Kephera Diagnostics, LLC
1 Grant St, Suite 300, Framingham, MA 01702
Tel: 774-777-3558; Fax: 774-777-3559
Laboratory Director, Andrew E Levin, PhD
clia@kepheralab.com

TEST REPORT

COVI-QUANT™ Quantitative Antibody Test (SARS-CoV-2 Quantitative Antibody ELISA)

Patient Name:	**JOHN H DOE**	**Patient Date of Birth:**	11-Dec-1987
Provider Name:	*Jane Blank*	**Sample ID:**	210623_0001
Provider Facility:	*First Clinic*	**Sample collection date:**	22-Jun-2021

TEST RESULT

Anti-SARS-CoV-2 IgG Concentration [1] ***100 BAU/mL***

INTERPRETATION OF RESULT:

Reportable range *Lower Limit of Range* **13.2 BAU/mL** *Upper Limit of Range* **1,700.0 BAU/mL**

IgG Antibody Concentration (BAU/mL)	Interpretation
< 13.2	Level of IgG antibody to SARS-CoV-2 Spike antigen is below the measurable range of this test [2]
13.2 - 1700	IgG antibody to SARS-CoV-2 Spike antigen is detected and within the measurable range of this test [3]
> 1700	Level of IgG antibody to SARS-CoV-2 Spike antigen is above the measurable range of this test [3]

NOTES AND LIMITATIONS:

1. Binding Antibody Units/mL (BAU/ml) are the International Standard Units determined by the World Health Organization (WHO). *Read more here.*

2. A low level of antibody may not indicate the absence of protection against SARS-CoV-2 infection. Samples collected earlier than two weeks after vaccination or infection may not have a detectable level of antibody to SARS-CoV-2 Spike antigen.

3. Detected level of IgG antibody may not indicate acute or previous infection. IgG level may not correspond to the level of protection against SARS-CoV-2 infection.

4. The Low, Moderate, and High groups are defined based on BAU/mL values of Low, Moderate, and High samples from the WHO International Reference Panel for anti-SARS-CoV-2 immunoglobulin (NIBSC code: 20/268).

Date Test Completed: 24-Jun-2021

This test was established and validated by Kephera Diagnostics, LLC, 1 Grant Street, Framingham, MA 01702 (CLIA ID #22D2182419), Laboratory Director: Andrew E Levin, PhD. Its performance was determined to be pursuant to the requirements of CLIA '88 for clinical testing. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not required.