

iFlash-2019-nCoV NAb

potwierdzenie że test jest jakościowy

A Reliable Guardian for your health during COVID-19 pandemic



iFlash-2019-nCoV NAb (Neutralization Antibody) assay is a CLIA solution for the qualitative determination of 2019-nCoV Neutralization Antibodies in human serum or plasma. This assay, which simulates the in vivo binding of SARS-CoV-2 RBD to ACE2-receptor in human host cells, can detect all neutralization antibodies that can prevent the binding between virus RBD and ACE2 receptor after SARS-CoV-2 infection or vaccination.

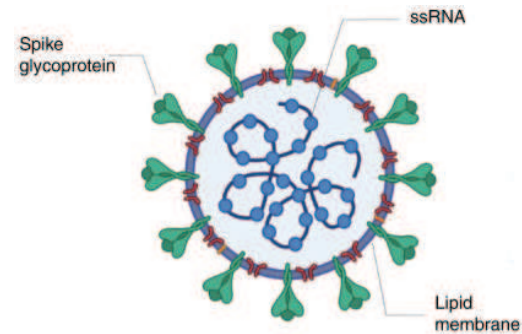
Features & Characteristics:

- **Automation:**
Less manual operation,
suitable for large population testing
- **Testing capacity:**
Flexible testing capacity, first result
within 30 minutes.
- **Special design:**
Mimic of in vivo SARS-CoV-2 (2019-nCoV)'s
RBD and ACE2 receptor binding



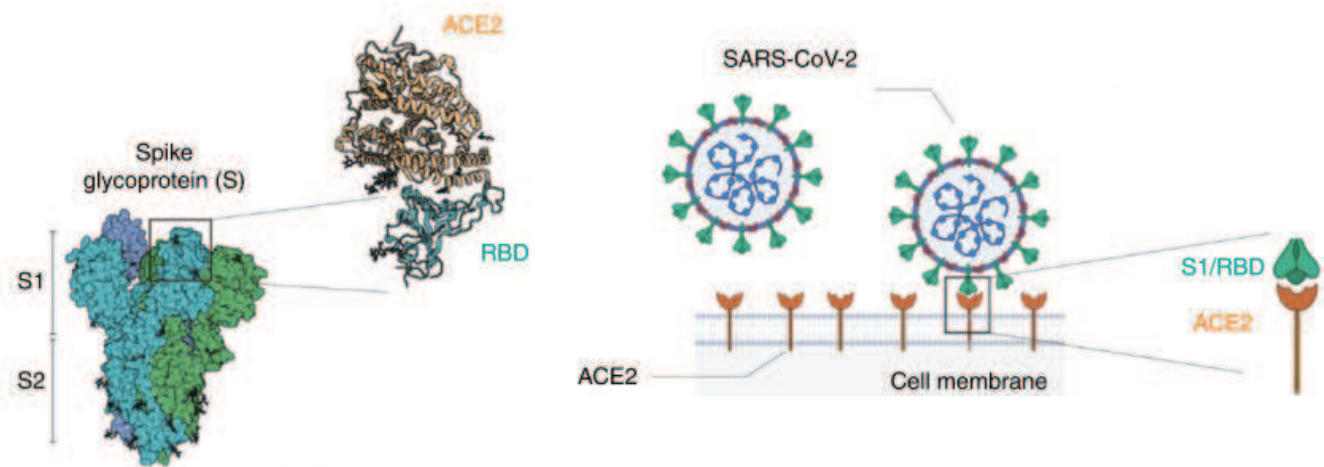
Summary:

SARS-CoV-2 is an enveloped and single-stranded RNA virus, belonging to the beta-CoV genera in the family Coronaviridae^[1]. Its genome RNA encodes a nonstructural replicase protein and several structural proteins, including spike (S), envelope (E), membrane (M) and nucleocapsid (N) proteins^[2,3].



Pathogenesis:

The S protein is responsible for virus binding and entry into host cells, which consists two functional subunits, S1 and S2, and the receptor binding domain (RBD) is located within the S1 subunit. The RBD of the SARS-CoV-2 S protein interacts with host angiotensin converting enzyme 2 (ACE2)^[1-7], triggering conformational changes in the S2 subunit that result in virus fusion and entry into the target cell. Human secretory proteases, such as TMPRSS2 and furin, localize to virally-target cells. These proteases enhance viral entry into host cells through the proteolysis of both the S1, S2, and ACE2 proteins^[8-10].



a) The complex between the RBD and the ACE2 receptor^[7].

b) Schematic of SARS-CoV-2 S1 sub-unit RBD binding to the ACE2 receptor^[7].

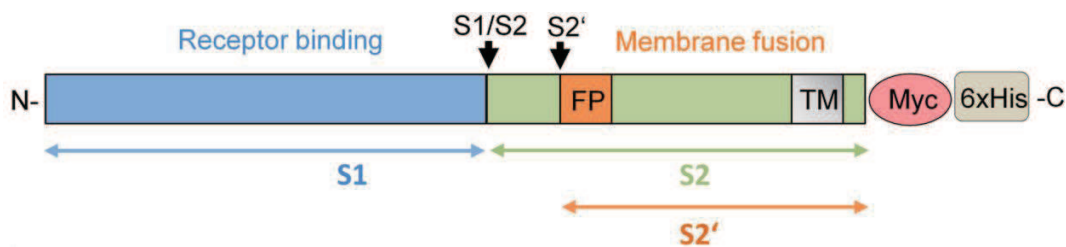


Figure 1. Schematic representation of the SARS-CoV-2 precursor and the S1 and S2 subunits^[11].

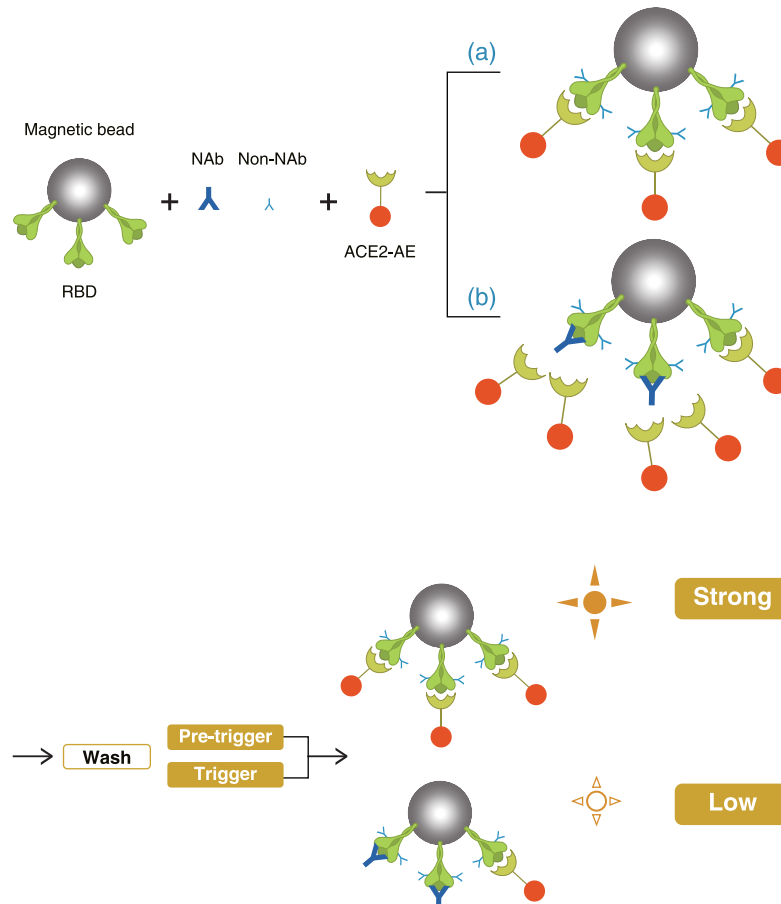
Neutralizing Antibodies:

During normal virus infection, a small percentage of antibodies, known as neutralizing antibodies (NAbs), can inhibit the entry of this virus into the host by disabling part of virus to interact with host cell receptor. Measurement of NAbs can identify antibodies that provide long term immunity against certain infections, especially after vaccination or recovery.

Traditional assays for NAbs measurement, for example, plaque reduction neutralization test (PRNT) is considered as the gold standard for determination of immunity^[12,13]. However, due to its low throughput, PRNT is not practical for large scale serodiagnosis and vaccine evaluation. This is a major gap for COVID-19 surveillance and vaccine development^[14].

iFlash-2019-nCoV NAb:

iFlash-2019-nCoV NAb assay is a one-step competitive immunoassay using direct chemiluminescence immunoassay.



(a) Negative Result:

If there is insufficient NAb in the blood sample, ACE2 protein labelled with AE will react with RBD on the magnetic beads, which create a strong signal with high relative light unit (RLU).

(b) Positive Result:

If there are NABs in the blood sample, these NABs will react with RBD on magnetic beads, ACE2 protein labelled with AE will compete with NABs to bind to RBD on magnetic beads, which will create a weaker signal with low RLU as compared with above situation.

Special Design:

iFlash-2019-nCoV NAb (Neutralization Antibody) assay, unlike ELISA or PRNT, adopts freely-moved magnetic beads and AE as a dynamic mimic of human body internal environment. NABs in the serum or plasma can react with RBD to block its binding to ACE2.

Clinical Benefits:

- Evaluate COVID-19 vaccines development and efficacy^[15].
- Monitor the NAb titers in COVID-19 patients and vaccinated individuals.
- Analyze herd immunity status to guide policymakers.
- Monitor during convalescent plasma therapy^[14].



Performance:

iFlash-2019-nCoV NAb assay was evaluated in some Chinese hospitals. More evaluation data will be available later.

- The positive rate is more than 95% for people who had SARS-CoV-2 vaccination (>2 weeks after vaccination).
- The sensitivity for people who had been confirmed as COVID-19 infection is more than 90%.
- The specificity is more than 98% for healthy people who had no COVID-19 infection.

Specification

Testing principle	one-step competitive immunoassay
Calibration	4-point
Sample type	serum and plasma (heparin and EDTA-2K anticoagulant plasma)
Sample volume	20 µL
Testing time	28 min
Cut-off value	10 AU/mL
Coefficient of variation	CV < 10%

iFlash COVID-19 Solutions

Product Code	Description	Spec.
C86109	iFlash-2019-nCoV NAb	2 x 50 T/kit
C86096	iFlash-2019-nCoV Antigen	
C86095M	iFlash-2019-nCoV IgM	
C86095G	iFlash-2019-nCoV IgG	
C86095A	iFlash 2019-nCoV IgA	

Reference:

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