City and County of San Francisco

COVID-19 Command Center

MEMORANDUM

DATE: **October 5, 2021**

TO: **Facilities and programs which use COVID-19 antigen tests**

FROM: **DPH COVID Task Force**

RE: **Update on recommended algorithms for antigen testing**

What SFDPH guidance has changed?

Confirmation with NAAT, including PCR, is **no longer recommended after a negative antigen test in *symptomatic individuals***, with the following exceptions:

1) **For residents or staff in skilled nursing facilities (SNFs) or residential care facilities for the elderly (RCFEs) who are symptomatic and have a recent close contact with someone confirmed or suspected of having COVID-19.** Given implications of false negatives are high in these settings, it is reasonable and recommended to confirm negative antigen tests among those with highest pretest positivity. These individuals are those who are *both* symptomatic and have had a recent close contact.
2) **Whenever clinician suspicion for COVID-19 remains high.** Given sensitivity of antigen testing is lower than with NAAT, whenever a clinician feels that the clinical context is highly consistent with COVID-19, a confirmatory NAAT test is reasonable and recommended.

For rapid testing supply orders or technical assistance please contact the Testing Innovation Projects (TIP) team: Covid-RapidTesting@sfdph.org

Instructions in this document do not supersede your institutional requirements or a healthcare provider's advice. See institutional requirements for *types of tests* accepted.

For questions regarding at-home self-tests, see: sfcdcp.org/athomecovidtest.

Background:

Antigen tests are one way to test for COVID-19. Antigen tests detect fragments of viral proteins. Benefits include faster turnaround time and point-of-care use. A drawback is lower sensitivity, which means there is a higher chance of a test being negative when a person has COVID-19. There are several antigen tests authorized by the Food and Drug Administration (FDA). The San Francisco Department of Public Health (SFDPH) has broadly followed antigen testing guidance from the California Department of Public Health (CDPH) for both symptomatic and asymptomatic individuals, as below. **Instructions in this document do not supersede your healthcare provider's individual advice or any specific institutional requirements for testing type or algorithm.**

Asymptomatic Individuals:

CDPH guidance endorses the use of antigen testing for screening tests, post-exposure testing, pre-entry testing or response testing with asymptomatic individuals. In the community, a positive or negative antigen test in an asymptomatic person does not require confirmatory testing with a nucleic acid amplification test (NAAT). **Due to implications of false positives in congregate living settings for isolation and outbreak management, a positive antigen test in an asymptomatic patient who lives in a congregate living should be confirmed with NAAT, such as a polymerase chain reaction (PCR) test.**

Symptomatic Individuals:

For symptomatic people in the community or in congregate settings, a positive test does not need confirmation with NAAT. However, the Centers for Disease Control and Prevention (CDC) and CDPH* have so far recommended that **symptomatic people with negative antigen** have a confirmation test with NAAT given concerns about sensitivity of antigen testing.

Rationale for SFDPH Guidance Changes:

Reported sensitivities (64-97%)[1-13] of antigen tests are lower than with NAAT testing (including PCR), yet specificity is high (87-99%).[1-13] One of the widely available antigen tests, the BinaxNOW™ COVID-19,[10-13] likely has higher sensitivity among infectious individuals. PCR results that are positive at low cycle thresholds are more likely to correctly identify persons who are infectious for COVID-19. When studies compared results of BinaxNOW™ COVID-19 to PCR tests that were positive at cycle thresholds less than 30 (i.e., when infectivity is more likely), there was increased sensitivity for BinaxNOW™ COVID-19 in both symptomatic (92-100%) and asymptomatic (78-100%) people.[10-13] Therefore, antigen test sensitivity is higher among symptomatic individuals than among asymptomatic individuals, and more likely to detect transmissible virus. SFDPH has changed its guidance on recommendations for confirmatory PCR testing given this emerging evidence.

Resources

California Department of Public Health

- Updated Testing Guidance: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Updated-COVID-19-Testing-Guidance.aspx ***Based on the latest evidence, SFDPH new recommendation that antigen testing does not require NAAT (e.g., PCR) testing differs from CDPH guidance. Many factors can impact the result of any test and clinical suspicion should always be considered in testing decisions.***

Food and Drug Administration

- In Vitro Diagnostics Emergency Use Authorizations - Antigen Diagnostic Tests for SARS-CoV-2: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

Key Studies on Antigen Test Characteristics

1. Kilic, et al. Evaluation of performance of the bd veritor sars-cov-2 chromatographic immunoassay test in patients with symptoms of covid-19. *Journal of Clinical Microbiology*,2021
2. Young, S et al. JCM. Clinical evaluation of BD veritor™ Sars-cov-2 point-of-care test performance compared to PCR-BASED testing and versus THE Sofia® 2 SARS Antigen point-of-care test. 2020
3. Pray, et al. Performance of AN ANTIGEN-BASED test for asymptomatic and Symptomatic SARS-CoV-2 testing at two university CAMPUSES — Wisconsin, september–october 2020. *MMWR. Morbidity and Mortality Weekly Report*, 2021
4. Beck et al. Comparison of THE QUIDEL Sofia Sars FIA test to the Hologic aptima SARS-COV-2 TMA test for diagnosis of COVID-19 in Symptomatic Outpatients. JCM. 2021
5. Bianco et al. Evaluation of an antigen-based test for hospital point-of-care diagnosis of sars-cov-2 infection. *Journal of Clinical Virology*, 2021
6. Drain et al. A rapid, HIGH-SENSITIVITY Sars-cov-2 nucleocapsid Immunoassay to Aid diagnosis of Acute Covid-19 at the point of care: A clinical performance study. *Infectious Diseases and Therapy*, *10*(2),2021
7. Krüger et al. Evaluation of accuracy, Exclusivity, LIMIT-OF-DETECTION and ease-of-use of Lumiradx™-antigen-detecting POINT-OF-CARE device For sars-cov-2. Prepub. 2021
8. Cento et al. Frontline screening For SARS-CoV-2 infection at emergency Department admission by third Generation rapid Antigen test: Can we Spare RT-qPCR? *Viruses*,2021.
9. Abbott Media Room. https://abbott.mediaroom.com/2020-12-16-Abbotts-BinaxNOW-COVID-19-Rapid-Test-Receives-FDA-Emergency-Use-Authorization-f or-First-Virtually-Guided-At-Home-Rapid-Test-Using-eMeds-Digital-Health-Platform
10. Prince-Guerra et al. Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites — Pima County, Arizona, November 3–17, 2020. MMWR Jan 22 2021
11. Pilarowski et al. Performance Characteristics of a Rapid Severe Acute Respiratory Syndrome Coronavirus 2 Antigen Detection Assay at a Public Plaza Testing Site in SF. JID, 2021
12. Pollock et al. Performance and Implementation Evaluation of the Abbott BinaxNOW Rapid Antigen Test in a High-Throughput Drive-Through Community Testing Site in Massachusetts. Journal of Clinical Microbiology. May 2021
13. Pollock et al. Performance and Implementation Evaluation of the Abbott BinaxNOW Rapid Antigen Test in a High-Throughput Drive-Through Community Testing Site in Massachusetts. Journal of Clinical Microbiology. May 2021