SARS-CoV-2 IgG, Nucleocapsid

Order Name: **CoV2 IgG NucCap**
Test Number: 6901550
Revision Date: 12/15/2023

TEST NAME	METHODOLOGY	LOINC CODE
SARS-CoV-2 IgG, Nucleocapsid	Chemiluminescent Micropartical Immunoassay	94507-1

SPECIMEN REQUIREMENTS

Specimen	Specimen Volume (min)	Specimen Type	Specimen Container	Transport Environment
Preferred	**2 mL (0.7 mL)**	**Serum**	**Clot Activator SST**	**Room Temperature**
Instructions	Stability: Ambient 14 days; Refrigerated 14 days; Frozen 14 days, (Freeze if testing will be delayed more than 14 days Freeze/thaw cycles Stable x3) Minimum Volume 0.7 mL (Note: This volume does not allow for repeat testing.)			

GENERAL INFORMATION

Expected TAT	2-4 Days
Clinical Use	Qualitative detection of high affinity antibodies to SARS-CoV-2 nucleocapsid (N) protein, the virus that causes COVID-19, to aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Note: This assay will not detect antibodies induced by currently available SARS-CoV-2 vaccines. This assay enriches detection of higher affinity antibodies which are more likely to be specific for SARS-CoV-2 N protein. While this assay in principle can detect high affinity antibodies of all isotypes (i.e., IgG, IgA, IgM), it preferentially detects IgG antibodies since these are more likely to evolve to become high affinity. Serologic results should not be used as the sole basis to diagnosis or exclude recent SARS-CoV-2 infection. This test is recommended for individuals at greater than or equal to 14 days post-symptom onset or following exposure to individuals with confirmed COVID-19.The incubation period for COVID-19 ranges from 5 to 7 days.
Performing Labcorp Test Code	164068
Notes	This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. False positive results infrequently occur due to prior infection with other human Coronaviruses. **Note: This assay will not detect antibodies induced by currently available SARS-CoV-2 vaccines.**
CPT Code(s)	86769
Lab Section	Reference Lab