

Infection Prevention and Lab Call

September 17, 2020

NOTE: Recording starts partway through call



South Dakota Confidential Disease Report

South Dakota Department of Health
Office of Disease Prevention

[SDCL 34-22-12](#) and [ARSD 44:20](#) [Reportable Disease List](#)

OPTION #1

FOR FACILITIES PERFORMING IN-HOUSE ANTIGEN TESTING

Instructions:

- Please fill out the form as completely as possible before submission.
- Use the Tab key to move to the next field.
- Only press the Enter key when you are ready to submit the form.
- Note: Fields with an asterisk(*) are required.

Other disease reporting options:

Phone: 1-800-592-1861 or 605-773-3737 for a disease surveillance person during normal business hours
Fax: 605-773-5509
[Outbreak Report](#) [Weekly Influenza Report](#)

Patient Information

Report Type: New Update

Report Date: 9/2/2020

*Last Name: *First Name: Middle:
Street Address:
Mailing Address: (if different from Street) Zip:
*City: State: County:
Home Phone: Other Phone: Work Cell
*Race: *Ethnicity:
Occupation: *Date of Birth: (mm/dd/yyyy) *Gender:
Email Address:

Disease Information

*Disease or Condition: -- Select -- Category I Diseases are in RED, Category II Diseases are in BLUE

Attending Health Care Provider

First Name: Last Name: Suffix:
Phone: Ext:
Comments: (0 of 2000 max)

Person Reporting

*First Name: *Last Name: Suffix:
*Phone: Ext: Email:
*Facility Name: Other, not listed
To add or change your facility name please spell out the name(no abbreviations) in the text box below before submitting this form.
New Facility Name:

SUBMIT FORM

<https://apps.sd.gov/ph93morbidity/secure/index.aspx>

- **All** Positive and Negative Antigen tests
Need to be reported by facilities
- Fill out as many fields as possible
- Timely data entry – Report immediately
- Click submit – avoid print and fax
 - Secure Form
- Support staff can report this information

Disease Information

*Disease or Condition: *Coronavirus Disease 2019 (COVID-19)
Date of Onset: (mm/dd/yyyy)
*Lab Test Performed? Yes No Name of Lab:
Lab Test Name: Antigen test for SARS-CoV-2
Specimen Source: Date Collected: (mm/dd/yyyy)
Lab Test Result: Lab Report Date: (mm/dd/yyyy)
Facility Ordering Test:
*Was Patient Hospitalized? Yes No
Outcome: Survived Expired Date of Death: (mm/dd/yyyy)

Treatment Information



SOUTH DAKOTA DEPARTMENT OF HEALTH

OPTION #2

FOR FACILITIES PERFORMING IN-HOUSE ANTIGEN TESTING

- **All** Positive tests reported Immediately via Option #1 on the disease reporting webpage
- All Negative tests get reported via Excel spreadsheet
- **Steps**
- E-mail: Caleb.VanWagoner@state.sd.us with request to submit Excel spreadsheet
 - Caleb will work with facility to submit information to set up Secure File Transfer Protocol (SFTP).
 - (Facility Information, CLIA # and/or OID #, etc)
 - SD DOH will set up SFTP location that is individual to your facility
 - SD DOH will provide Excel Spreadsheet for facilities to fill out, and submit with negatives
- This is still a timely process. SD DOH is currently working on streamlining this process, more information will be shared once finalized.

Q & A

Q: Do I have to report test results from specimens I send to another lab (i.e. Avera, Sanford, LabCorp) to the SD DOH?

A: No, laboratories provide these results to the SD DOH on your behalf

Q: My facility has an antigen testing machine (BD Veritor, or Quidel Sofia). Do I have to report these test results to the SD DOH?

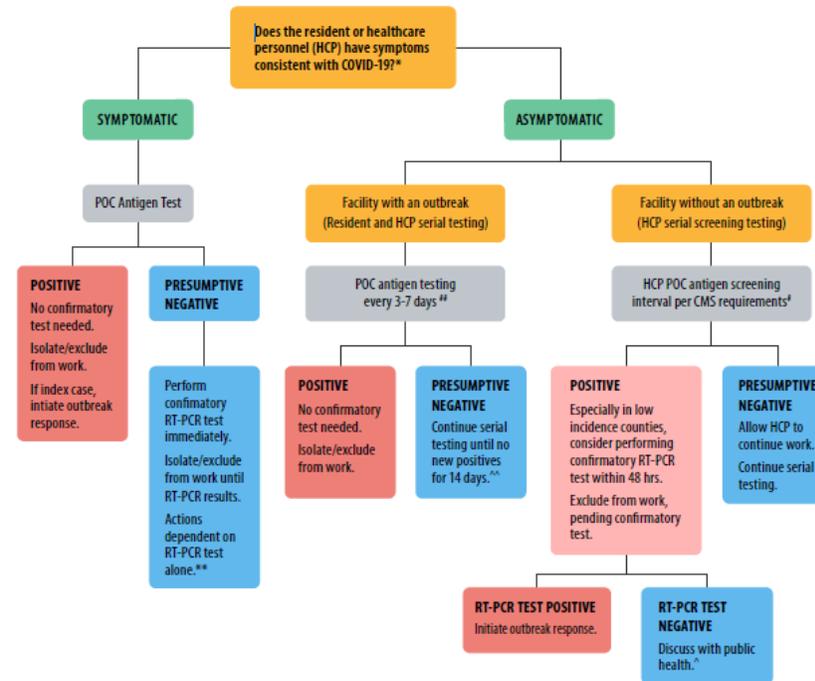
A: YES, All positive and negative test results need to be reported via the disease reporting webpage, or submitted via SFTP as described in previous slides

Why is this important?

<https://apps.sd.gov/ph93morbidity/secure/index.aspx>

CONSIDERATIONS FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES

CONSIDERATIONS FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES



This algorithm should be used as a guide, but clinical decisions may deviate from this guide if indicated. Contextual factors including community incidence, characteristics of different antigen testing platforms, as well as availability and turnaround times of RT-PCR, further inform interpretation of antigen test results.

RT-PCR: reverse-transcriptase polymerase chain reaction
POC: point-of-care
HCP: healthcare personnel

Index case: a newly identified case of SARS-CoV-2 infection in a resident or HCP in a nursing home facility with no known infections of SARS-CoV-2 infection in the previous 14-day period.

COVID-19 outbreak response in a nursing home is triggered when one nursing home-onset SARS-CoV-2 infection in a resident or one HCP SARS-CoV-2 infection.

* Asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing do not need to be retested. If an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

** Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if retesting by RT-PCR is warranted.

† CMS recommendations for testing asymptomatic HCP in facilities without a case
‡ CDC guidance on testing residents of nursing homes, CDC guidance on testing HCP

§ In discussion with the local health department, community incidence and time between antigen test and RT-PCR test can be utilized to interpret discordant results and determine when HCP can return to work.

¶ If an antigen test is presumptive negative in a facility with an outbreak, residents should be placed in transmission-based precautions or HCP should be allowed to continue working while monitoring for symptoms.



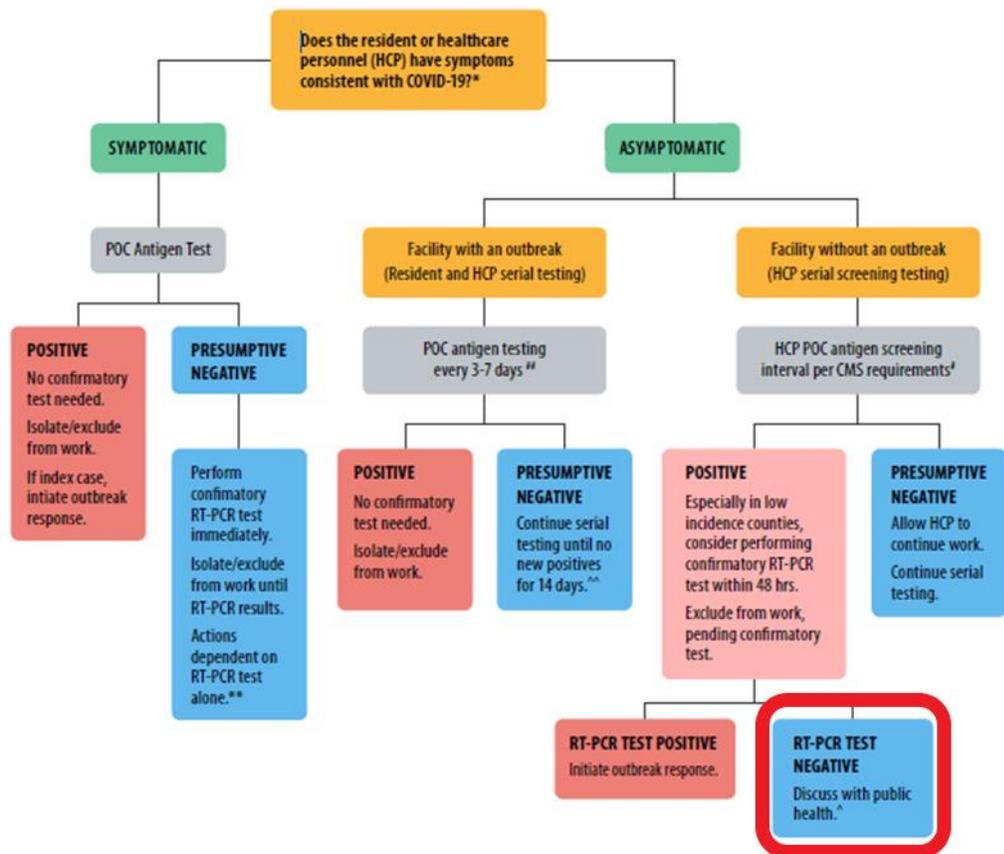
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cdc.gov/coronavirus

<https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf>



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SOUTH DAKOTA DEPARTMENT OF HEALTH

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<p>Process and Documentation of Informed Consent for Subjects Involved in...</p> <p>This course will provide information on many aspects of informed consent and focuses on the unique challenges with special pathogen research, including the process of informed consent, general...</p> <p>NETEC</p> <p>Self-paced FREE 0.75 credits</p>	<p>A Balance of Safety and Efficiency: Pearls and Pitfalls for COVID-19 Testing...</p> <p>Describe various institutional testing strategies utilized during COVID-19. Discuss the planning and processes that support pre-procedural testing. Identify unique challenges related to testing and...</p> <p>NETEC</p> <p>Started Aug 28, 2020 FREE 1 credit</p>	<p>Approach to Anticoagulation in COVID-19: Evidence and Practice Patterns</p> <p>Articulate the pathophysiology of the hypercoagulable state seen in COVID-19, discuss the current evidence surrounding anticoagulation in COVID-19, and describe institutional practice patterns for...</p> <p>NETEC</p> <p>Started Aug 28, 2020 FREE 1 credit</p>	<p>A Steep Curve: Managing the Surge of COVID-19 Patients Requiring Dialysis</p> <p>In this course we will identify the importance of assessment and on-the fly planning when caring for an unplanned influx of patients needing dialysis.</p> <p>NETEC</p> <p>Started Aug 14, 2020 FREE 1 credit</p>
<p>FREE</p>	<p>FREE</p>	<p>FREE</p>	<p>FREE</p>

Statewide Priority Populations for SARS-CoV-2 Testing

It is a statewide priority that ALL individuals with symptoms of COVID-19 be tested for SARS-CoV-2 with the recommendation from a health care provider

- Hospitalized individuals
- Healthcare workers, first responders, and active military
- Critical infrastructure workers in food manufacturing and agriculture
- Individuals in communal living settings like long-term care facilities
- Underinsured or uninsured individuals
- Low-income individuals or individuals unable to pay for testing
- Homeless individuals

SDPHL COVID-19 Testing Priorities

- Symptomatic hospitalized patients
- Symptomatic healthcare workers, first responders, and active military
- Symptomatic individuals in congregate living settings like long-term care facilities
- Symptomatic individuals with no way to pay for testing
- Asymptomatic participants in state-sponsored sentinel surveillance:
 - Long-term care (staff and residents)
 - K-12 schools (adults)
 - Tribes (October 1, 2020)

FDA EUA Updates

- FDA has issued Emergency Use Authorization for the following:
 - 162 (2): Molecular Diagnostic Tests for SARS-CoV-2
 - 45 (2): Serological Tests
 - 35: Molecular-Based Laboratory Developed Tests for SARS-CoV-2
 - 4: Antigen Diagnostic Tests for SARS-CoV-2
- This week, DOH will review the recent request for information released by the Office of the Assistant Secretary of Health
- On 9/24, DOH will review the Abbott BinaxNow SARS-CoV-2 antigen test

HHS Request for Information



FEDERAL REGISTER

The Daily Journal of the United States Government



- The Office of the Assistant Secretary for Health released a Request for Information on September 10, 2020
- The intent of the Request is to obtain information about the ability of CLIA-approved laboratories to provide additional COVID-19 testing capability if supplementary testing instruments from **Thermo Fisher Scientific** were made available.



SOUTH DAKOTA DEPARTMENT OF HEALTH

HHS Request for Information

The Office of the Assistant Secretary for Health released a Request for Information on September 10, 2020. The purpose of the RFI is to obtain information about the ability of CLIA-approved laboratories to provide additional COVID-19 testing capability if supplementary testing instruments from Thermo Fisher Scientific were made available.

Q: What laboratories should respond to the RFI?

A: CLIA-certified commercial, academic, medical center, and public health

laboratories [with the capability to perform high-complexity diagnostic testing]

HHS Request for Information

Q: What instruments are offered for SARS-CoV-2 testing by Thermo Fisher Scientific?

A: Nucleic acid extraction and real-time PCR equipment such as:

Nucleic acid extraction:

- Automated extraction: KingFisher Flex Purification System
- Manual extraction: Invitrogen Magnetic Stand-96

Real-time PCR:

- Applied Biosystems 7500, 7500 Fast, 7500 Fast Dx
- QuantStudio 5 Flex or 7 Flex

Thermo Fisher Scientific Instrumentation



KingFisher Flex
Nucleic Acid Purification
System



ABI 7500 Fast Dx
Real-Time PCR Instrument

HHS Request for Information

Q: What information should be included in the RFI?

A: HHS asks that you provide the following:

1. Do you represent a CLIA-certified or accredited laboratory?
2. What is your current laboratory testing capacity (e.g., installed base of platforms, throughput, level of personnel)?
3. What is your current ability to accession specimens and report out laboratory results in no less than 24-48 hours?
4. What level of additional capacity could your laboratory provide if additional testing instruments were made available?
5. What instruments and other equipment do you need?
6. What is your timeline for implementation of increased capacity if instrumentation is provided?

HHS Request for Information

Q: When is the deadline for RFI submission?

A: September 21, 2020

Q: Where can I find more information about the RFI?

A: Additional information can be found on the [Federal Register website](#) including [PDF](#)