County of Orange
Health Care Agency
Agency Operations Center

COVID-19 Test Kit – Resource Request Instructions for Healthcare Facilities/Organizations
Updated May 26th, 2022

If you are an organization submitting a resource request (RR) for COVID Testing Kits, you must follow these instructions and fulfill the requirements needed to receive the kits:

1. You must be an Orange County business with an Orange County business address. All business names and addresses will be confirmed prior to filling the resource request. If you do not provide your official county business name or if you use a personal/home address or personal email, your resource request will be denied.

2. You must be a **healthcare facility/organization**. Non-healthcare organizations eligible to receive testing kits may submit a resource request to their regional partner.

   ***The State has made an exception to this, and some non-healthcare organizations are eligible to receive over the counter antigen tests as per the instructions below.**

3. If you have an agreement with the State to receive testing kits through them, please submit your Resource Request to the State as directed.

4. You must properly complete the following two (2) forms and submit them the AOC Logistics Section at aocresourcerequestlead@ochca.com:

   a. OCHCA Resource Request Form
   b. Facility/MHOAC Situation Status (SitRep) for Testing Supplies
   c. If ordering iHealth COVID-19 Rapid Antigen Tests, additional information is required. See below for further instructions.

   NOTE: For State or County supplied testing kits, #4 (Financial Responsibility Acknowledgement Signature) on the Resource Request form may be left blank.

5. **COVID-19 Antigen Tests for professional use**: The **Abbott BinaxNOW** and **Access Bio CareStart COVID-19 Antigen Testing** kits are the professional use kits, not the Self-Test antigen kits. As such, ordering entities must be doing the test under a CLIA Certificate of Waiver at minimum.
   - **BinaxNOW COVID-19 Antigen Tests kits are available in limited supplies. Prioritization will be given to groups testing vulnerable and high-risk populations as per CDPH criteria.**
   - The AOC no longer has CareStart tests in stock. This webpage will be updated if and when more supply arrives.
     a. If you are using the State's CLIA number with an MOU, please submit a copy of the signed page of the MOU initiated with the State.
     b. If you are using your own CLIA number, please note the number on the top line of the resource request (If you are submitting the RR electronically put the number on line 1g—Facility/Organization Name)
     c. If you are using your own CLIA number and have applied but not yet received it, please submit proof of application for the CLIA number with your Resource Request.

~~d. Please note each time a CLIA waived laboratory uses a new type of antigen test, such as the CareStart test, the new test MUST be added to the laboratory's existing CLIA waiver.~~

e. Per updated CDPH guidance, laboratories adding a waived test to the CLIA Certificate of Waiver do not need to notify CMS of the change and do not need to file a new state registration to add the test.
   i. Non-profits are limited to 15 waived tests
   ii. During the renewal process, all tests need to be listed.

6. **Over-the-Counter COVID-19 Antigen Tests**: The **BinaxNOW COVID-19 Antigen Self-Tests** are self-test kits that come in boxes of 2 tests per pack. These do not require a CLIA waiver, and users perform and interpret the test themselves.
   a. Note that these tests are of limited supply and distribution will be prioritized based on health equity considerations and testing strategies per CDPH and local health jurisdiction recommendations.
   b. Requesters must indicate intent to prioritize the tests toward areas of the highest health vulnerability [particularly zip codes 92701 and 92703 (Santa Ana), 92805 (Anaheim), and 92844 (Garden Grove)], the uninsured/under-insured, and other vulnerable populations with limited testing access (congregate care/living, homeless, etc.).
   c. Please also fill out and attach the following form for these tests only:

      Supplemental Form for At home test Requests

   d. Note that **iHealth COVID-19 Antigen Rapid Tests** are currently no longer available but can be purchased by going to the iHealth website.

7. **COVID-19 Molecular Tests**: The **Ambry Test kits** (saliva test) and **Fulgent Test Kits** (nasal swab) are self-collected molecular tests that need to be sent in (not point of care tests) so a CLIA waiver is not required.
   a. **THESE KITS ARE NO LONGER AVAILABLE FOR DISTRIBUTION AT THIS TIME.**
   b. However, individuals who live or work in Orange County may still order both of these test kits for free from:

   COVID-19 Testing | Novel Coronavirus (COVID-19) (ochealthinfo.com)

8. **Rapid Influenza Diagnostic Antigen Tests**: The **BioSign Flu A + B Antigen Tests** are point of care tests that are professional use kits, not the Self-Test antigen kits. As such, ordering entities must be doing the test under a CLIA Certificate of Waiver at minimum. See the considerations for CLIA waived antigen testing above.
   a. These tests have been allocated in small quantities for Skilled Nursing Facilities to have on hand for influenza testing.
   b. Quantities are very limited and some have short expiration dates so please order soon.

   NOTE: If you do not follow the proper steps noted above and do not and fill out the required forms accurately, your Resource Request will be denied.

9. Reporting Antigen and Point of Care testing results **(***Updated April 4th, 2022***)**

a. Federal regulations require laboratories (including providers conducting CLIA-waived tests) to report ~~both~~ only **positive** ~~**and non-positive (negative, indeterminate, and specimen unsatisfactory)**~~ antigen test results. Any laboratories conducting SARS-CoV-2 antigen testing must report all positive ~~and non-positive~~ test results through the CalREDIE Electronic Laboratory Reporting system (ELR) **within eight hours** from the time the laboratory notifies the health care provider or other person authorized to receive the report.

   CDPH Test Reporting Update

b. For organizations using the state's CLIA waiver and ordering physician, the state's contracted IT platform (Primary) will automatically report all results directly to CalREDIE in accord with California Code of Regulations Title 17, Section 2505 reporting requirements.
c. Organizations using their own CLIA ID and ordering physician may have IT vendors who also automatically report all results to CalREDIE (e.g., NAVICA, the platform deployed by Abbott for its BinaxNow testing kits).
d. For manual reporting, use the following instructions:
   Reporting Methods for COVID-19 Antigen and Point of Care Reporting
e. Further clarification can be found from CDPH at:
   https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/LFSCOVID19ltr-1.aspx
f. Over-the-Counter tests do not need to be reported, but do not have the validity of laboratory performed tests, e.g., for travel clearance purposes.

10. Use of expired testing kits.

a. Many of the testing kits have been granted, by the FDA, extensions of expiration dates that were originally noted on the packaging. The Lot numbers on each of the kits can be looked up to determine the new expiration dates.

   i. BinaxNOW Expiration Update Letter (Updated January 2022)
   ii. CareStart Expiration Update Letter
   iii. iHealth Expiration Date Extension notice:
   https://ihealthlabs.com/pages/news#expiration

b. In addition, CDPH has released guidance on using test kits even beyond the extended expiration dates:

   i. CDPH Antigen Test Expiration Date Guidance Letter
   ii. CDPH Temporary Extension At Home Test Expirations (Updated March 2022)