SARS-CoV-2 Quantitative Neutralizing Antibody Test (qNAT) Report

PROMUS DIAGNOSTICS

Laboratory Director:
Dr. Nicole Massoll, M.D.

CAP #: 8412352 CLIA #: 45D2156626

Patient Information	Physician Information	Sample Information
Jane Smith **Age/Sex:** 36/F **Date of Birth:** 05/12/1985	Dr. Nicole Massoll, M.D. **NPI:** 1265545099 2300 Dean Way, Suite 130 Southlake, TX 76092	**Sample ID:** - **Order #:** **Collection Date:** 08/10/2021 **Received Date:** 08/10/2021 **Report Date:** 08/10/2021 **Specimen Type:** serum

Test Results

qNAT Result	**MEDIUM Neutralization**
SARS-CoV-2 Neutralizing Activity (%)	**89.20%**
SARS-CoV-2 Neutralizing Antibody Titer Value (Units/mL)	**4920.56**

Comments

This report determines the presence and quantity of virus neutralizing antibodies in patient serum. Scientific studies have suggested a relationship between the presence of neutralizing antibodies and the development of immunity for SARS-CoV-2 infection. This report may help illustrate your current immune status, which may change over time. Consult your healthcare provider for further guidance.

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Reference Values

Neutralizing Antibody Titer Value (Units/mL)	% Neutralizing Activity	Semi-Quantitative Result Interpretation
-	-	Inconclusive
-	< 30%	Not Detected
-	≥ 30%	Neutralization Detected
< 1500	30% to < 60%	LOW Neutralization
1500 - 5000	60% to < 90%	MEDIUM Neutralization
> 5000	90%	HIGH Neutralization

**If the titer and % Neutralization values are in two different interpretation categories, the higher designation is reported.*
**An inconclusive result indicates that no result determination can be made for that specimen. This can result due to inadequate specimen collection, transport, or handling. It is recommended to collect a new specimen and send for re-testing as soon as possible.*

Methodology and Clinical Significance: SARS-CoV-2 Neutralizing Antibody Test (qNAT) is a Laboratory Developed Test (LDT) using functional Enzyme-Linked Immunosorbent Assay (ELISA) for semi-quantitative detection and titer analysis of SARS-CoV-2 neutralizing antibodies. This test has not been cleared or approved by the FDA; however, this test was developed and its performance characteristics have been determined by Promus Diagnostics LLC. Furthermore, approval/clearance is not required, as Promus Diagnostics LLC is certified under CLIA as qualified to perform high-complexity clinical laboratory testing. This test is used for clinical purposes, and should not be regarded as investigational or for research. Results from this test should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. Negative results do not rule out SARS-CoV-2 infection and can occur if the titer is below the sensitivity of the test. Positive results may not indicate previous SARS-CoV-2 infection and, although rare, may be due to current or past infection with SARS-CoV-1.