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DEPARTMENT OF HEALTH

Updated Webpage: Guidance for SARS-CoV-2 Point-of-Care Testing

<u>This webpage includes content involving POC testing including:</u>

- How to obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate

- How to safely perform POC specimen collection, handling, and testing for COVID-19

- How to comply with result reporting requirements.

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

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Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers

False positives may occur if certain recommendations are not followed:

- Manufacturing instructions found on the package insert are not followed accurately (Cards not stored properly, handling of test cartridge/card, etc.)
- Timing and reading test results: **Reading the test before or after the specified time could result in false positive or false negative results.**
- Processing multiple specimens in batch mode may make it more challenging to ensure correct incubation time for each specimen.
- Potential for cross-contamination if not effectively cleaning workspace or utilizing proper PPE.
- Remember that positive predictive value (PPV) varies with disease prevalence when interpreting results from diagnostic tests. PPV is the percent of positive test results that are true positives. As disease prevalence decreases, the percent of test results that are false positives increase.

For more information, please visit this link @: FDA.GOV

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The following Healthcare IPC Guidance has been updated on the CDC:

PPE GUIDANCE	SUMMARY OF RECENT UPDATES
Strategies for Optimizing the Supply of Eye Protection	Added considerations for returning to conventional capacity practices.
Strategies for Optimizing the Supply of Disposable Medical Gloves	Added considerations for returning to conventional capacity practices.
Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators	
Strategies for Optimizing the Supply of Isolation Gowns	Added considerations for returning to conventional capacity practices. • Moved the use of reusable (i.e., washable or cloth) isolation gowns to conventional capacity strategies. • Edited the section on consideration of the use of coveralls. • Added language to the section on prioritizing the use of gowns. • Moved the crisis capacity strategy of re-use of isolation gowns to the bottom of the list and added cautionary statements about the risks of this strategy on HCP and patient safety.

PPE

Resources on surge capacity use of PPE
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

Burn Rate Calculator:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html

Emergency PPE requests from state:
COVIDResourceRequests@state.sd.us or 605-773-3048
 Please be very specific with the type and amount of PPE that you are requesting for your facility.

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Deadline Extension: LTCF COVID Vaccine Pharmacy Program

The Pharmacy Partnership for Long-term Care Program for COVID-19 Vaccination enrollment deadline has been extended to **November 6, 2020**.

CMS-certified long-term care facilities should log into NHSN via the [SAMS portal](#) to make their selection. Assisted living facilities (residential long-term care facilities providing assistance and supervision to primarily elderly residents with activities of daily living and skills for independent living), and similar congregate living settings where most individuals receiving care/supervision are older than 65 years of age, should enroll via this online form https://redcap.link/LTCF.

NHSN Antigen reporting in for LTCF

Facilities that are entering Antigen testing results into NHSN for staff and residents, need to enter results into NHSN ONLY.

No need to double report on the SD DOH disease reporting website also.

Laboratory Guidance

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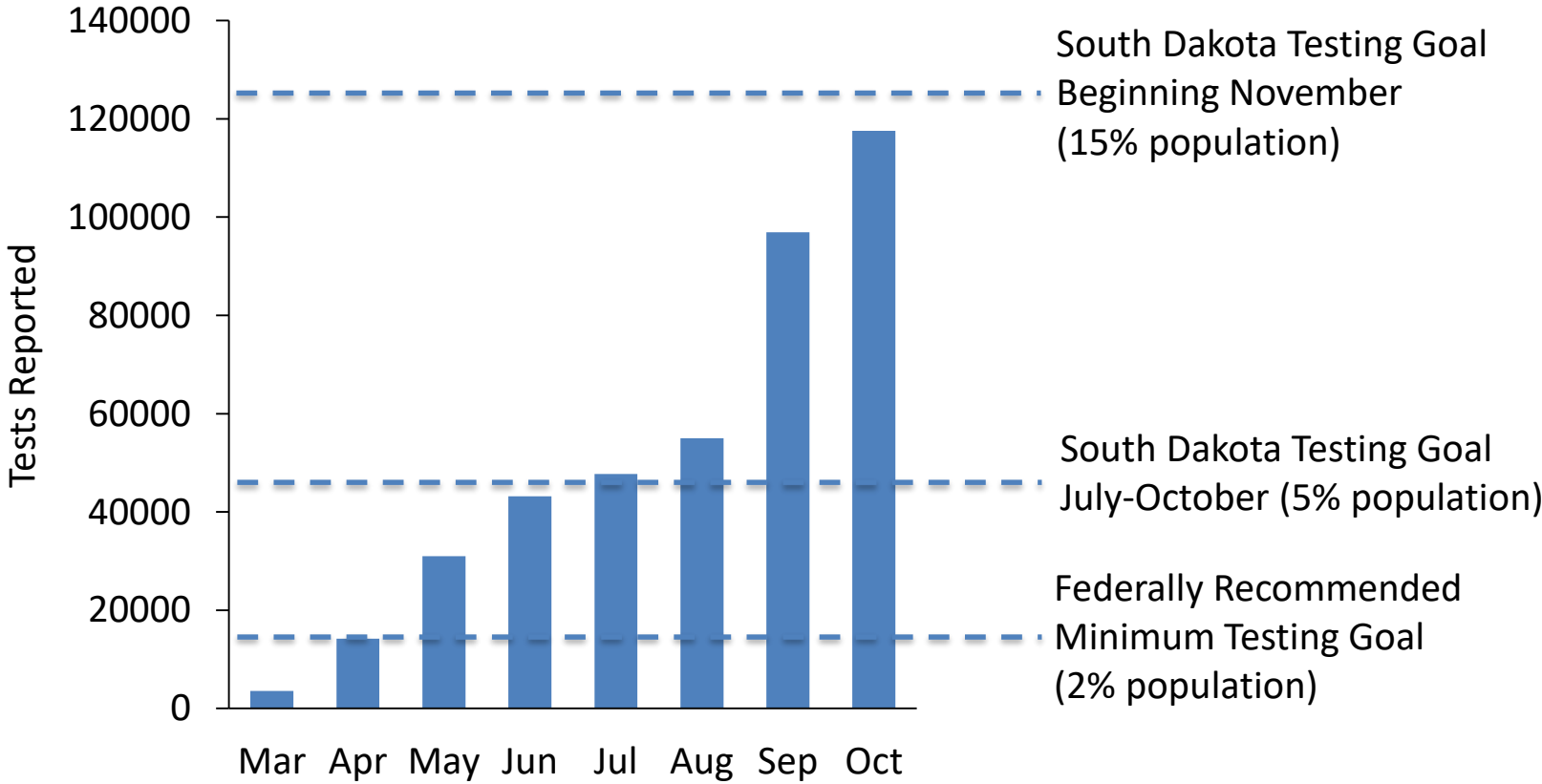# Statewide Priority Populations for SARS-CoV-2 Testing

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

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SDPHL COVID-19 Testing Priorities

- <u>Symptomatic</u> hospitalized patients
- <u>Symptomatic </u>healthcare workers, first responders, and active military
- <u>Symptomatic</u> individuals in congregate living settings like LTC facilities
- <u>Symptomatic</u> individuals with no way to pay for testing

- <u>Asymptomatic</u> participants in state-sponsored sentinel surveillance:
  - Long-term care (staff and residents)
  - K-12 schools (adults)
  - Corrections (inmates and staff)
  - Tribes (tribal members)
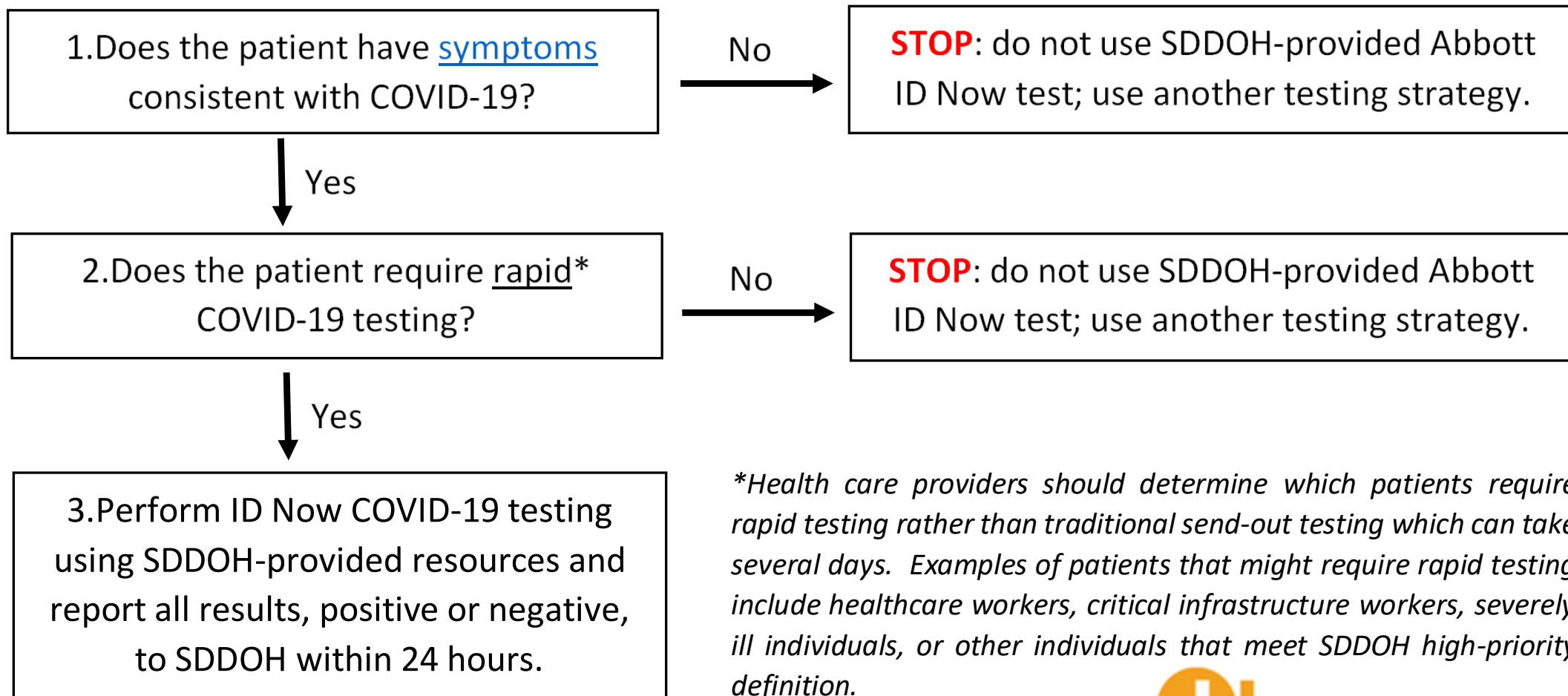
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Initiatives to Increase SARS-CoV-2 Testing

- Report <u>ALL</u> COVID-19 test values to SDDOH

- Tribal Sentinel Surveillance Testing:
  - As many as 8,000 tests/month

- Statewide distribution of BinaxNOW antigen tests:
  - 260,000 tests will be available in South Dakota

- At-home saliva testing:
  - As many as 10,000 tests for several initiatives

- Other state and federally supported testing initiatives:
  - As many as 10,000 tests by end of year

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Abbott ID Now: Recommendations for Use

1.Does the patient have symptoms consistent with COVID-19?

— No → **STOP**: do not use SDDOH-provided Abbott ID Now test; use another testing strategy.

↓ Yes

2.Does the patient require rapid* COVID-19 testing?

— No → **STOP**: do not use SDDOH-provided Abbott ID Now test; use another testing strategy.

↓ Yes

3.Perform ID Now COVID-19 testing using SDDOH-provided resources and report all results, positive or negative, to SDDOH within 24 hours.

*Health care providers should determine which patients require rapid testing rather than traditional send-out testing which can take several days. Examples of patients that might require rapid testing include healthcare workers, critical infrastructure workers, severely ill individuals, or other individuals that meet SDDOH high-priority definition.

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Confirmation of Antigen Test Results: Updated

- Confirmation of antigen test results should be considered for the following scenarios:

  ➢ <u>Symptomatic</u> individuals in settings with <u>high positivity</u> rate who test <u>negative</u> for SARS-CoV-2 using an antigen test

  ➢ <u>Asymptomatic</u> individuals in settings with <u>low positivity</u> rate who test <u>positive</u> for SARS-CoV-2 using an antigen test

- It is not recommended to confirm one antigen test with another antigen test. Confirm antigen test results with a molecular test if possible.

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FDA EUA Updates

- FDA has issued Emergency Use Authorization for the following:

  - 189 (2): Molecular Diagnostic Tests for SARS-CoV-2

  - 56 (1):   Serological Tests

  - 34:   Molecular-Based Laboratory Developed Tests for SARS-CoV-2

  - 7:   Antigen Diagnostic Tests for SARS-CoV-2

- Notable Updates:

  - Serology Test: Access Bio CareStart COVID-19 IgM/IgG (lateral flow assay)

  - Diagnostic Test: LabCorp RT-PCR (pooling)

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