# COVIANT™

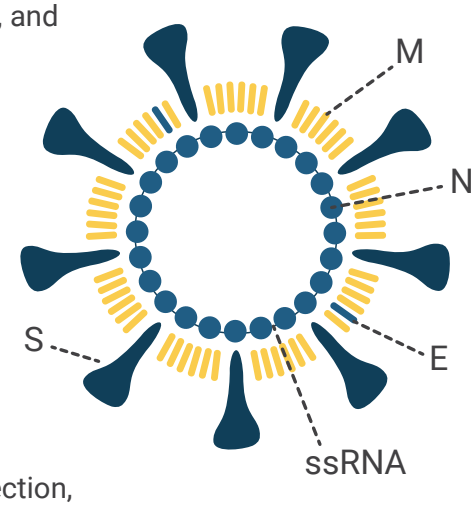
## COVID-19 ANTIBODY TEST

Qualitative Detection of the Novel Coronavirus SARS-CoV-2 IgG Antibody in Human Blood

Interpace Diagnostics®

# SARS-CoV-2 (COVID-19) Antibody Testing

**COVIANT™** is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG antibodies to the novel coronavirus SARS-CoV-2 in human plasma and serum. Coronaviruses, such as SARS-CoV-2 which is responsible for the COVID-19 disease, are composed of single strand RNA and several protein antigens including the spike (S), envelope (E), membrane (M), and nucleocapsid (N) proteins.[1] These proteins are antigenic and can trigger a humoral immunologic response during infection.[2]

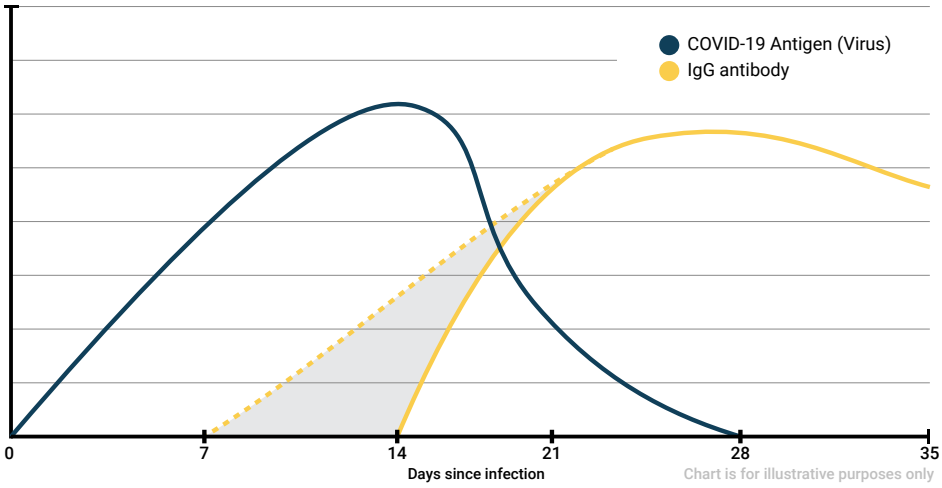



When a person is exposed to SARS-CoV-2 the virus may be able to gain entry into the body, usually through the upper airway where it then enters the lungs. Infection may follow and can at first be present without symptoms, followed in a proportion of cases by active disease, often in the form of upper or lower respiratory tract involvement (e.g., fever, coughing, shortness of breath).[3]

The time from first exposure to manifestation of symptoms can vary from 7 to 14 days or, on occasion, longer.[2] During this asymptomatic phase of infection, the affected individual can actively spread the virus despite feeling relatively well.[4] The asymptomatic stage of disease in a subset of patients will be followed by the symptomatic stage. While most patients will recover, a small minority of patients, usually older than 60 years old and/or with coexistent illnesses or immunocompromised states, can become extremely ill and suffer mortality.[5]

As the COVID-19 infection progresses during the asymptomatic and symptomatic phases, the host will mount an immunologic response to various viral proteins by the formation of antibodies which act to antagonize and reverse infection. IgG is the most abundant antibody produced and the presence of this antibody to the SARS-CoV-2 antigen is an indication that the patient has been exposed to the virus. At this time, however, understanding of the long-term immunity offered by IgG to the COVID-19 disease is limited.[2,6]

## Variation of the Levels of SARs-CoV-2 RNA Antigen and IgG After Infection[7]




# Interpace Diagnostics Testing for Detection of COVID-19 Antibodies

**COVIANT™** testing for the SARS-CoV-2 (COVID-19) IgG is performed from a standard blood sample. Tubes must contain a minimum of 2 mL of cell-free EDTA plasma [lavender cap] or 1 mL serum [red or gold caps]. Testing is completed within 3 days and results are transmitted by fax or electronically. The assay is qualitative and based on the capacity to distinguish between relatively high and low levels of antibody.

IgG antibodies to SARS-CoV-2 (COVID-19) are detected by ELISA using microwells coated with the structural protein of COVID-19. The patient's blood sample is placed into the microwell and incubated. If specific antibodies are present they will be captured and immobilized by binding to the antigen coated on the microwell. Following a wash step, bound specific antibodies are then detected by the addition of an enzyme labeled anti-human IgG (rabbit) catalyzing a color reaction. The amount of color produced correlates to the amount COVID-19 IgG antibodies in the patient's blood.

# Test Performance[7]

## Analytical Accuracy

The analytical accuracy for tests run by Interpace Diagnostics was determined within a cohort of 29 specimens. There was 100% agreement with 100% sensitivity and 100% specificity compared to a gold standard reference lab's performance utilizing the same EUROIMMUN test kit.

| | KNOWN IgG Status | | |
|---|---|---|---|
| | Positive | Negative/Borderline | Total |
| **Positive** | 16 | 0 | 16 |
| **Negative/Borderline** | 0 | 13 | 13 |
| **Total** | 16 | 13 | 29 |
| **% Agreement** | 100% | | |
| **Sensitivity** | 100% | | |
| **Specificity** | 100% | | |

## Clinical Accuracy

The clinical accuracy for tests run by Interpace Diagnostics was also determined using specimens with known COVID-19 disease status established by PCR analysis. Test results demonstrated 90% agreement with 84% sensitivity and 100% specificity. These results are very favorable when compared to the EUROIMMUNE test kit stated performance for samples >10 days of 80% sensitivity and 98.5% specificity.

| | KNOWN Diagnostic PCR | | |
|---|---|---|---|
| | Positive | Negative | Total |
| **Positive** | 16 | 0 | 16 |
| **Negative/Borderline** | 3 | 10 | 13 |
| **Total** | 19 | 10 | 29 |
| **% Agreement** | 90% | | |
| **Sensitivity** | 84% | | |
| **Specificity** | 100% | | |

# Additional Information and Limitations

Interpace Diagnostics is a CLIA-certified, CAP-accredited, and New York state licensed reference laboratory performing high-complexity *in vitro* diagnostic molecular testing for clients throughout the United States and the world. Laboratory testing is carried out to the highest standard with an active ongoing quality management program to deliver best-in-class results. All testing is performed with careful attention to positive and negative controls constantly overseen by internal and external proficiency testing programs.

## Disclaimers

Our understanding of the COVID-19 disease is evolving and not yet fully achieved. This understanding also applies to the biology and clinical significance of antibody formation and function. Test results should not be the only basis for clinical decision-making. Also, please note that patients with lowered immunity are especially susceptible to SARS-CoV-2 (COVID-19) infection and may exhibit low or no antibody responsiveness.

- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions
- The sensitivity of the test early after infection is unknown
- A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay
- False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection
- For *in vitro* diagnostic use under emergency use authorization only. Interpace Diagnostics is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high-complexity tests

### References


1. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. *Nat Rev Microbiol*. 2019;17(3):181-192.
2. Guo L, Ren L, et al. Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). [epub ahead of print, 2020]. *Clin Infect Dis*. doi: 10.1093/cid/ciaa310.
3. He F, Deng Y, et al. Coronavirus disease 2019: What we know? [epub ahead of print, 2020]. *J Med Virol*. doi: 10.1002/jmv.25766.
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5. Chen T, Dai Z, et al. Clinical characteristics and outcomes of older patients with coronavirus disease 2019 (COVID-19) in Wuhan, China (2019): a single-centered, retrospective study. [epub ahead of print, 2020]. *J Gerontol A Biol Sci Med Sci*. doi: 10.1093/gerona/glaa089.
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7. Data on File.


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