Q&A | SARS-CoV-2 ANTIBODIES TEST [164068]

Q: What is the SARS-CoV-2 Antibodies test?

A: The **SARS-CoV-2 Antibodies test [164068]** is a qualitative assay that detects the presence of high affinity antibodies to the SARS-CoV-2 virus. While the assay does not differentiate between antibody types, it preferentially detects IgG antibodies since these are most likely to evolve to become high affinity.[1]

Q: What is the intended use of the test?

A: The SARS-CoV-2 Antibodies test is intended to determine antibody status for individuals at least 10-14 days post-COVID-19-symptom onset or at least 10-14 days following exposure to individuals with confirmed COVID-19. This is not a test to determine if an individual is currently infected with SARS-CoV-2. The diagnostic test that detects the SARS-CoV-2 virus is the reverse transcriptase polymerase chain reaction (RT-PCR) test **2019 Novel Coronavirus (COVID-19), NAA [139900]**.

Q: How does this compare to the current SARS-CoV-2 Antibody, IgG test?

A: Both tests have the same intended use, similar turnaround time, and similar performance characteristics. The main difference is that the **SARS-CoV-2 Antibody, IgG [164055]** test determines the presence of IgG antibodies only, whereas the **SARS-CoV-2 Antibodies [164068]** test is not class specific when determining the presence of high affinity antibodies to the virus. **Note:** Do not order both tests on the same patient; select one only.

Q: What do the results mean?

A:
- A positive result indicates that an individual has likely produced an immune response to the SARS-CoV-2 virus.
- A negative result suggests that an individual has not developed detectable antibodies at the time of testing.
- This test does not indicate how effective a patient's immune response is or what its duration will be. Antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

Q: What is the test code?

A: The test code is 164068.

Q: What are the sample requirements?

A: The test requires 0.8 mL of serum collected in a gel-barrier tube, serum from a red-top tube, or serum transfer tube.

Q: Where can the blood collection occur?

A: Antibody test collections (via a blood draw) can be performed in office and sent to the laboratory via courier or are available through LabCorp's network of patient service centers, including LabCorp at Walgreens locations.

Q: What is the cost and CPT code for this test?

A: The CPT code is 86769. The price of the test is the lesser of 100% of the Centers for Medicare and Medicaid Services (CMS) 2020 National Limitation Amount (NLA) or $50.

Reference

1. Roche. (2020). Elecsys® Anti-SARS-CoV-2 Immunoassay.

These tests have not been FDA cleared or approved. These tests have been authorized by the FDA under an emergency use authorization for use by authorized laboratories. These tests have been authorized only for the detection of the presence of antibodies against SARS-CoV-2, and not for any other viruses or pathogens. These tests are 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.

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