



## Standard™ Q COVID-19 Ag Test 2.0

CORONAVIRUS (COVID-19) ANTIGEN TEST

EUA approved for use in High, Moderate,  
and CLIA-waived laboratories

# Standard™ Q COVID-19 Ag Test 2.0 offers detection of active infection caused by SARS-CoV-2 in as little as 20 minutes

Fast and accurate detection of SARS-CoV-2 is important when diagnosing patients suspected of having COVID-19.

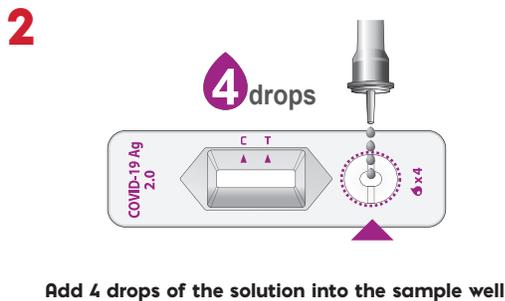
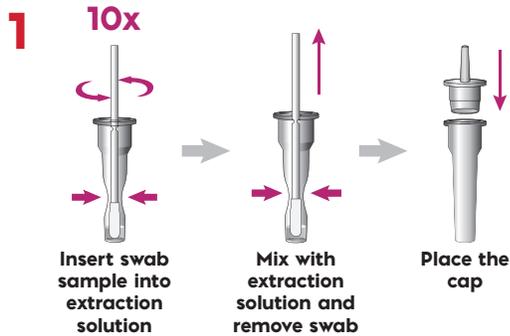
- Standard Q COVID-19 Ag Test 2.0 provides direct detection of SARS-CoV-2 antigens from nasal swabs
- This test can be used for diagnosis of patients suspected of having a COVID-19 infection, individuals without symptoms, or serial screening testing
- Quick, reliable diagnostic tests can help impact patient care, providing physicians with actionable results

# Standard™ Q COVID-19 Ag Test 2.0

## Provides the following:

- Detection of SARS-CoV-2 antigens indicates an active infection
- Nasal swab and External Controls provided in the kit
- No need for instrumentation or special equipment

## Standard™ Q COVID-19 Ag Test 2.0 Procedure Steps



## Product Specifications

The Standard™ Q COVID-19 Ag Test 2.0 is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first six (6) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

### Turnaround Time

20-30minutes

### Sample Type

Nasal swabs

### Kit Storage

2-30 C

### Performance

**93.2%** Relative Sensitivity

**100%** Relative Specificity

### Catalog Number

Standard™ Q COVID-19 Ag Test 2.0 — 09COV174D

Standard™ Q COVID-19 Ag Control Swab — 10COVC14J

### CPT Code

87811

### Test Kit Size

25 tests per kit

5 pos/neg control swabs

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigens, which is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. All negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Testing of anterior nasal swab specimens is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, The emergency use of this product 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 declaration is terminated or authorization is revoked sooner.

## Ready to get a handle on COVID-19 testing? Let's talk.

Contact a specialist at 1-888-763-6769.

[meridianbioscience.com/contact-us](https://meridianbioscience.com/contact-us)

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**SD BIOSENSOR**