Testing Strategies for SARS-CoV-2

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Key Points

- This guidance describes and compares different types of SARS-CoV-2 (the virus that causes COVID-19) testing strategies, including their intended use and applications, regulatory requirements, and reporting requirements.
- This guidance is intended for those who offer and perform SARS-CoV-2 testing.

Diagnostic Testing

Diagnostic testing is intended 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 people who have symptoms consistent with COVID-19 and who present to their healthcare provider
- Testing people as a result of contact tracing efforts
- Testing people who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19
- Testing people who attended an event where another attendee was later confirmed to have COVID-19

Screening Testing

Screening tests are intended to identify infected people who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening helps to identify unknown cases so that measures can be taken to prevent further transmission.

Examples of screening include testing:

- Employees in a workplace setting
- Students, faculty, and staff in a school setting
- A person before or after travel
- At home by someone who does not have symptoms associated with COVID-19 and no known exposures to someone with COVID-19

Public Health Surveillance Testing

Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice. See CDC's Introduction to Public Health Surveillance.

Public health surveillance testing is intended to monitor community- or population-level outbreaks of disease, or to characterize the incidence and prevalence of disease. Surveillance testing is performed on de-identified specimens, and thus, results are not linked to individual people. Public health surveillance testing results cannot be used for individual decision-making.

Public health surveillance testing may sample a certain percentage of a specific population to monitor for increasing or decreasing prevalence, or to determine the population effect from community interventions such as social distancing. An example of public health surveillance testing is when a state public health department develops a plan to randomly select and sample a percentage of all people in a city on a rolling basis to assess local infection rates and trends.

Regulatory Requirements for Diagnostic, Screening, and Public Health Surveillance Testing

Any laboratory or testing site that performs **diagnostic** or **screening** testing must have a Clinical Laboratory Improvement Amendments (CLIA) certificate and meet all applicable CLIA requirements. For more information, see the Centers for Medicare & Medicaid Services CLIA website . Assays and test systems used for SARS-CoV-2 diagnostic or screening testing must have received an Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) or be offered under the policies in FDA's Policy for COVID-19 Tests .

Assays and test systems used for SARS-CoV-2 **public health surveillance** testing do not need to meet FDA and CLIA requirements for diagnostic and screening testing.

Reporting Diagnostic, Screening, and Public Health Surveillance Testing Results

Both **diagnostic** and **screening** testing results can be reported to the people whose specimens were tested and/or to their healthcare providers.

In addition, laboratories that perform diagnostic and screening testing must report test results (positive and negative) to the local, state, tribal, or territory health department in accordance with Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The Department of Health and Human Services published guidance on COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 that specifies what data, in addition to test results, laboratories and testing sites should collect and electronically report.

Public health surveillance testing results cannot be reported to the people whose specimens have been tested and are not reported to their healthcare providers. Public health surveillance testing results – test results that are de-identified – can be reported in aggregate to local, state, tribal, or territory health departments upon request. Results from testing that is performed outside of a CLIA-certified facility or without an FDA-authorized test can only be reported to a health department if those results are used strictly for public health purposes, and not used for individual decision making.

Summary of Testing Strategies for SARS-CoV-2

	Diagnostic	Screening	Public Health Surveillance
Symptomatic or Known or Suspected Exposure	Yes	No	N/A
Asymptomatic without Known or Reporting Suspected Exposure	No	Yes	N/A

Characterize Incidence and Prevalence in the Community	N/A	N/A	Yes
Testing of Personally Identifiable Specimens	Yes	Yes	No
Results may be Returned to Individuals	Yes	Yes	No
Results Returned in Aggregate to Requesting Institution	No	No	Yes
Results Reported to State Public Health Department	Yes	Yes	If requested
Testing can be Performed in a CLIA-Certified Laboratory	Yes	Yes	Yes
Testing can be Performed in a Non-CLIA-Certified Laboratory	No	No	Yes

Test System Must be FDA Authorized or be Offered under the Policies in FDA's Guidance	Yes	Yes	No

Resources

- Overview of Testing for SARS-CoV-2 (COVID-19)
- FDA FAQs on Testing for SARS-CoV-2

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Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases