

Speed Without Compromise

- ✓ Lab-quality performance
- ✓ Results in 5 minutes
- ✓ Test almost anywhere



An important tool to understand **immune response**.

The LightDeck COVID-19 Total Antibody Test helps clinicians assess an individual's immune response. An antibody test can reveal if a person had COVID-19 even if they were asymptomatic or never diagnosed with the disease. The LightDeck assay is designed to detect the receptor-binding domain (RBD) of the S1 spike antigen to detect antibodies that block the virus entry into the cells. This assay design is aligned with the multiple vaccines that target or include the SARS-CoV-2 S1 RBD, with the goal to elicit antibodies in vaccinated subjects. The spike protein and particularly the RBD are the most common target of vaccine designs.

HOW IT WORKS

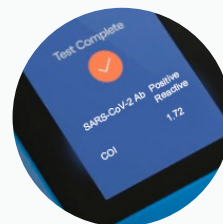
Simple procedure.
Results in **5 minutes**.



1.
Add sample



2.
Insert cartridge



3.
Results in 5 minutes

Lab-Quality Performance



Sensitivity = 98.2%

Sensitivity, or positive percent agreement (PPA), describes how well an assay correctly detects antibodies when the sample is positive.

Specificity = 99.4%

The LightDeck assay reported 318 True Negative and 2 False Positives from 320 PCR+ samples. A low false positive rate allows clinicians to deliver highly accurate results about immune response to the SARS-CoV-2 virus.

With specificity of 99.4%, you can expect a false positive in only 6 out of 1000 LightDeck tests. In contrast, a lateral flow test with specificity of 95% means 50 out of 1000 tests report a false positive.

TESTING IN HOT SPOTS

 **Hospitals**
Doctors, nurses and staff


 **Prisons and Jails**
Staff and inmates


 **Nursing homes**
Residents and staff

 **Community**
Outbreaks and universities

CRITICAL ROLE OF ANTIBODY TESTING

 **Determine past infection**
Determine whether a person had been infected by SARS-CoV-2.

 **Assess seroprevalence**
Determine the percentage of people in a community had a prior infection

 **Assess immune response**
Help identify adaptive immune response to infection or vaccination

The LightDeck COVID-19 Total Antibody Test is for in vitro diagnostic use only. For prescription use only. The LightDeck COVID-19 Total Antibody Test has completed the Section IV.D notification process under FDA's "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)."