



FDA's Work with the Tri-Agency Task Force for Emergency Diagnostics Helped Labs Implement COVID-19 Tests

Key Results

FDA's engagement with the task force demonstrates the value of interagency coordination and collaboration to facilitate emergency test implementation in labs. FDA's continued participation holds further potential for improved responses in the future.

Why OIG Did This Review

In 2019, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS) established the Tri-Agency Task Force for Emergency Diagnostics (the task force) to enhance the effectiveness of the Federal response to emergencies that require labs to implement tests. FDA is responsible for regulating in vitro diagnostic tests for infectious diseases (hereinafter referred to as tests), including authorizing them for use, in a public health emergency. After a test is authorized, FDA, CDC, and CMS have distinct responsibilities to ensure that labs appropriately implement, or use,

tests. However, multiple setbacks plagued the early testing rollout for COVID-19, which was the first emergency since the task force was established. In the context of this failure, this study focused on whether FDA's engagement with the task force helped labs appropriately implement COVID-19 tests.

How OIG Did This Review

We focused our review on the task force's activities from its establishment in February 2019 through October 2020. We reviewed task force documents, including meeting minutes, for insight into task force activities and to determine how FDA worked with task force members to prepare for future emergencies and respond to COVID-19. We also interviewed eight FDA staff members.

What OIG Found

Prior to the COVID-19 pandemic, FDA worked with the task force to identify gaps in responses to prior emergencies (e.g., the Zika virus outbreak). The task force made two recommendations within FDA's jurisdiction: (1) require test manufacturers to include certain information with tests, and (2) require test manufacturers to provide test verification materials with tests. FDA implemented both recommendations during the COVID-19 pandemic and reported that these were helpful for labs.

Starting in January 2020, the task force pivoted to respond to the COVID-19 pandemic. FDA found the task force meetings served as opportunities to collaborate, coordinate, and communicate across member agencies. It worked with task force members on drafting written products, troubleshooting, and solving problems. FDA members found that participating in the task force fostered relationships that were beneficial both within the task force's scope and beyond it.

Conclusion

The task force experience demonstrates the importance and potential benefits of expanding interagency exchanges, including for those parts of the testing process that struggled during the pandemic. Indeed, FDA's continued coordination with the task force holds potential for further improvements in emergency test implementation in labs.

BACKGROUND

OBJECTIVE

To determine the extent to which Food and Drug Administration (FDA) engagement with the Tri-Agency Task Force for Emergency Diagnostics helped facilitate laboratories' ability to implement COVID-19 tests.

The COVID-19 pandemic challenged our Nation's ability to mobilize a robust testing response to an emerging infectious disease. Testing is a key first step in responding to any infectious disease outbreak because it helps to identify cases and contain the spread of disease. When a public health emergency is caused by a novel pathogen, such as with COVID-19, the response is especially complex because typically no in vitro diagnostic test (hereinafter referred to as test) for a novel infectious disease exists.¹ Developers must quickly create tests and request authorization to use and manufacture their tests. FDA is responsible for regulating tests, including authorizing them for use, in a public health emergency.^{2, 3} However, after authorizing a test, FDA works with the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) to ensure that labs implement, or use, tests appropriately.⁴ Furthermore, no single Federal entity oversees the many public and private stakeholders involved in emergency testing.

The setbacks to COVID-19 testing in early 2020 illustrate the failed rollout of testing in the U.S.⁵ In February 2020, FDA authorized CDC's COVID-19 test, making it the first and only in the nation. However, CDC's test was problematic and for weeks only a small number of labs were able to use it. The resulting void in testing came at a crucial moment in the pandemic response, as no other test was available to fill the gap. Other challenges, including limited access to materials required to demonstrate that tests work as intended and other supply shortages, further impeded the testing rollout.

Amidst the overall testing failure, FDA worked with CDC and CMS as part of the Tri-Agency Task Force for Emergency Diagnostics (hereinafter, the task force) to facilitate the appropriate implementation of tests authorized for emergency use in labs. Established in response to lessons learned from prior infectious disease outbreaks, the task force leverages each agency's unique expertise to ensure that labs implement emergency tests appropriately and effectively. FDA's engagement with that task force is the subject of this report.

FDA's emergency use authorization for tests during a public health emergency

FDA is responsible for regulating tests, including authorizing them for use, in a public health emergency.^{6, 7} FDA may issue emergency use authorizations (EUAs) to allow test developers to clinically use and market their tests when there are no adequate, approved, and available alternatives.^{8, 9, 10} To request EUA, developers must submit data to FDA to demonstrate that their test performs as intended. However, an EUA allows for a more relaxed evidentiary standard ("reasonable belief that the product may be effective") than is required for medical products that FDA approves or clears in nonemergency circumstances ("reasonable assurance of safety and effectiveness").^{11, 12, 13} This enables FDA to review and authorize products more quickly than in nonemergency circumstances.¹⁴ After FDA authorizes a test, labs must use this test exactly as specified within the EUA.¹⁵

Because EUA tests do not undergo the same level of review, FDA establishes conditions of authorization (COAs) as necessary to protect the public's health.^{16, 17} FDA requires stakeholders, including developers, distributors, and labs (as applicable), to meet COAs for as long as the EUA is in effect. Some COAs are required by law, and FDA may apply others at its discretion.¹⁸ FDA outlines the COAs that each stakeholder must meet. COAs for labs include providing relevant information to health care providers with test results, ensuring that lab staff are appropriately trained, and collecting information on test performance, among others. For example, labs must report suspected false positive or false negative test results to FDA.¹⁹

FDA, CDC, and CMS roles in emergency testing

FDA regulates and monitors the tests it authorizes. FDA requires that developers and labs report performance concerns for each test, including false positives and negatives. Health care providers and patients also may report problems with tests to FDA.²⁰ CMS and CDC may report performance concerns that they hear from labs to FDA. As appropriate, FDA may work with a developer to modify an EUA or revoke a test's EUA.^{21, 22}

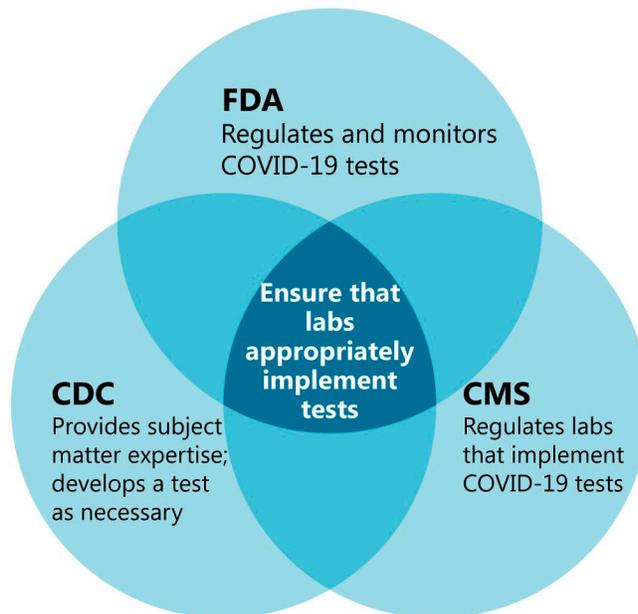
CDC provides subject matter expertise for the emergency testing process, which may include expertise on the nature and epidemiology of the disease.²³ It establishes testing guidance for labs, such as how to determine a positive test result, and may advise FDA and CMS on testing. CDC is also responsible for developing and seeking EUA for its own diagnostic test if one is not otherwise available (as was the case for COVID-19). CDC labs and CDC partners use CDC's test.²⁴

CMS regulates all nonresearch labs that conduct clinical tests.^{25, 26} Labs must adhere to regulations set forth in the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which establishes quality standards for labs.^{27, 28} To perform testing, labs must obtain certification from CMS.²⁹ CMS surveyors assess labs' compliance with CLIA quality standards, including having qualified staff and following quality control

procedures.³⁰ FDA categorizes all lab tests by level of complexity.³¹ CMS permits a lab to use an EUA test only if the lab meets complexity requirements for that test.³²

In their emergency response roles, FDA, CDC, and CMS have distinct but interrelated responsibilities to ensure that labs appropriately implement tests during a public health emergency (see Exhibit 1). Labs implement tests by using them as authorized by FDA and according to CLIA standards. Test implementation excludes developing, manufacturing, and distributing tests.

Exhibit 1. FDA, CDC, and CMS work together to ensure that labs appropriately implement tests.



The Tri-Agency Task Force for Emergency Diagnostics

Because of the interrelated nature of their responsibilities, close coordination among CDC, CMS, and FDA during a pandemic is critical. These three agencies created the task force to enhance the effectiveness of the Federal response to emergencies that require tests.³³ The task force aims to prepare for future emergencies so that the agencies are better positioned to facilitate implementing tests in labs and can efficiently manage their overlapping responsibilities. During an emergency, the task force also aims to serve as a forum for agencies to coordinate and collaborate on their responses.³⁴

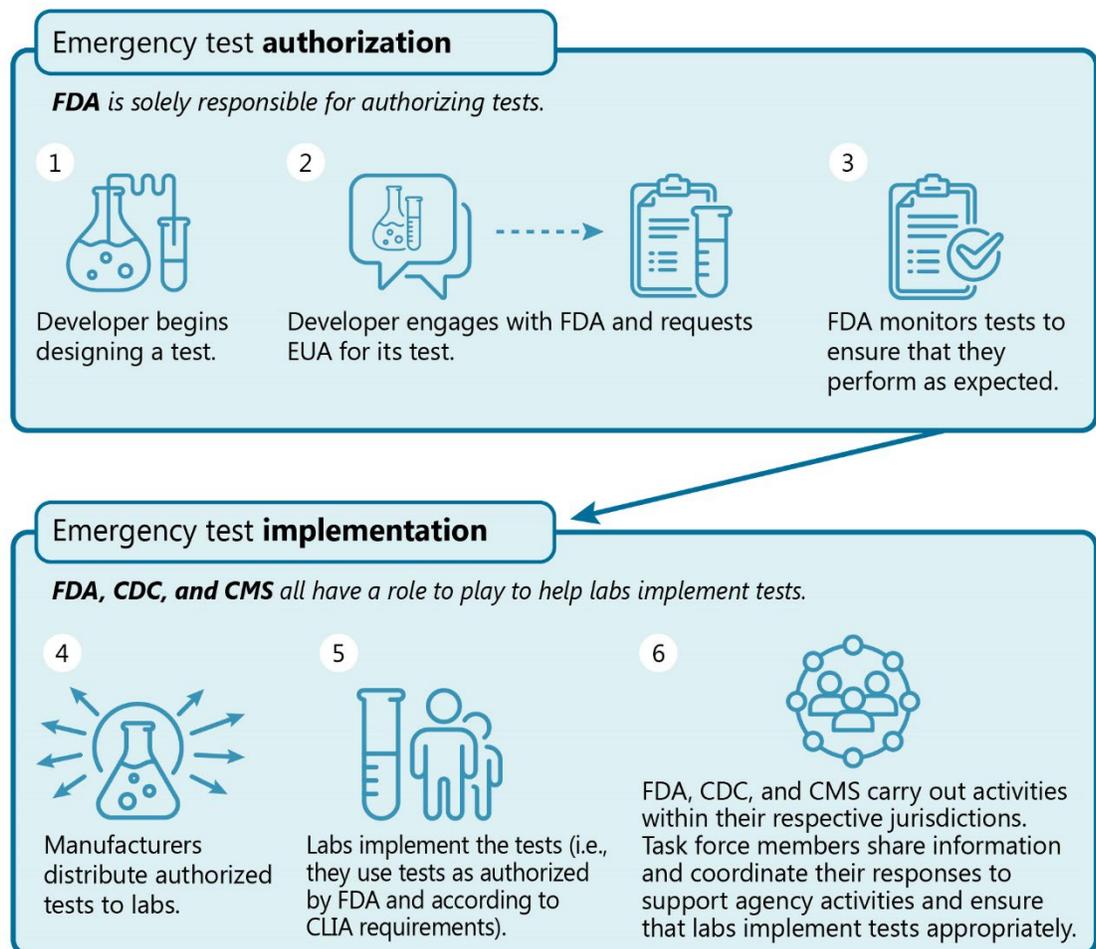
FDA, CDC, and CMS launched the task force in 2019.³⁵ The task force charter clarifies agencies' roles during an emergency response and outlines how agencies should collaborate and establish efficient communication channels to share information. CDC serves as the task force chair and is responsible for activating the task force, facilitating meetings, tracking action items, communicating task force activities with

external partners, and developing agendas. Agencies provide representatives to each task force meeting, which can also include subject matter experts as appropriate.

Prior to public health emergencies, members meet biannually to prepare for future emergencies. Based on task force activities, including reviews of prior emergency responses, the task force may make recommendations for improvement to itself and to member agencies. The task force's recommendations are based on consensus and made with deference to agency statutory authority and areas of expertise.

The task force convenes at the beginning of an emergency that requires testing (see Exhibit 2). These meetings provide a forum for members to work together to facilitate rapid test implementation during that emergency, which may include suggesting advice and guidance for labs and other stakeholders.

Exhibit 2. After authorizing tests during a public health emergency, FDA works with task force members to facilitate test implementation in labs.



RESULTS

During COVID-19, FDA made process improvements recommended by the task force

Reflecting on the Ebola and Zika virus epidemics, the task force noted gaps in implementing tests in labs. The task force charter requires that the task force identify gaps to improve labs' efficiency and effectiveness in implementing tests. The task force made recommendations, some to itself and some to the individual agencies, to address each gap. Each agency decides whether to act on recommendations that fall solely within its scope.³⁶

"It really all stemmed from Zika and realizing that once FDA issued an EUA, it's not the final step... to having it actually being implemented in the laboratory. And so the task force was formed to try and address some of the apparent gaps in... once the EUAs been issued, how it actually gets implemented into a laboratory." – FDA staff member

The task force made several recommendations to itself, and has yet to finish implementing them. One of those recommendations involved developing interagency workflows to clarify each agency's role in facilitating test implementation in labs. Another focused on creating universal fact sheets to help providers and patients interpret lab test results. Task force members were working on products to respond to these recommendations when COVID-19 emerged.

Among other actionable gaps the task force identified, two are solely within FDA's jurisdiction and FDA implemented corrective actions during the pandemic:

- *Labs' lack of understanding on how to meet EUA requirements.* In prior outbreaks, FDA posted tests' COAs on its website but did not distribute them separately to labs, which potentially made them more difficult to access. The task force recommended requiring test manufacturers to include COAs in package inserts with tests, which the task force hoped would reduce confusion among lab staff implementing tests as well as CMS surveyors. During the COVID-19 pandemic, FDA began requiring this for all EUAs granted for COVID-19 tests. Several FDA task force members noted that this clarified test implementation responsibilities for labs. One member noted that "the inclusion of the conditions of authorization clearly helped [labs] to quickly understand what they are, what their responsibilities have been, and [enabled] them to be up and running faster."

- *Labs' limited access to control material early in an outbreak.* Labs require control material, such as clinical samples of the virus, to make sure that tests work before using them. This process is called verifying a test, and verifying tests is a CLIA requirement for labs. Early in an outbreak, clinical sample shortages are a common challenge when infection rates are low. The task force proposed that FDA modify COAs by requiring test manufacturers to include control material for verifying tests in their test kits to avoid labs having to source the materials themselves, which would take longer. When COVID-19 emerged, the task force also discussed what other kinds of control material would be acceptable to verify tests until clinical samples became more available. Where appropriate, FDA had test manufacturers provide control material with their authorized COVID-19 tests so that labs could verify them. FDA task force members stated that carrying out this recommendation was a success; labs were able to immediately begin implementing tests..

FDA found the task force useful for collaborating and communicating among its member agencies about implementing tests in labs when COVID-19 emerged

FDA reported that task force meetings provided opportunities to collaborate, coordinate, and communicate the efforts underway within member agencies and jurisdictions. On January 15, 2020, the task force held its first COVID-19 response meeting. After this initial meeting, task force meetings generally took place every week. (They became biweekly in October 2020.) FDA used task force meetings to hear other members' updates and to brief members on key developments with test authorizations. For example, at the second task force meeting that year, FDA briefed the task force on CDC's work requesting an EUA for its test. FDA also updated members on topics including EUA policy changes and the level of interest from developers to seek EUA.

Task force meetings served as opportunities for FDA to collaborate with other members. For example, FDA collaborated within the task force on written products to support labs implementing COVID-19 tests (see Exhibit 3). As appropriate, task force members coordinated to ensure that information released by the agencies was consistent. Members also worked to make sure that disseminated information was clear and understandable to labs as well as other stakeholders, such as CMS surveyors. In addition, FDA collaborated with CMS and CDC on COVID-19 EUA language to ensure that labs can meet FDA requirements without violating CLIA regulations. For example, when FDA began authorizing at-home tests, working with CMS and CDC helped ensure that FDA's authorization language would apply to both home users and labs.

Exhibit 3. Examples of written products that FDA worked on with the task force during the COVID-19 pandemic



An infographic for labs that described different kinds of COVID-19 tests, defined which labs can use tests, and described CLIA requirements (FDA and CMS collaboration)



Guidance for home collection kits, including instructions for specimen collection (FDA and CDC collaboration)



A coordinated rollout of information on how to screen asymptomatic individuals via frequently asked questions on each agency's website (FDA, CDC, and CMS collaboration)

FDA also collaborated with the task force to solve problems that arose during the pandemic (see Exhibit 4). During task force meetings, FDA discussed challenges and FDA's progress towards addressing them. Members from CMS and CDC sometimes offered advice for FDA to consider. For example, FDA noted confusion in the academic and clinical communities about whether tests used for disease surveillance required EUA, which they did not. Task force members discussed not only how to use non-EUA tests for surveillance but also how to communicate that to stakeholders. In addition, CMS and CDC, which both interact more closely with labs than FDA does, often shared information that they heard. This information included reports about potential performance concerns, fraudulent behavior, and problems with implementing tests. For example, during a task force meeting, CDC informed FDA that some serology test manufacturers were improperly selling lab tests to nonlabs. CDC told FDA that it would provide FDA with the names of the manufacturers. FDA noted that it would issue warning letters if needed to respond to this fraudulent behavior.

Exhibit 4. Examples of troubleshooting and problem solving between FDA and other task force members during the COVID-19 pandemic



CDC reported information about fraudulent behavior to FDA



Task force members alerted one another to concerning reports about a COVID-19 test's performance in labs



FDA reached out to CDC for help with outreach to labs to understand why test information was not reaching patients or health care providers



FDA communicated its efforts to address challenges with obtaining testing supplies to task force members

Agency members also took advantage of one another's expertise and capabilities both during and outside of task force meetings. For example, FDA benefited from CDC's experience with virus mutations as well as from CMS's familiarity with how to convey information in language that lab staff and CMS surveyors would understand. Task force members could also benefit from agency-specific tools to support other agency efforts. For example, after FDA informed the task force of serology tests that no longer met EUA requirements, CDC sent out a message using its own Lab Outreach Communication System to alert labs not to use these tests.

FDA's task force members reported fostering relationships with key experts in CDC and CMS through the task force. Several FDA task force members whom we interviewed said that they particularly benefited from information sharing among task

"[The task force] allows us to have points of contact, so we have unusual questions we can reach out within the agency, and if the task force doesn't know the answer directly, they can, you know give us or set up a meeting with the appropriate subject matter expert to address those questions." – FDA staff member

force members. One member described this information sharing as the "real value" of the task force. It allowed members to develop a deeper understanding of their respective areas of expertise. For example, task force members held separate calls to discuss specific topics in more depth. FDA members reported that connections they made with colleagues on the task force from

CDC and CMS helped them solve problems between meetings and outside the task force's scope. They mentioned that they were comfortable reaching out to task force members in other agencies, including when they had a question or problem unrelated to the task force's primary functions.

CONCLUSION

As FDA carried out its responsibilities during the first months of the COVID-19 pandemic, the task force served as a forum for FDA to collaborate and coordinate with CDC and CMS to facilitate emergency test implementation in labs. Not only did the task force's preparatory work identify gaps to address for future emergencies, but from day one of the COVID-19 emergency, the task force provided a venue for member agencies to coordinate their responses to challenges that arose during the pandemic. Indeed, task force members took advantage of connections made to address issues in their response to COVID-19 that went beyond the task force's scope.

This experience underscores the value of interagency exchanges and highlights the importance of building collaborative relationships in advance of an emergency. Establishing forums that allow collaboration, and maintaining them in nonemergency times, enables the Federal government to more nimbly respond when emergencies happen. Emerging infectious diseases like COVID-19 will always pose challenges broader than any single government agency can address alone. For this reason, interagency collaboration will remain important.

In our report on FDA's EUA process, *FDA Repeatedly Adapted Emergency Use Authorization Policies to Address the Need for COVID-19 Testing* (OEI-01-20-00380), we recommended a broader collaboration with Federal partners, including CDC. This would allow FDA and other Federal partners to consider more holistic improvements to this country's approach to rapidly creating, authorizing, manufacturing, and deploying tests during emergencies.³⁷ Additionally, as part of OIG's Top Management Challenges for HHS, OIG recommends that HHS programs collaborate effectively with one another and with other Federal agencies.³⁸

FDA's continued membership in the task force holds potential for further improvements in emergency test implementation in labs. Maintaining the momentum gained during COVID-19 is vital to building the tools, structures, and relationships necessary to address current challenges and prepare for the next emergency before it strikes.

METHODOLOGY

Scope

This inspection examines FDA's work with the task force from the task force's establishment in February 2019 through October 2020. We relied on the following sources: (1) task force documents such as the task force's charter, meeting minutes, and fact sheets; and (2) interviews with eight FDA staff members. We did not interview staff members from either of the other two agencies that participate in the task force, CDC and CMS.

Data Sources and Analysis

Documents. FDA and CDC (the task force chair) provided the following task force documents: the task force charter, meeting minutes, newsletter, press releases, information sheets, fact sheets, and presentation slides. FDA also provided us with drafts of EUA process workflows. We spoke with CDC to ensure that we received all documents pertaining to the task force. We then analyzed these documents to identify task force activities before and during the pandemic.

Interviews. We interviewed eight FDA staff members involved with the task force. Interview topics included how they participate and communicate within the task force, the extent to which they implemented task force recommendations, and challenges that they experienced in working with the task force. We analyzed these interviews to identify themes.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

ACKNOWLEDGMENTS AND CONTACT

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ENDNOTES

¹ In vitro diagnostic tests are tests done on patient samples, such as blood or saliva, to indicate if a patient has a disease or antibodies produced in response to that disease. All COVID-19 tests are in vitro diagnostic tests.

² 21 U.S.C. § 360bbb-3.

³ Charter: Tri-Agency Task Force for Emergency Diagnostics. Accessed at <https://www.fda.gov/media/120328/download> on April 21, 2022.

⁴ *Ibid.*

⁵ We discuss U.S. testing challenges from January through May 2020 in our companion report, *FDA Repeatedly Adapted Emergency Use Authorization Policies to Address the Need for COVID-19 Testing* (OEI-01-20-00380).

⁶ 21 U.S.C. § 360bbb-3.

⁷ Charter: Tri-Agency Task Force for Emergency Diagnostics. Accessed at <https://www.fda.gov/media/120328/download> on April 21, 2022.

⁸ 21 U.S.C. § 360bbb-3.

⁹ FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on March 22, 2022.

¹⁰ The Secretary of Health and Human Services must declare that a public health emergency has significant potential to affect national security and, on the basis of this determination, declare that circumstances exist to justify that certain products be authorized for emergency use in order for FDA to begin issuing EUAs. EUA for a product expires at the end of the public health emergency, or sooner if FDA revokes the authorization.

¹¹ 21 CFR § 860.7.

¹² 21 U.S.C. § 360bbb-3.

¹³ FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on March 22, 2022.

¹⁴ Jeffrey Shuren, *FDA's Ongoing Work to Support and Advance COVID-19 Diagnostic Test Accuracy and Availability*. Accessed at <https://www.fda.gov/news-events/fda-voices/fdas-ongoing-work-support-and-advance-covid-19-diagnostic-test-accuracy-and-availability> on September 23, 2021.

¹⁵ FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on March 22, 2022.

¹⁶ *Ibid.*

¹⁷ Charter: Tri-Agency Task Force for Emergency Diagnostics. Accessed at <https://www.fda.gov/media/120328/download> on March 22, 2022.

¹⁸ FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on March 22, 2022.

¹⁹ *Ibid.*

²⁰ FDA, *Adverse Event Reporting for Medical Devices Under Emergency Use Authorization (EUA) or Discussed in COVID-19 Related Guidance Documents*, July 15, 2021. Accessed at <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/adverse-event-reporting-medical-devices-under-emergency-use-authorization-eua-or-discussed-covid-19> on March 24, 2022.

²¹ FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on March 22, 2022.

²² Charter: Tri-Agency Task Force for Emergency Diagnostics. Accessed at <https://www.fda.gov/media/120328/download> on April 21, 2022.

²³ *Ibid.*

²⁴ *Ibid.*

²⁵ CMS, *Clinical Laboratory Improvement Amendments (CLIA)*. Accessed at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA> on April 21, 2022.

²⁶ CMS, *Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency Updated as of 12/17/2020*. Accessed at <https://edit.cms.gov/files/document/frequently-asked-questions-faqs-clia-guidance-during-covid-19-emergency-updated-12-17-2020.pdf> on April 21, 2022.

²⁷ 42 CFR § 493.

²⁸ HHS, *Quality, Safety, & Oversight- General Information- CLIA* (originally issued by CMS on March 5, 2012), December 31, 2020. Accessed at <https://www.hhs.gov/guidance/document/quality-safety-oversight-general-information-clia#:~:text=Congress%20passed%20the%20Clinical%20Laboratory,where%20the%20test%20was%20performed> on March 24, 2022.

²⁹ FDA, *Clinical Laboratory Improvement Amendments (CLIA)*, September 13, 2021. Accessed at <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia> on March 24, 2022.

³⁰ CMS, *State Operations Manual Appendix C- Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services*, Rev. 166, 2-03-17. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf on March 24, 2022.

³¹ CMS, *MLN Fact Sheet: CLIA Program and Medicare Lab Services*, December 2021. Accessed at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CLIABrochure.pdf#:~:text=CLIA%20applies%20to%20all%20laboratories%20that%20examine%20%E2%80%9Cmaterials,%2842%20Code%20of%20Federal%20Regulations%20%5BCFR%5D%20%20C2%A7%20493.2%29> on March 22, 2022.

³² CMS, *Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency Updated as of 12/17/2020*. Accessed at <https://edit.cms.gov/files/document/frequently-asked-questions-faqs-clia-guidance-during-covid-19-emergency-updated-12-17-2020.pdf> on April 21, 2022.

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³⁴ Charter: Tri-Agency Task Force for Emergency Diagnostics. Accessed at <https://www.fda.gov/media/120328/download> on April 21, 2022.

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³⁶ FDA, *Information for Laboratories Implementing IVD Tests Under EUA*, November 15, 2021. Accessed at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua?msckid=fdb190afab7311ecb9885bf37f841ac5> on March 24, 2022.

³⁷ *FDA Repeatedly Adapted Emergency Use Authorization Policies to Address the Need for COVID-19 Testing* (OEI-01-20-00380).

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