BioAgilytix Diagnostics

Technical Brief for the detection of antibodies to the COVID-19 virus using the Elecsys Anti-SARS-CoV-2 immunoassay

Specimen Type	Serum or Plasma
Specimen Volume	1 mL
Collection	For Serum: Collect specimen in a red top tube with no additives or a serum gel tube. Allow sample to clot for 30 minutes. Centrifuge at 3000 rpm for 10 minutes and pour serum into a transport tube. For Plasma: Collect specimen in lavender top tube with EDTA, or green top tube with heparin. Allow sample to clot for 30 minutes. Centrifuge at 3000 rpm for 10 minutes and transfer plasma into a transport tube.
Minimum Volume	0.25 mL
Handling	Ship refrigerated on gel packs, or frozen on dry ice
Rejection Criteria	Specimens clearly not serum or plasma Specimens outside of listed stability Specimens with bacterial of fungal contamination
Stability	Ambient for 3 days Refrigerated for 7 days. Frozen (-20) for 28 days
Methodology	Electrochemiluminescence immunoassay (ECLIA)
Reference Range	Non-reactive (Negative for anti-SARS-CoV-2 antibodies)
Turnaround Time	3 days from receipt in lab
CPT Code	**86769:** Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]).
Clinical Significance	Use of this assay as an in vitro diagnostic (IVD) assay, performed under the FDA Emergency Use Authorization (EUA) is limited to laboratories certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) authorized to perform high complexity testing. Elecsys Anti-SARS-CoV-2 is an immunoassay intended for qualitative detection of antibodies to SARS-CoV-2 in

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	human serum and plasma (K2-EDTA, K3-EDTA, Li-heparin). The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Currently it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Elecsys Anti-SARS-CoV-2 assay should not be used to diagnose acute SARS-CoV-2 infection. The sensitivity of the Elecsys Anti-SARS-CoV-2 assay early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19 regardless of Elecsys Anti-SARS-CoV-2 Immunoassay results. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Patients may have detectable virus present for several weeks following seroconversion. Other diagnostic information and the patient's clinical history should be taken into consideration when determining the patient's infection status. A negative result does not preclude SARS-CoV-2 infection and this test should not be used as sole determinant for decisions on patient management. Currently all SARS-CoV-2 testing results must be reported to relevant local health authorities by the performing laboratory.

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Principle

The Elecsys Anti-SARS-CoV-2 assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2. Basically sample is incubated with recombinant antigen labeled with biotinylated SARS-CoV-2-specific recombinant antigen and SARS-CoV-2-specific recombinant antigen labeled with a ruthenium complex, forming a sandwich complex with antibodies against SARS-CoV-2. Addition of streptavidin-coated microparticles, allows the complex to be magnetically captured onto the surface of the electrode within the measuring cell. Unbound substances are removed by washing and application of a voltage to the electrode induces chemiluminescent emission which is measured by a photomultiplier.
Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.
The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index (COI; signal sample/cutoff).

Numeric result	Result message	Interpretation
COI < 1.0	Non-reactive	Negative for anti-SARS-CoV-2 antibodies
COI ≥ 1.0	Reactive	Positive for anti-SARS-CoV-2 antibodies

The magnitude of the measured result above the cutoff is not indicative of the total amount of antibody present in sample.
The individual immune response following SARS-CoV-2 infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.