (such as fever, cough, shortness of breath, etc.) and are later diagnosed with COVID-19 are collected and tested with Mindray SARS-CoV-2 IgG and SARS-CoV-2 IgM assays.

Days after onset	SARS-CoV-2 IgM reactive (%)	SARS-CoV-2 IgG reactive (%)	SARS-CoV-2 IgM or IgG reactive (%)**
1 to 5 days	71.43%	57.14%	71.43%
1 to 14 days	78.95%	84.21%	89.47%

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

** SARS-CoV-2 IgM or IgG reactive includes SARS-CoV-2 IgM solely reactive, SARS-CoV-2 IgG solely reactive, and SARS-CoV-2 IgM and IgG both reactive.

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