

## Disclaimer

### cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit

#### The limitations of the assay are

- cPass™ test is a serology test that checks the neutralizing antibody against SARS-CoV-2 in response to infection. It should be used in conjunction with other clinical parameters, medical history, and other factors.
- cPass™ test cannot be used solely to diagnose acute SARS-CoV-2 infection, as the antibodies are not generated in a short period of time after showing symptoms.
- 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 patients may have a delayed or no immune response to produce adequate neutralizing antibodies.
- If acute infection is suspected, direct testing for SARS-CoV-2, such as a nucleic acid test, would be necessary. If symptoms persist and the cPass™ test is negative, it is recommended to collect a new sample from the patient a few days later and test again.
- 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 cPass™ 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 cPass™ test result must continue to protect themselves and others from COVID-19, following CDC and government guidelines.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. For laboratories outside the United States, please follow the guidance of the country's public health authorities.
- It is recommended to perform cPass™ 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 cPass™ reagents of various neutralizing antibodies from different patients.