City and County of San Francisco

COVID-19 Command Center

MEMORANDUM

DATE: January 7, 2021

TO: Facilities and programs wishing to use BinaxNOW™

FROM: COVID Command Center

RE: Intended uses, distribution, and requirements for the BinaxNOW™ rapid, point-of-care antigen test

Background: The BinaxNOW™ COVID-19 test is being distributed from the California Department of Public Health (CDPH) to county health departments through the Medical Health Operational Area Coordinator (MHOAC) system. This memorandum outlines the San Francisco Department of Public Health (SFDPH) plans and requirements for distribution of BinaxNOW™ kits to facilities and programs within San Francisco.

What is the BinaxNOW™ test? BinaxNOW™ is a point-of-care (POC) lateral flow test that detects the presence of protein antigens from SARS-CoV-2 in individuals suspected of COVID-19 infection by their healthcare provider within the first 7 days of symptom onset. The test is rapid (results in <20 minutes), situated on a card (requires no machine), with sensitivity of 97.1% (positive percent agreement with PCR), and specificity of 98.5% (negative percent agreement) when performed on symptomatic individuals within 7 days of symptom onset. Because antigen tests have lower sensitivity than PCR, false negative results are possible. False positive results have been noted in the field possibly due to improper reading of results.

False positive results have also been reported when antigen tests have been used for screening of asymptomatic persons. This is not unexpected as the test was developed for people with symptoms of COVID-19. This test would be expected to have 20% false positives if used in a population in which only 10% of people were infected and potentially 70% false positives if used in a population in which only 1% of people were infected. Thus, SFDPH does not recommend this test for screening asymptomatic persons at this time.

At present, BinaxNOW™ is being distributed free of charge to counties through the CDPH. After January 2021 the expected commercial price is $5 per test.

What are the intended uses for BinaxNOW™? SFDPH is following the guidance of the CDPH for the prioritization of facilities and uses of the BinaxNOW™ tests. The CDPH recommends the following priorities for the distribution of the BinaxNOW™ within each county:

- Distribute for COVID-19 symptomatic individuals to hospital emergency departments, prioritizing the public safety net hospitals that provide healthcare to individuals regardless of insurance or ability to pay such as county hospitals which predominantly care for those disproportionately impacted by COVID-19 and/or have limited access due geographic or socioeconomic barriers.

- Distribute for COVID-19 symptomatic individuals in urgent care clinics associated with Federally Qualified Health Centers (FQHCs), Community Health Centers, Tribal Clinics, Migrant Health Centers, Health Care for the Homeless, Health Centers for Residents of Public Housing, and Rural Health Clinics.
- Distribute for COVID-19 symptomatic individuals for utilization in COVID-19 outbreaks.
- Distribute for COVID-19 symptomatic individuals in congregate settings (i.e., correctional facilities, homeless shelters, skilled nursing facilities, and assisted living facilities) that are not already receiving direct allocation from the federal government.
- Distribute for COVID-19 symptomatic frontline healthcare workers and first responders with inadequate time (<48 hours) between weekly shifts to await PCR testing results.

How will the SFDPH distribute BinaxNOW™ within San Francisco? SFDPH will distribute BinaxNOW™ to facilities and programs following the CDPH priorities and uses listed above. In addition, to receive BinaxNOW™, facilities and programs must to adhere to the following requirements and guidelines.

- **For inquiries on requirements, how to obtain BinaxNOW™, and questions on its intended uses, contact Ashley Scarborough, SF COVID Command Liaison, at ashley.scarborough@sfdph.org.**

- **FDA EUA authorized use.** Until further notice from the SFDPH, facilities and programs are required to adhere to the FDA EUA intended uses for BinaxNOW™:

    - For diagnostic testing of individuals suspected to have COVID-19 infection by healthcare providers within the first 7 days of symptom onset. For further information on authorized uses, the FDA EUA is available at: https://www.fda.gov/media/141567/download; Instructions for Use (IFU) is available at: www.fda.gov/media/141570/download. A Fact Sheet for Providers (www.fda.gov/media/141568/download) and Fact Sheet for Patients (www.fda.gov/media/141569/download) are also available on the FDA website.

    - On December 16, the FDA EUA was amended to include **three modes of anterior nares specimen collection:**
        - directly by health care providers,
        - self-collection observed in the presence of a health care provider, and
        - home self-collection observed by a health care provider via telemedicine

    - **Use of BinaxNOW™ for testing asymptomatic persons is currently not authorized by the FDA EUA.** Until further notice, SFDPH does not endorse the use of antigen tests for asymptomatic persons due to the high false positive rate when the test is used with a low likelihood of disease.
        - SFDPH is monitoring emerging evidence and evaluating BinaxNOW™ test's performance for specific groups of asymptomatic persons, particularly in high prevalence communities and in the context of frequent screening or "surveillance testing".
        - Two recent studies suggest reasonable performance of BinaxNOW™ when used for testing in communities experiencing high COVID-19 prevalence. One study was conducted by UCSF in the Mission District of San Francisco (available at:

https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1890/6052342). A second study was conducted in Massachusetts (available at: https://archives.lib.state.ma.us/handle/2452/835819).
    - As new evidence emerges, or with changes to FDA EUA, CDC, or CDPH guidance for asymptomatic testing, SFDPH will revise recommendations accordingly.
    - For general guidance on rapid antigen testing for COVID-19, see CDC guidance (available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html) and Appendices 1 through 4 below.

- **CLIA-waived laboratory oversight.** Facilities and programs using BinaxNOW™ must operate under the oversight of a CLIA-certified or CLIA-waived laboratory and adhere to its quality assurance protocols.

    - Every facility that conducts COVID-19 testing is considered a "laboratory" and must be certified under CLIA

    - https://www.cms.gov/newsroom/press-releases/cms-takes-action-protect-integrity-covid-19-testing

- **California state registration or license issued by Laboratory Field Services (LFS)**. California requires all testing sites to have a California state registration or license issued by LFS. Please visit the LFS Website for facility license information and application. https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalLaboratoryFacilities.aspx

- **Training.** The accuracy of the BinaxNOW™ is dependent upon reading results by well-trained technicians. Persons performing the BinaxNOW™ must complete the test's specific training under the supervision of a CLIA-waived laboratory. Training materials can be accessed through the following links.
    - **Abbott BinaxNOW™ training,** video found at: www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html
    - **UCSF & Unidos en Salud training,** see attachment below "Reader decision tree for BinaxNOW™ Covid-19 Ag test" and YouTube training video developed by UCSF during the 16th and Mission Transport study found at: https://unitedinhealth.org/binax-training

- **Reporting.** Positive and negative BinaxNOW™ results are required to be reported to the health department within 8 hours, and ultimately entered into the CalREDIE surveillance system. BinaxNOW™ results may be given directly to patients and also can be shared with patients via the accompanying Navica App. Because the test is POC, each facility or program must develop a workflow to ensure the timely reporting of results and other required data (e.g., demographics such as race/ethnicity). Options to report include:

1. **The Manual Lab Reporting (MLR) option** that CalREDIE offers via web-based module **– recommended for facilities with a small volume of reports only.** For guidance, the CalREDIE Manual Lab Reporting Module is available at: https://www.hsag.com/contentassets/a990207566d046aabb7a4c253d130d3b/3_calrediemanuallabreporting.pdf

2. **Using a ".csv" flat file format to be sent via SFTP** – an account must be created. CalREDIE Help will assist you, call (866) 866-1428 or email CalREDIEHelp@cdph.ca.gov. This option is recommended if you do not have or need full ELR/HL7 interface. See below for further instructions.

- **Equity justification.** The SFDPH will consider the health disparities in the populations served by the facility or program to make decisions for distribution of BinaxNOW™. CDPH recommends that counties use the Health Equity Metric that addresses COVID-19 testing positivity disparities within counties and prioritizes underserved communities for contact tracing, isolation, and quarantine, available at: www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CaliforniaHealthEquityMetric.aspx

- **Confirmatory testing with PCR.** When used to test symptomatic persons under the FDA EUA, confirmation of positive BinaxNOW™ results is not recommended, given the high prior probability of a positive result among persons in the early period of symptomatic infection. However, negative results among symptomatic persons should be considered "presumptive" and confirmed with a PCR assay if the outcome of the PCR result would change clinical decision-making or mitigation measures. See Appendices 1 to 4 below.

- **For general considerations on the appropriate use of point-of-care tests for COVID-19**, please see the guidance developed by the Alameda County Public Health Department at: https://covid-19.acgov.org/covid19-assets/docs/clinical-guidance/point-of-care-testing-guidance-2020.10.22.pdf and CDC guidance on antigen testing at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html**.**

How should sites that receive BinaxNOW™ approach quality assurance? The implementation of quality assurance (QA) and quality improvement (QI) strategies (e.g., concurrently running a centrally performed molecular assay in a series of patients who are also tested with BinaxNOW™) are required when introducing a new test into any setting for clinical diagnostic or screening purposes. The state of Nevada provided a real-world example demonstrating the importance of QA strategies when they identified a 60% false positivity rate when two new antigen tests were introduced into skilled nursing facilities. This outcome may have been due to the use of these tests to screen for COVID-19 in asymptomatic persons, which is not authorized by the FDA EUA. This information underscores the essential requirement for careful introduction, including QA/QI strategies to verify test reliability under their conditions of use, and adherence to the instructions to use this test only for people who have symptoms of COVID-19. **All sites implementing BinaxNOW™ should conduct concurrent PCR tests on the first 40 samples for validation. Results of the first 40 samples of validation for QA/QI must be submitted to the SF COVID Command Liaison through Ashley.Scarborough@sfdph.org.** Thereafter, your program's QI/QA plan can be followed.

How should facilities order BinaxNOW™ from the City and County of San Francisco? Please follow the Non-City & County of San Francisco Healthcare Facilities 213 Scarce/PPE Resource Request (213RR).

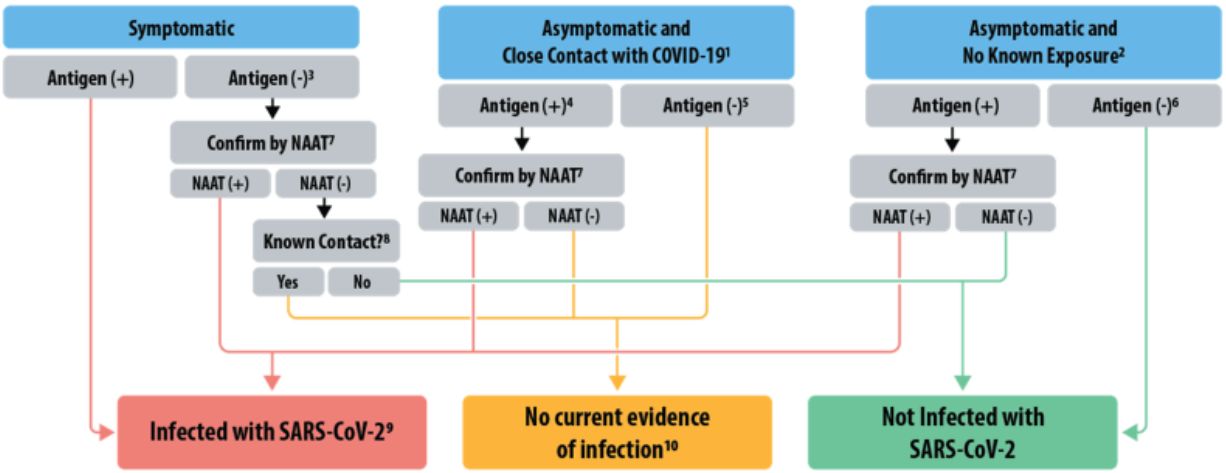
Forms and further instructions can be obtained through Ashley.Scarborough@sfdph.org.

1. For your first order, please complete the BinaxNOW Allocation Evaluation form accessed at: https://forms.office.com/Pages/ResponsePage.aspx?id=z8LVIj7OPUSaf9_MAjH3PwcUONKroDpOuiDvoa9cozhUM0syWlA0VjVXMTJWVFE1NDNSNkRWVUkwUS4u.
2. Complete the 213RR and send to SF COVID Command through the SF COVID Command Liaison at Ashley.Scarborough@sfdph.org.
3. Your SF COVID Command Liaison will contact you if any additional information is needed.
4. You will receive an email from the Supply Team when your order is ready for pickup. The email will contain an order number (e.g., MED 001) which you will need to reference for pickup.
5. For additional requests, send a new 213RR form to your SF COVID Command Liaison.

RESOURCES

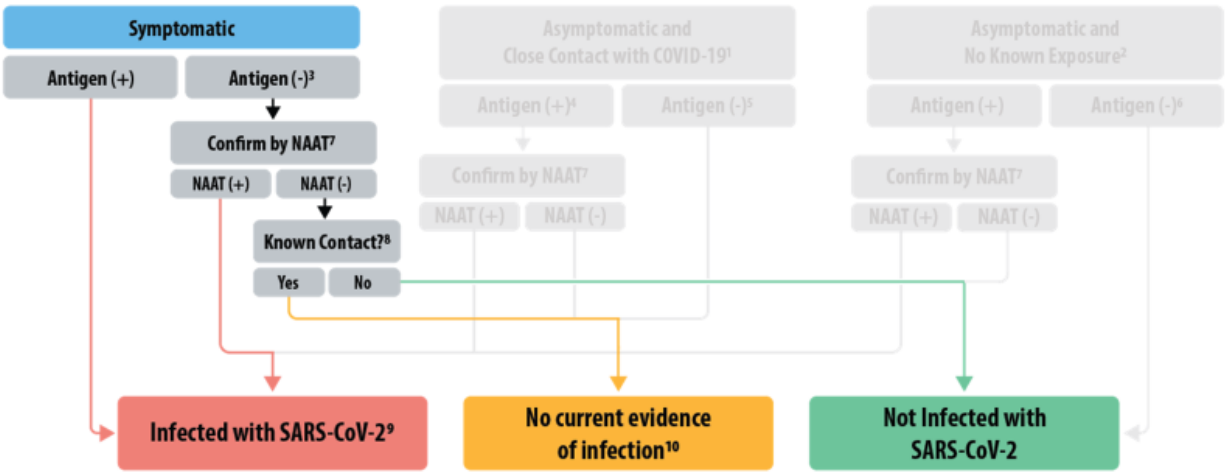
- **Directions to set up an SFTP account for a large file .csv file to CalReddie.** Please email CalREDIEHelp@cdph.ca.gov with the following information needed to set up an SFTP account:
  - Lab Name, Address & Phone Number
  - CLIA #
  - Full names & email addresses of the contact(s) that you expect to send us files (no more than 3 contacts)
  - The .csv and additional guidance is attached, and also available at: CDPH Flat File Format Guidance, .csv sample template . Please submit this file daily labeling the file using this exact format: ***LabName_DateSubmittedToCDPH_FileCount.csv**
- **Food and Drug Administration information for BinaxNOW™:**
  - Emergency Use Authorization letter: www.fda.gov/media/141567/download
  - Fact Sheet for Providers: www.fda.gov/media/141568/download
  - Fact Sheet for Patients: www.fda.gov/media/141569/download
  - Instructions For Use: www.fda.gov/media/141570/download
- **Centers for Disease Control and Prevention (CDC):**
  - Interim Guidance for Antigen Testing for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- **US Health and Human Services Department:**
  - Abbott BinaxNOW™ COVID-19 Ag Test Fact Sheet: www.hhs.gov/sites/default/files/abbott-binaxnow-fact-sheet.pdf
  - Distribution Plans: www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html

Appendix 1. Antigen test algorithms.



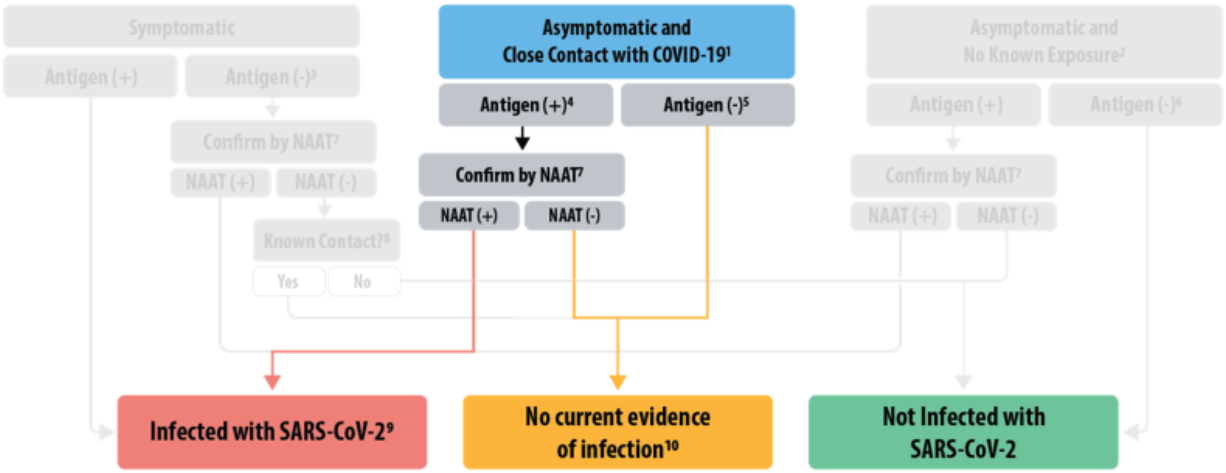
From the CDC, available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Appendix 2. Antigen test algorithm for symptomatic persons (FDA EUA authorized use). Confirmatory PCR testing should be considered for antigen negative results (considered presumptive).



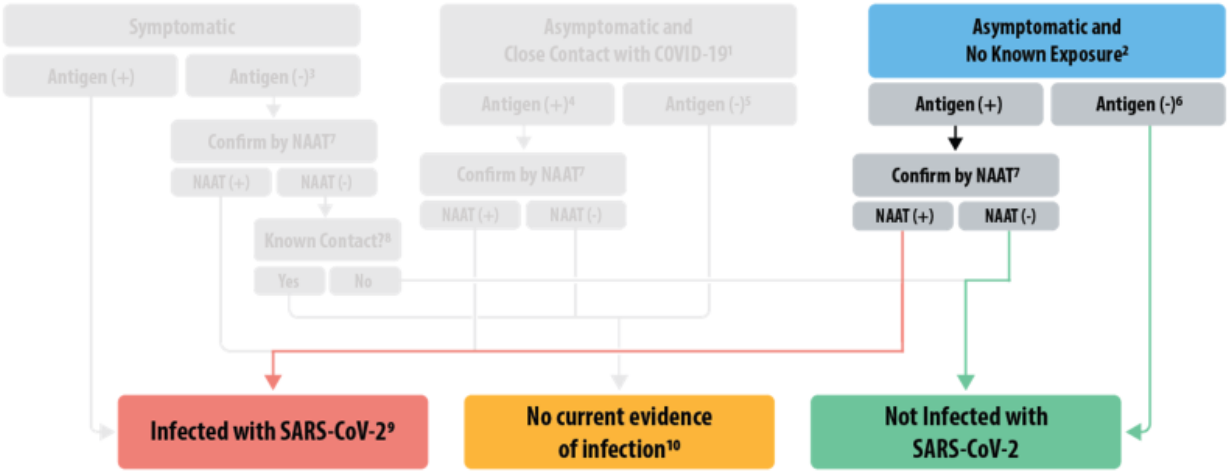
From the CDC, available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Appendix 3. Antigen test algorithm for asymptomatic persons, including known close contact or high community prevalence. Confirmatory PCR testing should be considered for presumptive positive antigen results.



From the CDC, available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Appendix 4. Antigen test algorithm for asymptomatic persons with no known exposures, low community prevalence, or for screening ("surveillance") testing. Confirmatory PCR testing should be considered for presumptive positive antigen results.



From the CDC, available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Appendix 5: Reader decision tree developed by Unidos en Salud / United in Health and UCSF