BOSTON HEART
COVID-19 Testing

Boston Heart is using our expertise in genetic, antibody, and inflammation testing to help fight the COVID-19 pandemic.

We are offering reverse transcriptase polymerase chain reaction (RT-PCR), serum antibody and inflammation testing because CVD patients are at substantially higher risk of mortality from Coronavirus SARS-CoV-2 infection.

Over 50% of those infected with SARS-CoV-2 are asymptomatic[1-2]

Blood Antibody Testing Adds Value to RT-PCR Testing

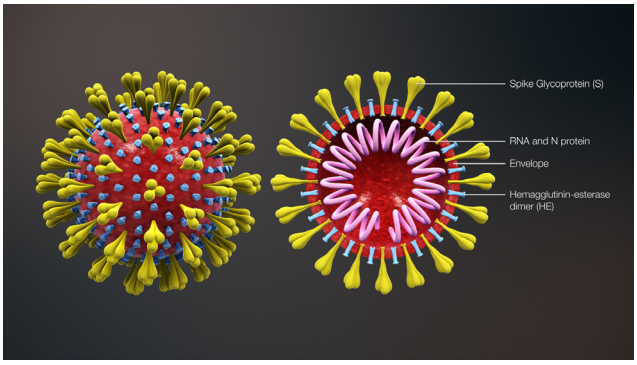
Symptoms often develop an average of 5 days (range 2-14 days) after SARS-CoV-2 infection. Diagnosis of a current infection is made by having a positive RT-PCR nasal swab test usually within 3 days of infection and may become undetectable after 2-4 weeks from disease onset.

PCR detects viral RNA from nasal swabs and is often detected in the early stages of infection but may become undetectable with increasing time from disease onset.

A positive antibody test indicates prior exposure. Serum IgM indicates recent infection, and is typically positive within 3 to 10 days of symptom onset, while serum IgG is often present within 1-2 weeks from symptom onset and can remain positive for several months. Antibody levels also become positive 2-5 weeks after complete course of vaccination.

- A positive PCR indicates active infection
- A negative PCR with a positive IgM indicates recent infection
- A negative PCR with negative IgM and positive IgG indicates past infection and presumed immunity
- A negative PCR with a negative IgM and IgG indicates no active or recent past infection

With any testing there is the possibility of false positives and false negatives.



About Coronavirus Testing

RT-PCR Testing for Active Virus

- Uses a nasal, nasopharyngeal or oropharyngeal swab to detect SARS-CoV-2 virus using an FDA EUA approved test.
- Detects the S, N, and ORF1ab gene targets.
- This assay detects both the common and UK variant of the SARS-CoV-2 virus.
- Detects SARS-CoV-2 RNA with high sensitivity as low as approximately 100 copies per reaction.

Antibody Testing for Immune Response

- We offer FDA EUA approved antibody tests.
- Diazyme IgM & IgG panel (Order Code 6400, or individual IgM order code 641, or individual IgG order code 642).
- Diazyme panel is optimal for evaluating current or previous virus exposure (but does not reflect immune response to vaccination).
- Roche Elecsys Anti-SARS-CoV-2 S (Spike Antibody) quantifies IgG antibodies made against the spike protein in response to either virus exposure or vaccination (Order Code 648, this assay does not provide IgM results).
- After vaccination, testing is best done $\geq$3 weeks after 1st dose, or $\geq$3 week after 2nd dose.
- These assays have no cross reactivity with antibodies for other coronavirus strains or other respiratory viruses.
- The sensitivity and specificity of our COVID-19 antibody tests are >95%, with CVs of <4%.[4]

Inflammation Testing for COVID Severity

- IL-6 and hsCRP can distinguish between PCR positive patients that need hospitalization and those that do not.
- Having two or more of the following criteria: IL-6 values >10 pg/mL, hs-CRP >10 mg/L, and/or IgM >1.0 AU/mL in positive cases was found in 97.7% of those needing hospitalization versus 1.8% of those who did not (50-fold increased risk).[6]
- 59% of hospitalized patients with IL-6 values >35 pg/mL required a ventilator.[7]

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Ordering, Sample Collection, and Reporting

Ordering Information

Order Codes:

- 895 - BHD COVID-19 NP SWAB
- 896 - BHD COVID-19 NASAL SWAB
- 898 - BHD COVID-19 OP SWAB
- 6400 - SARS-COV-2 IgM/IgG Panel
  - 641 - SARS-CoV-2 IgM Serum
  - 642 - SARS-CoV-2 IgG Serum
- 648 - SARS-COV-2 Spike Serum
- 1190 - Interleukin-6 (COVID-19 Only)
- 601 - hs-CRP

Common COVID-19 ICD-10 Codes

- U07.1 - Confirmed or presumptive COVID-19
- Z20.828 - Contact with and (suspected) exposure to other viral communicable diseases
- Z11.59 - Encounter for screening for other viral diseases
- R05 - Cough
- R06.02 - Shortness of breath
- R50.9 - Fever, unspecified
- Z01.84 - Encounter for antibody response examination

https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf

Sample Collection

RT-PCR Swab (Order Code: 895, 896 or 898)

- Collect and label a nasal, nasopharyngeal or oropharyngeal sample (patient's full name and DOB) per normal procedure.
- Ensure that a minimum of 2 mL of media is present in collection device.

IgM, IgG, and spike protein antibodies against SARS-CoV-2 (Order Code: 6400, 641,642 or 648)

- Serum collected via SST, allowed to clot, and spun down, labeled (patient's full name and DOB) per normal procedure, and sent to the lab.
- Samples are stable for 7 days when refrigerated.

Reporting

COVID-19 diagnostic tests are reported in the Infectious Disease section of the lab report.

- BHD COVID-19 NP SWAB is reported as "Detected" or "Not Detected"
- SARS-CoV-2 IgM Serum and SARS-CoV-2 IgG Serum are reported as AU/mL. Values ≥1.00 AU/mL are considered positive.
- SARS-CoV-2 Spike Serum is reported as U/mL. Values ≥0.80 U/mL are considered positive.
- Reportable ranges: IgM 1.00-10.00 AU/mL, IgG 0.20-100.0 AU/mL, and Spike antibody 0.4-250 U/mL.

Test Name	Test Result	Interpretation
Infectious Disease Tests		
BHD COVID-19 RT-PCR NASAL SWAB	Not Detected	A not detected (negative) test result for this test means that SARS- CoV-2 RNA was not present in the specimen above the limit of detection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Results will be reported to government agencies as required.
SARS-CoV-2 IgM Serum	<1.0 AU/mL Negative	A result less than 1.00 AU/mL is considered to be negative. Negative results do not rule out SARS-CoV-2 exposure. Positive IgM antibody results are often present early in the infectious process. Results will be reported to government agencies as required.
SARS-CoV-2 IgG Serum	7.89 AU/mL Positive	A result greater than or equal to 1.00 AU/mL is considered to be positive. Positive IgG antibody results are often present late in the infectious process (from 7 days onward). This test does not have cross reactivity to non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. It also does not have cross reactivity to other common viruses including influenza A and B. Results will be reported to government agencies as required.
Anti-SARS-CoV-2 Spike Serum	19.7 U/mL Positive	A result greater than or equal to 0.8 U/mL is considered to be positive. This is a semi-quantitative IgG assay against the spike protein. It does not have cross reactivity to other common viruses including influenza A and B. Results will be reported to government agencies as required.

Assay Limitations

RT-PCR testing

This test has received Emergency Use Authorization (EUA). We will continue to follow federal and state requirements for COVID-19 reporting. This test was developed and its performance characteristics determined by Boston Heart Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration but has been given emergency use authorization. Results should be used in conjunction with clinical findings and should not form the sole basis for a diagnosis or treatment decision. Methods: SARS-CoV-2 Multiplex RT-PCR Assay

Spike Antibody, IgM and IgG testing

These assays are used for the detection of IgM and IgG antibodies against SARS-CoV-2 in human serum or plasma. The Roche Diagnostics Elecsys Anti-SARS-CoV-2 S semi-quantitative assay has been authorized for use under the FDA's Emergency Use Authorization (EUA). The Diazyme SARS-CoV-2 IgG and IgM semi-quantitative assays are for use under the FDA's Emergency Use Authorization (EUA# 200217). Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic assay should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

References

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3. Lippi G, Salvagno GL, Pegoraro M et al. Assessment of immune response to SARS-CoV-2 with fully-automated MAGLUMI 2019-nCoV IgG and IgM chemiluminescence immunoassays. Clinical Chemistry and Laboratory Medicine 2020 (epub);
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