COVID-19 TESTING IN THE CONTEXT OF OMICRON

TALKING POINTS, FAQ & KEY RESOURCES

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INTENDED AUDIENCE: PUBLIC HEALTH PROFESSIONALS

This information is based on currently available scientific evidence, reports, and expert opinion, and is subject to change. This document is accurate as of January 2022 and will be frequently updated as new evidence and information becomes available.

Talking Points

What we know

- **PCR tests are an effective tool to detect the Omicron variant**
    - PCR tests have been shown to effectively detect the Omicron variant, particularly early in the incubation period when a person may be infectious and other tests may not be as sensitive.
    - However, access and cost issues may limit their widespread use in the U.S. Additionally, in much of the country, PCR tests have slow turnaround time (24-48 hours+, with much longer wait times during periods of especially high demand) for results—time during which a person can spread COVID-19 to others. Rapid PCR tests with much shorter turnaround times do exist, but are generally not widely available.
    - PCR tests are effective at detecting the virus early but may continue to give positive results after a patient is infectious, which may make this test less useful for post-quarantine/isolation use.
- **Preliminary evidence suggests that some rapid antigen tests also effectively detect infections caused by the Omicron variant, with a few important caveats**
    - Early small-scale data indicate that some rapid tests appear to lag in ability to detect cases (compared to PCR tests) in the early period of disease. However, molecular tests (PCR) are inherently able to better detect low levels of a virus than antigen tests. We need more information to determine whether available rapid antigen tests detect Omicron with similar sensitivity compared to other variants.
    - In the midst of a massive surge of cases, pre-test probability (the chance a patient has a disease/infection, estimated before the test result is known) should be considered. In this case, the current likelihood of having Omicron is quite high, especially if there is a known exposure, so any negative results should be viewed with caution. If symptoms are consistent with COVID-19 infection, people should behave as if they have COVID-19 and retest if they receive a negative test early in symptom onset.
- **Access to tests in the U.S. is currently insufficient to support timely diagnosis, isolation, and quarantine**
    - Support to increase testing is coming, but details of allocation, distribution, and implementation are unclear in their ability to reach those most in need.

What we're watching

- **Rapid antigen test effectiveness against Omicron**
    - Formal recommendations by regulatory agencies have not indicated significant performance issues with rapid antigen tests and their ability to detect the Omicron variant. The performance of rapid antigen tests is reassessed continually as new variants emerge; as such, test recommendations and endorsement may change as more data is collected.

        - The FDA and test makers monitor performance and may change design or discontinue use in response to variants; however, only a few tests have been formally impacted to date.
    - Sampling technique may influence test sensitivity
        - Preprints suggest antigen tests performed using saliva or throat sample collection may indicate a positive result earlier than those performed using nasal samples. In the context of this emerging data, we are awaiting potential revised guidance regarding recommended sampling site. The FDA currently recommends current use only as authorized.
    - The recommended timing of rapid antigen tests may change as influenced by Omicron's shorter incubation period—and potentially its infectious period.
        - Omicron has a shorter incubation period than Delta (symptoms emerge 2-3 days after exposure, compared to 4-5 with Delta). This may imply earlier onset of infectiousness, suggesting testing sooner after exposure (and/or relying on tests that have shown to be more sensitive earlier) may help prevent transmission.
    - Preprint data suggest at least one rapid antigen test is significantly more sensitive among patients with high viral loads (95% sensitivity with high viral load vs 65% overall). This could mean the viral load (and peak infectious period) may be a key metric by which to understand test sensitivity.
        - The period of infectiousness for Omicron is still under investigation; at this time, regulatory agencies have not yet changed recommended timing for testing procedures.
- **Access to tests is insufficient, but increasing; implementation and equity implications are currently unclear**
    - Current access to testing is insufficient to support timely diagnosis, isolation, and quarantine, or meet the needs of the U.S. population in the context of the Omicron variant.
    - The U.S. government has recently announced major efforts to introduce significant numbers of new tests to the U.S. market. This includes 1 billion new tests, 10 million tests per month (5 million rapid antigen, 5 million PCR) made available to schools, and support to stand up at least 20,000 testing sites throughout the country.
    - In an effort to address access and cost, the White House recently announced that insurance companies and group health plans will be required to cover the cost of up to 8 over-the-counter at-home tests per covered individual per month, starting January 15.
    - These measures to increase access to testing may positively impact the U.S. testing landscape; however, the process of distribution and rollout is unclear. Importantly, we do not yet know the equity implications for these plans, and to what extent planning, prioritization, or allocation will consider equity and access, especially among at-risk or historically marginalized communities. Particular concerns include limited access to resources based on computer access/literacy or lack of permanent address, hoarding resulting in inequitable distribution, and communication discrepancies based on language preference.
- **Effect of decreased testing access on new/viable treatment options (antivirals)**
    - Antivirals are new and promising treatments, but their best use is within 3-5 days of symptom onset. Prescription hinges on diagnosis, so insufficient access to timely testing may limit their use in the most at-risk patients. As such, this is an opportune time to shore up testing infrastructure to maximize benefit of these treatments. We do not yet know the impact of the currently insufficient testing landscape on at-risk patients; as antiviral supply and distribution increases we will know more.

COVID-19 Testing FAQ

What type of diagnostic tests are available for COVID-19 testing?

There are two main types of diagnostic tests for COVID-19: molecular tests (PCR), that detect the virus' genetic material, and antigen tests, that detect specific proteins on the surface of the virus. Both types use samples from nasal or throat swabs, or saliva collection.

Most of the PCR tests in the U.S. offer high sensitivity (meaning the tests are able to detect a positive case of the virus very well) but slow turnaround time (24-48 hours+, with much longer wait times during period of especially high demand) for results—time during which a person can spread COVID-19 to others. Rapid PCR tests with much shorter turnaround times do exist, but are generally not widely available.

Rapid antigen testing is generally more accessible in terms of cost and access, though sensitivity is lower than PCR tests and varies, depending on context (whether a person has symptoms, when the test is taken after exposure, etc.). These tests can show results within 15 minutes, which provides potential to reduce transmission and enable access to isolation and social supports.

Do tests still work against the Omicron variant?

The presence of mutations in a virus can impact test performance. Different types of tests may be affected differently due to the inherent design differences in each test. Experts are studying the effectiveness of available tests to understand if they remain able to detect cases of the Omicron variant.

PCR testing appears to be an effective tool to identify the Omicron variant. Preliminary evidence suggests that some rapid antigen tests also effectively detect infections, including those caused by the Omicron variant, but may have reduced sensitivity.

As of December 28, 2021, the FDA continues its long-standing rapid test recommendations: if a person tests negative with an antigen test but is suspected of having COVID-19, such as experiencing symptoms or have a high likelihood of infection due to exposure, follow-up molecular testing is important for determining a COVID-19 infection. If a person tests positive with an antigen test, they should self-isolate and seek follow-up care with a health care provider to determine appropriate next steps.

The FDA and test makers monitor performance and may change design or discontinue use in response to variants; however, only a few tests have been impacted to date. The FDA's webpage, SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests, is a reliable source of information about the impact of viral mutations on test performance and recommendations for clinical staff. This page will be updated as new information becomes available. In the meantime, the FDA advises all to use current tests as intended until new information arises.

Have test timing recommendations changed because of the Omicron variant?

Preliminary data have shown that rapid antigen tests may lack sensitivity early on in an infection (potentially for a variety of reasons that need to be studied more). If symptoms are consistent with COVID-19 infection, the CDC recommends that a person should behave as if they have COVID-19 and retest if they receive a negative test early in symptom onset.

Given that the Omicron variant appears to have a shorter incubation period (the length of time between when a person is infected and when symptoms appear) than previous variants, there is potential for recommended timing of testing to change.

However, at this time, regulatory agencies have not yet changed recommended testing procedures.

Can a COVID-19 test tell if a person has the Omicron variant?

COVID-19 diagnostic tests are designed and authorized to test broadly for COVID-19 infection—not for specific variants. There are not any authorized COVID-19 tests that specifically report the presence of a certain variant in patient samples.

Public health agencies identify and track variants using a technique called whole genome sequencing—which happens at the community level and not for each person. If you do test positive for COVID-19, your health care provider will base recommendations and treatment on your symptoms and not on which variant you may have.

What should I do if I test positive?

If you test positive for COVID-19 or have symptoms, *regardless of vaccination status*, the CDC recommends the following (please note that certain cities/states/jurisdictions may follow more strict recommendations for positive test/symptomatic/isolation procedures; refer to your local recommendations for more specific information):

- Isolate:
  - Stay home for at least 5 days and isolate from others in your household.
  - Wear a well-fitted high-quality mask if you must be around others in your home.
  - Monitor your symptoms (if any) and seek medical care if necessary.
  - *Calculating isolation (isolation = if you are sick or test positive; quarantine = if you were exposed): Day 0 is your first day of symptoms or a positive viral test. Day 1 is the first full day after your symptoms developed or your test specimen was collected. If you have COVID-19 or have symptoms, isolate for at least 5 days.*
- Ending isolation:
  - If you had COVID-19 symptoms, end isolation after 5 full days if you are fever-free for at least 24 hours (without the aid of fever-reducing medication) and your symptoms are improving.
  - If you did not have COVID-19 symptoms, end isolation after at least 5 full days after your positive test.
  - If you were severely ill with COVID-19, you should isolate for a minimum of 10 days and consult your doctor before ending isolation.
  - If you have access to a COVID-19 antigen test, use the test toward the end of the 5-day isolation period, only if you are fever-free for at least 24 hours without the aid of fever-reducing medication.
    - If your test is positive, continue to isolate until at least day 10.
    - If your test is negative, you may end isolation but continue to follow the below recommendations re: masking and travel.
- Continue to take precautions until at least day 10:
  - Wear a mask at all times when around others; if you cannot wear a mask at all times (restaurants, gyms, etc.), avoid these locations for at least 10 days.
  - Avoid travel.
  - Avoid high-risk settings and avoid being around people who are at high-risk (elderly, immunosuppressed, unvaccinated).

What if I am unable to access a test but think I have been exposed to COVID-19?

If you have been exposed to someone with COVID-19 but have not been able to test, your vaccination status and symptoms will dictate your actions, as recommended by the CDC. Refer to the table below:

	Initial Actions (Days 1-5)	After Quarantine	Precautions until Day 10
If you were exposed to COVID-19 and are NOT up-to-date on COVID-19 vaccinations*	• Quarantine at least 5 days • Wear a mask • Get tested at least 5 days after you last had close contact with someone with COVID-19	• Watch for symptoms until 10 days after you last had close contact with someone with COVID-19 • If you develop symptoms, isolate immediately and get tested	• Wear a mask for 10 full days. Do not go to places where you are unable to wear a mask • Avoid travel • Avoid being around people at high risk
If you were exposed to COVID-19 and ARE up-to-date on COVID-19 vaccinations*	• You do not need to quarantine unless you develop symptoms • Get tested at least 5 days after you last had close contact with someone with COVID-19	• Watch for symptoms until 10 days after you last had close contact with someone with COVID-19 • If you develop symptoms, isolate immediately and get tested	• Wear a mask for 10 full days. Do not go to places where you are unable to wear a mask • Avoid travel • Avoid being around people at high risk
If you were exposed to COVID-19 and had confirmed COVID-19 within the past 90 days (tested positive using a viral test)	• You do not need to quarantine unless you develop symptoms	• Watch for symptoms until 10 days after you last had close contact with someone with COVID-19 • If you develop symptoms, isolate immediately and get tested	• Wear a mask for 10 full days. Do not go to places where you are unable to wear a mask • Avoid travel • Avoid being around people at high risk

*** Up-to-date on vaccinations is considered:** people 18+ who have received all recommended COVID-19 vaccine doses, including boosters and additional primary shots for some immunocompromised people; people 5-17 who have completed the primary series of COVID-19 vaccines.

Key Resources

Resource	Source	Notes/Key Takeaways
Home-Based Test EUA Database (Antigen)	FDA	Input "home" in search field; filter results by "Prescription Home Testing" and/or "OTC Home Testing" in Attributes column
Home-Based Test EUA Database (Molecular)	FDA	Input "home" in search field; filter results by "Home Testing" in Attributes column
SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests	FDA	Information about impact of viral mutations on test performance and recommendations for clinical staff
Pre-Print Article: *Direct Comparison of SARS Co-V-2 Nasal RT- PCR and Rapid Antigen Test (BinaxNOW™) at a Community Testing Site During an Omicron Surge*	medRxiv	Study of 731 persons at a walk-up testing site in San Francisco in January 2022 compared sensitivity of RT-PCR tests and nasal rapid antigen tests (BinaxNOW). Sensitivity of BinaxNOW was ~65% overall, though it was ~95% among patients with high viral load. In a small subset of samples, rapid antigen tests using an oral cheek swab were significantly less sensitive than rapid antigen tests using nasal sampling (both BinaxNOW).
Pre-Print Article: *Discordant SARS-CoV-2 PCR and Rapid Antigen Test Results When Infectious: A December 2021 Occupational Case Series*	medRxiv	Small retrospective cohort study of diagnosed individuals at 5 workplaces (New York, Los Angeles, San Francisco) in December 2021 compared saliva PCR and two widely used nasal rapid antigen test results for discordance during the early stages of infection. Rapid tests appeared to lag in

		ability to detect SARS-CoV-2 during the first few days of infection when most individuals were likely infectious based on viral load. It is not clear if this discordance was due to inherent differences in test sensitivity or differences in sample site.
Translated Materials Library	National Resource Center for Refugees, Immigrant, and Migrants (NRC-RIM) - University of Minnesota	Array of resources including fact sheets, posters, videos, audio recordings, and other resources in English and 100 other languages, free of charge (some editable). Materials are collected from organizations across the country working with refugee, immigrant, and migrant communities. Search under language, topic, or resource type as needed. Testing is available as a search category.