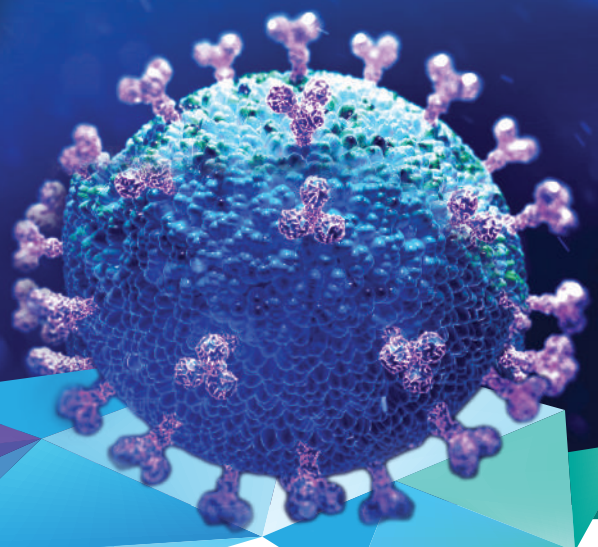
COVID-19 Testing Now Available for Employers!

IGeneX Inc.

Fast, accurate testing to determine the presence of the SARS-CoV-2 virus.



ARE YOUR EMPLOYEES SAFE FROM COVID-19?

As companies look to resume normal operations from the COVID-19 pandemic, it's clear that widespread and accurate testing of employees will play a critical role in ensuring a safe workplace. Break rooms, meeting rooms, and warehouse floors are just a few of the places where potentially at-risk employees come together and viruses can be transmitted.

IGeneX, a fully certified lab with a long history of performing molecular and immunological diagnostic testing, is pleased to offer testing for employers across the country. We offer a Real-time RT-PCR test that determines if an employee is currently infected with SARS-CoV-2, as well as two ImmunoBlot tests to determine if an employee's immune system has produced antibodies against the infection. The information from these tests can help determine if it's safe for an employee to return to work.

How to get your employees tested

Contact IGeneX at 1-800-832-3200 to learn about special pricing.

IGeneX will provide test kits, as well as guidance on how to collect specimens from employees and organize transportation of specimens to IGeneX.

Results will be provided between 24-48 hours after receipt of samples. Results will be reported to State agencies where required.

RECOMMENDED TEST PANEL

IGeneX studied 60 patients, of whom 25 were Real-time RT-PCR positive for SARS-Cov-2. Of the 25 positive patients, two had no symptoms. Of the 35 negative patients, two were very sick and tested positive for antibodies to SARS-CoV-2. Based on this data, we recommend the COV2 SARS-CoV-2 COMPLETE PANEL 2, which includes Real time RT-PCR (C100) and antibody testing (COV1).

Contact IGeneX today at 1-800-832-3200 to get started!

TEST RESULTS & INTERPRETATIONS

C100 SARS-CoV-2 RT PCR

CPT CODE: U0003

Limit of Detection: 2500 (cp/mL)

- A positive result is considered definitive evidence of infection
- If no viral sequence is present, amplification will not occur, resulting in a negative result

A negative result means that no SARS-Cov-2 RNA was detected in the sample because it was either absent or below the limit of detection. Therefore, test results need to be considered in the context of employee symptoms and exposure history.

C400 IMMUNOBLOT IgG

CPT CODE: 86769

Sensitivity: In a study, 79.3% of patients had IgG antibodies by the 36th day (range 7-36 days) after their Real-time PCR was positive. This is based on a study on 44 samples from 29 patients positive by Real time RT-PCR for SARS-CoV-2. **Specificity:** 99.5% (n=205)

- A sample is considered positive if two of the four bands are present: 75, 58, 50 and 25 kDa
- A positive result suggests exposure to the virus and the patient is recovering/or recovered
- Negative: Not exposed to SARS-CoV-2 virus (or does not make antibodies)

Cross reactivity to other Coronaviruses has not been tested.

COV1 IMMUNOBLOT PANEL 1 IgM/IgG

CPT CODE: 86769 X 2

Sensitivity: In a study, 86.2% of patients had antibodies by the 36th day (range 7-36 days) after Real-time PCR was positive. 6.9% had IgM antibodies, 27.6% had IgM and IgG antibodies, and 51.7% had IgG antibodies only. This is based on a study on 44 samples from 29 patients positive by Real time RT-PCR for SARS-CoV-2. **Specificity:** 99.5% (n=205)

- A sample is considered positive if two of the four bands are present: 75, 58, 50 and 25 kDa
- IgM Positive: Recent exposure to SARS-CoV-2 virus (Active disease)
- IgM and IgG Positive: Converting from IgM to IgG (Active infection)
- IgG Positive: Exposed and has already converted from IgM to IgG (Recovering)
- Negative: Not exposed to SARS-CoV-2 virus (or does not make antibodies)

Negative results do not preclude SARS-CoV-2 infection as IgM antibodies may not be detected in the first few days of infection. Cross reactivity to other Coronaviruses has not been tested.

WHY AN IMMUNOBLOT IS A SUPERIOR TEST

In an ImmunoBlot, purified SARS-CoV-2 specific antigens are sprayed as straight lines onto a nitrocellulose membrane and cut into 3mm wide strips. The antigen strip is incubated with patient serum in each trough of an incubation tray. If specific antibodies to SARS-CoV-2 antigens are present, they will bind to the corresponding antigen bands. After washing away unbound antibodies, the bound SARS-CoV-2 specific antibodies are detected with alkaline phosphatase conjugated goat anti human IgM or IgG antibody. A dark purple precipitate will develop on the antigen-antibody complexes. Bands are visualized and scored for intensity relative to the positive and negative controls.

Currently many Lateral flow assays and ELISA tests for detection of SARS- CoV-2 antibodies in human blood samples are available. The Lateral Flow tests are rapid and only require a drop of blood. However, they lack sensitivity and specificity. ELISA tests currently on the market are claiming high specificity, however there is very little information about sensitivity of these tests. Based on the studies to date, the ImmunoBlots prepared using recombinant proteins have superior specificity and sensitivity compared to ELISA and Lateral Flow assays.

CONTACT IGENEX

IGeneX is pleased to be one of the few CLIA certified labs that offers both PCR and antibody tests for COVID-19. For more information on our testing, please contact us today or visit igenex.com to learn more.

IGeneX, Inc. 556 Gibraltar Dr. Milpitas, CA 95035 | 1-800-832-3200
igenex.com

IGeneX Inc.