BOSTON HEART
COVID-19 Testing

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

We are offering nasal-pharyngeal swab RT-PCR along with blood IgM and IgG antibody testing because CVD patients are at substantially higher risk of mortality from Coronavirus SARS-CoV-2 infection.

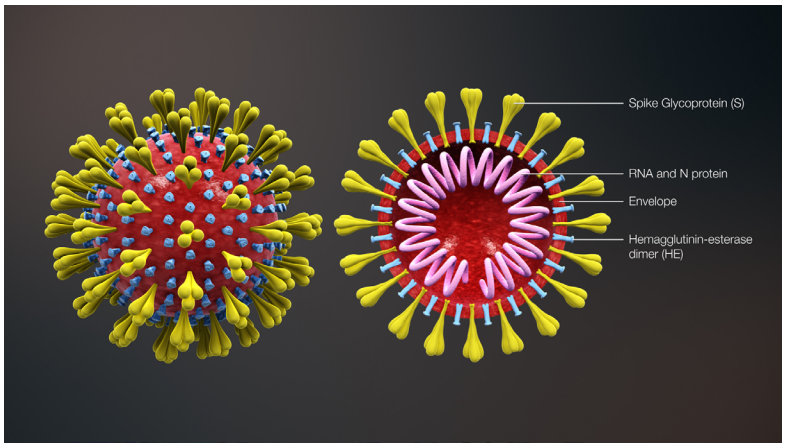
Blood Antibody Testing Adds Value to RT-PCR Testing

Diagnosis of a current infection is made by clinical observation and testing. The combination of PCR and antibody testing is important for confirming or excluding recent or past infection.

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.

Antibody levels indicate immune response. Serum IgM indicates recent infection and is typically positive within 3 to 10 days of symptom onset. Serum IgG is often present within 1 to 2 weeks from symptom onset and plateaus around 3 weeks, indicating current or past infection.[3-5]

- A positive PCR indicates active infection
- A negative PCR with a positive IgM indicates active or 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 past infection



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

About Coronavirus Testing

RT-PCR Testing for Active Virus

- Uses a Nasopharyngeal swab to detect active SARS-CoV-2 virus.
- The assay shows 100% homology to all SARS-CoV-2 variations at the ORF1ab, S gene, and N gene targets.
- Can detect SARS-CoV-2 RNA with high sensitivity as low as approximately 15 copies per reaction.

IgM and IgG Serum Testing

- No cross reactivity with antibodies for non-SARS-CoV-2 coronavirus strains HKU1, NL63, OC43, or 229E.
- No cross reactivity with antibodies for influenza A and B, parainfluenza, respiratory syncytial virus, adenovirus, Epstein-Barr virus NA and VCA, measles virus, cytomegalovirus, varicella zoster, Mycoplasma pneumoniae, Chlamydia pneumoniae, and Candida albicans.
- Based on studies in China, the sensitivity of this IgG antibody test for identifying SARS-CoV-2 RNA positive subjects was reported to be 91.2%, and with both IgG and IgM antibody testing it was 95.6%.[4]
- The specificity in SARS-CoV-2 RNA negative subjects was reported to be 96.0% when IgG and IgM were used in combination.[4]
- Within run and between run CVs are < 4.0% for both assays.

bostonheart diagnostics®

Ordering, Sample Collection, and Reporting

Ordering Information

The order codes are:

- 895 - TaqPath COVID-19 NP SWAB
- 641 - SARS-CoV-2 IgM Serum
- 642 - SARS-CoV-2 IgG Serum
- 6400 SARS-COV-2 IgM/IgG Panel

Sample Collection

RT-PCR Nasopharyngeal Swab

- Collect and label nasopharyngeal 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 and IgG antibodies against SARS-CoV-2

- Serum collected via SST, allowed to clot, and spun down
- Serum (minimum 1.0 mL) is then poured into a standard 13x75mm transfer tube, labeled (patient's full name and DOB) per normal procedure, and sent to the lab.

Reporting

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

- TaqPath COVID-19 NP SWAB is reported as Detected and 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.
- The reportable range for IgM is 1.00-10.00 AU/mL and the reportable range for IgG is 0.20-100.0 AU/mL.

Test Name	Test Result	Interpretation	Footnotes
Infectious Disease Tests			
TaqPath COVID-19 NP 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.	9
SARS-CoV-2 IgM Serum	<1.00 AU/mL Negative	A result less than 1.00 AU/mL is considered to be negative. For samples with concentrations near the cut-off point, follow-up tests should be performed. 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.	10
SARS-CoV-2 IgG Serum	41.46 AU/mL Positive	A result greater than or equal to 1.00 AU/mL is considered to be positive. For samples with concentrations near the cut-off or positive, follow-up tests should be performed. 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.	11

Assay Limitations

RT-PCR testing

This test has been validated but FDA's independent review of the validation is pending. This test is performed as a laboratory developed test; independent review of the validation under the FDA's Emergency Use Authorization (EUA) authority will be performed according to current guidance requirements. We will continue to follow federal and state requirements for both notification of results and any confirmatory testing that is required by another agency. 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. Results should be used in conjunction with clinical findings, and should not form the sole basis for a diagnosis or treatment decision. Methods: TaqPath COVID-19 NP SWAB: TaqPath SARS-CoV-2 Multiplex RT-PCR Assay IVD

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. This testing has not been reviewed by the FDA, but the manufacturer and our laboratory have notified the FDA that these tests have been validated in accordance with Section IV.D. of the FDA's "Policy for Diagnostic Tests for Coronavirus Disease-2019 (COVID-19) during the Public Health Emergency", and both the manufacturer (Diazyme) and our laboratory are listed on the FDA website as offering tests under this policy. 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

1. Hirk, Rainer & Kastner, Gregor & Vana, Laura. (2020). Investigating the dark figure of COVID-19 cases in Austria: Borrowing from the deCODE Genetics study in Iceland. 10.13140/RG.2.2.18427.05928.
2. Day Michael. Covid-19: four fifths of cases are asymptomatic, China figures indicate BMJ 2020; 369 :m1375
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);
4. Guo L et al. Profiling early humoral response to novel coronavirus disease (COVID-19). Clin Infect Dis. 2020 Mar 21 (epub).
5. Okba NMA, Müller MA, Li W et al. Severe acute respiratory syndrome coronavirus 2–specific antibody responses in coronavirus disease 2019 patients. Emerg Infect Dis. 2020 Jul (epub).

877.425.1252 bostonheartdiagnostics.com

bostonheart diagnostics®