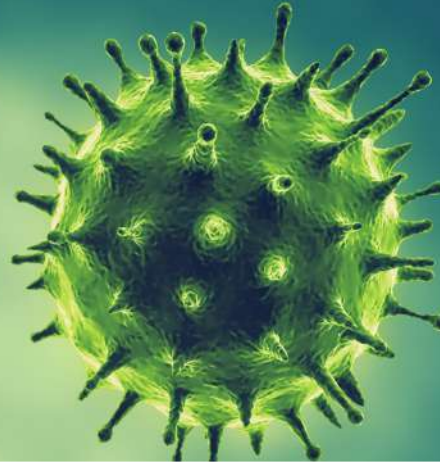


# VIBRANT COVID-19 IMMUNE CHECK



## Vibrant COVID-19 Immunecheck

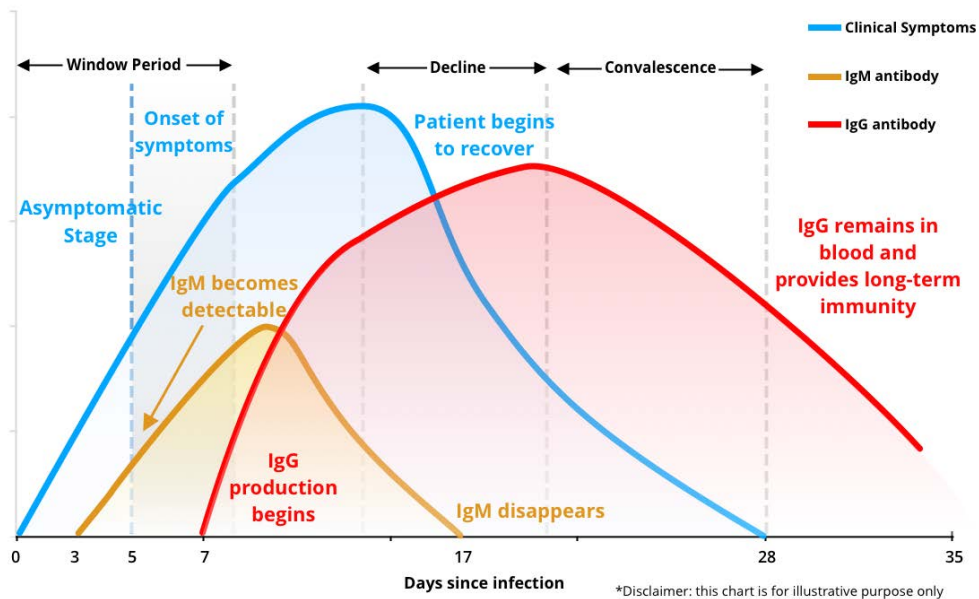
The CDC reports that the following symptoms may appear 2-28 days after exposure:

- Coughing
- Fever
- Shortness of breath
- Sore throat
- Fatigue
- Body aches
- Headaches
- Gastrointestinal distress
  - Diarrhea
  - Abdominal cramping



## Why Test Antibodies?

- ✓ Antibodies have been found to be a highly sensitive biomarkers in infectious disease diagnosis, previous studies on SARS, MERS and more recently the ones on SARS-CoV2 have shown IgM antibodies to appear about the 3rd day from infection and IgG antibodies appear after 8 days. Profiling an individual's antibody response is the only way to determine infections with few or no symptoms.
- ✓ Studies in China,<sup>1</sup> the country of origin, have shown that antibody tests have 100% sensitivity in COVID19 disease population. The serology shows the *modulation of the immune system within days of infection and patterns from Day 0 to day 5 have been documented.*



Reference 1: Molecular and serological investigation of 2019-nCoV infected patients: implication of multipleshedding routes



## Vibrant COVID-19 Testing

- ✓ Vibrant has developed a novel test for COVID-19. This test is a highly sensitive and accurate finger-prick dried-blood assay for COVID-19 viral antibodies.
- ✓ Our test was internally developed and validated according to FDA EUA requirements. The independent review of this validation by the FDA is pending. This test does not require confirmation by CDC prior to reporting results

**Please Note:**

*A patient cannot order their own tests  
A doctor's requisition is required for all testing*



## What Does the Vibrant COVID-19 Test Include?



*IgG, IgA and IgM antibodies against the following antigens are tested:*

- ✓ **S1 Spike protein** - The S1 subunit of the ectodomain mediates binding of the virion to host cell-surface receptors through its receptor-binding domain (RBD)
- ✓ **Receptor Binding Domain** - Part of the S1 Spike subunit that actually binds to the ACE2 receptor of human epithelial cell
- ✓ **S2 Spike protein** - The S2 subunit fuses with both host and viral membranes, by undergoing dramatic structural changes
- ✓ **Nucleoprotein** - Packages the positive strand viral genome RNA into a helical ribonucleocapsid (RNP) and plays a fundamental role during virion assembly through its interactions with the viral genome and membrane protein M. Plays an important role in enhancing the efficiency of subgenomic viral RNA transcription as well as viral replication.



*Test Methodology:*

**Qualitative chemiluminescence-based antibody detection using an array of 4 COVID-19 antigens.**



## Quick Interpretation of Results

**Advantage of testing all three types of antibodies:**

Profiling an individual's antibody response is the only way to determine infections with few or no symptoms and allow for better interpretation as below:

| IgM | IgG/IgA | Interpretation   |
|-----|---------|--|
| NEG | NEG     | Patient may not be infected or in the window of infection if DNA results are positive from NP or fecal swabs. Consider follow up within few days if symptoms persist or refer patient out for a confirmatory NP swab test. |
| POS | NEG     | Patient may be in the early stage of infection   |
| POS | POS     | Patient may be in the active phase of infection  |
| NEG | POS     | Patient may be in the late or recurrent stage of infection   |

### Regulatory Statement

This test has not been reviewed by the FDA.

- 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 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.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.