U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
Draft Guidances on Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration Under Section 564 (applicable to LDTs) and Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency (applicable to IVDs)

Date:
June 5, 2024

Draft Guidance Documents: IVDs for Public Health Response in the Absence of and During a Declaration Under Section 564

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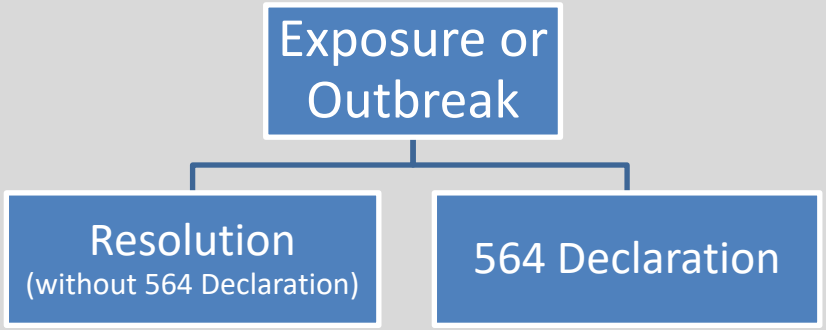
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Background

Appropriately safe and effective diagnostic tests are critical to the diagnosis, treatment, tracking, and interruption of transmission of infectious diseases during outbreaks, as well as for diagnosing and treating diseases or conditions caused by chemical, biological, radiological, and nuclear (CBRN) threat agents

Background



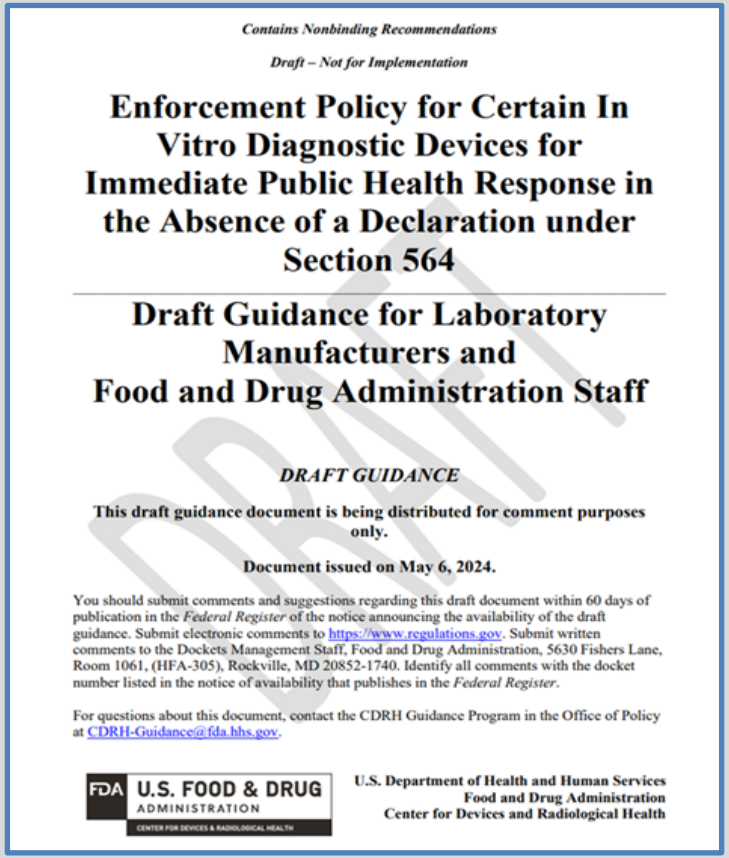
In the Absence of a 564 Declared Emergency

- Historically, laboratory manufacturers offered laboratory developed tests (LDTs) for which FDA had a general enforcement discretion approach when there was no applicable declaration under section 564.
- As described in the preamble to the LDT final rule, FDA is **phasing out this general enforcement discretion approach for LDTs**.

During a 564 Declared Emergency

- If the HHS Secretary declares circumstances exist justifying the issuance of **Emergency Use Authorizations (EUAs)** under section 564, FDA may authorize certain unapproved medical products or unapproved uses of approved medical products to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN agents when certain criteria are met.
- After all previous declarations under section 564, FDA has generally **expected LDTs to comply with applicable requirements**.

Draft Guidances



Contains Nonbinding Recommendations

Draft – Not for Implementation

Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564

Draft Guidance for Laboratory Manufacturers and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on May 6, 2024.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the CDRH Guidance Program in the Office of Policy at CDRH-Guidance@fda.hhs.gov.

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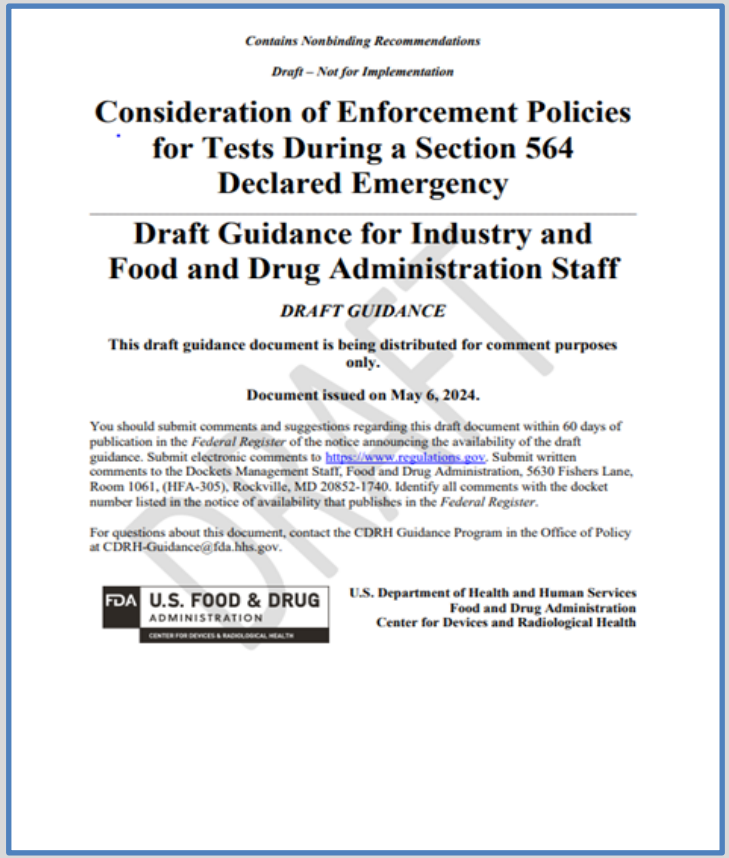

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Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency

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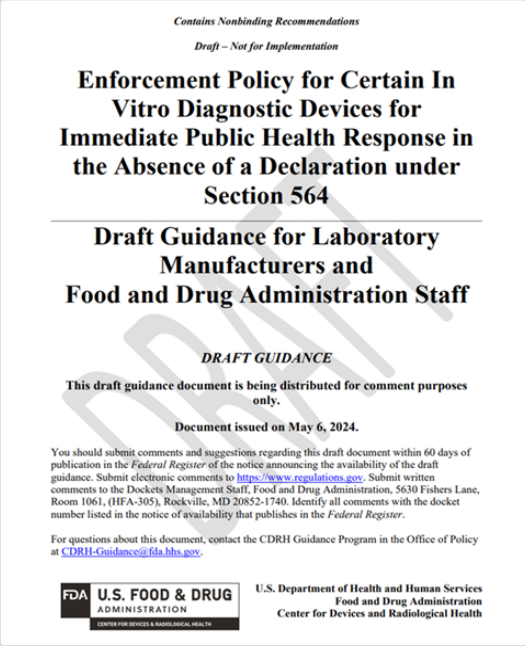
Draft Guidance

In the Absence of a Declaration under Section 564



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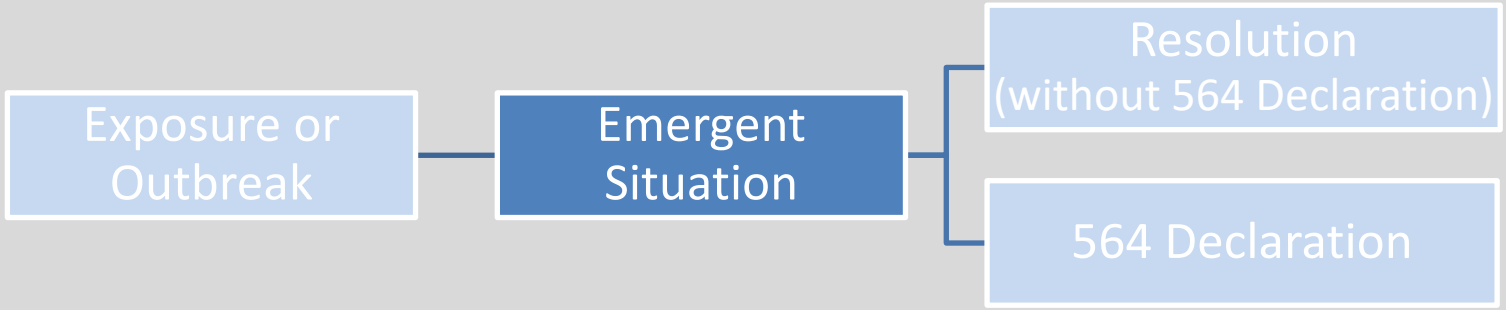
When finalized, will describe the FDA's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of a declaration applicable to IVDs under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Emergent Situation



- For purposes of this guidance, FDA defines the period of time between detection of the exposure or outbreak and, either, resolution of the exposure or outbreak or issuance of an applicable 564 declaration as an Emergent Situation.
- Based on consultation with CDC, when appropriate, FDA intends to broadly announce that the enforcement policies described in section V.B of the preamble to the LDT Final Rule do not apply due to an emergent situation and the public health benefits of the considerations described in the guidance.

Proposed Enforcement Discretion Policy for "Immediate Response" Tests

FDA does not intend to object to the offering of "immediate response" tests when:

- The test is manufactured and offered by **certain laboratory manufacturers;**
- The test has been **appropriately validated;**
- FDA is **notified** prior to or concurrent with initiation of testing;
- Appropriate **transparency** is provided (e.g., summary validation and performance information are made publicly available);
- The test is labeled for **prescription use only;** and
- There is **no applicable 564 declaration**

This proposed policy addresses only premarket review requirements.

Tests within the Scope of the Proposed Enforcement Discretion Policy

The policy would apply only to **"immediate response" tests**:

Intended to detect or diagnose a **serious or life-threatening** disease or condition that may be attributed to a **newly identified, previously unknown, or unusual** CBRN agent or agents; or a known agent or agents that result in a **newly identified or unusual** clinical presentation of such a disease or condition;

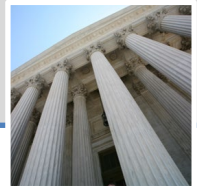
Needed for immediate response **in an emergent situation** to a potential case or cases of such disease or condition for which there is **no adequate, approved/cleared/authorized, and available alternative** to the test for detecting or diagnosing such disease or condition; and

Intended to help ensure **the government's** coordinated and effective public health response **during an emergent situation**.

This policy would **NOT** apply to:

Tests with home specimen collection or at home tests.

Manufacturers within the Scope of the Proposed Enforcement Discretion Policy



- Single laboratory* designs, manufactures and uses the test
  - United States Government (USG) laboratory,
  - State or local public health laboratory, or
  - Laboratory operating under an agreement (formal or informal) with the USG
- Demonstrated the ability to develop a similar diagnostic test consistent with FDA regulatory requirements;
- An entity with which FDA has not communicated any current compliance concerns

- CDC designs, manufactures, and distributes the test to laboratories* that are:
  - Within CDC,
  - Within CDC's Laboratory Response Network (LRN), or
  - Under an agreement with CDC

* Under CLIA, laboratories must be certified and meet the requirements to perform high complexity testing

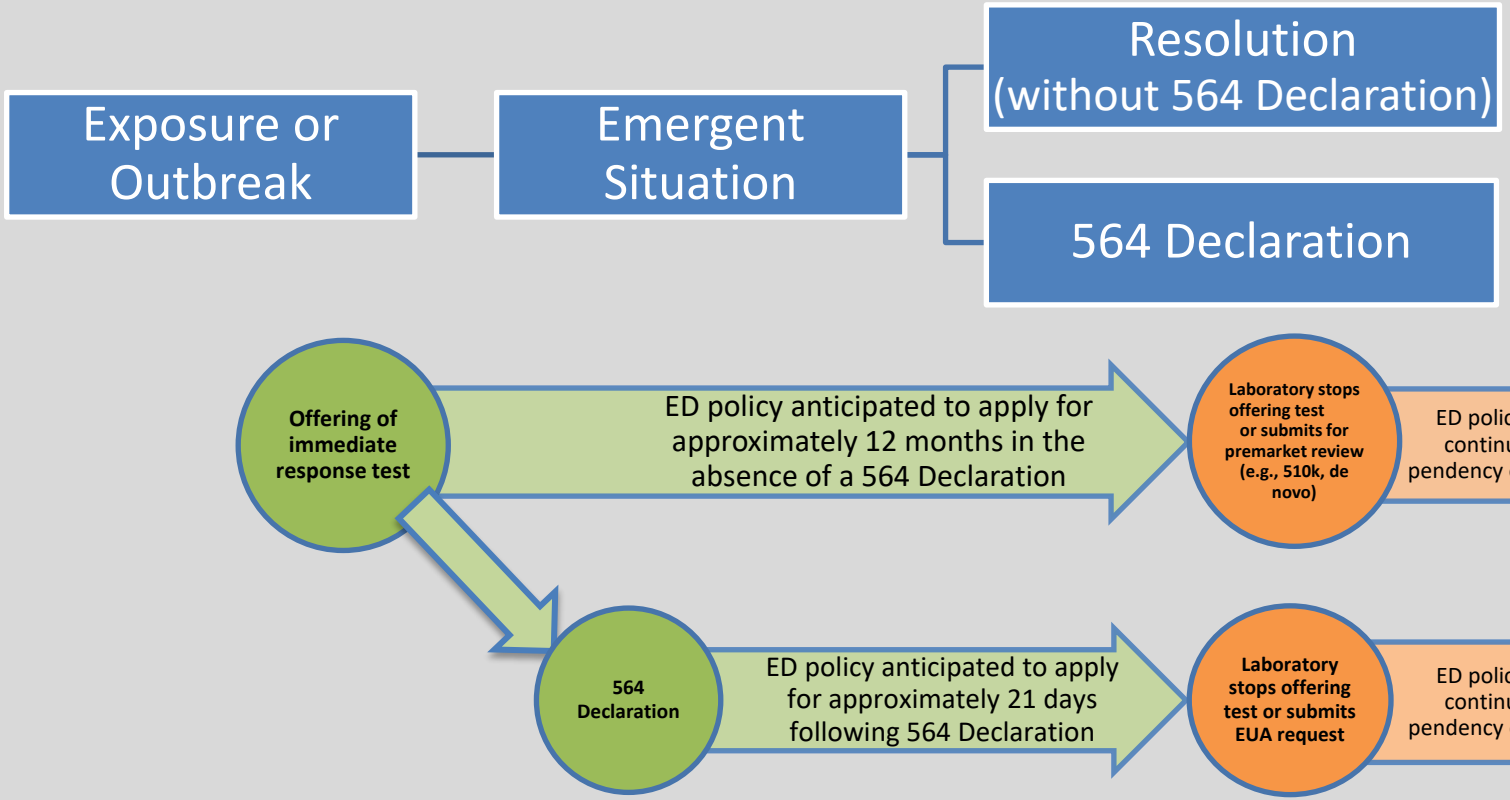
Additional Mitigations

The laboratory manufacturer should appropriately validate the test system intended for clinical use, e.g., performing recommended clinical and analytical validation studies and making summary validation and performance information publicly available.

Prior to or concurrent with initiation of testing, the laboratory manufacturer should notify FDA via email to provide applicable test information.

The laboratory manufacturer should prominently disclose in the test report and test ordering information that the test was manufactured for use as part of an immediate public health response during an emergent situation and has not been reviewed or authorized by FDA.

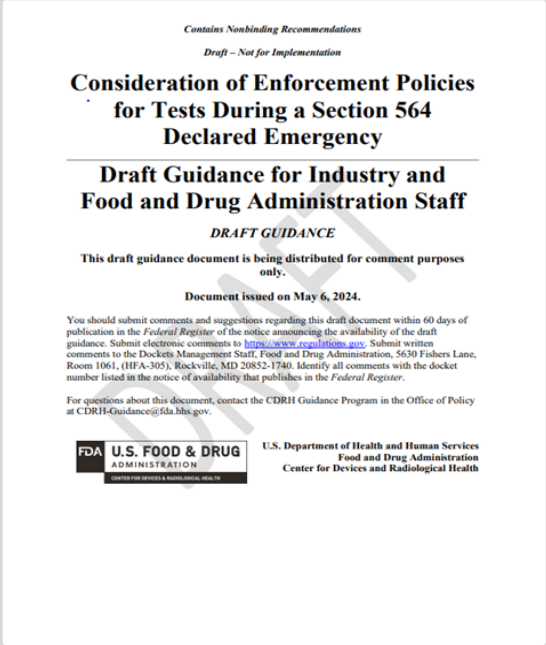
Timing of Proposed Enforcement Discretion Policy



Draft Guidance

During a Declaration under 564

- When finalized, will describe the factors that FDA intends to consider in determining whether to issue an enforcement policy regarding test manufacturers' offering of certain devices, specifically unapproved tests, for the diagnosis of disease or other conditions during a declared emergency.
- This draft guidance encompasses considerations that could be applicable to enforcement policies for all test manufacturers, not only laboratory manufacturers.



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Background

COVID-19 and mpox Outbreaks

During the recent COVID-19 and mpox responses, FDA issued guidance with enforcement policies for certain tests to help facilitate availability and quickly increase national testing capacity.

The US Government Accountability Office (GAO) Report

The US GAO published a report recommending “that FDA develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies. This policy should include the conditions under which FDA would begin and end the use of such discretion.”

Enforcement Discretion Policies During Applicable 564 Declarations

This guidance includes the factors FDA generally intends to consider in developing and issuing such future guidance

In future guidance FDA generally intends to include

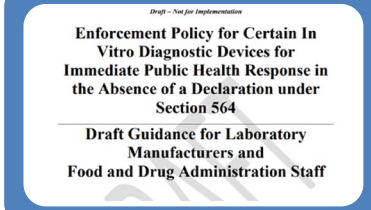
- The scope of the policy (e.g., premarket review, quality system)
- The rationale for the policy
- General performance expectations for tests offered as described in the policy
- The intended duration of the policy

Proposed Factors FDA Intends to Consider

Need	•Consideration of the number of, and access to, FDA-approved/authorized tests; •The time sensitivity of the need of a test •The volume of tests needed to address the testing needs •The type of test best suited to assist in the response; and •The turnaround time for results of authorized tests.
Risk	• The seriousness of the life-threatening disease or condition, • The complexity of the technology of the test, and • The experience of test manufacturers.
Alternatives	• The manufacturing capacity of any alternatives, and • The ability for the alternative(s) to meet the testing need.
Mitigations	• Manufacturer experience; • Participation in a government evaluation program; • Submission of an EUA request within a reasonable period of time.

Comment on Draft Guidances

- Submit comments by July 5, 2024, to ensure that FDA considers your comments before we work on final guidance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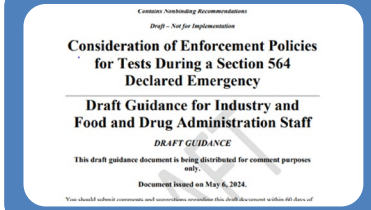
Docket Number FDA-2024-D-0083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Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency

Docket Number FDA-2023-D-5365

- You can comment on any guidance at any time (21 CFR 10.115(g)(5))

Next Webinar

[Laboratory Developed Tests | FDA]

Date
July

Time
TBD

Topic
IVD Classification

Please submit questions in advance to:
CDRHWebinars@fda.hhs.gov

Resources

Slide Number	Cited Resource	URL
4	Final Rule Regarding LDTs	www.federalregister.gov/documents/2024/05/06/2024-08935/medical-devices-laboratory-developed-tests
5	Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency Draft Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-tests-during-section-564-declared-emergency
5	Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564 Draft Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-in-vitro-diagnostic-devices-immediate-public-health-response-absence
14	Policy for Coronavirus Disease-2019 Tests (Revised)	www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised
14	Policy for Monkeypox Tests to Address the Public Health Emergency	www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-monkeypox-tests-address-public-health-emergency
14	GAO Report: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed	www.gao.gov/products/gao-22-104266
17	Docket Number FDA-2024-D-0083: Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564	www.regulations.gov/document/FDA-2024-D-0083-0002
17	Docket Number FDA-2023-D-5365: Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency	www.regulations.gov/document/FDA-2023-D-5365-0002


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Previously Submitted Questions

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