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Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance

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Background

- Guidance issued February 29, 2020 describes a policy regarding certain laboratories immediately using tests they developed and validated while pursuing an emergency use authorization (EUA) in order to achieve more rapid testing capacity in the U.S.

- Guidance updated March 16, 2020 describes additional policies:
  - regarding States taking responsibility for tests developed by certain laboratories in their State
  - regarding manufacturers immediately distributing tests they validated while pursuing an EUA
  - regarding certain serology tests

- To address the COVID-19 public health emergency, the FDA has determined that prior public participation for this guidance is not feasible or appropriate and issued this guidance without prior public comment.

- This guidance document is immediately in effect, but it remains subject to comment in accordance with the FDA's good guidance practices.

A. Policy for CLIA High Complexity Labs Using Their Validated Tests Prior to EUA Submission

The guidance includes recommendations regarding:

- Validating newly developed SARS-CoV-2 tests prior to clinical use
- Notifying FDA when clinical use of a validated test begins
- Confirming the first 5 positive and negative samples with an EUA authorized test
- Indicating in test reports that the test has been validated but independent review by FDA is not yet complete
- Submitting an EUA within 15 business days of initiating testing
- Steps to take if any specimens fail confirmatory testing or if FDA is unable to authorize the EUA

B. Policy for State Authorization of CLIA High Complexity Labs to Perform Testing without Submitting an EUA to FDA

The guidance includes recommendations for States or territories regarding:

- Optionally choosing to authorize laboratories within that State or territory to develop and perform a test for COVID-19 under authority of its own State law, and under a process that it establishes.
  - FDA will not be reviewing the process adopted by the State or territory
  - FDA expects that such oversight processes will require laboratories to validate tests prior to use.
- Notifying FDA if they choose to use this flexibility to expedite COVID-19 testing in their State or territory

The guidance encourages laboratories to notify FDA when starting clinical testing under this policy

C. Policy for Commercial Manufacturer Development and Distribution of Tests Prior to EUA Submission

The guidance includes recommendations regarding:

- Validating newly developed SARS-CoV-2 tests prior to clinical use
- Notifying FDA when distribution for clinical use of a validated test begins
- Posting the instructions for use, including performance summary, on website
- Indicating in test reports that the test has been validated but independent review by FDA is not yet complete
- Submitting an EUA within 15 business days of initiating distribution for clinical testing

D. Policy for Commercial Manufacturer Development and Distribution and Laboratory Development and Use of Serology Tests Without an EUA

The guidance includes recommendations regarding:

- Validating newly developed serology tests that detect antibodies to SARS-CoV-2 prior to clinical use
- Notifying FDA when clinical use of a validated test begins
- Indicating in test reports information along the lines of the following:
  - This test has not been reviewed by the FDA
  - Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
  - Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
  - Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Policy/Recommendation Highlights

	Applicable technologies	Validation?	Notification to FDA	EUA to FDA after testing initiated?	Location of Testing
Policy A	molecular, antigen, antibody	Yes	From high complexity lab	Yes	High complexity labs only
Policy B	molecular, antigen, antibody	Yes	From State; encouraged from labs	Not required	High complexity labs in certain states only
Policy C	molecular, antigen, antibody	Yes	From manufacturer	Yes	Clinical labs or point of care; not for home use
Policy D	antibody	Yes	From developer (manufacturer or high complexity lab)	Not required	Clinical labs or point of care; not for home use

Test Validation

- Clinical Agreement
- Cross Reactivity
- Limit of Detection (for molecular and antigen tests only)
- Inclusivity (for molecular tests only)
- Microbial interference (for antigen tests only)
- Class specificity (for antibody tests only)

Submissions to FDA

- **Notification** of clinical use of a validated test should be directed to CDRH-EUA-Templates@fda.hhs.gov and should include:
  - name of the laboratory or manufacturer
  - address
  - contact person
  - Instructions for use, if distributing a kit

- **Notification** by a State or territory of their intent to authorize laboratories within that State or territory to develop and perform tests for COVID-19 under authority of its own State law, and under a process that it establishes should be directed to CDRH-EUA-Templates@fda.hhs.gov

- **EUA** should be submitted to OIR-Operations@fda.hhs.gov and should include:
  - Form 3514 available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf
  - Completed EUA template available at: https://www.fda.gov/media/135658/download

Notifications & Authorizations as of 3/24/2020

	# of notifications/ authorizations	Listings of notifications/ authorizations on FDA Website
Policy A	98	https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#labtestpolicy
Policy B	4	https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#whatstate
Policy C	4	https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#whatcommanufacturer
Policy D	12	https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#whatserologytest
EUAs	16	https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

Laboratory Modifications to Authorized Tests

- As noted in the guidance, FDA does not intend to object to the use of a test, without a new or amended EUA, where the test is validated using a bridging study to an EUA-authorized test.
- As noted in the guidance, FDA would like to see your validation data informally through an email to CDRH-EUATemplates@FDA.HHS.GOV. If FDA's review of validation data indicates that it could be applicable to modifications of other tests with an authorized EUA, and the laboratory agrees to FDA sharing that information on our website for use by other laboratories, FDA intends to update our FAQs so other laboratories can refer to the validation for their testing, without conducting their own bridging study for the same modification.
- FAQ includes potential alternatives for:
  - Swabs
  - Transport media
  - RNA extraction
  - PCR instruments
  - Validation and control materials

  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#whatif

Manufacturer Modifications to Distributed Kits

- Modifications to a manufacturer's EUA-authorized test are submitted as an amendment to the EUA.
- Where validation data supporting the modification has been submitted in the amendment, FDA does not intend to object to implementation of the modification while FDA conducts its review.

Resources

- FAQ: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2
- COVID-19 Diagnostic Test Guidance Document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior
- General EUA Guidance Document: https://www.fda.gov/media/97321/download
- FDA's Novel Coronavirus (COVID – 19) webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19

Questions?

For questions on the guidance and accelerated EUA template, or if you wish to consider use an alternative specimen type, contact the Division of Microbiology devices at (301) 348-1778 or: CDRH-EUA-Templates@fda.hhs.gov.

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http://www.fda.gov/training/cdrhlearn

Under Heading: Specialty Technical Topics; Subheading: In Vitro Diagnostics

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