

COVID-19 Testing at Community Pharmacies

There are three levels of regulatory oversight for test kits.

1. **Tests approved by FDA** under Emergency Use Authorization: [nasopharyngeal specimen](#) is sent for molecular analysis at a CLIA-certified laboratory to detect SARS-CoV-2. This also includes tests which have been validated by the manufacturer while it prepares an EUA request. [Click here to search EUA status.](#)
2. **Tests approved by state authority:** Similar to above but in a state which has notified FDA and set up a system for authorizing tests and laboratories to detect SARS-CoV-2.
3. **Unapproved tests:** Specimen collected for serologic testing at the point of care to identify antibodies to the virus. These tests are validated by the manufacturer and FDA is notified of the manufacturer's intent to distribute. Unapproved tests must state they have not been reviewed by FDA and that results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. False negative and false positive results are more common with antibody testing.
[Click here for FDA's testing FAQ including a list of state programs and companies preparing EUA.](#)

Testing collaboration scenarios

1. **Drive-thru testing:** Pharmacy hosts public health department pod or other setup to conduct mass testing. Public health officials follow up with patients.
2. **Drive-thru testing:** Pharmacy hosts a private company to conduct mass testing for virus. Testing company follows up with patients.
3. **Specimen collection:** Pharmacy collaborates with an ordering physician to collect nasopharyngeal specimens and ship them to a CLIA-certified or state-approved lab for molecular virus detection. Laboratory or ordering physician follows up with patients; pharmacist may include their notification in terms of collaboration.
4. **Home testing kits:** Pharmacy sells home testing kits. Patient completes a screening questionnaire or telehealth visit, collects a sample at home, and ships it to a laboratory for molecular virus detection. **Note:** **As of 3/25/2020 No kits are approved for home use, including self-collection of samples to be sent to a clinical laboratory.**
5. **Point-of-care testing:** Pharmacy collects specimen and uses unapproved serologic test to detect antibodies. Pharmacist reviews results with patient at point of care and makes recommendations for self-care based on symptoms and results.

Business feasibility questions

- Does the pharmacy desire or require compensation for use of property to conduct mass testing?
- Does the pharmacy desire or require compensation for specimen collection?
- Does the pharmacy require notification of positive test results?
- Does the pharmacy have access to enough personal protective equipment?
- What are the overhead costs for performing specimen collection?
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or inform infection status. Does the pharmacy have a protocol to refer seriously ill patients to medical care and help patients understand test results and actions necessary to prevent the spread of the virus?
- Does offering testing services exceed the pharmacy's tolerance for risk of exposure to employees?