Overview

Useful For
Screening for the detection of IgG-class antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using dried blood spot specimens

This test should not be used to detect recent or acute coronavirus disease 2019 (COVID-19) or for documentation of SARS-CoV-2 vaccine response.

Highlights
This test can be used to screen for IgG-class antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19).

This test will not yield a positive result following vaccination against SARS-CoV-2.

Special Instructions
- Blood Spot Collection Instructions-Fingerstick
- Blood Spot Collection Instructions-Fingerstick-Portuguese
- Blood Spot Collection Instructions-Fingerstick-Spanish

Method Name
Microsphere Multiplex Flow Immunoassay (MFI)

NY State Available
Yes

Specimen
Specimen Type
Whole blood

Ordering Guidance
Molecular testing is recommended for diagnosis of coronavirus disease 2019 (COVID-19) in symptomatic patients. For more information see COVOO / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA Detection, Varies.

If SARS-CoV-2 vaccine-induced antibody testing is necessary, see VCOV2 / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) IgG Antibody, Serum.

The dried blood spot specimen should be collected under the supervision of a medical professional or health care provider.

Necessary Information
1. Patientâ€™s race and ethnicity are required.

2. If ordering electronically, answers must be provided for the order entry questions.

3. If not ordering electronically, patient race and ethnicity must be provided on the request form.
Specimen Required

**Supplies:** Card-Blood Spot Collection (Filter Paper) (T493)

**Container/Tube:**

**Preferred:** Blood Spot Collection Card

**Acceptable:** Whatman Protein Saver 903 Paper, Ahlstrom 226 filter paper and Munktell filter paper

**Specimen Volume:** 2 Filled blood spots

**Collection Instructions:**

2. Let blood dry completely on filter paper at ambient temperature in a horizontal position for a minimum of 3 hours.
3. At least 2 spots should be complete, i.e., unpunched.
4. **Do not** expose specimen to heat, moisture, or direct sunlight.
5. **Do not** stack wet specimens.

**Additional Information:**

1. For collection instructions, see [Blood Spot Collection Instructions-Fingerstick](#) in Special Instructions.
2. For collection instructions in Portuguese, see [Blood Spot Collection Instructions-Fingerstick-Portuguese](#) in Special Instructions.
3. For collection instructions in Spanish, see [Blood Spot Collection Instructions-Fingerstick-Spanish](#) in Special Instructions.

**Specimen Minimum Volume**

1 Blood spot

**Reject Due To**

| Blood spot specimen that shows serum rings or has multiple layers | Reject |
| Insufficient specimen spots | |
| Unapproved filter papers | |
| Multiple applications | |

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>Ambient</td>
<td>25 days</td>
<td>FILTER PAPER</td>
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Clinical and Interpretive

Clinical Information

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a positive-sense, single-stranded RNA virus that causes coronavirus disease 2019 (COVID-19). Like other coronaviruses that infect humans, SARS-CoV-2 can cause both upper and lower respiratory tract infection. Symptoms can range from mild (ie, the common cold) to severe (ie, pneumonia) in both healthy and immunocompromised patients. SARS-CoV-2 transmission occurs primarily via respiratory droplets. During the early stages of COVID-19, symptoms maybe nonspecific and resemble other common respiratory tract infections, such as influenza.

The incubation period for COVID-19 ranges from 2 to 14 days. Typically, immunocompetent individuals with COVID-19 develop detectable SARS-CoV-2 IgG-class antibodies 8 to 14 days following onset of symptoms. Patients tested prior to this time may be negative for SARS-CoV-2 IgG antibodies.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

Negative:

No IgG antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) detected. Negative results may occur if the test is done too soon following infection, in patients who are immunosuppressed, or in patients with very mild or asymptomatic infection. This test does not rule out active or recent coronavirus disease 2019 (COVID-19) and will not detect SARS-CoV-2 vaccine-induced antibodies.

Positive:

Results suggest infection with SARS-CoV-2 at some time in the past. A positive result does not indicate protection against reinfection with SARS-CoV-2. False-positive results may occur. Confirmatory testing using a venipuncture blood draw may be considered in low-risk individuals or those residing in low-prevalence regions.

Inconclusive:

Presence or absence of antibodies to SARS-CoV-2 could not be determined. Repeat testing on a new dried blood spot specimen or a venipuncture blood draw may be considered.

Cautions

Serologic testing should not be used to diagnose severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in symptomatic patients presenting soon after symptom onset due to the risk of false-negative serologic results.

This test detects IgG-class antibodies separately, against the SARS-CoV-2 nucleocapsid protein, receptor-binding domain (RBD) and spike glycoprotein subunit 1 (S1). In order for the test result to be interpreted as positive, reactivity must be identified against the nucleocapsid protein and the RBD and/or S1 protein. All current SARS-CoV-2 vaccines induce antibodies to the spike glycoprotein only. Therefore, due to the requirement for reactivity to the nucleocapsid protein in this test, SARS-CoV-2 vaccinated individuals will appear negative by this assay.
Test Definition: CORBS
SARS-CoV-2 IgG, Bld Spot

Negative serologic results may occur in specimens collected too soon after symptom onset. Typically, the majority of patients seroconvert between 8 to 14 days post-symptom onset; specimens collected and tested prior to this time point may be negative.

False-positive results may occur due to presence of antibodies to other infectious agents or other interferences. For individuals residing in low-prevalence regions or at low risk of prior infection consider confirmatory testing using a venipuncture drawn specimen.

Clinical Reference

Performance

Method Description
A 3-mm disk is punched out of the blood spot in to a 96-well plate. Elution buffer is then added and the disks are eluted for 2 hours and are then analyzed via xMAP (Multi-Analyte Profiling) SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) Multi-Antigen IgG Assay.(Unpublished Mayo method)

Sample is incubated with the multiplexed microspheres. The SARS-CoV-2 specific IgG antibodies present in the sample bind to the S1, RBD, and N antigen specific microspheres. The microspheres are washed and incubated with a fluorescently labeled, IgG-specific detection reagent. The microspheres are washed again to remove unbound detection reagent and suspended in wash buffer for analysis on a Luminex xMAP compatible instrument. The presence or absence of SARS-CoV-2 specific IgG-antibodies is determined by automated xMAP MULTI IgG CoV-2 Assay Software.

The Luminex FLEXMAP 3D (FM3D) system, in combination with xMAP technology, will simultaneously measure up to 500 analytes from a single sample. Polystyrene microspheres discriminated by color are excited by 2 lasers in the FM3D system. The resulting emission is detected by avalanche photo diodes (APDs) in three classification channels (CL1, CL2, CL3) and then further analyzed using a separate APD in a doublet discriminator channel, which measures bead size through side-scatter.

Reporters, tagged with fluorescent labels excited at a different wavelength than the internal dyes, bind to the analyte of interest and are detected by a photomultiplier tube in a reporter channel (RP1), allowing for quantitative analysis. As the microspheres in a fluid stream pass rapidly through the laser beams, high-speed digital signal and computer algorithms discriminate which analyte is being carried on each microsphere and quantifies the reaction based on fluorescent reporter signal. The results are analyzed by the system software xPONENT.(Package Insert: xMAP SARS-CoV-2 Multi-Antigen IgG Assay 89-30000-00-872 Rev A. Luminex Corporation; 07/2020)

PDF Report
No
Day(s) Performed
Monday, Thursday

Report Available
2 to 7 days

Specimen Retention Time
7 days

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
86769

LOINC® Information

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<td>SARS-CoV-2 IgG, Bld Spot</td>
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