



# PROJECT TESTING REQUIREMENT GUIDE

RADx-UP is one of four programs in the [Rapid Acceleration of Diagnostics \(RADx\)](#) initiative launched by the National Institutes of Health (NIH) to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. The RADx-UP Coordination and Data Collection Center (CDCC) has a Testing Core that provides technical assistance and scientific guidance on existing and emerging COVID-19 diagnostics, testing supply management, and implementation to RADx-UP projects. This includes guidance on vendor management and supply chain considerations. [Watch this short video about the testing core](#) to learn more.

In this guide, the RADx-UP CDCC Testing Core has assembled useful information for current and prospective RADx-UP projects. To keep pace with the evolving nature of the pandemic, the test methods, and the FDA regulatory landscape, this guide—and the resources linked below— will be updated regularly, and pulls information from the FDA [In Vitro Diagnostics Emergency Use Authorization page](#).

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## Resources & Quick Links

- [COVID-19 Testing Tips](#) — Information and guidance on COVID-19 testing for current and prospective RADx-UP projects. Find quick reference guides on different test types, as well as alerts and recalls of COVID-19 tests that may impact RADx-UP projects.
- [RADx-UP CDCC Testing Core FAQs](#)—find a list of testing-related FAQs.
- [Testing Project Information](#)—Download the testing project information intake form for RADx-UP projects.
- [RADx Vendors](#) — A list of NIH-supported companies with FDA EUA COVID-19 assays.
- [MedWatch](#) — If you suspect issues with testing, inform the manufacturer via MedWatch

## Testing Requirements for RADx-UP Projects Funded from 4/16/21 to Present

All projects using SARS-CoV-2 tests as part of their award are required to use either FDA-cleared tests or those that have received emergency use authorization (EUA) by the FDA. The FDA EUA policy for testing applies to SARS-CoV-2 tests that detect antigen, nucleic acid, or an immune response to SARS-CoV-2.

Projects are required to apply SARS-CoV-2 testing according to the manufacturer's instructions for use and device labeling. Each product label will specify acceptable specimen types (e.g., nares, nasopharyngeal swab, saliva), location of specimen collection (e.g., home or supervised by healthcare provider), use in symptomatic and/or asymptomatic populations, use in certain age groups, and location of testing (e.g., home, CLIA waived point of care, mod-high complexity CLIA certified laboratory).

- Laboratory-developed tests (LDTs) without FDA clearance or EUA are not acceptable for RADx-UP projects awarded after 4/16/2021.
- When reporting COVID-19 test results to participants and/or making clinical decisions based on COVID-19 test results. Projects must use tests with FDA emergency use authorization (EUA) ([read more here](#)) and must apply testing strictly according to the manufacturer's product label.
- Investigators seeking to use FDA EUA Point of Care (POC) antigen and/or POC antibody tests must, at a minimum, obtain a CLIA Certificate of Waiver.

## Testing Requirements for Projects Funded Prior to 4/16/21

The NIH has required that RADx-UP projects funded after April 16, 2021 use FDA EUA COVID-19 assays. This requirement helps establish a consistent standard for assays used across the RADx-UP program.

However, when the RADx-UP program was first funded in Oct. 2020, there were few FDA EUA assays available for use. The FDA was also not able to keep pace with the LDTs submitted for EUA consideration, as their focus was on home assay review. For that reason, RADx-UP projects were allowed to use validated LDTs in a CLIA-certified laboratory. However, with over 400 EUA assays available and the FDA reviewing LDTs again, there are now ample choice of assays within the FDA EUA parameter.

Previously reviewed and NIH accepted Laboratory Developed Tests (LDTs) must be performed in a laboratory certified and operating under a Certificate of Compliance or Accreditation (CLIA).

## Guidance for Asymptomatic Testing and Screening including FDA Off-label Use

- For assistance with safe and effective implementation of FDA EUA POC antigen tests (including off label use), refer to the [CDC testing algorithm](#).
- For FDA guidance on off-label surveillance use and asymptomatic indications, [read here](#).

## FAQs

- **Q:** Does FDA have validation or other recommendations regarding SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19? (Updated 11/16/20) [Read here](#).
- **Q:** Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19? (Updated 11/16/20) [Read here](#).
- **Q:** May an EUA-authorized SARS-CoV-2 diagnostic test be used for COVID-19 surveillance? (New 6/16/20) [Read here](#).

If you have specific questions about a test, please reach out to your Engagement Impact Team (EIT).

## How to Obtain a CLIA Certificate of Waiver

- [How to obtain a CLIA Certificate of Waiver](#)
- [Frequently Asked Questions \(FAQs\), CLIA Guidance During the COVID-19 Emergency](#)
- [Clinical Laboratory Improvement Amendments \(CLIA\) Application for Certification](#)
- [List of CLIA contacts for each State in the USA](#)

## How to Establish a CLIA Certified Laboratory

- [Laboratory Quick Start Guide to CMS CLIA Certification](#)

## How to look up COVID-19 tests with FDA EUA authorization on the FDA website

1. [Select here](#) to navigate to the FDA In Vitro Diagnostics page.
2. Identify if the assay you are searching for is a [molecular test](#), [antigen test](#) or [serology test](#) and select the appropriate link.
3. Scroll down to the search bar above the tests list and type in test name or manufacturer of interest as shown in example below.

Search:  Show 25 entries

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s) <sup>1</sup>	Authorization Documents <sup>2</sup>
08/10/2021	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Antigen Self Test</a> 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	<a href="#">HCP Individuals, IFU, IFU (Home Test)</a>
04/20/2021	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card</a> 08/26/2020	Lateral Flow, Visual Read	H, M, W	<a href="#">HCP Patients, IFU</a>
04/12/2021	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card</a> 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	<a href="#">HCP IFU, IFU (Home Test)</a>
03/31/2021	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card 2 Home Test</a> 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	<a href="#">HCP Individuals, IFU, IFU (Home Test)</a>
03/31/2021	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag 2 Card</a> 03/31/2021	Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening	H, M, W	<a href="#">HCP Patients, IFU</a>

Showing 1 to 5 of 5 entries (filtered from 33 total entries) Previous 1 Next

4. Review the authorization documents to determine the test requirements--specimen type; collection oversight (self / health care provider); age restrictions; serial testing requirements etc--to identify the best assay for your project. Contact your EIT to request Testing Core assistance.
5. Ensure you can adhere to the FDA EUA letter and Information for Use (IFU) requirements for the test you select for your project. Once you've selected your test, fill out the [Testing Project Information](#) and send to your EIT to send to the Testing Core via the routine Intake Survey process or whenever a new COVID-19 test is added or replaced in your Project.

## Guidance on Data Collection for RADx-UP projects

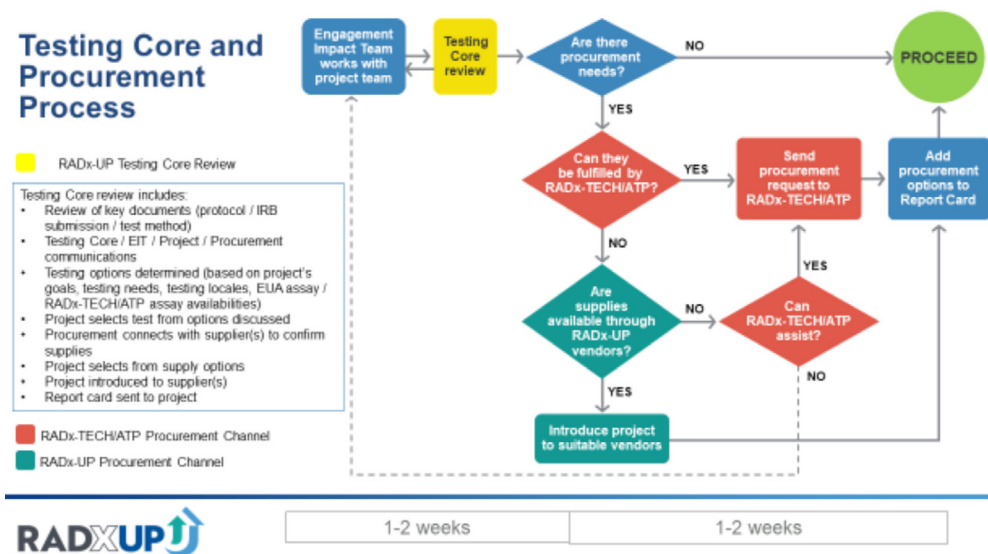
We would like to remind RADx-UP Projects about the CDCC requirement to collect and transfer common data elements. The shortlist of testing-related CDEs include the following:

1. Location specimen collected (clinic, community outreach center, mobile van, drive-thru, home, etc.)
2. Type of specimen collected (nasopharyngeal swab, nasal swab, self-collect nasal swab under supervision, throat swab, saliva, self-collect at home) for each test performed
3. Type of test (antigen, nucleic acid) for each test performed
4. Location test performed (at point-of-care, at home, at central lab)
5. Test manufacturer for point-of-care (if applicable); test manufacturer for central lab test (if applicable)
6. Turn-around-time to receive test results
7. Wait time to get tested.
8. Test result (positive, negative, inconclusive)
9. Method for test results to be communicated to participant and returned to Project team (phone call, email, text, in person, electronic interface)

For more information about the NIH RADx-UP CDEs, [select here](#).

## Workflow Summation

The below graphic illustrates the Testing Core's procurement and review process.



## Frequently Asked Questions

For more information about the COVID-19 Testing Core, please visit the [full FAQ](#) page on myRADx-UPhome.

### **We would like to use a SARS-CoV-2 point of care lateral flow antigen test for testing symptomatic children in our school system. The school nurse will collect the nasal swabs and perform the tests. Is this feasible?**

We encourage Projects to review the manufacturer's labeling because some tests are limited to certain age groups. Also, manufacturers may indicate when testing should occur relative to the onset of symptoms and these limitations should be accounted for in your project's testing plan.

For details on FDA EUA antigen tests and their authorization documents, [refer to this guidance](#).

### **We would like to use a SARS-CoV-2 point of care antigen test for screening asymptomatic individuals. Can I use the CDC algorithm for off-label use of antigen tests for asymptomatic screening?**

Projects must follow the manufacturers' instructions for use as defined on the product label. If an asymptomatic claim is not part of the FDA EUA label, Projects cannot use that specific test. Some manufacturers of antigen tests have an asymptomatic claim in their label and Projects are encouraged to review these instructions for their specific testing needs. Please note that serial testing is frequently required when testing asymptomatic individuals using point of care antigen tests.

For details on FDA EUA antigen tests and their authorization documents, [refer to this guidance](#).

### **Can we use a molecular test at a centralized laboratory for pooling saliva or nasal swab specimens to screen students in our school system?**

Many manufacturers with molecular SARS-CoV-2 FDA EUA tests are authorized to test pooled specimens in a laboratory meeting CLIA requirements for high complexity testing. Not all manufacturers have pooling or saliva in their indications for use and Projects are encouraged to carefully review the product labeling to ensure compliance with product specifications.

For details on FDA EUA molecular tests for pooling and their authorization documents, [refer to this guidance](#).

### **What if we see unexpected test results, for example false positives or false negatives? How can we report these findings? Who can we alert?**

If unexpected testing results, i.e. false positives or false negatives, are observed, RADx-UP projects can work with their testing lab, if applicable, to submit those findings to [MedWatch](#). Note that every EUA has a link to the MedWatch website that goes directly to FDA.