COVID-19 TESTING IMPLEMENTATION GUIDE (CTIG)

Supply, Personnel, Facilities, and Documentation Guidance for Creating a Covid-19 Test Program

This project has been funded by the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, through the NIH RADx™ Initiative

This guide does not provide medical advice and should not be used as a substitute for specific medical advice. Information and materials are to inform and educate readers. Consult a qualified healthcare provider for answers to your medical questions. Contents of the COVID-19 Testing Implementation Guide are to be used for guidance only and do not represent medical recommendations.
Intended Purpose and Audience

This guide aims to provide practical guidance on the implementation of a COVID-19 testing program. This includes consideration of various supply, personnel, facilities, and documentation best practices.

This guide is intended to assist organizations, such as schools, businesses, or non-profits, to implement a testing program for COVID-19 among their employees and/or constituents.

NOTE: Coronavirus Disease 2019 (COVID-19) is the disease caused by the SARS-CoV-2 virus. Tests designed to detect the presence of the SARS-CoV-2 virus may be referred to as either COVID-19 tests or SARS-CoV-2 tests depending on the source. For the sake of simplicity, these tests will be referred to as COVID-19 tests throughout this document.

Exclusions/Out of Scope

This guide does not intend to cover:

- Various infection prevention and outbreak mitigation measures that should be implemented in addition to testing, as recommended by federal, state, and local authorities
- The relative costs and benefits of testing for COVID-19
- Methods for assessing risk within your community or organization
- Testing strategies based on your risk assessment
- Selection and acquisition of specific COVID-19 tests
- Setup and operation of a high- or moderate-complexity lab
Test Selection and Testing Strategy Resources

Some resources that may be useful in conjunction with this guide:

**Testing Strategy Considerations**

**CDC**

General considerations on COVID-19 testing strategies for non-healthcare workplaces. Provides employers with strategies for consideration of incorporating testing into a workplace COVID-19 preparedness, response, and control plan.

**Whentotest.org**

**CIMIT and MIT**

Modeling tool that compares testing plan options while showing the effects of other mitigation strategies on testing requirements and outcomes. Can be used to estimate the potential costs of various types and frequency of testing.

**COVID-19 Test Databases**

The databases below may be useful resources for browsing currently authorized COVID-19 tests. Additionally, refer to the FDA website to verify the current authorization status of any test.

**AdVeritasDx**

**FIND**

**Arizona State University**

Effective Testing and Screening for COVID-19

**Rockefeller Foundation**

Describes the different purposes for COVID-19 testing, types of tests available, and selection of a testing strategy based on local and community factors.\(^1\)
For the purposes of this guide, an organization’s implementation of COVID-19 testing will be considered in three different scenarios, each necessitating familiarization with different sections of the guide (referenced below). These sections are intended to be modular to allow for the construction of more scenario-specific guides.

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Considerations Before Deciding on a Testing Strategy

Before deciding on a testing strategy (fully or partially on/off-site) you may want to think about the following:

- **Control of Testing:** From an organizational perspective, would you prefer to own the testing process? Do you want to take on the responsibility of implementing a testing/collection program on-site? (See Third Party Considerations, Personnel, Physical Space and Workflow, Sample Collection, Transport, Test Operation, Reporting, and Follow-up)

- **Location/Space for Testing:** Does your facility have the physical space for testing or sample collection on-site? (See Physical Space and Workflow)

- **Personnel:** Do you have the proper personnel to perform sample collection and/or test operation? Are they adequately supplied and trained? (See Personnel, Sample Collection, and Test Operation)

- **Timing:** How quickly do you need test results? Conducting tests on-site will allow you to receive results quicker than outsourcing to regional or national labs. Do you require the turnaround time of results to be quicker than 2-5 days?
Cost: Implementing a testing program on-site may be more cost effective than fully outsourcing, depending on the needs of your organization. Whentotest.org provides cost estimates for various testing strategies.

Off-site Collection and Testing (Fully Outsourced)

This includes any scenario in which the entire testing process is “outsourced.” For example:

- Contracting with an outside clinic or testing site to regularly test your personnel
- Hiring an outside firm to perform regular testing for employees on-site (e.g., via a mobile testing lab)
- Having participants use home collection kits to ship samples to a central lab

If an organization's testing plan can be categorized as this type of scenario, they will most likely not have to consider the sample collection, transport, or test operation sections of this guide, as their contracted party will handle these components. The third party considerations, reporting and follow-up sections may still be relevant for such an organization.

In addition, a separate Outsourcing Addendum provides suggestions to follow when partnering with a third-party testing service.

On-site Collection with Remote Testing “Lab” (Partially Outsourced)

This includes any scenario in which an organization plans to collect test samples to be tested elsewhere. For example:

- Collecting swabs from individuals on-site, then shipping the swabs to a local/regional lab for testing
- Having employees/students/etc., self-collect samples for shipment to an outside lab

If an organization's testing plan can be categorized as this type of scenario, they will most likely not have to consider the test operation sections of this guide. The third party considerations, sample collection, transport, reporting, and follow-up sections may be relevant for such an organization.

On-site Testing “Point of Care” (In-House)

This includes any scenario in which an organization intends to implement all aspects of testing on-site. Generally this means that the organization plans to collect samples and run the tests themselves on a point-of-care test. If this is the case, then all of the following sections may be relevant for that organization.
Third Party Considerations

If an organization intends to conduct testing on-site, there are several third-party requirements that may need to be considered and addressed prior to testing implementation.

**CLIA Waiver**

**Who needs a CLIA Waiver?**

If your organization will be operating a COVID-19 test designated as a “waived” complexity test by the FDA, then you will require a CLIA certificate of waiver. Tests of “moderate” or “high” complexity require additional CLIA certifications beyond the scope of this guide.

If your organization is only performing sample collection, either with approved self-collection kits or in partnership with a third-party testing service, then you will not need a CLIA certificate (the lab performing the test will possess the CLIA certification).

This section will cover test complexity designations and the process of obtaining a CLIA waiver.

All of the COVID-19 tests currently granted an Emergency Use Authorization (EUA) by the FDA fall into one of four categories:

- **HIGH COMPLEXITY (H)** - Laboratories certified under CLIA that meet requirements to perform high complexity tests
- **MODERATE COMPLEXITY (M)** - Laboratories certified under CLIA that meet requirements to perform moderate complexity tests
- **WAIVED (W)** - Patient care settings operating under a CLIA Certificate of Waiver
- **Home prescription use, self collection kits, and direct-to-consumer or over-the-counter (OTC) tests**

Refer to the [FDA Database](https://www.fda.gov) for a current list of EUA authorized tests. The Authorized Setting(s) column will contain some combination of H/M/W(or n/a), corresponding to High Complexity/Moderate Complexity/Waived or home prescription use and self collection kits.

**What is CLIA?**

CLIA stands for the Clinical Laboratory Improvement Amendments (CLIA). Congress passed CLIA in 1988 to establish standards for the regulation of clinical laboratory testing. CLIA defines a laboratory as a facility that performs testing on materials from the human body for the purposes of diagnosis, prevention, or treatment of disease.²

**What is a CLIA Certificate of Waiver?**

A CLIA Certificate of Waiver allows a lab to perform any tests that have been determined by the FDA to be "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."²
How to obtain a CLIA Waiver

Refer to this document from CMS and the CMS CLIA webpage for guidance on obtaining a CLIA waiver. Additionally, some states may have state-specific requirements. Refer below for more information:

State Contacts
NCPA – CLIA Requirements by State

Licensed Healthcare Provider

The majority of currently authorized EUA COVID-19 tests are intended for use in individuals who are suspected of COVID-19 by their healthcare provider; most of these tests require a prescription from a healthcare provider. Other tests are approved for asymptomatic, or over-the-counter (OTC), use; these may or may not require a prescription for use.

An organization planning to implement COVID-19 testing using a test that requires a prescription must coordinate with licensed healthcare providers. This may be beneficial even when using OTC tests. Having a process in place for referring personnel with positive test results to a healthcare provider will allow for rapid confirmatory testing and follow-up care.

Consider local health systems and physician networks as potential partners and resources for healthcare providers. Telemedicine services may also fill this need (see below for telemedicine resources).

- State and regional telehealth networks
- Find a health center – The HRSA’s Bureau of Primary Healthcare funds clinics throughout the US, with the goal of providing care to underserved populations
- HHS – Finding telehealth options

Health insurers have responded to the pandemic in a variety of ways in an effort to increase access to and quality of care. Refer to the guide below from AHIP for information specific to each insurance provider:

- Health Insurance Providers Respond to COVID-19
Proper communication is critical throughout the testing process. Every step, from ensuring compliance with infection control measures to effective contact tracing, relies on messaging that will promote buy-in and reduce concern and confusion among constituents. Some general considerations:

- Consider establishing a web page or testing portal that serves as a centralized location for testing personnel and participants to find up-to-date information, schedule testing, read results, coordinate with healthcare providers, and find answers to their questions. Some of the Testing and Data Management apps and resources listed above may provide this service.

- Post an FAQ related to COVID-19 testing in general and your organization’s specific testing program. Some general COVID-19 FAQ can be found from the CDC, the FDA, Johns Hopkins, and usa.gov/coronavirus.

- Establish a clear line of communication related to your testing program (hotline, helpdesk, etc.)

- Identify stakeholders in the testing process and clearly communicate your organization’s testing strategy to all including standard operating procedures, protocols, and expected outcomes

- Provide regular updates through email or the webpage/portal regarding program performance and outbreak status

The guides below provide suggestions related to communication and messaging:

- Rockefeller – Messaging Handbook
- WHO – A guide to preventing and addressing social stigma associated with COVID-19
05  Personnel

Having the right people, in the right roles, properly trained, well coordinated, and following well-established standard operating procedures will help ensure that your testing program is safe and effective. Careful communication between your organization and all personnel will also play a key role in this process.

Roles and Responsibilities

The number and roles of personnel required for any testing program will vary based on the specific circumstances of that program. As always, your organization should coordinate with local public health authorities when establishing a testing program. In general, the following roles and their associated responsibilities should be considered (some personnel may fill multiple roles):

- **SITE LEAD** - responsible for management of site operation, personnel, resources
- **CLINICAL LEAD** - oversees healthcare personnel and/or those directly performing sample collection
- **SAFETY LEAD** - ensures SOPs are followed and responds to emergency situations
- **GREETER** - verifies patient information, directs flow of participants to appropriate stations. May also check for symptoms/fever/etc.
- **DATA ENTRY** - enters patient information and ensures proper sample ID
- **SAMPLE COLLECTION** - collects sample swabs. These personnel should have limited additional responsibility to reduce cross-contamination risks
- **TEST OPERATION** - processes samples and operates device
- **SAMPLE TRANSPORTATION** - handles packaging, storage, and transportation of samples depending on testing scenario

Training

All personnel involved in the process should be appropriately trained and evaluated based on their roles. This includes training on proper use of personal protective equipment (PPE) and familiarization with all SOPs developed for the testing program.

Consider providing data handling, privacy, or security training to any personnel who may have access to patient information or test results. Some resources below:

- DHS – [Protecting Personal Information](#)
- HHS – [HIPAA Training Resources](#)

Any personnel performing sample collection or operating the test should meet the requirements outlined in the test’s **IFU** (Instructions for Use). In addition to initial training and orientation, an initial quality control check should be performed via a mock run of the test. Occasional proficiency examinations should be performed, with a list documented of all personnel that have met training requirements.
Checklists could be provided at each station/role for reference by personnel.

Some resources for personnel training:

- CDC – Guidance for SARS-CoV-2 Point-of-Care Testing
- CDC – Ready Set Test!
- WHO – SARS-CoV-2 Antigen Rapid Diagnostic Test training package

**Standard Operating Procedures (SOPs)**

Your organization will need to develop standard operating procedures (SOPs) for all aspects of the testing program. These will help ensure consistent and safe operation. All personnel should be thoroughly familiarized with and occasionally tested on these SOPs. These SOPs should also be made available to participants in order to answer questions and address concerns. Some potential subjects for SOP development may include:

- **Personal Protective Equipment (PPE) Use**
  Standard PPE requirements based on role and location. Donning and doffing procedures. Changes to workflow and testing strategy based on PPE availability.
  For more information, see the CDC’s Infection Control Guidance page, Standard and Transmission-based Precautions, and HHS COVID-19 Personal Protective Equipment Resources.

- **Patient Preparation**
  Your test’s IFU will contain any instructions for patients prior to sample collection. For example, avoiding food or drink for a certain time period beforehand, etc.

- **Sample collection and storage**
  Standard sample collection procedures and storage requirements will vary based on the specific test used. Refer to your test’s IFU and the CDC’s Specimen Collection Guidelines.

- **Test operation**
  This SOP will also vary based on your specific test. Refer to the IFU, and for more general guidance, see the CDC’s Guidance for SARS-CoV-2 Point-of-Care Testing page.

- **Quality control procedures**
  If operating tests on-site under a CLIA waiver, quality control (QC) tests are regularly performed to ensure testing accuracy. Refer to CDC guidance on developing a lab QC program.

- **Information collection and data entry**
  Standard procedures and forms for gathering patient information. See the What to Report section for a list of CDC recommended reporting elements as well as the HIPAA and Privacy section for information about privacy concerns.

- **ID verification**
  Procedures for verification of the patient’s identity as well as proper identification and labeling of the sample during the collection and testing process. See Patient and Sample ID.
PERSONNEL continued

- **Results Interpretation and reporting**
  These SOPs should establish a standard procedure for the interpretation and reporting of test results (to both individuals and the organization).

  You may also choose to include procedures to follow if results are unable to be shared (for example, if employee refuses to sign a release).

  See the Reporting and Communication sections for more information regarding reporting, privacy, and messaging considerations.

- **Sample pooling**
  If your testing program involves pooled testing, some additional procedures may need to be established. See the CDC’s Interim Guidance for Use of Pooling Procedures for more. The COVID-19 Lab Pool Testing Operational Playbook is a practical guide that includes a standard workflow as well as a high-level overview of the regulatory guidance and resources needed to accomplish pool testing for COVID-19.

- **Response to test failures**
  If a test leads to an inconclusive result, procedures should be established for notification and retesting of that individual.

  This can be applied in both on-site and off-site testing scenarios.

- **Personnel exposure**
  Procedures to follow if personnel are exposed to confirmed or suspected COVID-19 patients, considerations based on PPE levels, possible PPE failure, etc. See the CDC’s Guidance for Healthcare Personnel with Potential Exposure to COVID-19.

- **Biohazard handling**
  General procedures for handling of biohazard materials. See the Biohazard Waste Disposal section for more information.

  Cleanup of biohazard waste spills. See the CDC’s Waste Management Guidance for SARS-CoV-2 Point-of-Care Testing for more info.

- **Environmental incidents** (weather, loss of power, etc.)
  Procedures to follow in the event of loss of power, severe weather, natural disasters, etc. Consider coordinating with local public safety, fire, and EMS depts.
Physical Space and Workflow Considerations

Some consideration should be made for both the physical space where testing will be conducted (sample collection and/or test operation) and the general testing workflow. Additionally, the time necessary to move each individual through the testing workflow should be considered to allow for accurate scheduling and to prevent unnecessary backlogs. The proper coordination and flow of participants through a testing area will help to minimize exposure risk and ensure efficient testing throughput. Each testing environment is unique, and local health officials should always be consulted prior to implementing any testing operation.

The Texas Division of Emergency Management’s K-12 Testing Guide was developed for a specific testing environment; however, their recommendations serve as an excellent example applicable to other testing scenarios. Their Best Practices for Schools guide covers considerations for physical testing space and testing workflow.  

Testing Space

- Outdoor locations are preferred for easier distancing and improved ventilation
- If an indoor space is used, allow for proper distancing
- Signs or physical barriers may need to be utilized to ensure proper (6 foot) distancing of participants
- The area where actual specimen collection occurs should be separated (individual rooms or physical barriers) to prevent exposure from aerosol generated during specimen collection
- Keep testing supplies outside of specimen collection area to avoid cross-contamination
- Ensure that the location where samples are being tested has all necessary amenities for the instrument being used (sturdy table, power supply, climate control, etc.)
- Clean and disinfect all surfaces between each patient

Testing Workflow

- Have “dry run” with staff prior to full-scale testing to ensure the process runs smoothly
- Use this to estimate time requirements, which can then be communicated with personnel in order to manage expectations and allow for reasonable scheduling without unnecessary backlogs
- Have all testing participants wear facemasks at all times except for the moment of sample collection
- Ensure that foot traffic through stations only moves in one direction (prevent two-way traffic)
- Provide clear roles and station assignments for staff members
- Provide PPE appropriate for each staff role (see PPE section above)
- Prevent cross-contamination by limiting staff movement out of the testing area (while in full PPE)
- Provide hand sanitizer dispensers at stations and entrance/exit
- Minimize participants’ time spent in testing area, and avoid crowding of participants
- If participants have already been cohorted (isolated work shifts or classes, etc.), testing them together may prevent outside exposure
Handouts and Signage

As outlined in the Communication section, concerns and confusion about the testing process can be reduced through effective communication with personnel before and during the process. Consider:

- General information posters outlining:
  - Testing process
  - FAQs
  - Contact information for questions/scheduling/etc.
- Visuals or videos demonstrating the sample collection and testing process
- Set expectations for required time

Every testing and sample collection area should have clear and legible signage present to ensure smooth flow of personnel through the testing area. Specific signage requirements will vary based on the site in question. Some general considerations:

- Clearly marked entrance and exit
- Markings showing proper 6ft spacing
- Markings to indicate the flow of foot traffic
- Reminders to wear masks unless told otherwise (during sample collection)
- Clearly marked hand sanitizer dispensers
- Signs indicating each specific station along with any prep instructions for each

More signage resources can be found at:
- Project Baseline – COVID-19 Community Based Testing Guide
- HHS – Healthcare Emergency Preparedness Information Gateway

Logistics

The Rockefeller Foundation has developed a comprehensive Logistics Plan Playbook specifically geared towards point-of-care COVID-19 testing sites. It covers high-level logistics planning, demand forecasting, detailed processes and activities, and metrics tracking.

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**Plan >**

Planners generate a baseline forecast and work to develop demand, inventory, supply, and distribution plans that incorporate intelligence across multiple functions

**Source >**

Suppliers are selected and test kits are sourced directly from manufacturers or through a distributor(s)

**Receive >**

Test kits received from Manufacturer or Distributor, are stored, and managed through warehouse operations

**Deliver (Intra-State) >**

Test kits are delivered to intrastate storage facilities to be stored and ultimately distributed to last mile locations

**Deliver (Last Mile) >**

Test kits are delivered from intrastate storage facilities to point-of-care test sites

**Return >**

Test kits are returned to distributor, received, and dispositioned

Rockefeller Foundation - Logistics Plan
Sample collection is a critical first step in the COVID-19 testing process. An improperly collected specimen can lead to incorrect test results. The CDC provides standard recommended procedures in these Specimen Collection Guidelines.

For any test, refer to the instructions for use (IFU) for specific instructions on acceptable sample types and collection procedures. The IFU will also provide any sample storage requirements necessary between collection and test operation. This CDC infographic provides general guidance for respiratory virus sample collection.

Sample Types

The most commonly utilized sample types for COVID-19 tests are:

1. Nasopharyngeal (NP) – Nasopharyngeal specimen collection infographic
2. Oropharyngeal (OP)
3. Nasal mid-turbinate (NMT) – Nasal mid-turbinate specimen collection infographic
4. Anterior nares (AN) – Anterior nares specimen collection infographic
5. Saliva

Sample Collection

As stated above, the collection workflow will depend on the test being used and sample type approved. Depending on the IFU, the sample may be collected by either:

- Trained healthcare personnel
- Self - supervised
- Self - unsupervised (home or on-site)
SAMPLE COLLECTION continued

Collection requirements by samples type are typically as follows:

- Nasopharyngeal (NP) or oropharyngeal (OP) swabs are collected by trained healthcare personnel
- Nasal mid-turbinate (NMT) swabs are collected by trained healthcare personnel or through supervised self-collection
- Anterior nares (AN) samples are collected by trained healthcare personnel, through supervised self-collection, or by unsupervised self-collection
- Saliva samples are self collected (either supervised on-site or unsupervised at home)

The sample collection process will generate biohazard waste that should be accounted for. See the Biohazard Waste Disposal section for more information.

For more detailed information on sample collection, see the CDC guidelines.4

Personal Protective Equipment

Personal protective equipment (PPE) requirements will vary depending on the test to be administered and sample type to be collected. Healthcare personnel, sample collectors or test operators should adhere to Standard and Transmission-based Precautions. Recommended PPE is described in the CDC’s Infection Control Guidance page. Additional PPE guidance and instructional graphics can be found on this page from the CDC.

The high likelihood of supply chain disruptions in the current climate makes allocation of PPE resources more critical than ever. The CDC provides a PPE burn rate calculator to help facilities plan and optimize PPE use:

- CDC PPE Burn Rate Calculator

Project N95 offers services as a clearinghouse for those looking to source PPE:

- Project N95

Most COVID-19 test kits designed for use outside of a laboratory setting will include all supplies necessary to perform the test. Refer to the test’s IFU for a list of required supplies. See also:

- FDA Testing Supplies FAQ
- HHS – COVID-19 Personal Protective Equipment Resources
- HHS – COVID-19 Supply Chain Resources
Sample Transport

Whether using a self-collection kit to collect samples for mailing, or transporting samples from a collection site to a local lab, it’s important to practice safe handling of potentially infectious materials.

Safe Handling for Mailed Samples

 Authorized self-collection kits that will be mailed to a third party should contain all appropriate packaging along with instructions located in the test’s IFU. Most will follow a procedure similar to the one shown below, with the specimen tube placed in a biohazard bag, into a sample box, then finally into outer packaging with the appropriate labeling already applied.

WHO and CDC guidelines for transport of infectious substances recommend similar steps, with all samples being triple packaged and appropriately labeled.

Patient and Sample ID

Any samples collected from a patient should be properly labeled at the time of collection in order to avoid later inaccuracies or misreporting of test results. Studies have shown (see CDC link below) that errors are far less common if barcoding is utilized over manual label recording.

In addition to the sample itself, the identification of the person being tested should be verified during the sample collection and/or testing process. Two unique identifiers are recommended at a minimum (e.g. full name and date of birth). If your testing program involves multiple stations, then several redundant ID checking steps may be prudent.

- ECRI – Best Practices for Specimen Handling
- CDC Lab Medicine Best Practices – Patient Specimen Identification - Barcoding
09 | Test Operation

If your organization intends to operate a COVID-19 test on-site, several elements should be considered to ensure safe and accurate testing.

Instructions for Use (IFU)

Any COVID-19 test given an Emergency Use Authorization (EUA) by the FDA will include an Instructions for Use document (IFU). A test may have multiple IFUs if it is approved for use in multiple settings (e.g. home collection and lab use). Before using a test, it is important to read through the entire IFU and follow the steps outlined in it carefully. See the appendix for a more detailed explanation of the content contained in an IFU.

Refer to the FDA Database of current EUA authorized tests for your specific test. Each test IFU (along with other documentation) will be available in the Authorized Labeling column.

Personnel Training - Test Operation

Personnel who are operating tests should be properly trained in order to ensure accurate test results and minimize health and safety risks. As always, refer to the IFU of your specific test for skill level requirements pertaining to sample collection and device operation. Each IFU should also include a quick reference sheet providing instructions for operating the test (see IFU section above).

The CDC’s Guidance for SARS-CoV-2 Point-of-Care Testing page provides useful resources and best practices, as well as training guides for specific tests. In addition, the following two training courses can be utilized to train test administration personnel:

- **CDC – Ready Set Test!**
  Intended for laboratory staff members performing patient testing with waived tests. Covers:
  - Basic requirements for performing waived testing
  - Good laboratory practices
  - Appropriate use of screening tools
  - Sample labeling
  - Sample testing
  - Recording and reporting results

- **WHO – SARS-CoV-2 Antigen Rapid Diagnostic Test training package**
  Training resources (presentations, exams, checklists) for an institution to train trainers and healthcare workers who will be operating rapid antigen tests.
Biohazard Waste Disposal

Any organization performing COVID-19 testing on-site may generate potentially infectious waste that must be disposed of properly. The CDC recommends that testing sites should consider all waste generated from COVID-19 testing (patient specimens, test kit components, etc.) as biohazard waste that should be disposed of in accordance with state or local regulations.6

More information can be found below:

**CDC** – Waste Management Guidance for SARS-CoV-2 Point-of-Care Testing

**EPA** – Information regarding the handling of wastes associated with COVID-19

**WHO** – Laboratory Biosafety Manual

Some medical waste management services include:

- Stericycle
- WM Healthcare
- MedPro Disposal
- Sharps Compliance
- Many local services
Why Reporting Matters

Accurate and appropriate reporting the results of COVID-19 tests to patients, healthcare providers, and the proper authorities is critical to ensure well-integrated care delivery and an effective and coordinated response to the pandemic from local, state, and federal health officials. Reporting requirements and considerations will vary based on your local and state regulations as well as your organization’s role in the testing process.

The results of a COVID-19 test conducted for diagnostic or screening purposes with an EUA test must first and foremost be conveyed to the individual who was tested. Communication and messaging considerations can be found below, in the Follow-up section. These test results are protected health information and can only be shared on a limited basis (covered in the HIPAA/Privacy section below). In most circumstances, public health authorities will also need to be notified of test results.

Currently, HHS is the sole source of federal reporting requirements for COVID-19 (see links below). As stated above, your state may have additional requirements (consult with your local dept of public health).

- CDC – How to Report COVID-19 Laboratory Data
- HHS – COVID-19 lab reporting requirements
- HHS – COVID-19 non-lab reporting requirements

Who Must Report

Any designated COVID testing site or laboratory must report testing results. Meaning, if your organization is performing tests under a CLIA certificate of waiver (see above), then you must report test results. If your organization is only collecting samples, then the laboratory performing the tests on these samples will be responsible for reporting test results. (Note: OSHA has given guidance for employer recording of occupational illness related to COVID-19, see below.)

When to Report

Any time a COVID-19 test is performed at a designated testing site, the result must be reported (positive or negative). The CARES Act requires testing sites to report the results of any COVID-19 tests daily, within 24 hours of completion, to appropriate state and local public health departments.
Who to Report to

HHS states that any laboratory performing COVID-19 testing, including those operating as temporary overflow, remote location, point-of-care, or those testing samples that were collected at home, must report data for all testing completed, for each individual tested, within 24 hours of the results being known, on a daily basis to the appropriate state or local public health department based on the individual’s residence.\(^8\)

A list of contact information for state health departments can be found here.

What to Report

The CDC provides a list of recommended data to report to state and local health departments: CDC - How to Report COVID-19 Laboratory Data

Privacy

Patient information should be handled in a manner that respects individual privacy. See the Training section for some resources on privacy training. If your organization is performing the actual COVID-19 test on-site, additional legal considerations may be relevant:

If your organization is running COVID-19 testing under a CLIA waiver, then the results of an individual’s COVID-19 test are protected health information and can only be used and disclosed as outlined in the Health Insurance Portability and Accountability Act (HIPAA). More information about HIPAA can be found below:

- HHS – Summary of the HIPAA Privacy Rule
- HHS – HIPAA and COVID

Under HIPAA, disclosure of test results to third parties (e.g., employers) requires written authorization from the patient being tested. Therefore, it is often recommended that the testing entity have the patient sign a written authorization for the release of test results that meets HIPAA requirements. Additionally, consent from a parent or guardian will be required prior to testing minors. There are limited circumstances under which a test provider can disclose COVID-19 test results without the individual’s authorization.

Norris-McLaughlin P.A. provides a summary explaining the limitations related to sharing COVID-19 test results.\(^9\)
Follow-up

Contact Tracing

When someone tests positive, rapid and thorough contact tracing can help to prevent an outbreak by identifying and isolating all others who had contact with the positive individual. The definition of what constitutes a close contact, and therefore involves significant risk of transmission, may be updated as new research data becomes available. For the most up to date definition, see CDC guidelines.

In general, contact tracing involves these 4 steps:

1. Identify COVID-19 cases through testing and then notify them, providing guidance for treatment and isolation
2. Identify people contacted by individual while they were infectious through interview and technological tools (apps, etc.)
3. Locate contacts, provide testing if possible and information regarding symptoms and quarantine
4. Monitor contacts and patients

Any contact tracing program will involve close coordination with local and state health departments. In general, the public health authority will take the lead on any contact tracing effort. Employers or other organizations may wish to assist, or run their own contact tracing program in parallel. This may involve legal and technological considerations covered in the above and following sections.

More information about contact tracing can be found below:

- CDC – Operational Considerations for Adapting a Contact Tracing Program
- CDC – Contact Tracing Resources
- Vital Strategies – Contact Tracing Playbook

Testing and Data Management Resources

There are a large number of applications and services on the market and currently under development to assist organizations with the testing implementation process, everything from symptom monitoring, to test integration and contact tracing.
Return to Work

Deciding to end isolation at the right time for positive patients and close contacts can help to reduce spread while minimizing negative impact on productivity and morale. CDC guidance for non-healthcare settings covers:

- Duration of isolation and precautions
- Role of viral diagnostic testing (PCR or antigen) to discontinue isolation or precautions
- Role of viral diagnostic testing (PCR or antigen) after discontinuation of isolation or precautions
- Role of serologic testing

For specific information and the most up-to-date recommendations, see:

- CDC – Ending Isolation and Precautions for People with COVID-19: Interim Guidance

Other Legal and Regulatory Issues

Legal and regulatory considerations will vary by locality. Some federal guidance is listed below, along with a compilation of state and local regulations:

- Alliant – Relevant Federal, State, and Local Guidance on COVID-19
- EEOC – What you should know about COVID-19 and the ADA
- DoL – FFCR Act paid leave requirements
- HHS – COVID-19 Legal/Regulatory/Authorities Resources
Appendix - IFU Sections Explained

An IFU will typically contain the following sections:

**Intended use**
Covers the intended use settings (see CLIA waiver section above), patient population to be tested (symptomatic or asymptomatic, time since symptom onset), and intended test operators

**Summary and Explanation of Test**
Basic summary and context for COVID-19 testing and purpose of this test

**Principles of the Test**
Explains the mechanisms of operation for this specific test

**Materials Provided**
Summary of materials included in the test kit. Will also list any materials required but not provided in the testing kit

**Warnings and Precautions**
List of warnings pertaining to regulatory approval, device precautions, test use, specimen handling, biohazard, and chemical considerations

**Storage and Stability**
Instructions for both specimen and device storage and optimal environmental conditions

**Quality Control**
Description and use instructions for any controls included with the test kit. Either internal device controls or external controls (positive control swab, etc.)

**Specimen Collection and Handling**
Appropriate specimen types (see sample collection section) for this test, along with handling and transport instructions

**Test Procedures**
Step-by-step guide to running the test

**Interpretation of Results**
List of possible test results along with an explanation of each. This could include, “positive,” “negative,” “invalid,” “error,” etc.

**Limitations**
Limitations of the test including sample type, pathogens detectable, environmental limitation, result interpretation, etc.

**Conditions of Authorization for Laboratory**
Lists the conditions and limitations of an EUA authorization
Performance Characteristics
This is an important portion of the IFU. It describes the performance of this particular test and the testing that was performed in order to obtain this performance data. This section may include:

- Clinical performance vs. a comparator (expressed as PPA and NPA)
- Analytical sensitivity, or limit of detection (LoD)
- Cross-reactivity (or exclusivity)
- Endogenous interference
- Analytical reactivity (or inclusivity)

For more information on interpreting test performance see:

FDA - SARS-CoV-2 Reference Panel
CAP - How Good are COVID-19 (SARS-CoV-2) Diagnostic PCR Tests?
EC - Current performance of COVID-19 test methods and devices

A Quick Reference Sheet
Instruction sheet for running the test and interpreting results.
GLOSSARY


CDC: Centers for Disease Control and Prevention
CIMIT: Consortia for Improving Medicine with Innovation & Technology
FDA: The United States Food and Drug Administration
MIT: Massachusetts Institute of Technology
NIH: The National Institutes of Health
RADx: The Rapid Acceleration of Diagnostics initiative
WHO: The World Health Organization

CITATIONS

Supply, Personnel, Facilities, and Documentation Requirements for Creating a Covid-19 Test Program

This project has been funded by the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, through the NIH RADx™ Initiative

This guide does not provide medical advice and should not be used as a substitute for specific medical advice. Information and materials are to inform and educate readers. Consult a qualified healthcare provider for answers to your medical questions. Contents of the COVID-19 Testing Implementation Guide are to be used for guidance only and do not represent medical recommendations.
This document is intended to provide additional guidance for any organization planning to implement COVID-19 testing through a third-party testing program. This includes any scenario in which the entire testing process is “outsourced.” For example:

- Sending employees to an outside clinic or testing site if they report symptoms
- Hiring an outside firm to perform regular testing for employees
- Contracting with a service to set up a mobile testing lab
- Having participants use home collection kits to ship samples to a central lab

This document will assist an organization with the selection of a third-party testing service by providing general best practices to look for, and examples and templates that can be applied to, a variety of testing scenarios. Every organization will have unique needs and challenges when it comes to testing for COVID-19. Coordination with your local or state public health department is always advisable.

In this document, the testing implementation process will be divided into three phases:

- Planning
- Execution
- Follow-up

Within each phase, best practices to consider when selecting a testing partner will be outlined.

There are many different approaches to testing for COVID-19. Some strategies may only test people with symptoms of the disease (symptomatic testing), while others may test any individual regardless of symptoms (asymptomatic screening). The appropriateness of different testing strategies for your organization should be discussed with your testing partner and local health authorities. The CDC provides an overview of different COVID-19 testing strategies.

Various types of COVID-19 tests will be referenced in this document. The FDA document below provides an overview of each type and their differences:

- FDA – Coronavirus Testing Basics
Planning

**CONSIDERATIONS MAY INCLUDE:**

- A testing strategy tailored to your organization's specific needs. For example:
  - A testing plan tied into local disease prevalence
  - A variety of COVID-19 tests available (rapid antigen, point-of-care, or lab-based molecular tests)\(^1\)
  - Consideration of both rapid antigen testing and/or lab-based molecular tests
  - Estimated testing volume requirements

- Availability of experts with experience in diagnostics, epidemiology, or public health for consultation during the planning process

- Agreements in place with licenced healthcare providers in order to provide for:
  - Patient screening
  - Test ordering
  - Follow-up care
  - Standing order for off-label screening use

- If a lab-based test is being utilized, the testing provider will often partner with central or local labs to perform the sample testing. Look for:
  - Disclosure of the specific lab that they are partnering with
  - Information about the specific lab-based (molecular) test being utilized

- These lab-based tests will either have FDA emergency use authorization (EUA)\(^2\) or be laboratory developed tests (LDT).\(^3,4\)

- If an EUA test is being used:
  - Look for verification data showing that the test being used in the lab meets expected performance as outlined in its EUA

- If an LDT is being used:
  - Look for a performance data packet showing performance similar to existing EUA authorized molecular tests.\(^5\)

- If a rapid point of care test is being utilized:
  - Look for the specific rapid test being used (should be EUA approved)
  - Look for a supply agreement with a guaranteed stable supply of test kits and instruments

- A certificate of liability insurance
Execution

CONSIDERATIONS MAY INCLUDE:

■ Arrangements for confirmatory (sometimes called “reflex”) testing of any positive results when a rapid point-of-care test is being used\(^6\)

■ If a rapid test is being utilized, then a CLIA waived lab will need to be established on-site:
  ● Look for a CLIA certificate of waiver\(^7,8\)
  ● Planning for a testing lab location and space/material requirements

■ Personnel requirements for on-site sample collection and testing, along with explanations of each role

■ Process for managing supplies needed (test kits, PPE, etc.) on-site

■ Arrangements for disposal of biohazard waste

■ Expected turn around times for results (turn around guarantees, etc.)

Follow-up

CONSIDERATIONS MAY INCLUDE:

■ Software tools to assist with integration of testing services:
  ● Centralized hub (website or app) for information, scheduling, or test results
  ● Symptom tracking
  ● Consultation with healthcare provider
  ● Results reporting to individuals, the organization (if consented), and any public health authorities

■ Preparation of appropriate legal documents to allow for informed consent and disclosure of test results when needed\(^9\)

■ Follow-up care and counseling for any individuals that test positive

■ Plans or mechanisms (such as apps) for contact tracing\(^10\)

■ Look for availability of references from other clients

■ Contracts
CITATIONS

1. FDA – Coronavirus Testing Basics
   https://www.fda.gov/media/138094/download
2. FDA – About Emergency Use Authorizations
3. HHS – FAQs on Laboratory Developed Tests (LDT)
   https://www.hhs.gov/sites/default/files/laboratory-developed-tests-faqs.pdf
4. FDA – Laboratory Developed Tests
   https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests
5. FDA – SARS-CoV-2 Reference Panel Comparative Data
6. FDA – Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers
7. CDC – Waived Tests
   https://www.cdc.gov/labquality/waived-tests.html
9. AMA – Informed Consent
   https://www.ama-assn.org/delivering-care/ethics/informed-consent
10. CDC – COVID-19 Contact Tracing