

CLINIC-BASED COVID-19 TESTING

Updated July 1, 2020

This resource is designed and intended to support Catalyst members in performing COVID-19 testing on site at their own clinics. This guide contains a suggested workflow but since practices vary in staffing, capabilities, etc., this guide may be adjusted as needed. Included:

- Outdoor/Indoor Setup
- Clinic-Based Step-By-Step Guide
- PPE Resources
- Rapid Testing

OUTDOOR AND INDOOR SITE SETUP

The first step to performing testing **at your own clinic** is setting up of workstations and supplies for performing and processing testing. You may adjust this setup to your unique layout, resources, and volume.

QUICK TIP: On demand PCR diagnostic or POC rapid testing will require a **higher PPE burn rate** due to PPE doffing between patients. To **conserve PPE** consider performing testing during **block testing times** (e.g., testing condensed to 9am – 12pm each day for patients seen prior afternoon or same morning)

Indoor:

- Computer (if needed for runner)
- Printer (if needed for runner)
- All required forms
- Centrifuge (if doing antibody testing)

Outdoor:

- Tent
- Cones to direct traffic flow (Cones set up to allow two lanes to drive up)
- Cooler with ice (to hold tests) on the side of the tent, outside the clean side

Outdoor "Dirty" Supplies and Set Up:

- Table
- Chair
- Hand Sanitizer (labeled dirty)
- 2 Biohazard bin and bags
- Pens
- Hook to hang dirty respirator (cleaned with hospital wipes between patients)

Outdoor "Clean" Supplies and Set Up:

- Table
- Chair
- Pens
- Lab tops
- Wireless printer (if needed to print labels)
- Trash Bin and bags
- Hook to hang clean mask
- PPE
 - Surgical Gloves (for under Nitrile)
 - Nitrile hand gloves (for over Surgical)
 - PPE gown
 - Painters Jump suit

TIP: Suits become hot quickly. Recommend fan or ice packs within suit and only wearing for 2-hour shifts.

- PPE Booties
- N95 masks or Respirator
- Surgical mask
- Face shield or goggles
- Cleaning Supplies
 - Mobile toolbox to hold all extra clean supplies
 - Hand Sanitizer (labeled clean)

- Tissues
- Lysol
- Hospital grade wipes
- Clear lab sample bags
- COVID Swabs for PCR Testing (both swabs in same container)
- Blood Draw Supplies for Antibody Testing
 - Shower Caddy and Rolling Cart (Standing height)
 - Venipuncture needles (Butterfly)
 - Hubs/Vacutainers SST / Tiger Tops
 - Band-Aids or Coban
 - Tourniquets
 - Alcohol Swabs
 - Cotton Balls / Gauze
 - Sharps Container
 - Test Tube Rack
- Step Stool for Car Window
- Emesis Basin or Bag
- Small Gatorades / Drinks (post blood draw)

CLINIC-BASED STEP-BY-STEP PROCESS

The following is the step-by-step process for performing testing **at your own clinic**. See Catalyst's video <u>HERE</u> for a quick overview and visual aid of this suggested workflow.

STEP 1: SCREEN THE PATIENT

Primary Care Provider:

- Screen for symptomatic and high-risk asymptomatic patients by telephone or telehealth visit
- All patients should be screened for COVID-19 risk. This includes:
 - Patients with complaint of any of the following symptoms:
 - Fever
 - Cough
 - Shortness of breath
 - Chills

- Muscle pain
- Headache
- Sore throat
- Shaking with chills
- Loss of taste or smell

Patients with history of exposure to a confirmed case of COVID-19 in the last 2 weeks

- For patients that meet the testing criteria:
 - Triage for need for transport to an emergency facility for urgent care and testing
 - If patient appears stable, patient should isolate in place, quarantine themselves from family and animals, and, if available, wear a face mask
 - **Utilize a virtual visit** rather than an in-office visit
 - Recommend PCR diagnostic testing or Rapid POC diagnostic testing with reflex PCR if negative

STEP 2: TEST SCHEDULING & PUI FORM COMPLETION

Primary Care Provider:

- Complete lab orders for the patient as soon as the televisit is completed
- Route orders and/or message to MA/Clinical Staff:
 - Patient Name
 - Patient DOB
 - Best Contact Phone Number
 - Testing ordered
- Inform the patient that a member of PCP office team will contact them with testing appointment details (location, time and additional information on what to expect)

Medical Assistant (MA) or Clinical Staff:

- Receives message/order from provider with patient information
- For PCR Testing, complete the PUI form (some details may already be included in televisit documentation)
- Contact the patient to:
 - Gather any missing details needed for the PUI Form
 - Schedule patient in a time slot to prevent site congestion
 - Review details to prepare patient for what to expect during testing

TIP: For COVID Antibody Blood Draw:

- If the patient has a specific/preferred arm for blood draws, instruct the patient to arrive already
 positioned in the car for easy access to that arm. (Ex: If the patient's preferred arm for blood
 draws is the right arm, ask them to have someone drive them so they can arrive in the passenger
 seat.)
- Instruct patient that it is **non-fasting** and to **hydrate**

STEP 3: TEST KIT PREP

Medical Assistant (MA) or Clinical Staff:

- Prints label with name, source, DOB and date to be put with specimen tube/vacutainer
- Place documents and label from lab with test kit

STEP 4: PATIENT TESTING ROLES

Example of staff roles for 'Block Testing': To minimize PPE burn you can reallocate some staff to the duty of testing while other staff focuses on virtual visits.

TIP: To maximize testing capacity, we suggest patients are scheduled for testing same day or next day). Requisitions and labels are printed in advance along with a daily testing log including patient names to track patients tested and results received.

Duties and Example Flow

"Dirty MA" - Greets/Directs/Tests Patients

Don PPE – Gown, gloves, N95, ear loop mask, goggles or face shield

- Greets patients in proper PPE as they arrive by walking up to their car window and gathering:
 - Name
 - DOB
- Confirm patient's identity with photo ID.
- Assign parking spot number to patient (if parking required, see below).
 - <u>Asymptomatic, Antibody Test Only</u> Go to Parking Spot
 - <u>Symptomatic, PCR Test Only</u> Stay in Drive-up lane
 - Asymptomatic, Antibody and PCR Test Go to Parking Spot
- Gives patient instructions to pull into one of the numbered parking spots if antibody testing only, or, immediately after swabbing if both PCR and antibody testing. (If needing blood draw, assess if eaten, history of passing out, needle fear, etc.)

"Clean MA" - Assists/Directs Testing MA and Processes Specimen

Don PPE - Gloves, face shield, ear loop mask, N95

- After Dirty MA confirms patient identity, Clean MA marks schedule, marks testing log as "sample received" and indicates the assigned parking spot on the schedule (to be referenced by phlebotomist when drawing blood for antibody testing)
- Retrieves test kit and requisition (pre-labeled test kits are kept in order of appointment time in a container along with the corresponding requisition)
- Hands Dirty MA the dirty specimen bag (inner bag), swab and collection tube

"Dirty MA"

- Confirm the patient DOB and name match the label on the tube
- Sample Collection Steps for PCR Testing:
 - 1. Instruct patient to roll up their window prior to beginning the self-swab process
 - 2. Instruct how to self-test using the nasal swab
 - 3. Hand swab to patient
 - 4. Confirm window has been rolled up
 - 5. Monitor the patient during swabbing and encourage/guide them through the collection process
 - 6. After swabbing, take nasal swab and place it in the inner (dirty) bag which is then folded up in preparation for being placed in the outer bag along with a copy of the CDC PUI form and the requisition.
 - 7. Give Patient Education sheet to patient: See <u>Guidance for Care and Isolation</u>
 <u>After Testing</u> and <u>Guidance for Care After Test Results Obtained</u>
 - 8. If antibody testing, instruct patient to proceed to their assigned parking spot.
 - 9. Change appropriate PPE based on collection method and possible contamination (discard soiled PPE in testing site biohazard bin)

NOTE: If patient uses a pen for any needed paperwork, patient should keep that pen (this workflow **does not require patient to complete paperwork** but that may vary from clinic to clinic.)

TIP: Instruct patient to **wait 5 minutes after blood draw** (consider providing emesis bag and Gatorade in case of nausea/lightheadedness)

Clean MA

- Prepare the outer bag for receipt of the dirty bag which contains the transport tube by placing the requisition and the PUI form in the outer bag
- Stand behind Dirty MA while they obtain specimen from the patient through the car window
- Once the swab specimen is obtained, Dirty MA will 'bag' the transport tube in the dirty bag and place it inside the clean bag.
- Outside clean bag is labeled with patient name by Clean MA and placed inside cooler.

NOTE: If "Asymptomatic, Antibody Test Only", Clean MA can perform venipuncture. If patient is symptomatic, we **do not** recommend antibody testing.

TIP: For Antibody Testing, place blood in test tube rack with patient's pre-printed label.

NOTE: A brief overview of the procedure for COVID-19 Nasal Swab Collection can be found <u>HERE.</u>

STEP 5: CLEANING & WASTE REMOVAL (FOR INDOOR TESTING ONLY)

After the patient leaves, the staff member who roomed the patient should:

- Put on new protective equipment
- Clean the room by first wiping all surfaces with the Sani Wipes, bleach or an approved antiseptic cleaner
- Then, spray the room with Lysol
- Place all protective equipment into a trash bag, tie off the bag, and then take the bag to the trash immediately after cleaning the room.

The CDC has determined the medical waste created from the evaluation, treatment, and testing of COVID-19 confirmed or suspected patients should be managed the same as routine clinic waste management procedures and protocols. Frequency of pick-ups may need adjustment.

- No-touch removal methods should be used to dispose of any waste material containing respiratory secretions
- Use current recommended methods for dangerous waste material

STEP 6: POST-TESTING FOLLOW UP

Following any COVID-19 testing, **patients require different types of follow up**, depending on the type of testing performed and the results.

For detailed guides on post-testing follow up, regardless of where their test was performed, click the applicable link below:

PCR Diagnostic Testing ONLY		
Negative PCR Test	Positive PCR Test	
Click here to download the PCR Diagnostic Testing Only Follow-Up Guide		
Combination Testing		
Negative PCR/Negative Antibody Test	Negative PCR/Positive Antibody Test	
Positive PCR/Negative Antibody Test	Positive PCR/Positive Antibody Test	
Click here to download the Combination Testing Follow-Up		
Antibody Testing ONLY		
Negative Antibody Test	Positive Antibody Test	
Click here to download the Antibody Testing Only Follow-Up Guide		

PPE RESOURCES

Find our **comprehensive list of PPE Resources**, including vendors and other strategies for optimizing PPE to avoid shortages, HERE.

PPE BURN RATE

The way your practice elects to conduct testing will determine the rate at which you go through PPE. All-day, on-demand testing hours will burn through the most PPE but designating specific testing hours will conserve the greatest amount of PPE.

To keep track of your PPE and Testing Kits, download our Testing Supplies Tracker <u>HERE</u>. The CDC also offers a **PPE Burn Rate Calculator** <u>HERE</u> for more real time predications.

RAPID TESTING

The need for testing and the desire for speed and convenience has driven the adoption of rapid testing across the state. **Several rapid tests are currently available under Emergency Use Authorization**. There are no current FDA approved rapid tests and use of EUA testing should be discontinued upon expiration of the state of emergency declaration.

A great deal of uncertainty remains as to the real-world reliability of the current rapid testing. Like rapid strep and rapid flu testing, **negative tests should be treated as presumptive** and treatment is based upon clinical judgement. A reflex PCR diagnostic test in the event of a negative rapid test would be recommended as a follow up in situations where COVID-19 is suspected.

NEW CPT CODE

A **new CPT code (87426)** for rapid testing was <u>released</u> the week of June 27^{th.} Associated reimbursement guidance is still pending.

PRODUCT HIGHLIGHT

A high-level overview of two of the most used rapid tests is below:

Quidel - Sofia 2 SARS Antigen - <u>Learn more</u>	
Identifies	SARS-Cov-2 via immunofluorescence-based lateral flow technology in a sandwich design for qualitative detection of nucleocapsid protein
Results	Returned within 15 min
Sensitivity/Specificity	Positive predictive value of 100%
	Negative Predictive Value between 88% and 99.2%

Abbott - ID Now - <u>Learn more</u>	
Identifies	SARS-CoV-2 RNA utilizing an isothermal nucleic acid amplification technology.
Results	Returned between 13-15 min
Sensitivity/Specificity	Positive predictive value between 83.8-94.7% Negative Predictive Value between 96.5 and 100%

NOTE: Much has been written about the ID Now accuracy. Some reports indicate the test fails to detect positives as much as 48% of the time. The FDA has asked for additional supporting information.

Updated: July 1, 2020