



Rapid SARS-CoV-2 Antigen Testing for Qualifying Organizations

BACKGROUND

In an effort to broaden the availability of COVID-19 testing in South Dakota, the South Dakota Department of Health (SDDOH) is considering purchase and strategic placement of the following antigen test and required equipment to qualifying organizations:

QIAGEN QIArearch SARS-CoV-2 Antigen Test. The QIArearch SARS-CoV-2 Antigen Test is a rapid diagnostic test that detects SARS-CoV-2, the virus that causes COVID-19, from upper respiratory specimens collected with a swab. This antigen test provides results in 2-15 minutes. Positive results indicate the presence of viral antigens while negative results are treated as presumptive and do not rule out SARS-CoV-2 infection. Individuals with relevant symptoms that test negative using any COVID-19 antigen test may need to be retested using a molecular test based on the recommendation of a healthcare provider.

QIAGEN Access eHub. The QIArearch SARS-CoV-2 Antigen Test is performed on the QIAGEN Access eHub. The eHub is a digital, portable device capable of performing eight QIArearch SARS-CoV-2 Antigen Tests at one time. The eHub can perform as many as 30 tests in an hour and as many as 250 tests in a typical workday.

PROJECT TIMELINE

SDDOH anticipates availability of QIAGEN antigen testing supplies and equipment in early December with placement by late December. However, these estimates are subject to change based on FDA EUA approval timeline and resource availability.

PRIORITY GROUPS FOR QIAGEN RESOURCES

SDDOH currently prioritizes the following groups for placement of QIAGEN antigen tests and equipment. However, groups not listed below will also be considered for test and equipment placement.

- Health care providers in geographic locations with unmet COVID-19 testing needs
- Federally qualified health centers and other clinics with unmet COVID-19 testing needs that serve rural and/or vulnerable populations
- Front-line medical providers and/or facilities not covered above
- First responders including law enforcement, EMS providers, etc.
- Correctional facilities
- Institutions of higher education
- Commercial food manufacturing, agriculture, and other critical infrastructure not listed above

PARTICIPATION REQUIREMENTS

Organizations must meet the following requirements to qualify for placement of the QIAGEN eHub and antigen testing supplies:

- Have an existing CLIA Certificate of Waiver or be eligible to obtain a [CLIA Certificate of Waiver](#)
- Identify an appropriate location with your facility to perform testing
- Train one or more adults to perform antigen testing using the QIAGEN eHub

- Obtain and appropriately use personal protective equipment (PPE)
- Perform testing in strict accordance with the manufacturer’s instructions
- Offer testing at no cost to consenting participants (consent must be obtained before testing)
- Immediately dispose of waste, including soiled PPE, generated by antigen testing in a manner that prevents any further contact with the waste
- Report all antigen test results to the SDDOH within 24 hours of antigen testing using the [confidential disease reporting website](#) or another method approved by the SDDOH
- Maintain supply inventory and order more tests from the SDDOH or manufacturer as needed

Organizations that want to be considered for QIAGEN eHub and antigen test placement must respond by November 25, 2020. Organizations must complete the form below and submit the completed document to Laurie.Gregg@state.sd.us or Tim.Southern@state.sd.us. Resources may be limited so please apply as soon as possible for consideration.

QIAGEN Access SARS-CoV-2 Antigen Test and Equipment Request Form					
Organization Name:					
Organization Address:					
Does the organization have a CLIA Certificate of Waiver?		Yes	No	Does the organization need additional information about obtaining a CLIA Certificate of Waiver ?	
				Yes	No
Organization Point of Contact (POC) name:					
POC Phone Number:					
POC Email Address:					
Population to be served (see above priorities for examples):					
Anticipated test volume per week:					