Exsera BioLabs

Anschutz

UNIVERSITY OF COLORADO **ANCHUTZ MEDICAL CAMPUS**

Patient Information

Patient Name: _____ MR# _____

Gender: ☐ Female ☐ Male DOB: _____/_____/_____

Reporting & Referring Physician Information	**Billing Information**
Physician Name (print): _____	Referring Institution:_____
Address: _____	Address: _____
City/State/Zip: _____	City/State/Zip: _____
Phone: _____	Phone: _____
Secure Fax: _____	Secure Fax: _____
Email: _____	Email: _____

Specimen & Clinical Information

Specimen Type: ☐ Serum (red/tiger top Specimen Collection Date/Time: _____*ICD-10:_____

SARS-CoV-2 IgG Antibody Testing		
	LOINC 94563-4	CU AMC SARC-CoV-2 IgG Dual Antigen Antibody ELISA

FOR PATIENTS

- This test does NOT diagnose COVID-19. If you suspect you have COVID-19, you should contact your physician for testing to detect the SARS-CoV-2 virus.
- The COVID-19 antibody test is for individuals who think they may have previously had COVID-19 and are currently asymptomatic.
- Detection of anti-SARS-CoV-2 IgG antibodies suggests past or present infection.
- False positive results occur in 4 out of 1,000 individuals who have not had COVID-19.
- Antibodies do not guarantee immunity or protection from future infection.
- Individuals with anti-SARS-CoV-2 IgG antibodies may still be carriers of the virus and should continue practices to prevent viral transmission (e.g. hand washing, wearing masks, social distancing, etc.).

FOR PHYSICIANS

- This test detects IgG antibodies developed by the immune system in response to SARS-CoV-2 infection.
- This test does NOT diagnose COVID-19.
- A "reactive" result suggests past or present infection. The presence of antibodies does not guarantee immunity or protection from future infection.
- False negatives: Approximately 84% of COVID-19 patients develop IgG antibodies more than 10 days after detection of the SARS-CoV-2 virus. Some patients do not seroconvert following infection (e.g. chemotherapy, immunosuppression, subclinical immune response, etc.). Repeat testing in 2-4 weeks is recommended for "non-reactive" patients with previous symptoms or high risk of COVID-19 exposure.
- False positives: This test has a specificity of 99.6%. False positive results will occur for 4 out of 1,000 individuals who have not had COVID-19.
- High test specificity derives from detection of antibodies against 2 different SARS-CoV-2 proteins, the receptor binding domain (RBD) of the spike protein and the nucleocapsid protein. A patient receives a "reactive" result if antibodies against both proteins are detected.
- Orthogonal testing is recommended according to the CDC Interim Guidelines for COVID-19 Antibody Testing, especially if either disease prevalence or a single test's positive predictive value is low. See: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html
- This test is under evaluation by the FDA for Emergency Use Authorization. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Comments/ Special Instructions	Exsera BioLabs USE ONLY Received (Initial/ Date) : _____ Received Condition (Circle) Ambient Frozen on Dry Ice Other Specimen Type & No: _____Serum _____ Other_____

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