Advanced Medical Services

1-866-531-6413

COVID-19 Antigen Test

Antigen Test at the **Point of Care**
Rapid 10-Minute Test Using **Nasopharyngeal** Swab
Product Code: COV-19C20CS

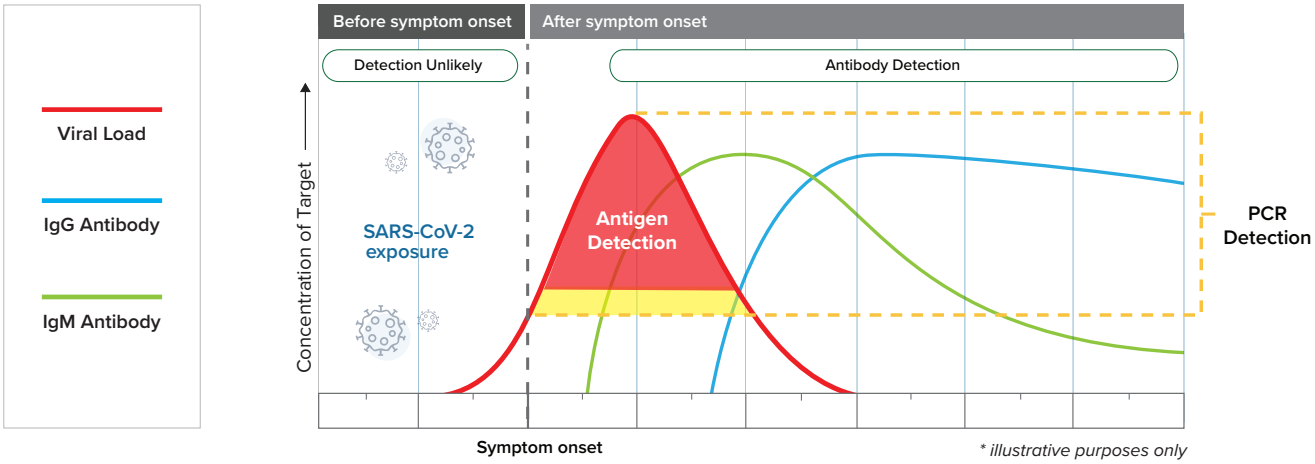
Authorized by FDA Under an **EUA** | **CLIA WAIVED**

Eligible for
Medicare Reimbursement CPT 87811

The rapid **COVID-19 Antigen Test** is **FDA Emergency Use Authorized**, **CLIA Waived,** and allows for an efficient, accurate, and cost-friendly method of detection at the **Point-of-Care**. In just 10 minutes, the test is able to detect the SARS-CoV-2 nucleocapsid protein antigen through visual interpretation of colored lines.The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in **nasopharyngeal** swab specimens during the acute phase of infection. This test is intended for individuals suspected of COVID-19 within five days of symptom onset.

ICD-10 Codes	Description
U07.1	COVID-19
Z20.828	Contact with & (suspected) exposure to other viral communicable diseases
Z11.59	Encounter for screening for other viral diseases
Z03.818	Encounter for observation for suspected exposure to other bilogical agents ruled out
R50.9	Fever, unspecified
R06.02	Shortness of breath
R05	Cough
J22	Unspecified acute lower respiratory infection

SARS-CoV-2 Testing Timeline



Clinical Performance

The clinical performance of the Antigen Test was compared to previously confirmed positive and negative COVID-19 nasopharyngeal (NP) swab specimens validated with Ct value by the FDA EUA RT-PCR as a comparator method. The results showed that the Antigen Test had a 88% Positive Percent Agreement (PPA) and a 100% Negative Percent Agreement (NPA).

Ordering Information

Product Code	Product Name	Tests per Kit	Kit Size (cm)	Kits per Carton
COV-19C20CS	CareStart COVID 19 Antigen Test Cassette	20	22.9 x 16.5 x 8.3	32

**Estimate was determined based on previous Medicare Reimbursements for Point of Care COVID-19 Antibody Tests.
To learn more contact Advanced Medical Services at **1-866-531-6413,** or email us at **ppe@advancedmedcorp.com**

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.