This is an **emerging, rapidly evolving situation**. Information in this presentation is current as of September 2, 2020. Please check the South Dakota Department of Health website for the most current information and guidance.

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

• Situation Update
• Laboratory Guidance
• Long Term Care
• 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 the website following the webinar.
Coronavirus Situation  (as of September 2, 2020)

- **International**
  - 25,102,665 confirmed cases
  - 852,758 deaths

- **United States** (50 states + DC)
  - 6,047,692 confirmed cases in U.S.
  - 184,083 deaths

- **South Dakota**
  - 14,003 confirmed cases in South Dakota
  - 169 deaths
  - 10,959 recovered
Epidemiologic “Epi” Curve of COVID-19 Cases, by Onset Date

Positive Cases by Date Reported to SD-D0H

As of September 2, 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

As of June 18, 2020

Reporting COVID-19 Tests to SD-DOH

• **Reminder**: Coronavirus respiratory syndromes are a Category I disease

• Report **immediately** on suspicion of disease

• Reporting mechanisms:
  • Electronic Laboratory Report (ELR) – HL7 message to SD Health Link (health information exchange)
  • Flat file (CSV) – Secure email
  • Disease reporting website – [sd.gov/diseasereport](sd.gov/diseasereport)
  • Fax – 605.773.5509
Community Impact Map

• Level of Community Spread
  • K–12 Schools
  • Long-term care opening

• K–12 Schools (Per CDC Daily Home Screening Guidance)
  • In counties with Substantial community spread, students and staff are excluded with these symptoms:
    • Temperature 100.4 degrees Fahrenheit or higher when taken by mouth
    • Sore throat
    • New uncontrolled cough that causes difficulty breathing
    • Diarrhea, vomiting, or abdominal pain
    • New onset of severe headache
  • Students and staff may seek care for asthma, seasonal allergies, other existing medical conditions
  • Might see increasing volume of patients

• Long-term care (Per SD LTC Reopening Plan)
  • Phase 1: Most austere restrictions in place when a county has Substantial or Moderate spread

https://doh.sd.gov/news/Coronavirus.aspx#SD
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
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)
  - Tribes
  - K-12 schools (adults)
K-12 Sentinel Surveillance

- K-12 Sentinel Surveillance officially began the week of August 31
- 61 groups are participating in surveillance this week
- Groups that enrolled last week will begin surveillance next week
- Enrollment will remain open so school districts can continue to enroll

<table>
<thead>
<tr>
<th>Program Status</th>
<th>Enrollment</th>
<th>Tests per Month</th>
<th>Tests per Week</th>
<th>Students Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooperative or Multi-District</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>79</td>
</tr>
<tr>
<td>Non-Public School District</td>
<td>7</td>
<td>44</td>
<td>9</td>
<td>1256</td>
</tr>
<tr>
<td>Public School District</td>
<td>48</td>
<td>425</td>
<td>92</td>
<td>47055</td>
</tr>
<tr>
<td>State Special School</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>22</td>
</tr>
<tr>
<td>Tribal/BIE School</td>
<td>4</td>
<td>20</td>
<td>4</td>
<td>1346</td>
</tr>
<tr>
<td>Grand Total</td>
<td>61</td>
<td>499</td>
<td>107</td>
<td>49758</td>
</tr>
</tbody>
</table>
Federal Remdesivir Allocation

• Remdesivir continues to be allocated to South Dakota for purchase by health care facilities

• To purchase remdesivir, health care facilities must:
  – meet the previously established criteria to administer the drug
  – be registered with Amerisourcebergen
  – agree to purchase the drug

• South Dakota received 20 cases of remdesivir the week of 8/31

• South Dakota is eligible for 30 cases of remdesivir the week of 9/7

• Questions about the remdesivir allocation and purchase process can be sent to: Bob.Coolidge@state.sd.us
Notable Changes to Remdesivir Use

- Previously, FDA indicated that remdesivir use should be limited to patients with severe disease that required oxygen therapy or intensive breathing support such as a mechanical ventilator.

- FDA recently determined that remdesivir may be effective for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult or pediatric patients.

- According to FDA, data from two randomized trials contributed to the agency’s decision.
Additional FDA EUA Updates

• FDA has issued Emergency Use Authorization for the following:
  – 156 (10): Molecular Diagnostic Tests for SARS-CoV-2
  – 42 (2): Serological Tests
  – 35: Molecular-Based Laboratory Developed Tests for SARS-CoV-2
  – 4: Antigen Diagnostic Tests for SARS-CoV-2

• This week SDDOH will review information from FDA including:
  – Predictive value calculator for COVID serology tests
Performance Characteristics Defined

- **Sensitivity**: the ability of a test to correctly identify a person with a disease as “positive” (a highly sensitive test will have few false-negative results)

- **Specificity**: the ability of a test to correctly identify a person who does not have a disease as “negative” (a highly specific test will have few false-positive results)

- **Predictive value**: the probability of having a disease
  - **Positive predictive value**: the probability that a patient with a positive test result has the disease
  - **Negative predictive value**: the probability that a patient with a negative test result does not have the disease
## Performance Characteristics: Serology Tests

<table>
<thead>
<tr>
<th>Prevalence of COVID-19 in the population</th>
<th>PPV for one test (SE=90%, SP=99.8%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2%</td>
<td>90.2%</td>
</tr>
<tr>
<td>5%</td>
<td>95.9%</td>
</tr>
<tr>
<td>10%</td>
<td>98.0%</td>
</tr>
<tr>
<td>30%</td>
<td>99.5%</td>
</tr>
</tbody>
</table>

PPV = positive predictive value  
SE = sensitivity  
SP = specificity
## FDA PPV/NPV Calculator

Calculator for Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for individual tests and combined.

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>13.7%</th>
</tr>
</thead>
</table>

#### Test 1

<table>
<thead>
<tr>
<th></th>
<th>%Pos1 (Test1=pos)</th>
<th>PPV1 for (Test1=pos)</th>
<th>%Neg1 (Test1=neg)</th>
<th>NPV1 for (Test1=neg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sen1</td>
<td>100.0%</td>
<td>99.4%</td>
<td>14.2%</td>
<td>96.4%</td>
</tr>
</tbody>
</table>

#### Test 2

<table>
<thead>
<tr>
<th></th>
<th>%Pos2 (Test2=pos)</th>
<th>PPV2 for (Test2=pos)</th>
<th>%Neg2 (Test2=neg)</th>
<th>NPV2 for (Test2=neg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sen2</td>
<td>0.0%</td>
<td>0.0%</td>
<td>86.3%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

#### Combined

<table>
<thead>
<tr>
<th></th>
<th>%Pos (Test1=pos, Test2=pos)</th>
<th>PPV for (Test1=pos, Test2=pos)</th>
<th>%Discordant (Test1=pos, Test2=neg)</th>
<th>NPV for (Test1=pos, Test2=neg)</th>
<th>%Neg (Test1=neg)</th>
<th>NPV for (Test1=neg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5%</td>
<td>0.0%</td>
<td>13.7%</td>
<td>0.0%</td>
<td>85.8%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
### Abbott Architect SARS-CoV-2 IgG

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Performance Measure</th>
<th>Estimate of Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG</td>
<td>Sensitivity (PPA)</td>
<td>100% (88/88)</td>
</tr>
<tr>
<td>IgG</td>
<td>Specificity (NPA)</td>
<td>99.6% (1066/1070)</td>
</tr>
<tr>
<td>IgG</td>
<td>PPV at prevalence = 5%</td>
<td>93.4%</td>
</tr>
<tr>
<td>IgG</td>
<td>NPV at prevalence = 5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### bioMérieux VIDAS SARS-CoV-2 IgM

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Performance Measure</th>
<th>Estimate of Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM</td>
<td>Sensitivity (PPA)</td>
<td>100% (22/23)</td>
</tr>
<tr>
<td>IgM</td>
<td>Specificity (NPA)</td>
<td>99.4% (306/308)</td>
</tr>
<tr>
<td>IgM</td>
<td>PPV at prevalence = 5%</td>
<td>89.0%</td>
</tr>
<tr>
<td>IgM</td>
<td>NPV at prevalence = 5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### FDA Calculator Data

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>13.7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test 1</td>
<td>Test 1</td>
</tr>
<tr>
<td>Sen1</td>
<td>Sp1</td>
</tr>
<tr>
<td>----------</td>
<td>------</td>
</tr>
<tr>
<td>100.0%</td>
<td>99.6%</td>
</tr>
</tbody>
</table>

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**South Dakota Department of Health**
Long Term Care
Disease Impact – United States as of 08.16.20

Resident Cases and Deaths

- Total COVID-19 Confirmed Cases: 198,153
- Total COVID-19 Suspected Cases: 119,701
- Total COVID-19 Deaths: 49,871

Long Term Care in South Dakota

- Total Cases in LTC/Residential Living – 440 (+28)
- Total Active Cases - 72 (+12)
- Total Deaths in LTC/Residential – 87 (+3)
- Total NH/ALC with Case - 89 (+8)
Federal Department of Health and Human Services

Highlights of CMS Testing Guidelines in Nursing Homes – QSO-20-38-NH

• This rule establishes Nursing Home testing requirements for staff and residents. Specifically,
  • Facilities are required to test staff on a routine basis, during an outbreak, or if symptomatic.
  • Facilities are to test residents during an outbreak or if they are symptomatic. Routine testing of asymptomatic residents is not recommended by regulation.
• Facility staff is defined as employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility’s nurse aide training programs or from affiliated academic institutions.
• Testing of staff and residents with COVID-19 symptoms should continue.

Federal Department of Health and Human Services - CMS

- Facilities can meet the testing requirements through the use of rapid Point-of-Care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory.
- The labs of choice may include Avera, LabCorp, Monument, or Sanford.
- Use the federal funds to help support your routine testing efforts.
- Nursing Homes received federal funds recently of $2.5 Billion dollars specifically for testing.
- The SDPHL will not conduct or pay for routine testing in Nursing Homes.
Federal Department of Health and Human Services - CMS

- Providers should have a testing plan for routine staff testing and outbreak testing of residents and staff.
- Test Frequency is based on the extent of the virus in the community (county) therefore facilities should use their county positivity rate as the trigger for staff testing frequency.
- Reports of COVID-19 county-level positivity rates are available on the CMS website identified on the CMS memo. 
Federal Department of Health and Human Services - CMS

• County positivity rate will be sent out through the OLC Listserv every Monday
  • Community Activity Low (<5%) test all staff once per month.
  • Community Activity Medium (5-10%) test all staff once per week.
  • Community Activity High (>10%) test all staff twice per week.
  • This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site lab testing is available.
Federal Department of Health and Human Services - CMS

**Documentation**

- If you do not have access to a Point-of-Care testing device or a reference laboratory to support the CMS testing.
- If no access to a lab for testing, you can revert to Sentinel testing or PPS testing when responding to positive cases in their facility (like the current practice).
- Symptomatic residents and staff.
- Identification of a new COVID case.
- Routine testing of staff.
Infection Prevention
COVID-19 Personal Protective Equipment (PPE) for Healthcare Personnel

- Preferred PPE - Use N95 or Higher Respirator
  - Face shield or goggles
  - Apron or coverall
  - Gloves

- Acceptable Alternative PPE - Use Facemask
  - Face mask
  - Goggles
  - N95 or higher respiratory protection

[Image of PPE guidelines]

Recent CDC COVID-19 Publications or Updates

- Interim Guidance for Rapid Antigen Testing for SARS-CoV-2 (8/29/20)
- Guidance for Dental Settings (8/28/20)
- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes (8/27/20)
- IPC Recommendations in Outpatient Hemodialysis Facilities (8/24/20)
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (8/10/20)
- Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection (8/10/20)
CMS Memorandums

- LTC Testing Requirements for Staff and Residents and Revised COVID-19 Focused Survey Tool (8/26/20)
- CLIA Updating Requirements for Reporting of SARS-CoV-2 Test Results (8/26/20)
In late August, CDC launched a revised webpage to improve navigation to CDC recommendations for nursing homes and long-term care facilities, including those for infection control, SARS-CoV-2 testing, ICAR, and related resources. Click here to access the landing page.
Community Mitigation
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 sources of information:

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?

Follow-up after the webinar
COVID Helpline: 800-997-2880
Epidemiology: 605-773-3737
Laboratory: 605-773-3368

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