2019 Novel Coronavirus (COVID-19)

South Dakota Department of Health

August 13, 2020

We will begin in just a few moments. Thanks!
This is an **emerging, rapidly evolving situation**. Information in this presentation is current as of August 12, 2020. Please check the South Dakota Department of Health website for the most current information and guidance.

[COVID.sd.gov](https://www.COVID.sd.gov)
Agenda

• Situation Update
• Laboratory Guidance
• Infection Prevention
• Community Mitigation
• Supply Chain Management
• On-going Communications
• Q&A Session

Note: Slides and a recording of the presentations will be posted to doh.sd.gov/news/COVID19/Calls.aspx following the webinar.
Situation Update
Coronavirus Situation (as of August 12, 2020)

- **International**
  - 20,162,474 confirmed cases
  - 737,417 deaths

- **United States** (50 states + DC)
  - 5,119,711 confirmed cases in U.S.
  - 163,651 deaths

- **South Dakota**
  - 9,815 confirmed cases in South Dakota
  - 147 deaths
  - 8,606 recovered
Epidemiologic “Epi” Curve of COVID-19 Cases, by Onset Date

As of August 12, 2020

Positive Cases by Date Reported to SD-DOH

Date Reported to SD-DOH

Positive Cases

Positive Cases

Date Reported to SD-DOH

Positive Cases

Date Reported to SD-DOH

Positive Cases

Date Reported to SD-DOH

Positive Cases

Date Reported to SD-DOH
COVID-19 Cases, by County

As of August 12, 2020
General Testing Recommendations

Medical providers are recommended to test individuals with signs and symptoms compatible with COVID-19 infection, including:

• Fever or chills
• Cough
• Shortness of breath or difficulty breathing
• Fatigue
• Muscle or body aches
• Headache
• New loss of taste or smell
• Sore throat
• Congestion or runny nose
• Nausea or vomiting
• Diarrhea

Testing of Close Contacts to Cases

- CDC recommends testing all close contacts to a COVID-19 case

- SD-DOH recommends the following be prioritized for tested following medical evaluation:
  - Hospitalized patients
  - Symptomatic individuals
  - Symptomatic close contacts to a COVID-19 case
  - Asymptomatic household close contacts to a COVID-19 case
  - Asymptomatic healthcare personnel and first responder close contacts to a COVID-19 case
  - Asymptomatic persons living or working in congregate settings close contacts to a COVID-19 case
    - Acute care, Mental health, Long-term care, correctional facilities, homeless shelters, educational institutions, mass gatherings, workplaces

Discontinuation of Isolation

Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions:

- At least 10 days* have passed since symptom onset and
- At least 24 hours have passed since resolution of fever without the use of fever-reducing medications and
- Other symptoms have improved.

*A limited number of persons with severe illness may produce replication-competent virus beyond 10 days, that may warrant extending duration of isolation for up to 20 days after symptom onset. Consider consultation with infection control experts. See Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance).

Persons infected with SARS-CoV-2 who never develop COVID-19 symptoms may discontinue isolation and other precautions 10 days after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.

Selected CDC Updates


Laboratory Guidance
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
K-12 Sentinel Surveillance

• Federal partners recommend that a minimum of \( 2\% \) of South Dakota’s resident population be tested for SARS-CoV-2 each month
  – This is approximately 18,000 tests each month

• South Dakota has set a goal to test at minimum the equivalent of 5\% of South Dakota’s population each month
  – This is a minimum of 44,400 tests each month

• SDDOH is building a sentinel surveillance program for public and private K-12 schools that will allow monthly testing of 5\% of our K-12 adult population
  – This is approximately 1,800 tests each month
K-12 Sentinel Surveillance

- Participation in K-12 sentinel surveillance is a voluntary process but is strongly encouraged.
- Private K-12 schools and public K-12 districts that want to participate in sentinel surveillance will enroll with the Department of Education.
- Enrollment information will be used to distribute educational materials, guidance documents, and specimen collection supplies to participating school districts.
K-12 Sentinel Surveillance

1. CDC-based guidance about K-12 sentinel surveillance
2. Personal protective equipment and guidance on how to use it
3. Specimen collection supplies and guidance on how to use them
4. Laboratory testing support at the state public health laboratory
5. Follow-up services such as case investigation and contact tracing
Antibody Testing for SARS-CoV-2

• **CDC** now recommends the use of a single antibody test if that test has a high specificity (99.5% or greater)

• CDC still recommends the use of a dual-test algorithm (orthogonal algorithm) for laboratories that use tests with specificity lower than 99.5%
**SARS-CoV-2 Antibody Testing at SDPHL**

**VIDAS SARS-CoV-2 IgM**
- FDA-EUA approval on 8/6/2020
- CLIA moderate/high complexity
- Qualitative assay
- Serum and plasma
- SDPHL will perform on the VIDAS3
- Verification is pending
- Implementation planned for 9/7

**Abbott SARS-CoV-2 IgG Assay**
- FDA-EUA approval on 4/26/2020
- CLIA moderate/high complexity
- Qualitative assay
- Serum and plasma
- SDPHL will perform on the Architect
- Verification is complete
- Implementation planned for 8/24
FDA EUA Updates

• Since the beginning of the COVID-19 response, FDA has issued Emergency Use Authorization for the following:
  – 138 (+7): Molecular Diagnostic Tests for SARS-CoV-2
  – 35:    Molecular-Based Laboratory Developed Tests for SARS-CoV-2
  – 2:      Antigen Diagnostic Tests for SARS-CoV-2

• There is growing interest nationwide in at-home tests and saliva tests for SARS-CoV-2.

• This week, SDDOH will provide a brief overview of FDA-EUA-approved antigen testing using the Quidel Sofia and BD Veritor

• SDDOH will also provide an overview of the Siemens line of SARS-CoV-2 total antibody assays
Antigen Testing: Instrumentation

Quidel Sofia SARS Antigen IFA

BD Veritor SARS-CoV-2 Rapid Test
Antigen Testing: Test Overview

**Quidel Sofia SARS Antigen IFA**
- CLIA waived
- Qualitative assay
- Nasal and nasopharyngeal specimens
- Direct testing from swab
- Detects the viral nucleocapsid antigen
- For use during acute infection
- Negative results are presumptive
- Negative results may need to be confirmed with a molecular assay

**BD Veritor SARS-CoV-2 Rapid Test**
- CLIA waived
- Qualitative assay
- Nasal swab specimens
- Direct testing from swab
- Detects the viral nucleocapsid antigen
- For use in first 5 days of symptoms
- Negative results are presumptive
- Negative results may need to be confirmed with a molecular assay
Siemens has been granted FDA-EUA approval for the following SARS-CoV-2 total antibody tests:

- ADVIA Centaur SARS-CoV-2 Total
- Atellica IM SARS-CoV-2 Total
- Dimension EXL SARS-CoV-2 Total Antibody Assay
- Dimension Vista SARS-CoV-2 Total Antibody Assay
Why so many Siemens total antibody tests?

- Siemens offers scalable solutions to fit the throughput needs of different size laboratories.
- Siemen’s lineup includes benchtop Centaur models all the way to the larger floor model Atellica and Dimension systems.
- Siemens offers a variety of technologies and chemistries to detect SARS-CoV-2 antibodies.
What about performance of Siemens SARS-CoV-2 antibody tests?

<table>
<thead>
<tr>
<th>FDA-EUA</th>
<th>Target</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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<tbody>
<tr>
<td>ADVIA Centaur</td>
<td>Spike</td>
<td>100%</td>
<td>99.8%</td>
<td>96.5%</td>
<td>100%</td>
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<tr>
<td>Atellica IM</td>
<td>Spike</td>
<td>100%</td>
<td>99.8%</td>
<td>96.7%</td>
<td>100%</td>
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<tr>
<td>Dimension EXL</td>
<td>Spike</td>
<td>100%</td>
<td>99.9%</td>
<td>97.6%</td>
<td>100%</td>
</tr>
<tr>
<td>Dimension Vista</td>
<td>Spike</td>
<td>100%</td>
<td>99.8%</td>
<td>96.3%</td>
<td>100%</td>
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For additional information about Siemens total antibody test performance, see the following:

- [FDA EUA authorized serology tests performance](#)
- [Siemens SARS-CoV-2 Total Assay](#)
Why use a total antibody test and not individual IgM and IgG tests?

That type of test used in a laboratory must correlate to the question that health care providers need answered.

**Question:** Does a patient have antibodies to SARS-CoV-2?
**Solution:** Perform total antibody test

**Question:** Is a patient in the acute phase of a SARS-CoV-2 infection?
**Solution:** Perform molecular testing and, if available, SARS-CoV-2 IgM testing

**Question:** Does a recovered individual have antibodies to SARS-CoV-2?
**Solution:** Perform SARS-CoV-2 total or IgG testing
What if my laboratory only has a total antibody test and my providers need more information about antibody response?

Solution #1: Migrate to individual IgM and IgG tests if possible

Solution #2: Develop a SARS-CoV-2 antibody panel such as:

<table>
<thead>
<tr>
<th>Test #1</th>
<th>Test #2</th>
<th>Extrapolate</th>
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<tbody>
<tr>
<td>Total Antibody</td>
<td>IgM</td>
<td>IgG</td>
</tr>
<tr>
<td>Total Antibody</td>
<td>IgG</td>
<td>IgM</td>
</tr>
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</table>
Serology Testing Resources

American Society of Microbiology: COVID-19 Serology Testing Explained
Infectious Disease Society of America: COVID-19 Antibody Testing Primer
CDC: Interim Guidelines for COVID-19 Antibody Testing
FDA: Antibody Testing for COVID-19: Information for Patients and Consumers
Johns Hopkins: Serology-Based Tests for COVID-19
Are Abbott ID Now Tests and Instruments available for purchase?

- Inquiries for Abbott ID Now Instrument purchase should be directed to: Amy.Kilburg@abbott.com

- Inquiries for Abbott ID Now test kit purchase should be directed to:
  Matt Van Dam
  McKesson Medical-Surgical
  South Dakota / NW IA / SW MN
  605-376-0090
  Matt.VanDam@McKesson.com
Infection Control
“HCP (Healthcare Personnel) who enter the room of a patient with suspected or confirmed SARS-CoV-2 infection should adhere to Standard Precautions and use a NIOSH-approved N95 or equivalent or higher-level respirator (or facemask if a respirator is not available), gown, gloves, and eye protection.”

Summary of Changes to the Guidance

Summary of Recent Changes as of August 10, 2020 to more closely align guidance with Decision Memo:

- For patients with severe to critical illness or who are severely immunocompromised, the recommended duration for Transmission-Based Precautions was changed to at least 10 days and up to 20 days after symptom onset.
- Recommendation to consider consultation with infection control experts.
- Added example applying disease severity in determining duration of isolation using Transmission-Based Precautions.
- Added hematopoietic stem cell or solid organ transplant to severely immunocompromised conditions.

Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection (Update 08/10/2020)

Summary of Recent Changes as of August 10, 2020

Summary of Recent Changes as of August 10, 2020 to more closely align guidance with Decision Memo:

- For HCP with severe to critical illness or who are severely immunocompromised¹, the recommended duration for work exclusion was changed to at least 10 days and up to 20 days after symptom onset.
- Recommendation to consider consultation with infection control experts.
- Added example applying disease severity in determining duration before return to work.
- Added hematopoietic stem cell or solid organ transplant to severely immunocompromised conditions.

¹Please refer to the original Decision Memo for detailed criteria.
Additional Infection Control Discussions

• EMS Provider Calls
• LTC Call
• LAB/IP Call
Community Mitigation
Dashboard

- **New Cases Today**: 89
- **Active Cases**: 951
- **Recovered Cases**: 8,080
- **Currently Hospitalized**: 43
- **Ever Hospitalized**: 856
- **Deaths**: 137
- **Total Cases**: 9,168
- **Total Persons Tested**: 116,374
- **Total Tests**: 145,555
- **% Progress (June Goal: 44,233 Tests)**: 97%
- **% Progress (July Goal: 44,233 Tests)**: 106%
- **% Progress (August Goal: 44,233 Tests)**: 9%

**Test Positivity Rate**:
- **Last 1 Day**: 7.5%
- **Last 7 Days**: 7.0%
- **Last 14 Days**: 6.6%
- **Cumulative**: 7.3%

**14-Day Trend of Positive Cases by Date Reported to SD-DOH**

<table>
<thead>
<tr>
<th>Date Reported to SD-DOH</th>
<th>Positive Cases</th>
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<tbody>
<tr>
<td>Jul 21</td>
<td>55</td>
</tr>
<tr>
<td>Jul 23</td>
<td>67</td>
</tr>
<tr>
<td>Jul 25</td>
<td>103</td>
</tr>
<tr>
<td>Jul 27</td>
<td>50</td>
</tr>
<tr>
<td>Jul 29</td>
<td>62</td>
</tr>
<tr>
<td>Jul 31</td>
<td>112</td>
</tr>
<tr>
<td>Aug 02</td>
<td>38</td>
</tr>
</tbody>
</table>

**Test Positivity Rate**: This rate is equal to the number of Positive Tests divided by Total Tests, within specified period of time.
Supply Chain Management
All requests for PPE from DOH must be:

- Emailed to COVIDResourceRequests@state.sd.us
- Faxed to 605.773.5942, or
- Called in to 605.773.3048 to ensure prioritization and coordination of requests.

- Do not duplicate your request by using all three means of communication.

- Any requests received through any other email or number will all be directed to email COVIDResourceRequests@state.sd.us OR call 605.773.3048 and requesting entities must provide information regarding their current facility status.
On-going Communication
Helpful Information Sources

COVID.sd.gov

coronavirus.gov

SD COVID-19 Help Line:  800-997-2880
Communications

- SD-HAN: sdhan.sd.gov
- Epi Listserv
- Lab Listserv
- HAI Listserv
- OLC Listserv

Visit COVID.sd.gov to subscribe
Questions?

COVID Helpline: 800-997-2880
Epidemiology: 605-773-3737
Laboratory: 605-773-3368

COVID.sd.gov
COVIDSD@state.sd.us