February 2021

# COVID-19 Testing Strategy

## Practical Considerations for Implementation

# Context for these materials

The ideas and testing methods presented in this deck reflect the latest public health thinking and scientific evidence as of February 2021. You are advised that the COVID-19 testing landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available.

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# Choice of test depends on the reason for testing

**1 Diagnosis**

- Aims to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.
- Examples of diagnostic testing include testing symptomatic persons, testing persons identified through contact tracing efforts who were exposed to someone with a confirmed or suspected case of COVID-19.

**2 Screening**

- Aims to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2.
- Performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.
- Examples of screening include testing in congregate settings, such as a long-term care facility or a correctional facility, a workplace testing its employees, or a school testing its students, faculty, and staff.

**3 Surveillance**

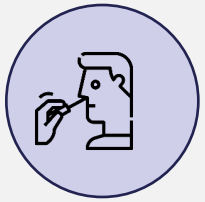
- Aims to monitor population-level infection and disease, or to characterize the incidence and prevalence of disease.
- Performed on de-identified specimens, and thus results are not linked to individuals; results of surveillance testing are only returned in aggregate. Thus, surveillance testing is not used for individual decision-making, but rather population interventions.
- Examples of surveillance testing include a plan developed by a state public health department to randomly select and sample a percentage of all persons in a city on a rolling basis to assess local infection rates and trends or wastewater surveillance



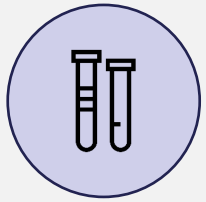
Source: CDC - https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html

# Testing strategy considerations

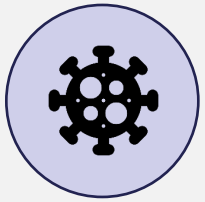
For optimal disease control during a pandemic, all populations would be tested frequently, with rapid turnaround times, and immediate contact tracing with supported isolation/quarantine for positive cases and contacts. With real-world constraints, jurisdictions must weigh these factors in designing an equitable and effective testing strategy.



**Test Capacity:** the number of tests that can be conducted and processed in a given time period, considering cost, availability, and throughput

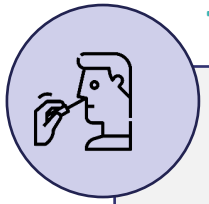


**Turnaround Time:** time between sample collection and delivery of test result to an individual and epidemiological reporting system



**Disease Prevalence:** approximated by percent positivity (# of positive test/all tests conducted) and/or # of cases per 100,000

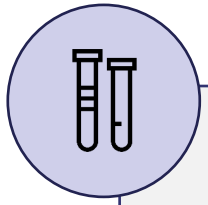
# Testing strategy considerations in practice



## Test Capacity: why it matters

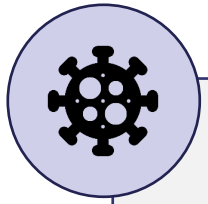
Operational limitations determine the number of tests that can be processed, including:

- **Throughput**: how many samples can be processed at once varies by test type
- **Cost**: varies by test type and manufacturer
- **Availability**: Not currently sufficient to meet needs in many jurisdictions; until appropriate federal investments are made, LHDs need to prioritize and align available tests to populations that need them



## Turnaround Time: why it matters

- Testing is not effective for epidemic control unless results can be delivered with adequate time to influence behavior based on results (1-3 days)
- All exposed contacts of an index case should be quarantined within 4.5 days of initial exposure to drive R=1 and achieve epidemic control, underscoring the need for rapid TAT
- If long TAT is due to capacity constraints, emphasize TAT above universal access, prioritizing key populations for testing when labs are unable to deliver results in target timeframe
- It's more effective to conduct fewer tests that enable public health actions than provide universal testing with TATs that are too long to act on results



## Disease Prevalence: why it matters

- Testing strategy shifts in response to the level of community spread, approximated by test positivity rates
  - For example, pooled testing and wastewater surveillance may be less informative when prevalence is high, as most sample pools would be returned as positive, providing little epidemiological insight
- Additionally, when disease prevalence is high, jurisdictions will need to make prioritization decisions in investigation and tracing
  - Deploying testing to outbreak clusters and testing all exposed contacts may be less logistically feasible when case counts are surging

# Testing strategies by test type: NAAT & antigen tests

**Nucleic acid amplification tests (NAAT)** detect the genetic material of the virus—often RNA—and therefore require "breaking open" the virus to obtain the genetic material inside

**Examples:** all polymerase chain reaction (PCR) tests and next generation sequencing (NGS)

**Antigen tests** detect physical components of the virus, such as the surface proteins on the outer layer, or nucleocapsids inside the virus

**Examples:** BinaxNOW

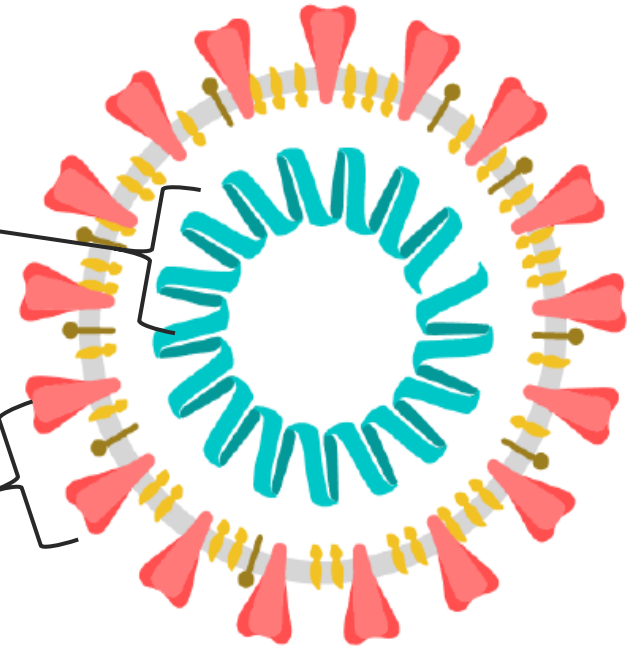




Image source: https://www.dropbox.com/s/6fx3ankq156xp80/How%20to%20deploy%20millions%20of%20COVID-19%20tests%20per%20day%20v.%200.4%20May%209%202020.pdf?dl=0/

# Testing strategies by test type: NAAT & antigen tests

| | NAAT | Antigen test |
|---|---|---|
| **Test Capacity: Availability** | • **241** molecular tests have Emergency Use Authorization (EUA) status from the FDA[1]<br>• Generally **higher throughputs** (longer processing time but more samples can be processed at once)<br>• **Limitations** can arise with lab personnel, reagents, kit components, and infrastructure/manufacturing capacity | • **14** antigen tests have EAU status from the FDA[2]<br>• Generally **lower throughputs** (shorter processing time but fewer samples can be processed at once)<br>• **Limitation** is primarily availability; scale-up requires significant federal investments in manufacturing and procurement |
| **Test Capacity: Cost** | • **More expensive per test** ($100-150)<br>• Price can be reduced by pooling samples, but this is only cost-effective in low prevalence populations | • **Less expensive per test** ($5-25)<br>• "Real" cost vs the cost billed to a patient varies<br>• Some providers charge as much as $200 per rapid test due to scarcity and convenience to patients |



1, 2: Data accessed February 9, 2021
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

# Testing strategies by test type: NAAT & antigen tests

| | NAAT | Antigen test |
|---|---|---|
| **Turnaround Time (TAT)** | • **Longer**: Processing the test can take a few hours, and delivery of results can take up to a week due to processing and reporting delays | • **Rapid:** Processing the test takes ~15 minutes, results can be delivered at the point-of-care for immediate commencement of investigation, tracing, linkage to medical and social services |
| **Accuracy** | • **Highly sensitive** (>90%) and **highly specific** at detecting viral RNA; both false positives and false negatives are very rare<br>• **Limitations:** High sensitivity may result in people testing positive long after their infectious period, which tends to be ~5 days (days 3-8 post-exposure)<br>• Some therefore argue NAAT tests may be "too sensitive" for routine screening of infectiousness | • **Highly sensitive, slightly less specific;** false negatives are very rare<br>• Reduction of specificity, even if only from 100% to 98% , results in relatively higher proportion of false positives in **low prevalence** settings.<br>• Make sure to follow the CDC antigen testing algorithm and do **confirmatory testing** (confirm negative tests in symptomatic patients with NAAT; confirm positive tests in asymptomatic patients with NAAT) |



https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

# Testing strategies by population

To develop strategic and equitable testing plans, jurisdictions should consider the real-world factors and constraints of test capacity, turnaround time, and disease prevalence.

See an in-depth table of recommendations stratified by population, priority level, and test type.

**High priority designation:** testing critical throughout all stages of the epidemic; supports the treatment and supported isolation of COVID+ individuals and their exposed contacts to break transmission chains

**Medium priority designation:** testing useful for identifying outbreaks and screening to safely resume activities, but can be de-prioritized when prevalence is high, and resources are limited

**Low priority designation:** testing most useful when disease prevalence is low and not during sustained community-level spread; provide population level epidemiological insights

# Home-Based Testing

Review recommendations on home-based testing here, including implementation considerations for equitable programs, examples of home-based testing programs, and information on available home-based tests.

To make testing more **equitable**, we must expand **access** through **decentralization**. The Surgo Foundation's report "Vulnerable Communities and COVID-19: The Damage Done, and the Way Forward; In-Depth Analysis and Policy Recommendations for Mitigating Impacts" shares an encouraging finding: disparities in accessing COVID-19 testing have improved over the course of the pandemic. Still, more progress needs to be made.

Home-based testing is one strategy to address the remaining gaps. It allows for convenience and privacy and reduces burden on community testing sites. It should be noted that most approved home-based tests are home-collection models, requiring individuals to send out their specimens for processing to receive results.

# US Public Health Accompaniment Unit

For more information please contact LearningCollab@pih.org

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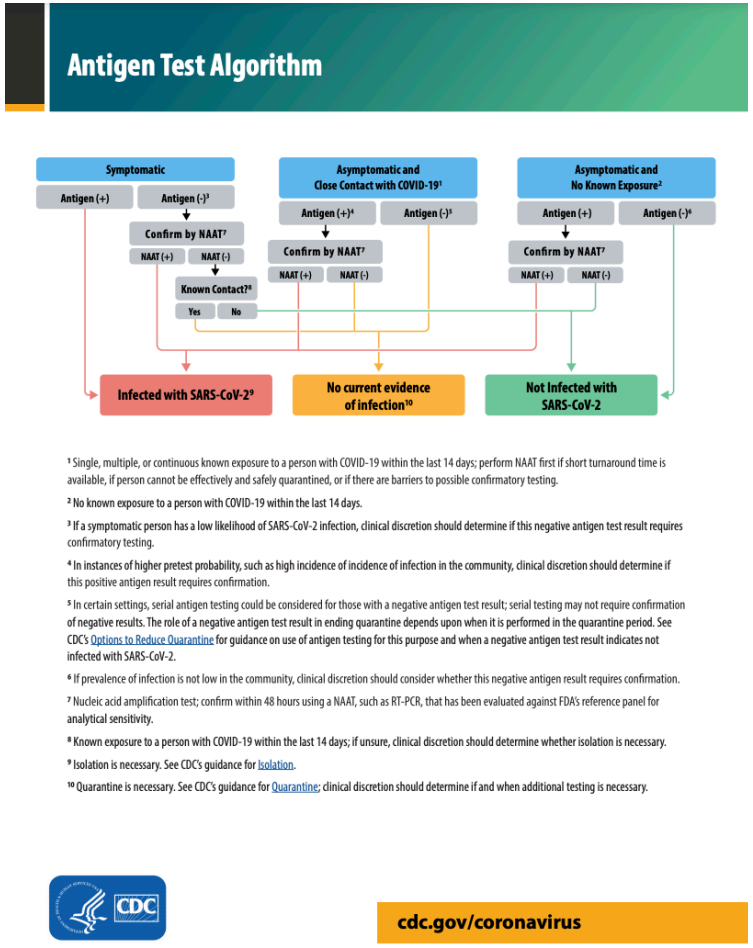
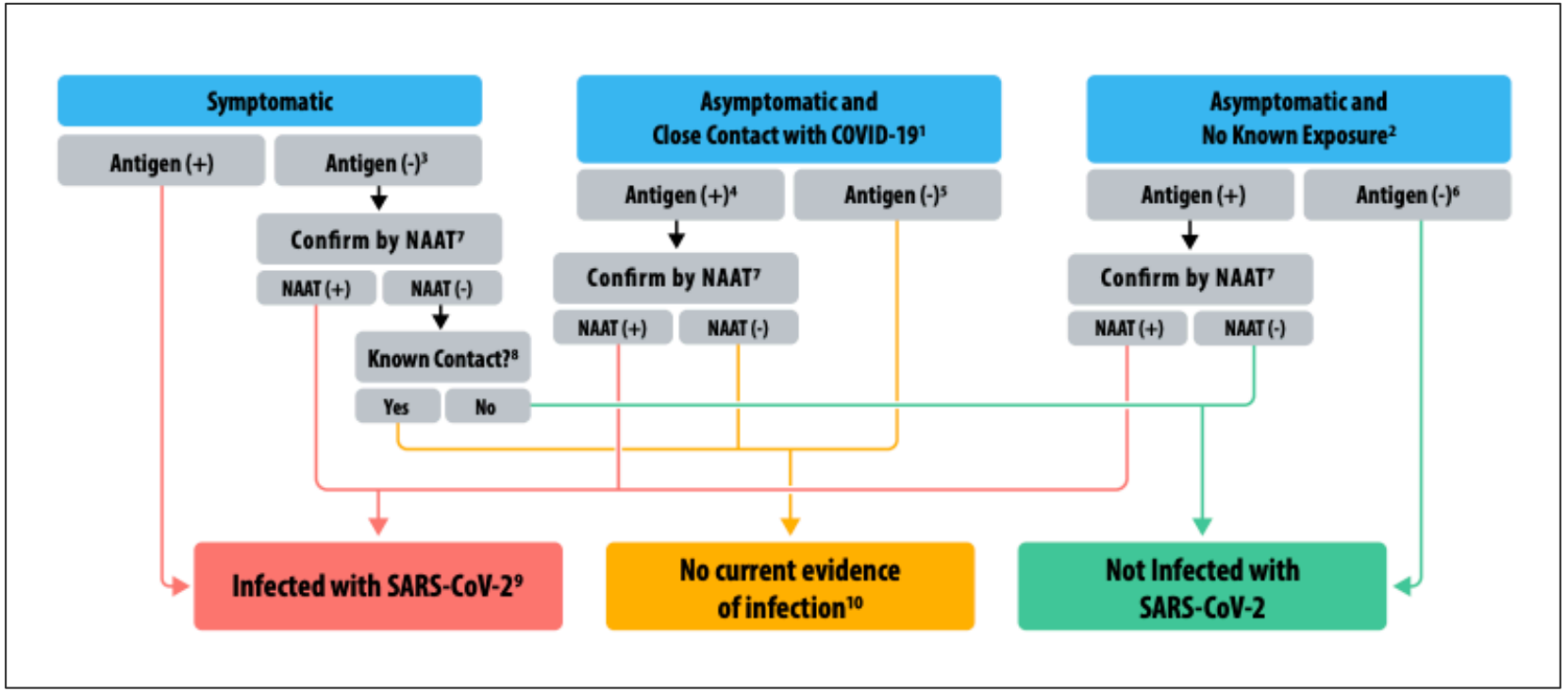
# Appendix: CDC Antigen Test Algorithm

Antigen tests are typically rapid and lower cost than NAAT tests and can add significant value. Due to somewhat lower sensitivity, however, a strategy to manage potential false positives is required.




CDC antigen testing algorithm