Disclaimer

SARS-CoV-2 Surrogate Virus Neutralization Test (sVNT) Kit (RUO)

The limitations of the assay are:

- sVNT test is a serology test that checks the neutralizing antibody against SARS-Cov-2 in response to infection. It is for research use only (RUO) and not for diagnostic purpose. We recommend use the results in conjunction with other parameters for your research.
- Negative results do not rule out SARS-CoV-2 infection, especially in those who have been exposed to the virus because:
    - Neutralizing antibodies are only detectable in blood 1-2 weeks after the initial infection.
    - Not all individuals develop the level of neutralizing antibodies after virus exposure that pass the detection threshold of this test.
    - Neutralizing antibodies might decline over time if the past infection occurred a long time ago.
    - Immunocompromised individual may have a delayed or no immune response to produce adequate neutralizing antibodies.
- If acute infection is suspected, we recommend re-test in a few days and combine nucleic acid test result when evaluating the results
- False-positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Non-SARS-CoV-2 strains, such as coronavirus NL63 and HKU1, have not been evaluated with this assay. Although no cross-reactivity has been observed from 60 patient samples with infection of Influenza A, Influenza B, HCV, RSV, ANA, HIV, OC43, 229E, and MERS-CoV, whereas some cross-reactivity has been observed in SARS-CoV, further clinical validation data may be required to confirm cross-reactivity and clinical specificity of sVNT test.
- Positive test results do not guarantee the protective immunity or preventing re-infection, or durability of the neutralizing antibody titer levels. Persons with a positive sVNT test result must continue to protect themselves and others from COVID-19, following CDC and government guidelines.
- It is recommended to perform sVNT test in a Biosafety level 2 or higher lab for human samples.
- The magnitude of the measured result is not indicative of the total amount of neutralizing antibodies due to the different isotypes and their binding affinities to sVNT test reagents of various neutralizing antibodies from different patients.

GenScript USA, Inc.
860 Centennial Ave. Piscataway, NJ 08854
Tel: 1-877-436-7274; 1-732-885-9188