

Antigen Testing Program Overview

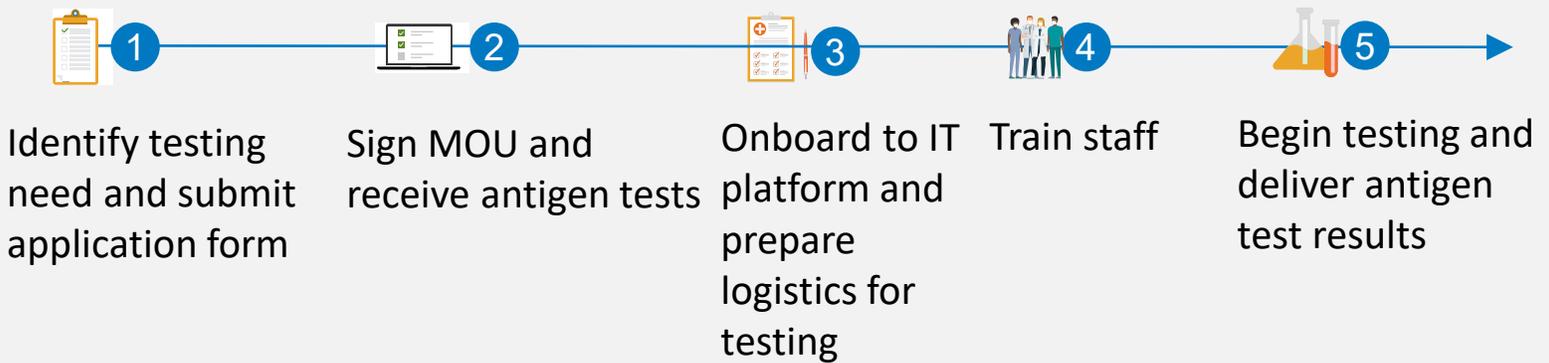


Antigen Testing Program Overview

Introduction

In an effort to improve the equitable distribution of testing resources to communities facing disproportionate effects of COVID-19, the State of California has established a comprehensive testing program that provides antigen and PCR testing resources (e.g., test kits, reporting platforms, and technical assistance).

5 Steps to Onboarding the Antigen Testing Program



For more information, read the full [Antigen Testing Playbook](#)

Training

All staff who will be involved in antigen testing are required to complete all the following trainings, in the order listed below:

1. Watch online videos

[Abbott BinaxNOW training modules](#)- *Modules 1-4 ONLY*

- q Module 1: Getting Started (1:50)
- q Module 2: Quality Control (4:08)
- q Module 3: Specimen Collection and Handling (1:32)
- q Module 4: Patient (Individual) Test (2:56)

2. Privacy and confidentiality training: [HIPAA Training \(no certificate required\)](#)
3. [Competency quiz](#): All staff must achieve a score of 100%.
4. CDPH hands-on virtual training (upon receipt of test kits)

Each staff person training will need **2 test cards, a white swab, a silver swab, reagent** (can be shared), **PPE** (gloves, mask, & eye protection), **and a camera** so that instructors can watch performance of tests

Site Lead Responsibilities

Each testing location must have a designated Site Lead. The Site Lead is responsible for overseeing antigen testing at the testing location(s). Detailed and ongoing responsibilities for the Site Lead are here:

1 Attest that that each testing personnel has met the training requirements

Each trained tester must have completed the following prior to starting testing:

- Pass the competency quiz with a score of 100%
 - Complete HIPAA training (certificate not required)
 - Complete a positive and negative control during the CDPH Hands-On Training session
- Q Report training completion for each tester via an [online Training Attestation](#)

2 Perform quality checks on tests to ensure proper test performance

- Q Complete one positive and one negative control per test lot number
- Q Complete one negative control per week while tests are in use
- Q Report results via an [online Quality Control Log](#) every month

3 Report any problems with test performance

- Q Submit an [online Antigen Test Product Issues Log](#) within 1 week for minor issues and immediately for major issues
- Q Send photos of product issues to AntigenLabDirector-Reporting@cdph.ca.gov

4 Communicate any updates from the CA Testing Taskforce

- Q Share updates to your team from the California Testing Taskforce Antigen Testing Program

On-Site Testing



1. Set up

Site Lead

Gather necessary material:

- a. Abbott BinaxNOW antigen tests (including reagent bottle, sterile swabs, and test cards)
- b. PPE: face mask, gloves
- c. Hand sanitizer
- d. Timers
- e. Permanent markers
- f. Paper towels to lay tests on
- g. Trash cans (regular trash can for negative results, biohazard bags for positive results or negative results in symptomatic participants)
- h. Appropriate technology devices to use Primary platform (e.g., laptops or tablets with webcam)
- i. Paper consent forms (in case site or participant lacks access to technology)
- j. Paper copies of EUA Fact Sheets

✓ 2. Check-in

Check-in

1

Check participant in on Primary platform and confirm registration information

2

Scan the QR code on a new BinaxNOW card to associate the test with the participant

3

Mark card with participant's initials and the testing date



3. Self-swab

Tester

PPE: Mask, gloves

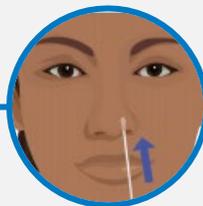
1. Ask participant to sanitize hands
2. Give participant new swab and the following instructions:

a



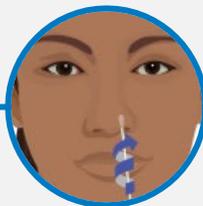
Pull down mask only for the duration of swabbing

b



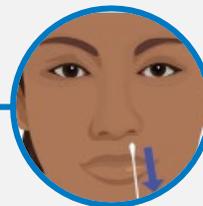
Insert swab **no more than ½ inch** into nostril

c



Rotate around nostril **5 times for 15 seconds**

d



Remove and repeat in other nostril with same swab

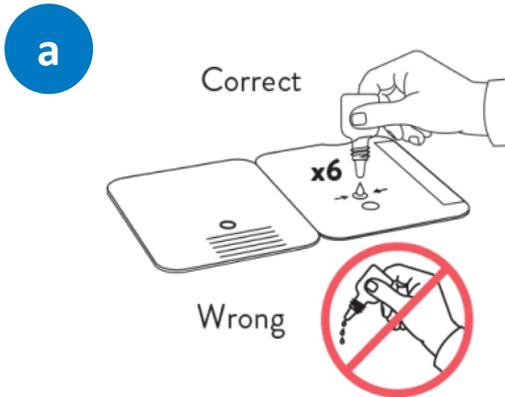
3. Ask participant to hand back swab to Tester

Source: [Manufacturer's Instructions For Use](#), Color

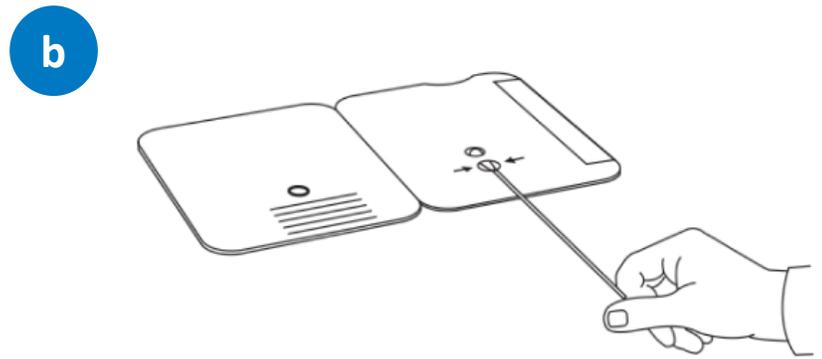


PPE: Mask, gloves (sanitize between tests, change every 6 tests or after symptomatic patient)

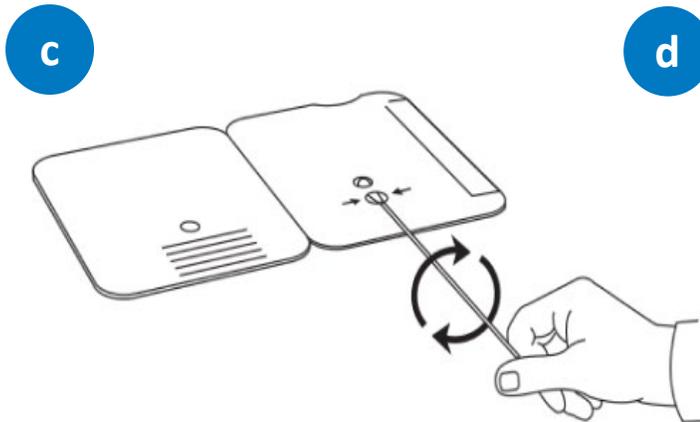
1. Mark testing start and end time (15 minutes later) on card
2. Perform test on flat surface:



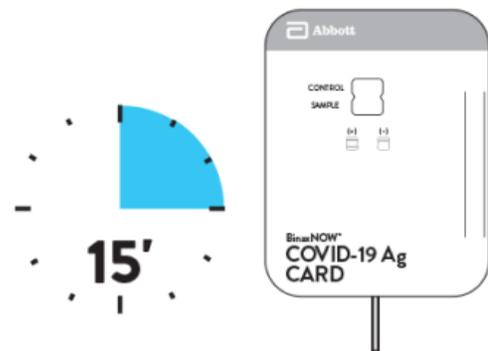
Hold Reagent bottle ½ inch vertically above the top hole and add **6 drops reagent**



Insert the testing swab in the bottom hole and firmly push upwards until the tip reaches the top hole



Twist swab **3 times clockwise** (do not remove swab)



Peel off adhesive and seal the card

3. Start timer for 15 minutes and place on flat surface
4. Tell participant results will be available in 15 minutes

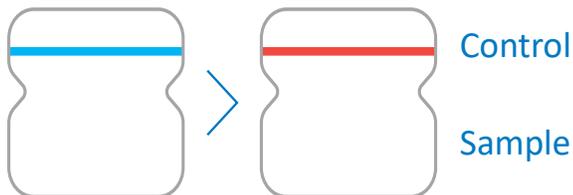


5. Report Results and Dispose of Tests

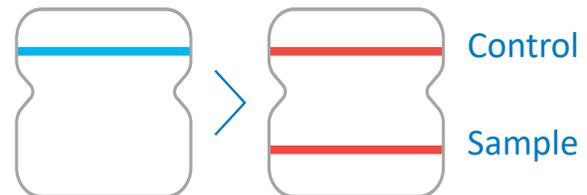
Tester

1. Once timer ends, mark results directly on the card and record in Primary platform (include image)
2. For positive results or negative results in symptomatic participants:
 - § Conduct confirmatory PCR test
 - § Dispose of test in biohazard bag
3. For negative results:
 - § Dispose of test in regular trash
4. For invalid results/test cards:
 - § Have second test operator read card
 - § Report results as inconclusive
 - § Send participant to redo antigen test
 - § Dispose of test in biohazard bag
 - § Send pictures of invalid results to antigenlabdirector-reporting@cdph.ca.gov

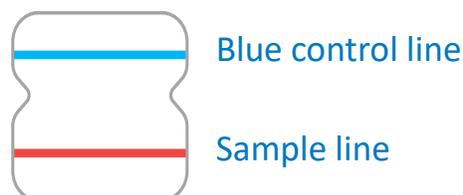
Negative



Positive



Invalid results/test cards





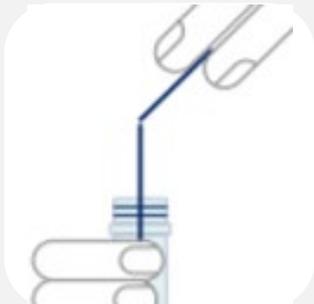
6. Conduct Confirmatory PCR (if applicable)

Tester

For all negative results in symptomatic participants

1. Log into Primary platform and find participant details
2. Have participant self-collect second sample using PCR kit
3. Package and mail specimen to Valencia Branch Laboratory (VBL) through a courier or drop at assigned California COVID-19 Courier Network (CCN) [dropbox](#)
4. Tell participant results will be available in Primary platform in 24-48 hours and to isolate until results are ready
5. Report discordant results (i.e., false positive or false negative results) to antigenlabdirector-reporting@cdph.ca.gov

Packaging PCR Sample



Snap the handle off.

Holding firmly onto the tube, snap the handle off where it naturally bends.

Careful: don't spill the liquid inside the tube.



Screw on the top of the collection tube.

You're almost done! Make sure the top is screwed on tightly.



Put the tube into the specimen bag.

Seal the bag by closing the ziplock seal.