MEMORANDUM

DATE: January 10, 2022
TO: Facilities and programs which use COVID-19 antigen tests
FROM: DPH COVID Task Force
RE: Update on recommended algorithms for antigen testing

Changes since November 9th, 2021

- Updated to include the guidance that PCR confirmation after positive antigen test in a congregate setting is only recommended in certain situations.

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, have had a recent close contact or in the setting of very high community prevalence.

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 (for example when there are highly specific symptoms like loss of taste or smell), 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, clinicians may consider confirming a positive antigen test with NAAT in an asymptomatic patient who lives in a congregate living, as long as case rates are low, the patient has no recent close contact and clinical suspicion is low.

Symptomatic Individuals:
The Centers for Disease Control and Prevention (CDC) recommends that symptomatic people with negative antigen have a confirmation test with NAAT given concerns about sensitivity of antigen testing. However, CDPH and SFDPH have decided that confirmatory NAAT testing is not necessary in symptomatic individuals with a negative antigen test due to the evidence cited below. SFDPH has fewer exceptions of groups who still require confirmatory PCR testing as listed above under “What SFDPH guidance has changed?”

Rationale Antigen Testing 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 and CDPH has changed its guidance on recommendations for confirmatory PCR testing given this emerging evidence.
Resources

California Department of Public Health

Food and Drug Administration

Key Studies on Antigen Test Characteristics

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