

Detection of Anti-SARS-CoV-2 in Human Serum with Roche e801

Test Name: In vitro test for the qualitative and semi-quantitative determination of antibodies to SARS-CoV-2 in human serum and plasma on Roche/Hitachi cobas e systems.

Method Name: The Elecsys Anti-SARS-CoV-2 S assay uses a recombinant protein representing the receptor-binding domain (RBD) of the spike antigen in a double antigen sandwich assay format. The Elecsys Anti-SARS-CoV-2 S assay detects antibodies to SARS-CoV-2 spike protein RBD.

Results: Technical Range: 0.40-250 U/mL
Reportable Range: 0.31-5.61 g/dL

Reference Ranges:

ACOV2S Result	Interpretation
< 0.80 U/mL	Negative
≥ 0.80 U/mL - ≤ 250 U/mL	Positive, numeric value within measuring interval
> 250 U/mL	Positive, numeric value reported as > 250 U/mL

Clinical Significance: SARS-CoV-2, the causative agent of Coronavirus Disease 2019 (COVID-19), is an enveloped, single-stranded RNA Betacoronavirus. Seven (7) coronaviruses have been identified as agents of human infection, causing disease ranging from mild common cold to severe respiratory failure.

SARS-CoV-2 is transmitted primarily from person-to-person through respiratory droplets and aerosols. The incubation period from infection to detectable viral load in the host commonly ranges from 2 to 14 days. Detection of viral load can be associated with the onset of clinical signs and symptoms, although a considerable proportion of individuals remains asymptomatic or mildly symptomatic. The interval during which an individual with COVID-19 is infectious has not yet been clearly established, however, transmission from symptomatic, asymptomatic, and pre-symptomatic individuals has been well described.

Coronavirus genomes encode 4 main structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N). The S protein is a very large transmembrane protein that assembles into trimers to form the distinctive surface spikes of coronaviruses. Each S monomer consists of an N terminal S1 domain and a membrane-proximal S2 domain. The virus gains entry to the host cell through binding of the S protein to the angiotensin-converting enzyme 2 (ACE2), which is enzymatically active on the surface of numerous cell types including the alveolar type II cells of

the lung and epithelial cells of the oral mucosa. Mechanistically, ACE2 is engaged by the receptor-binding domain (RBD) on the S1 subunit.

Upon infection with SARS-CoV-2, the host mounts an immune response against the virus, typically including production of specific antibodies against viral antigens. IgM and IgG antibodies to SARS-CoV-2 appear to arise nearly simultaneously in blood. There is significant inter-individual difference in the levels and chronological appearance of antibodies in COVID-19 patients, but median seroconversion has been observed at approximately 2 weeks.

Serologic assays can play an important role in understanding viral epidemiology in the general population.

Submission Criteria:

For specimen collection and preparation, only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin and K₂-EDTA plasma

Do not use fluoride plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, therefore not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Storage and Stability: 3 months at -20°C

14 days at 2-8°C

3 months at 20-25 °C

Rejection Criteria:

Rejection criteria include but are not limited to:

1. Specimens containing fibrin or clots.
2. Excessive platelet clumping
3. Leaking specimens
4. Substandard mixing or collection
5. Expired or improperly stored collection tubes.
6. Improperly filled tubes based on collection tube manufacturer's guidelines.
7. Contaminated specimens (IV fluid, foreign particles, etc.)
8. Specimens not analyzed within the appropriate time frame.
9. Samples not shipped at appropriate temperature.
10. Samples without 2 proper identifiers or samples having identifiers that do not match the electronic or paper lab requisition.

Authorization:

Diagnostic testing can only be performed with approval from an authorized provider/agency.

Turn Around Time:

1 day.

Instructions for Serum Specimen Submission

General Information

The detection of antibodies to SARS-CoV-2 in human serum and plasma is performed using a Roche cobas i58 analyzer. However, serum specimens are preferred.

Specimens must be collected and stored at 15-25 °C if to be analyzed within 3 days, at 2-8°C if to be analyzed within 14 days and stored at -20°C if to be analyzed within 3 months. Please be aware that storing specimens at $\leq -70^{\circ}\text{C}$ ($\leq -94^{\circ}\text{F}$) is not permissible.

Specimens MUST be received at Reditus Laboratories within 3 days of collection.

Collection Instructions for Serum Specimen

1. Do not use expired collection tubes. Store collection tubes as per manufacturers recommendations. Use standard venipuncture practices for collecting samples. Filled gold top serum tubes are preferred.
2. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen tube along with the name or initials of the individual collecting the sample.
3. Complete all the demographic information on a sample requisition form through the approved electronic submission process
4. Refrigerate the specimen between 2-8°C (36-46°F) and ship or courier the specimen(s) within 48 hours.
5. The specimen(s) *must* be received at the laboratory **no later than** 48 hours *from the time of collection*.
 - a. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.
 - b. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
6. For any questions pertaining to sample collection, storage, or shipping, please contact the Reditus Laboratories using the below contact information.

Instructions for Specimen Transport

1. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.
2. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.
3. *Ship specimens by overnight delivery* to the attention of Clinical Chemistry at Reditus Laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.
 - a. **If specimens are shipped on a Friday for Saturday delivery, you must include/indicate Saturday delivery** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result

- in specimens being rejected from testing.
4. The specimen(s) must be received at the laboratory **no later than** 48 hours *from the time of collection* and 24 hours from the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

NOTE: Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact the Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

Send to: Reditus Laboratories
200 Enterprise Drive
Pekin, IL 61554

Phone: (469) 498-0222

Website: <https://www.redituslabs.com/>