



CDRH

Virtual Town Hall Meeting

For developers of tests for SARS-CoV-2

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Resources for COVID-19 Test Development and Validation

How to Receive Information and Ask Questions by Email:

- To receive CDRH IVD topic emails, please subscribe to the - **In Vitro Diagnostics Mailing List:** www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists
- For questions about COVID-19 IVD EUAs please email: CDRH-EUA-Templates@fda.hhs.gov
- For questions about laboratory data harmonization for COVID-19 testing please email: SHIELD-LabCodes@fda.hhs.gov

Where to find CDRH Information:

- *In Vitro* Diagnostics EUAs webpage: www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised Nov. 2021) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised
- FAQs on COVID-19 Testing - Developers: www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2

November 15, 2021, Actions

*These slides present high level discussion points. Please refer to the guidance and EUAs for the details and official policies.

- **HHS Statement regarding LDTs:**
 - [Statement by HHS Secretary Xavier Becerra on Withdrawal of HHS Policy on Laboratory-Developed Tests](#)
 - *“Effective today, HHS no longer has a policy on LDTs that is separate from FDA’s longstanding approach in this area.”*
- **FDA Press Release regarding multiple actions:**
 - [Coronavirus \(COVID-19\) Update: FDA Updates Test Policies to Help to Ensure Accuracy and Reliability of Tests and Increase Access to At-Home Tests](#)
 - *“By focusing our review on [tests that will have the biggest impact on the nation’s ongoing COVID-19 testing needs, such as at-home and point-of-care diagnostic tests that can be produced in high volumes], and helping to ensure that available tests have appropriate oversight, we can better respond to the pandemic as the nation’s testing needs continue to evolve.”*

COVID-19 Test Policy



- **Reissued Guidance:**
 - [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- **Main Policy Areas:**
 - Prioritization of Review of EUA Requests for Tests – Section IV.A
 - State Authorization – Section IV.B
 - Distribution and Offering of Tests During FDA Review – Section IV.C
 - Modifications to EUA-Authorized Diagnostic COVID-19 Tests – Section IV.D

Guidance: EUA Review Priorities



*Details in Section IV.A of the [COVID-19 Test Policy](#)

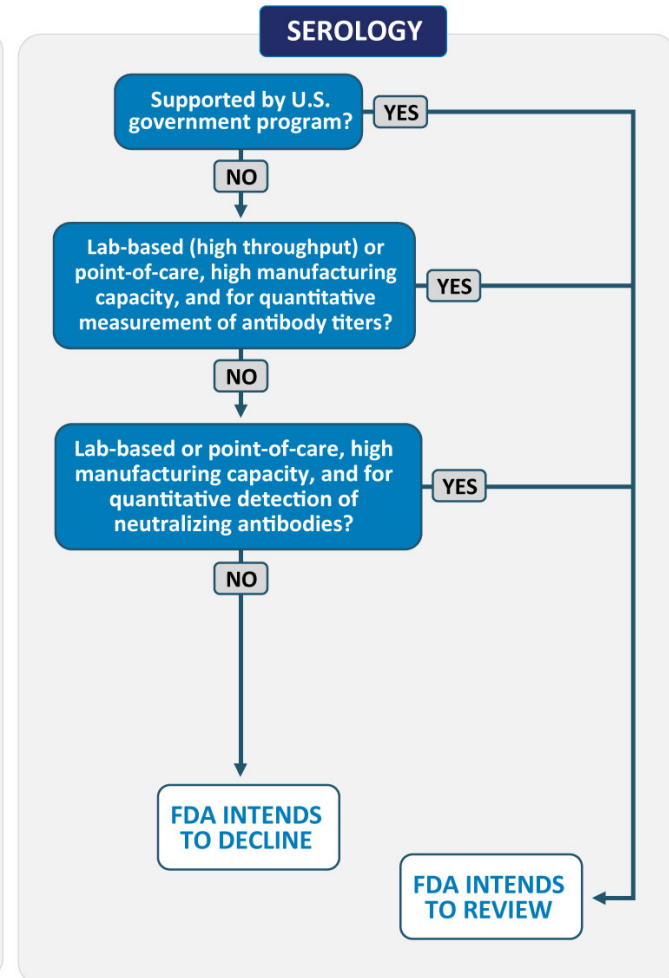
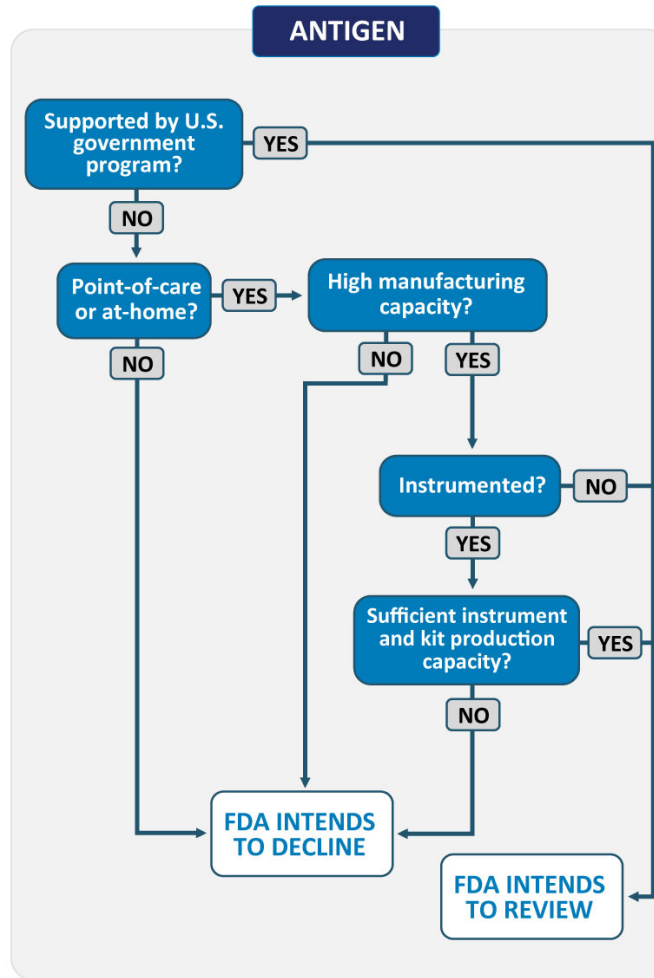
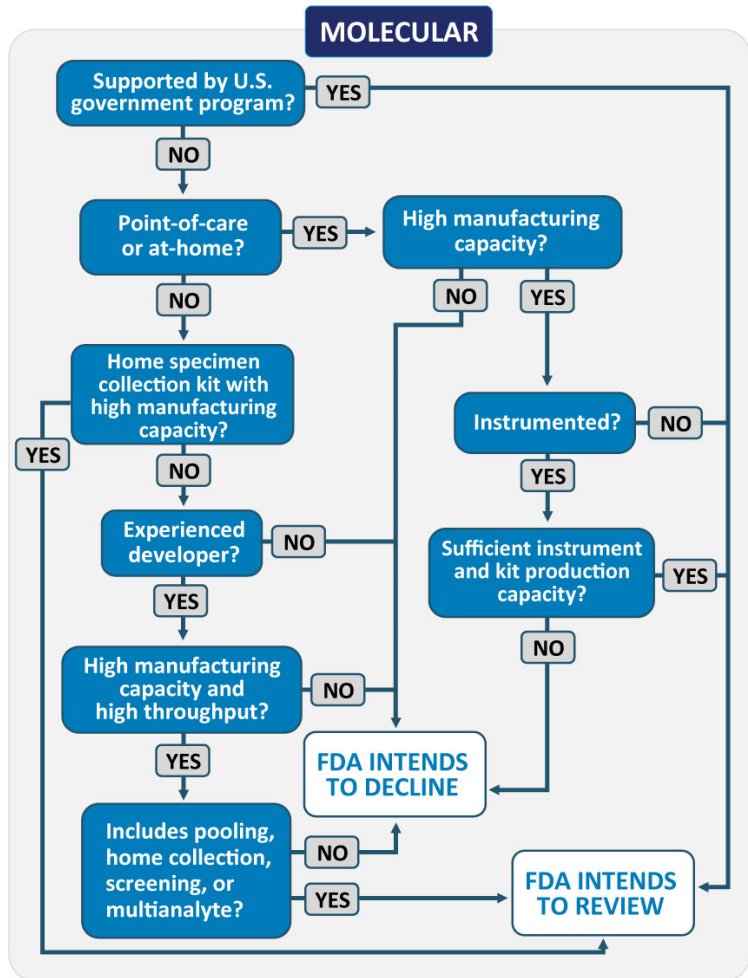
FDA generally intends to focus its review on EUA requests for the following types of tests (please see the guidance for additional details for each of these types of tests):

- **At-home** and **point-of-care (POC) diagnostic** tests for use with or without a prescription and that can be manufactured in high volumes;
- Certain **high-volume, lab-based molecular diagnostic** tests (and home collection kits for use with such tests) that **expand testing capacity or accessibility** such as through **pooling** of specimens to increase throughput, testing **specimens collected at home** and shipped to the lab, **screening** asymptomatic individuals, or detecting **multiple different respiratory viruses** at once;
- Certain lab-based and POC high volume antibody tests that can measure the amount of antibodies (**fully quantitative antibody tests**) or the amount of **neutralizing antibodies**; and
- Tests for which the request is from, or supported by, a **U.S. government stakeholder**, such as the Biomedical Advanced Research and Development Authority or the National Institutes of Health's Rapid Acceleration of Diagnostics (RADx).

Guidance: Background & Scope

- Enforcement policies in the Guidance do not address MDR (21 CFR Part 803); developers are expected to comply with applicable MDR requirements for tests offered prior to authorization as described in the guidance
- Unless and until an EUA is issued that authorizes additional testing environments for a specific test, under CLIA, use of that test is limited to laboratories that are certified under CLIA, and meet the requirements to perform tests of high-complexity, and at the point-of-care (POC) when covered by such a laboratory's CLIA certificate
- Policies regarding offering COVID-19 tests prior to or without an EUA have never applied to at-home tests or tests with home specimen collection, or any testing outside of a high-complexity CLIA-certified laboratory
- Notification policies have never applied to multi-analyte respiratory panels

Guidance: Appendix A Flowcharts



*The flowcharts above give a general overview of the policies in Section IV.A of the [COVID-19 Test Policy](#). Readers should refer to that section for the policies themselves. The flowcharts do not address policies discussed in other sections of this guidance.

Guidance: State Authorization



*Details in Section IV.B of the [COVID-19 Test Policy](#)

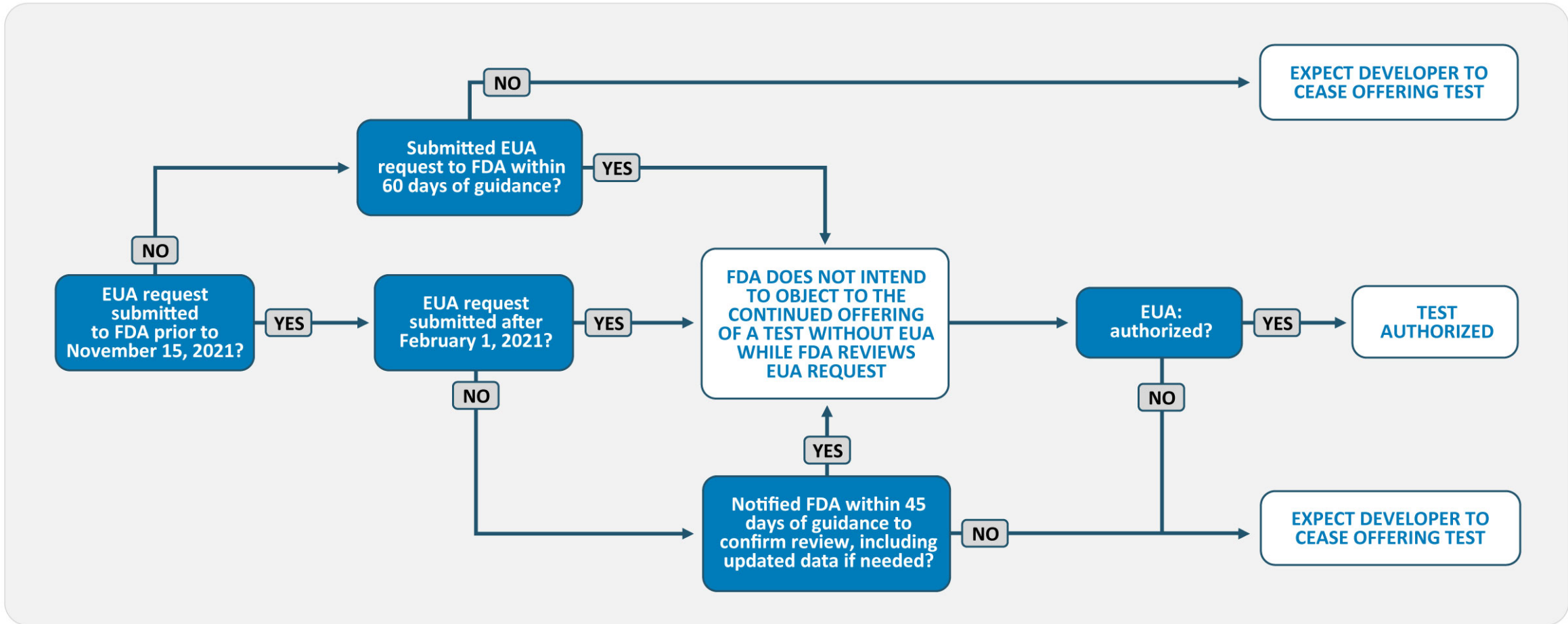
- **Previous Policy:** Addressed States and territories that authorize laboratories within their State or territory to develop their own COVID-19 tests and perform specimen testing, where the notification of SARS-CoV-2 test validation is not submitted to FDA and the laboratory does not submit an EUA request to FDA
- **Updated Policy:** FDA no longer intends to apply the policy to any additional States or territories going forward
 - For the States and territories listed on the notification list on FDA's website prior to November 15, 2021, that are continuing to authorize laboratories within that State or territory to develop and perform a test for COVID-19, FDA does not intend to object to the use of such tests for specimen testing where the notification of SARS-CoV-2 test validation is not submitted to FDA and the laboratory does not submit an EUA request to FDA, and where instead the State or territory takes responsibility.
- This policy applies only to tests designed, developed, and used within a single, high-complexity CLIA-certified laboratory.

Guidance: Distribution and Offering of Tests During FDA Review

*Details in Section IV.C of the [COVID-19 Test Policy](#)

- **Previous Policies:**
 - **FDA Guidance:** Addressed distribution and offering of certain tests for clinical use prior to or without an EUA – “notification policies”
 - **HHS August 2020 Announcement:** Addressed, among other things, laboratory developed tests (LDTs) for SARS-CoV-2 offered without FDA authorization
- **Updated Policy:** FDA generally expects COVID-19 tests to have been issued an Emergency Use Authorization (EUA) or marketing authorization (PMA, de novo, 510(k)) prior to the tests being distributed or offered
 - HHS withdrew August 2020 policy
 - FDA is ending notification policies going forward
 - EUA request generally expected for tests currently being offered without the submission of an EUA request, as described in the guidance
 - FDA generally intends to review the EUA requests
 - If the test is not subsequently authorized, developers expected to cease marketing the test within 15 calendar days of being notified

Guidance: Appendix B Flowchart



*The flowchart above gives a general overview of the policies in Section IV.C of the [COVID-19 Test Policy](#). Readers should refer to that section for the policies themselves. The flowchart does not address policies discussed in other sections of this guidance.

Guidance: Modifications to EUA-Authorized Diagnostic COVID-19 Tests

*Details in Section IV.D of the [COVID-19 Test Policy](#)

- Policies regarding offering modifications to EUA-authorized tests prior to or without an EUA have never applied to at-home tests or tests with home specimen collection, or any testing outside of a high-complexity CLIA-certified laboratory
- Transparency: recommendations regarding test reports and other information
 - Developer should post data about the modified test's performance characteristics on its website
 - Instructions for use or test protocol and the test reports should reflect the modification, disclose that the test has been modified and modified test has not been reviewed by FDA
- If FDA identifies a significant problem or concern with a modified test, based either on the provided information or external reports, that cannot be addressed in a timely manner, FDA generally would expect the developer to cease distribution, marketing and offering the modified test and address such problem, which could include conducting a recall of the modified test and/or notification concerning corrected test reports indicating prior test results may not be accurate.

Guidance: Modifications Made Before and After Guidance Update



*Details in Section IV.D of the [COVID-19 Test Policy](#)

- **Modifications made before November 15, 2021**
 - For modifications made and implemented as discussed in the policies in the previous version of the guidance, FDA does not intend to object to the following:
 - For modifications by a commercial manufacturer to its own EUA-authorized test: continued implementation of the modification while FDA reviews the EUA request
 - For modifications made and implemented by high-complexity CLIA-certified laboratories: continued offering of the modified test
- **Modifications made after November 15, 2021**
 - For modifications that do not change the indication for use set forth in the EUA and do not change the analyte specific reagents, FDA does not intend to object to the following:
 - For modifications by a commercial manufacturer to its own EUA-authorized test: implementation of the modification while FDA reviews the EUA request
 - For modifications made and implemented by high-complexity CLIA-certified laboratories: implementation of the modification without notification to FDA or a new or amended EUA, where the laboratory has validated the modification, confirmed equivalent performance as the authorized test, and use of the test is limited to the high-complexity CLIA-certified laboratory in which the modification was made

New Umbrella EUA – Serial Testing



*Details in the [EUA Letter of Authorization - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing](#)

- **Issued Umbrella EUA:** for serial testing with certain molecular diagnostic tests developed by laboratories:
 - [Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing](#)
 - Used for testing at regular intervals as part of serial testing programs, such as those established at places like schools, workplaces or community groups
 - Efficiently authorizes certain tests that meet specified criteria
 - For use with individual or pooled anterior nasal specimens for testing individuals, including individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least once per week
 - Options to include testing with home collected specimens
 - Appendices include validation required to be authorized for each optional indication
 - Limited to use in the single laboratory that developed the authorized test and that is certified under CLIA and meets requirements to perform high complexity tests

Additional Actions



*Details in the documents and websites linked below.

- **Website Updates:**
 - [FAQs on Testing for SARS-CoV-2](#)
 - [Coronavirus \(COVID-19\) and Medical Devices](#)
 - EUA-related pages
- **Reissued March 2020 EUA for Certain Molecular Diagnostic Tests:**
 - [EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests](#)
 - Only tests that are listed in Appendix A are authorized for use as described in the EUA
 - No additional tests will be authorized by this EUA
 - Updated Conditions of Authorization and Fact Sheets to reflect the most up-to-date information
- **Reissued July 2020 VTM Guidance:**
 - [Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#)
 - Revised to update references to the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency*

Let's Take Your Live Questions



- **To Ask a Question:**
 1. Please “Raise Your Hand”
 2. Moderator will announce your name to invite you to ask your question
 3. Unmute yourself when called to ask your question
- **When Asking a Question:**
 4. Announce your first, last, and business name
 5. Ask your question, 1 question only
 6. Please, no questions about specific submissions
- **After Question is Answered:**
 7. Please mute yourself again
 8. If you have more questions - raise your hand again

Thanks for Joining Today!



- **Presentation and Transcript will be available at:**
 - CDRH Learn: www.fda.gov/Training/CDRHLearn
 - Heading “Specialty Technical Topics”
 - Sub-Heading “Coronavirus (COVID-19) Test Development and Validation Virtual Town Hall Series”
- **If you have additional questions about today’s presentation/topics?**
 - Email: CDRH-EUA-Templates@fda.hhs.gov
- **Give Us Your Feedback – Fill Out this Short Survey:**
www.fda.gov/CDRHWebinar

Next Town Hall: December 1, 2021