

# COVID-19

Immunity Assessment Test



Simple, Accurate & Reliable

## LABORATORY REFERENCE DOCUMENT

# SARS-CoV-2 (COVID-19) Competitive Viral Neutralization Antibody

CPT Code: 86409



### Intended Use

COVID-19 Immunity Assessment Test is intended for use as an aid in the identification, quantification and longitudinal monitoring of protective neutralizing antibody response to SARS-CoV-2 post infection or as an aid in assessing the immune response of individuals that have been previously immunized with a COVID-19 vaccine.

### Infectious Targets

SARS-CoV-2 Competitive Viral Neutralization (cVNT) antibody.

### Turnaround Time

2 – 3 days.

### Specimen Collection

Reference [DxTernity MCD sample collection IFU video](#) or standard EDTA venous collection.

### Specimen Requirements

DxTernity Serology Micro Collection Device (MCD), 5 – 10 drops of blood, stable for 14-days at room temperature.

EDTA Lavender top plasma sample shipping instructions for venous blood:

- Specimens must be stored at 2-8°C prior to shipping
- Express delivery within 24-hours from collection
- Ship specimens with cold pack, two patient identifiers and a completed TRF

### Causes for Rejection

Insufficient blood volume for DxTernity MCD. Reference Instructions for Use.

### Limitations

This test result is only validated for the presence of SARS-CoV-2 total neutralizing antibodies and not for any other viruses or pathogens. Antibodies to SARS-CoV-2 are generally detectable several days after initial infection, although the duration of time neutralizing antibodies are present post infection is not well characterized. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is recommended. False positive results may occur due to cross-reactivity from pre-existing antibodies or other causes.

### Performance

cVNT Sensitivity (PPA) > 95% and Specificity (NPA) > 95%.

### Days Performed

Monday through Saturday.

### Report Type

Printable and downloadable PDF for mobile devices.

### References

Tan C.W. et al A SARS-CoV-2 surrogate virus neutralization test based on antibody-mediated blockage of ACE-2-spike protein-protein interaction. Nat. Biotechnol. (2020). <https://www.news-medical.net/health/What-are-Neutralizing-Antibodies.aspx>

Khoury DS, Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection, Nat Med (2021). <https://doi.org/10.1038/s41591-021-01377-8>

DxTernity White Paper – SARS-CoV-2 Neutralizing Antibody Levels Provide Estimate of COVID-19 Protection Following Vaccination or Infection. Data on File.