COLORADO
Department of Public Health & Environment

HEALTH ALERT NETWORK BROADCAST
MESSAGE ID: 11052020 09:45
FROM: CO-CDPHE
SUBJECT: HAN Update - COVID-19
RECIPIENTS: Local Public Health Agencies / IPs / Clinical Labs / EDs / ID Physicians / Coroners
RECIPIENT INSTRUCTIONS: Local Public Health Agencies – please forward to healthcare providers
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HEALTH UPDATE | COVID-19 | Nov. 5, 2020

Health care providers: Please distribute widely in your office

Key points

- As additional tests become available in Colorado, choosing and interpreting tests for SARS-CoV-2 (the virus that causes COVID-19) correctly can be challenging. Recommendations on the use and interpretation of different testing modalities can be found below.
- CDC has officially clarified that in the definition of a close contact, the 15 minutes is **cumulative within 24 hours:** https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html
- CDPHE continues to recommend testing asymptomatic contacts of COVID-19 cases at approximately seven days after their exposure. Symptomatic contacts should be tested at the onset of symptoms.
- CDPHE has released guidance on ventilation, which can be found at: https://drive.google.com/file/d/1oNUhQx2CCwSsMrbSklOreAN1Yjp62sYd/view
- CDPHE has released new guidance on critical workers, which can be found at: https://drive.google.com/file/d/1mo8ThFri69P1Y4XEDGYoPjJTvvxrAILL/view
- When testing a patient suspected to have COVID-19 or who has been exposed to someone with COVID-19, providers should consider offering patients information on the Healthy Family and Workplaces Act of 2020. This act requires employers to provide paid leave to an employee under certain conditions including having symptoms and seeking a medical diagnosis, isolation, quarantine, or caring for someone under isolation or quarantine: https://cdle.colorado.gov/interpretive-notice-formal-opinions-infos (see INFO #6A)
- FDA has new guidance on giving instructions to patients who are self-collecting nasal swabs, citing concerns for lower sensitivity in specimens collected without proper instructions: https://www.fda.gov/medical-devices/letters-health-care-providers/recommendations-providing-clear-instructions-patients-who-self-collect-anterior-nares-nasal-sample
- For information on reporting requirements for COVID test results and for assistance in determining the best reporting method for your facility, please complete the form linked here: https://forms.gle/bXeEXLRMhRk1ZQge8
- Skilled nursing facilities regulated by the Centers for Medicare & Medicaid Services (CMS) are required to report point-of-care (POC) test results into the "Test Reporting Tool" application in the CDC's National Healthcare Safety Network. Additional information on reporting in NHSN can be found here: https://www.cdc.gov/nhsn/ltc/covid19/index.html

Recommendations/Guidance

All positive **and negative** SARS-CoV-2 results, including point-of-care tests performed at an urgent care, outpatient clinic, school, skilled nursing facility, assisted living residence, or other clinical settings, should be reported to the local public health agency **and** CDPHE. All positive antigen tests are counted as probable cases for surveillance purposes based on case definitions. (https://docs.google.com/document/d/1e-IWLtzJNCgI2gzPONGvEASGgse85WuBmcToc9ev-74/edit?usp=sharing).

No type of negative test can shorten a person's quarantine if they have been exposed to COVID-19. In some circumstances, a negative PCR test in an exposed individual with symptoms can prevent them from being listed as a probable case; however, they should remain quarantined for the full 14 days following exposure. For the purposes of disease control and infection prevention, clinicians or local public health agencies can choose to treat a highly suspicious case as a presumed COVID case, even if they no longer meet the probable case definition, including in a school setting when following school guidance.

Testing Guidance Update Table

PCR testing			
Test characteristics	**Appropriate use**	**Need for confirmatory testing**	**Considerations for Serial Testing**
Generally high sensitivity and specificity. Comparative data now available at: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data	Most laboratory-based PCR tests are appropriate for use in symptomatic and asymptomatic individuals.	Not needed for positive or negative results. Inconclusive tests should be recollected as soon as results are received and treated as presumptively positive while pending.	Gold standard. Most appropriate tool for cohorting in residential facilities and other congregate settings.
PCR testing: Curative SARS-Cov-2 Assay with Buccal Swab ("Oral fluid swab")			
Test characteristics	**Appropriate use**	**Need for confirmatory testing**	**Considerations for Serial Testing**
When used according to EUA, can be considered similar to quantitative PCR tests.	Current EUA is for symptomatic individuals within 14 days of symptom onset. However, preliminary data on use in asymptomatic individuals suggest it may perform well in this population. Kit swab can be used as a nasal swab or for oral fluid specimen collection. **Must be directly observed and directed by a trained healthcare worker.**	Not needed for positive or negative results. Invalid test results should be recollected.	Appropriate for serial testing when individuals are tested at least once per week. May be used for cohorting in residential facilities and other congregate settings.

Non-PCR Molecular Point of Care (POC) testing: Abbott ID NOW			
Test characteristics	**Appropriate use**	**Need for confirmatory testing**	**Considerations for Serial Testing**
Generally lower sensitivity than PCR tests but good specificity (unlikely false positives).	The updated Abbott ID NOW EUA specifies that it is only appropriate for use in **symptomatic** individuals within seven days of symptom onset. Tests should be performed using direct swab **without** viral transport media.	Not needed when used on symptomatic individuals within seven days of symptom onset. New data on use of the test with direct swabs, without viral transport media, demonstrate improved sensitivity.	May be used for serial testing in lower-risk populations when individuals are tested at least once per week. This testing platform is **not** recommended for cohorting purposes in residential facilities or other congregate settings.
Antigen Point of Care (POC) Testing			
Test characteristics	**Appropriate use**	**Need for confirmatory testing**	**Considerations for Serial Testing**
Lower sensitivity than other testing platforms. Ongoing questions about specificity (potential for false positives with certain tests or if handled incorrectly). CDPHE Antigen FAQ: https://drive.google.com/file/d/1aHWxauGCNPoRwF6vmpJohQdaCKzHvAuD/view FDA *Letter to Providers* regarding false positive risk: https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory	**Community: only appropriate** for use in **symptomatic** individuals within the timeframe indicated by the test's EUA (usually within five days of symptom onset) unless they are part of a serial testing program. **Residential facilities*:** may be used as part of a serial screening program for residents and staff as indicated by CMS and CDC guidance. However, this testing platform is not currently recommended for making cohorting decisions given the ongoing questions about test characteristics.	**Community members not part of a serial testing program:** the need for confirmatory testing of **negative** results depends on pre-test probability (**see table below****); all positive antigen tests will be classified as probable cases regardless of any additional negative results. **Residential facilities*:** per CDC algorithm (https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf) However, all results should be confirmed prior to any cohorting decisions.	EUA is for symptomatic individuals, but may be used for serial testing when individuals are tested at least once per week. Due to ongoing questions about test characteristics, antigen test results should not be used for cohorting purposes in residential facilities and other congregate settings. As additional information about test performance becomes available, this recommendation may change.
Serology (antibody) testing			
Test characteristics	**Appropriate use**	**Need for confirmatory testing**	**Considerations for Serial Testing**
Extremely variable test characteristics based on specific tests. More information at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-me	CDC Guidance: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html Antibody tests can tell you whether you **might** have had COVID-19.	Antibody testing cannot rule-in or rule-out active COVID-19 infection. Additional testing such as PCR should be performed if trying to diagnose current infection and should be	Not recommended.

dical-devices/eua-authorized-serology-test-performance Test performance varies considerably based on a person's likelihood of having had COVID-19, which is primarily based on community prevalence.	Antibody tests cannot be used to determine **when** a person had COVID-19, **if a person is currently infectious**, or **if they are immune** to COVID-19. Antibody testing is helpful for the diagnosis of Multisystem Inflammatory Syndrome in Children (MISC)	considered for those with antibody results suggestive of recent infection (e.g. high IgM to IgG ratio).	

*In certain facility settings, a positive antigen test performed concurrently (ideally at the same time but no longer than 48 hours apart) may be considered a false positive for purposes of isolation and contact tracing under certain circumstances as indicated in CDC guidance. Such cases should be determined in consultation with public health. However, in community members not part of a serial testing program, all positive antigen tests will be treated as probable cases. Use of POC antigen results alone for cohorting purposes is not recommended. This is especially true when test results are not consistent with clinical suspicion, when cohorting in vulnerable populations or high-risk settings, or when incorrect results would lead to unintended COVID-19 exposure(s).

**CDPHE Interim Guidance on when to confirm negative POC antigen test results (Ex: BinaxNOW) in community members not part of a serial testing program:

If all of the following conditions are met, confirmation of a negative antigen test with PCR is not needed (in all other circumstances, a negative must be confirmed with PCR)
-No known exposure to a person with known or suspected COVID-19 (or part of an outbreak)
-No travel to an area with high incidence of COVID-19
-Lives/works/attends school in a community with 2-week incidence <50 cases per 100,000 (this information can be located at https://covid19.colorado.gov/data under Incidence and Epi Curves)
-Experiencing minor symptoms only: sore throat; runny nose or congestion; muscle or body aches; headache; fatigue; nausea; vomiting; diarrhea)

Antigen testing in the community should only be done in symptomatic individuals, ideally within five days of symptom onset; negative test results, regardless of confirmation, cannot end a person's quarantine early.

Point-of-care (POC) Antigen Testing for School Settings

- Positive POC antigen tests should be treated as cases with appropriate isolation and contact tracing.
- All POC tests, whether positive or negative, are reportable to public health (https://forms.gle/bXeEXLRMhRk1ZQge8).
- In general, negative antigen tests should be confirmed with PCR testing before clearing a symptomatic student or teacher who is not a close contact to a case to return to school; however, considerations for when confirmatory testing may not be needed are above -- **CDPHE Interim Guidance on when to confirm negative POC antigen test results (Ex: BinaxNOW) in community members not part of a serial testing program.
- No negative testing of any kind can clear a student or staff member who is quarantined to return to school.

Updates and Continued Considerations

- CDPHE continues to recommend that individuals who test positive by PCR not be retested for 90 days after their initial infection, unless very high clinical suspicion for reinfection exists. Repeat testing is not needed to clear a person to return to work once they have been cleared from isolation.
- A person with a confirmed positive PCR for COVID-19 does not need to be quarantined if they are re-exposed within 90 days of their positive test/symptom onset date. After 90 days, quarantine and retesting is recommended following close contact to a COVID-19 case.
- After 90 days, a person with a positive COVID-19 test should be treated as potentially infectious and should be isolated; contact tracing should be performed. These cases will be considered re-infections based on surveillance definitions.
- The interpretation of the surveillance definition of a probable case has changed as of Oct. 19, 2020 (https://docs.google.com/document/d/1e-IWLtzJNCgI2gzPONGvEASGgse85WuBmcToc9ev-74/edit); however, providers and local public health should continue to use their discretion to decide when a symptomatic individual with known COVID-19 exposure and a negative PCR test should be treated as a likely case for purposes of clinical treatment, isolation, and contact tracing. **However, negative testing in these circumstances still does not release the exposed individual from quarantine, despite the change in their case definition.**

More information

- CDPHE COVID-19 web page: covid19.colorado.gov
- CDC COVID-19 web page: https://www.cdc.gov/coronavirus/2019-ncov/index.html
- For questions about COVID-19 in Colorado, call the **CDPHE Disease Reporting Line:** 303-692-2700 or 303-370-9395 (after hours)
- Health care provider FAQs from CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html
- CDC Clinician Outreach and Communication Activity (COCA) Calls: https://emergency.cdc.gov/coca/calls/index.asp
- List of updated CDC guidance: https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html