OneLab
A Unified Response to Training Needs

Life of a Test Method Part 2: Emergency Use Authorizations (EUAs)

Featuring Representatives from the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and Quest Diagnostics

September 22, 2021

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Agenda

- Introduction
  - Today's Presenters
  - New/Featured OneLab Resources
- Life of a Test Method Part 2: Emergency Use Authorizations
- Q&A
- Upcoming Events

Presenters

Michael J. Wagner, Esq., *Senior Corporate Counsel*

Legal Department

Quest Diagnostics Incorporated

Christine Sabol CG(ASCP)^{CM}, CCS, CPC, *Senior Director for Medical Operations & Regulations*

Legal Department

Quest Diagnostics Incorporated

Presenters

Toby Lowe, *Associate Director for Regulatory Programs in OHT7*

Office of In Vitro Diagnostics and Radiological Health (OIR)

Office of Product Evaluation and Quality (OPEQ)

Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration (FDA)

Monique Spruill, *Director*

Division of Clinical Laboratory Improvement and Quality (DCLIQ)

Quality, Safety, and Oversight Group (QSOG)

Centers for Medicare & Medicaid Services (CMS)

NEW RESOURCES

CLIA Curriculum
Provider-performed Microscopy Procedures

Laboratory Risk Management Curriculum

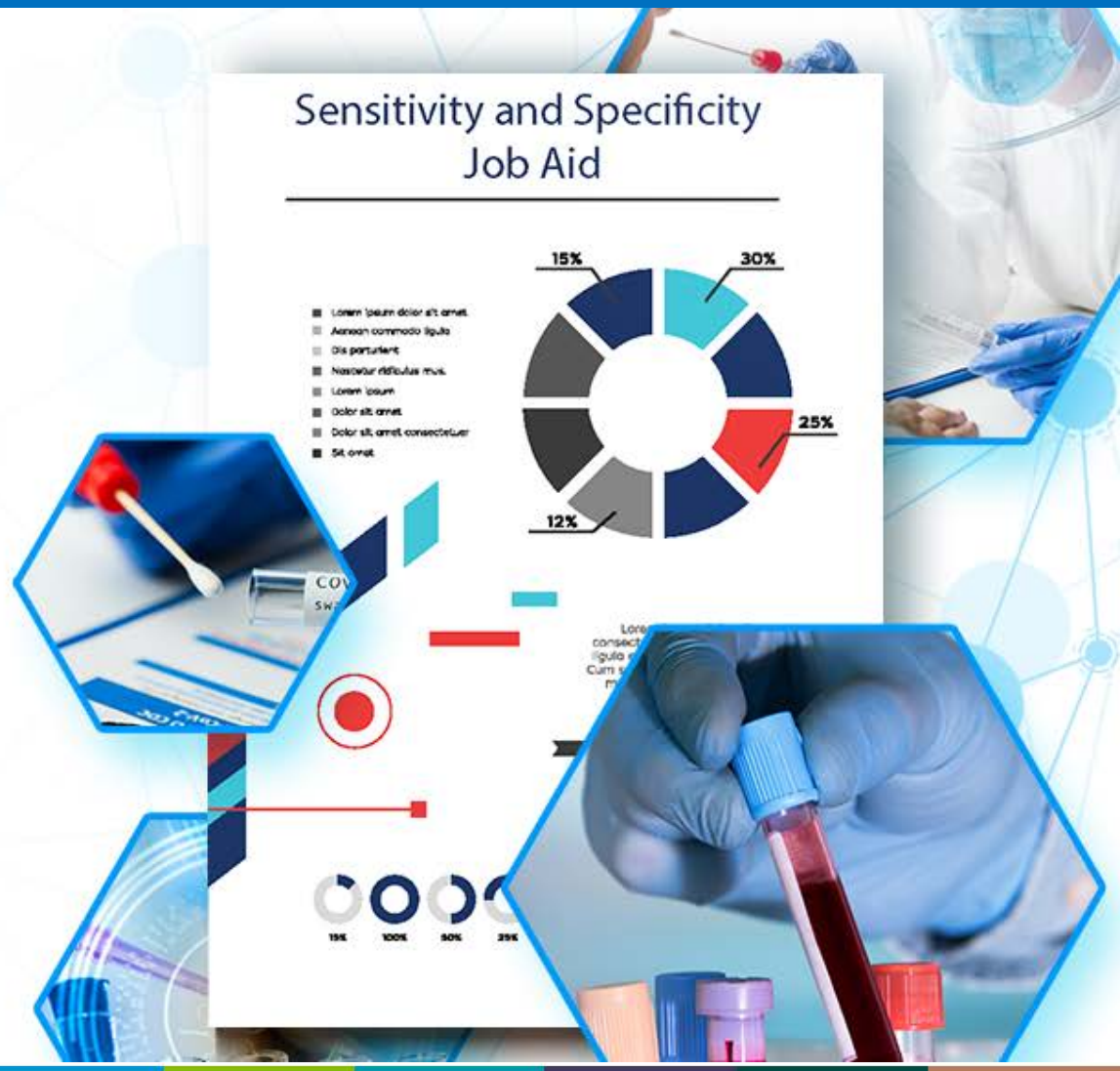
Introduction to Laboratory Risk Management

Laboratory Communications Toolkit

Communication strategies help simplify the process of translating complex information into meaningful messages for your audience.

Sensitivity and Specificity Job Aid

Understanding sensitivity and specificity help determine test selection and whether retesting might be necessary.



LIFE OF A TEST METHOD PART 1: VALIDATION, VERIFICATION, AND MANAGING QUALITY

Life of a Test Method Part 1

- Roles in the Laboratory System
- Complexity Model
- The “Test Method Life” Paradigm
- Important Terminology used by the FDA and CLIA
- Importance of “Instructions For Use”

Rex Astles, Ph.D

Health Scientist
Informatics and Data Science Branch, DLS, Center for Surveillance, Epidemiology, and Laboratory Services (CSLES), CDC

LIFE OF A TEST METHOD PART 2: EMERGENCY USE AUTHORIZATIONS

PANEL PRESENTATION

QUEST DIAGNOSTICS: PERSONAL EXPERIENCES WITH ZIKA AND COVID-19

MICHAEL J. WAGNER, ESQ. & CHRISTINE SABOL CG(ASCP)^{CM}, CCS, CPC

Quest Diagnostics

Collaboration – Communication – Focus – Resilience

September 22, 2021

Michael J. Wagner, Esq.
Christine E. Sabol, CG(ASCP)^{CM}, CCS, CPC

Quest Diagnostics™

Personal Experiences with Zika and COVID-19

Stressful Thankful Collaborative
Cooperative Communicative Community Support

- The Zika outbreak was a front-loaded sprint.
- COVID-19 has been a grueling marathon:
  - Exponentially ramp up testing capacity and specimen collection.
  - Ran at capacity 24/7 for over a year.
  - Personal health risk of staff and arranging for curfew exemptions
- We appreciate the incredible collaboration with FDA.

Test Development vs. Purchase

Driving Factors:

- **Availability of Alternatives**
- **Testing Capacity Needs**
- **Resources**
- **Costs**
- **Business Drivers**

Purchase Advantages

- No EUA studies or submission.
- Inventory is simpler to manage.
- Simpler quality system requirements.
- No manufacturing.
- Simpler post-marketing.
- Much less recordkeeping.
- Less likely to need to manage royalty accruals.

Purchase Disadvantages

- May not be available immediately.
- Cost
- Customization is limited.

Recent Experiences:

- **A combination of test development and kit purchases were key as circumstances change**

Zika

- Quest Diagnostics received the first EUA for a commercial Zika PCR
- Then transitioned months later to a commercially available kit when they became available at a reasonable price.

COVID

- Quest Diagnostics brought up a molecular LDT in February 2020, launched a test in early March under the emergency use notification program, and got authorization 8 days later
- Added three commercially available high-throughput molecular tests as soon as they became available in March 2020

Test Development: Build Your Own Test

Big hurdle early on is obtaining the pathogen and/or patient specimens while managing the intellectual property considerations.

Other considerations:

- ✓ Need the appropriate biosafety program in place
- ✓ Some pathogens require permits from the CDC or USDA to import or possess the pathogen or genetic elements
- ✓ Materials from some specimen banks and universities have use limitations.
  - For example, the materials may be provided for research use only and not for any commercial purposes.
  - The supplier may want to license the material for an upfront fee and a percentage.
  - Negotiating leverage is lost if the supplier's material is incorporated in your authorized test.
- ✓ Local public health labs may also be a source of material, but they may be stretched thin and transferring pathogens for commercial use may not be a common practice.
- ✓ Quest Diagnostics traditionally has relied on ongoing relationships with other labs and researchers globally.

Build Your Own Test

Keys to Success

COVID-19 Response

- FDA was even more flexible and collaborative than usual.
- FDA was discussing pre-submissions and had guidance before the emergency was declared. As early as Jan and Feb.
- Quest Diagnostics welcomed and utilized the emergency use notification program allowing our test to be available 8 days prior to authorization.
- FDA expanded the types of submission templates.
- FDA communicated guidance and answered questions in ongoing townhalls.

Resources for the EUA request including studies

- FDA EUA templates. There is a recommended format but not a required format.
- Labeling of any tests that have already been authorized.
- Consider discussing any questions with FDA.
  - Recommend framing the question in writing for FDA and scheduling a call to discuss.
  - Recommend presenting options to FDA for evaluating whatever risk the study is estimating.
  - Don’t expect FDA to waive a study because it isn’t easy or solve the problem for you. FDA has dozens if not hundreds of requesters that they are trying to support.
  - Present a solution for their consideration.

Emergency Use Notification Process

EUN is available to high complexity labs, who could launch a LDT so long as:

- The LDT was validated under CLIA.
- The lab gave a simple written notice to FDA at the time of launch.
- The lab provided proper disclosure about the regulatory status in test reports and printed materials.
- The lab promptly confirmed performance with local public health (1st ten positives and negatives?).
- The lab submitted an EUA request to FDA within a short amount of time (2 weeks?).
- Other details available in the guidance.

Benefits

- Early test launch allowing for patient testing in support of public health concerns when timing is crucial.
- Quest Diagnostics launched the COVID-19 test 8 days earlier which was critical in reaction to the pandemic crisis.

Considerations

- Until the test is authorized, the affiliate labs need to validate* the EUN test which is more labor intensive especially when time is critical.
- Payers may have concerns about a notified test.
- A notified test may not have the same liability shield as an authorized test.
- Potential confusion related to updating the regulatory notices on the test reports and any marketing material.
- Disclosure for multiple tests that have different regulatory statuses can be challenging, e.g., when adding new specimen types to an authorized test.

***Validation vs. Verification**

- **Validation** is the process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method delivers reliable results for the intended application. Validation studies must assess the: analytical accuracy, analytical precision, reportable range, analytical sensitivity, analytical specificity, and any other performance characteristic required to ensure analytical test performance.
- **Verification** is the process used to determine than an unmodified FDA-cleared/approved test performs according to the specification set forth by the manufacturer when used as directed. Verification studies must assess the: analytical accuracy, analytical precision, and reportable range.

Our Work is Ongoing

Laboratories and the FDA continue to respond to the current pandemic crisis

- As the need for testing capacity has increased throughout the past year, laboratories and manufacturers have responded by making testing improvements

- Each improvement requires:
  - Research and development
  - Additional studies
  - Collaboration with the FDA
  - An EUA amendment submission to the FDA
  - EUA authorization of the amendment

Special thanks to everyone involved in these ongoing efforts!

Quest Diagnostics submissions

Authorized	Platform	Description
3/17/2020	Quest Diagnostics LDT	Original EUA
3/27/2020	Quest Diagnostics LDT	2-well to 1-well
5/27/2020	Quest Diagnostics LDT	Unobserved self-collection
7/15/2020	Roche cobas® Hologic Panther Fusion® Hologic Aptima®	Observed self-collection
7/18/2020	Quest Diagnostics LDT	Specimen Pooling
7/28/2020	Quest Diagnostics LDT	Additional extraction platform
8/7/2020	Quest Diagnostics LDT	Remove RNase P
8/21/2020	Roche cobas Hologic Panther Fusion Hologic Aptima	Unobserved self-collection
9/14/2020	Quest Diagnostics LDT	Reference Panel
11/13/2020	Quest Diagnostics LDT	Clarify Pooling Disclosure
11/27/2020	Roche cobas	Specimen Pooling
12/4/2020	Roche cobas	Covid + Flu Home Self-Collection

Thank you so much for your time

Quest Diagnostics

FDA OVERSIGHT OF MEDICAL DEVICES: EMERGENCY USE

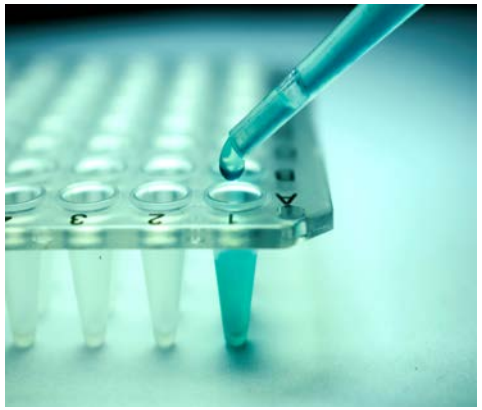
TOBY LOWE

FDA Oversight of Medical Devices

In Vitro Diagnostics (IVDs) are medical devices regulated by FDA

Traditional Pathways

- Pathway determined by risk-based classification
  - Exempt
    - Lowest risk
    - No FDA review
  - Premarket Notification (510(k))
    - Low to moderate risk
    - FDA review - demonstrate substantial equivalence (SE) to a legally-marketed predicate device
  - De Novo Classification Request
    - Low to moderate risk novel devices (no available predicate)
    - FDA review and classification of new device type
  - Premarket Approval (PMA) Application
    - Highest risk devices
    - FDA review – demonstrate reasonable assurance of safety and effectiveness

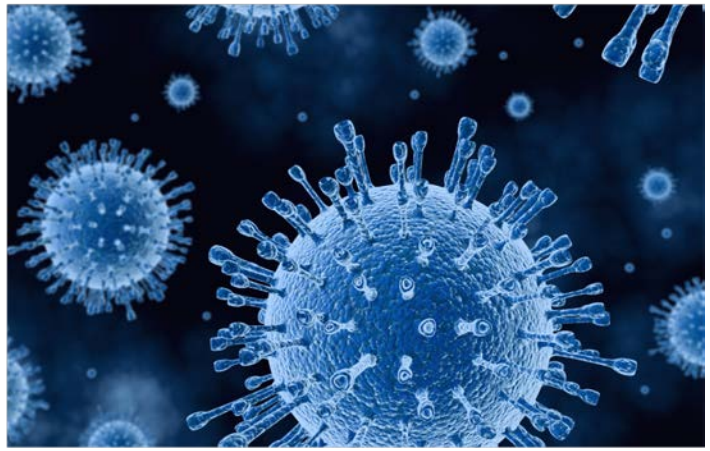


Emergency Pathway

- Emergency Use Authorization (EUA)
- FDA review – demonstrate that device may be effective and the known and potential benefits outweigh the known and potential risks
- Rapid and collaborative review to facilitate availability and access to medical devices necessary for the public health response

Prior Public Health Emergencies (PHEs)

- 2009 - H1N1 Influenza
- 2013 - Avian Influenza A (H7N9)
- 2013 - Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
- 2014 - Ebola Virus
- 2015 - Enterovirus D68
- 2016 - Zika Virus



FDA's Role in COVID-19

- Facilitate availability of and access to medical devices
- Stakeholder Engagement
- Mitigate supply chain shortages

Increasing Access to Testing

Testing remains an important cornerstone of our nation's fight against COVID-19.

This includes schools, workplaces, communities and other locations using testing to screen asymptomatic individuals who may still spread the virus.

Pandemic Testing Needs and Regulatory Flexibilities

Regulatory Strategies

- FDA Guidance for COVID-19 Tests during the PHE; notification pathway for COVID-19 tests to distribute after validation and notification
- FDA Guidance for viral transport media during COVID-19 PHE; notification pathway for VTM to distribute after validation and notification
- FDA Guidance modifications to FDA-Cleared molecular Influenza and RSV Tests
- EUA prioritization based on current needs
- Identifying and helping to correct/remove unsafe products from the market

Testing Supplies

- Airlifting supplies: swabs (Copan) and pipette tips (Tecan)
- FDA served as a clearinghouse for testing supply alternatives
- Expanding allowable specimen types for swabs (e.g., anterior nares (AN) in place of nasopharyngeal (NP) and swab types (spun fiber as well as foam)); 3D printed swabs
- Expanded use of alternate types of transport media
- Testing Supply Substitution Strategies web app

Transparency and Outreach

Templates for EUA Submissions

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic Template for Commercial Manufacturers (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (updated July 28, 2020)
- Home Specimen Collection Molecular Diagnostic Template (May 29, 2020)
- Antigen Template for Test Developers (October 26, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (July 29, 2020)
- Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (March 16, 2021)

Serology/Antibody Templates

- Serology Template for Test Developers (March 17, 2021)
- Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (March 17, 2021)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (November 24, 2020)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*, which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

- 69 Virtual Town Halls (>47,500 participants)
- FAQs on Testing for SARS-CoV-2
- Safety Communications
- Resources for Patients, Healthcare Providers, and Developers
- COVID-19 Diagnostics Mailbox (185,000+ inquiries)
- 2 stakeholder calls to discuss the guidance/policy
- 1 virtual town hall to discuss 3D Swabs
- Enforcement actions

Authorized as of September 9, 2021

287

Molecular diagnostic tests

- 32 Pooling
- 48 Asymptomatic single use screening
- 8 Serial screening
- 17 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 14 Point-of-care
- 78 Home collection
  - 16 Standalone home collection kits
  - 21 Direct-to-consumer
  - 3 Multi-analyte
  - 14 Saliva home collection
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 2 Over-the-counter at-home test

34

Antigen diagnostic tests

- 28 Point-of-care
- 3 Prescription at-home tests
- 7 Over-the-counter (OTC) at-home tests
- 14 Serial Screening
- 3 Multi-analyte (i.e., SARS-CoV-2 + Influenza)

88

Serology and other immune response tests

- 13 Point-of-care
- 1 Neutralizing antibody test
- 16 Semi-quantitative
- 1 Quantitative

Emergency Use Authorizations: Key Details

- Letter of Authorization
  - Indication
  - Authorized Settings
  - Conditions of Authorization
- Instructions for Use
- Patient and Health Care Provider Fact Sheets

EUA: Indication for Use

- Found at the beginning of the Letter of Authorization
- Identifies how the test is authorized to be used
  - What the test does (i.e., qualitative detection of nucleic acids from SARS-CoV-2, qualitative detection and differentiation of multiple virus nucleic acids)
  - Specimen type (i.e., anterior nasal, mid-turbinate, nasopharyngeal, oropharyngeal) and whether specimens can be self-collected and/or collected at home
  - Target population (i.e., individuals suspected of COVID-19 and/or those without symptoms or other reasons to suspect COVID-19)
  - Additional options such as testing pooled samples

Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acids from SARS-CoV-2 in healthcare provider-instructed self-collected anterior nasal (nasal) swab specimens (collected on site), and healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens collected from any individuals, including those suspected of COVID-19 by their healthcare provider and those without symptoms or other reasons to suspect COVID-19. Qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to and including six individual samples from healthcare provider-instructed self-collected nasal swab specimens (collected on site), or healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens. Emergency use of this test is limited to authorized laboratories.

Indication:	A multiplexed nucleic acid test intended for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids in upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.[1] Emergency use of this test is limited to authorized laboratories.

Diagnostic/Screening/Surveillance Testing

Diagnostic

- identifies current infection at the individual level and is performed when a person has signs or symptoms of infection, or is asymptomatic but has recent known or suspected exposure
- most tests FDA has authorized are for diagnosing SARS-CoV-2 in people suspected of COVID-19 by their health care provider

Screening

- tests for individual infections in a group of asymptomatic individuals who do not have known or suspected exposure to COVID-19 in order to make individual decisions based on the test results
- intended to identify infected individuals prior to development of symptoms or those infected individuals without signs or symptoms who may be contagious, so that measures can be taken to prevent those individuals from infecting others

Surveillance

- used to gain information at a population level, rather than an individual level
  - Individual results not returned
- includes ongoing systematic activities, including collection, analysis, and interpretation of health-related data, essential to planning, implementing, and evaluating public health practice

Authorized Settings

- Found under the Indication in the Letter of Authorization
- Provides information on where a test can be performed
  - High complexity CLIA labs
  - Moderate complexity CLIA labs
  - Certificate of Waiver CLIA labs

Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests, except testing of pooled samples is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Conditions of Authorization

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

- Found towards the end of the Letter of Authorization
- Includes sections for the test developer, distributors, and laboratories; some section apply to multiple parties
- May vary for different tests based on the attributes and indications

Authorized Laboratories

U. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

V. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

W. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

X. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Y. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov), and you (Technical Support: https://inbios.com/technical-support/) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

Z. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Modifications to an EUA Authorized Assay

- Regulatory flexibility provided in the COVID-19 Test Policy Guidance to increase availability of COVID-19 tests
- FDA does not expect an EUA for certain modifications made by a high-complexity CLIA-certified laboratory when the modified test is appropriately validated
  - Changing an instrument or other test component
  - New specimen type where the new specimen type has been previously authorized for another test of the same technology
- Modified tests offered without authorization are considered high-complexity by default
- The policies in the COVID-19 Test Policy Guidance do not apply to home collection of specimens or at-home tests

Lessons Learned from COVID-19

The value of regulatory flexibility

- During the pandemic we were able to act quickly and better tailor our oversight to facilitate the availability of critical devices due to the flexibility provided to us through our emergency use authorities

The power of engagement

- During the pandemic we provided multiple ways for stakeholders to work with our experts in real or near-real time

The need for transparency

- Templates and guidances to provide clear direction of FDA expectations
- Tests should include clear, standardized, comprehensible information on performance for laboratories, clinicians, and patients.

Resources

- In Vitro Diagnostics EUAs
  - https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas
- FAQs on Testing for SARS-CoV-2
  - https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2
- COVID-19 Test Policy Guidance
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised
- Questions?
  - CDRH-EUA-Templates@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION
& Devices

EXPERIENCE DURING THE COVID-19 RESPONSE

COVID-19 PUBLIC HEALTH EMERGENCY AND CLIA RESPONSE

MONIQUE SPRUILL

Experience During the COVID-19 Response

COVID-19 Public Health Emergency and CLIA response

Monique Spruill

Director

Division of Clinical Laboratory Improvement and Quality

September 21, 2021

Disclaimer

This presentation was prepared for informational purposes and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages.

This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program, but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of CLIA information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

Agenda

Centers for Medicare & Medicaid Services (10 min)

- The COVID-19 Public Health Emergency and CLIA response
- Enforcement Discretion

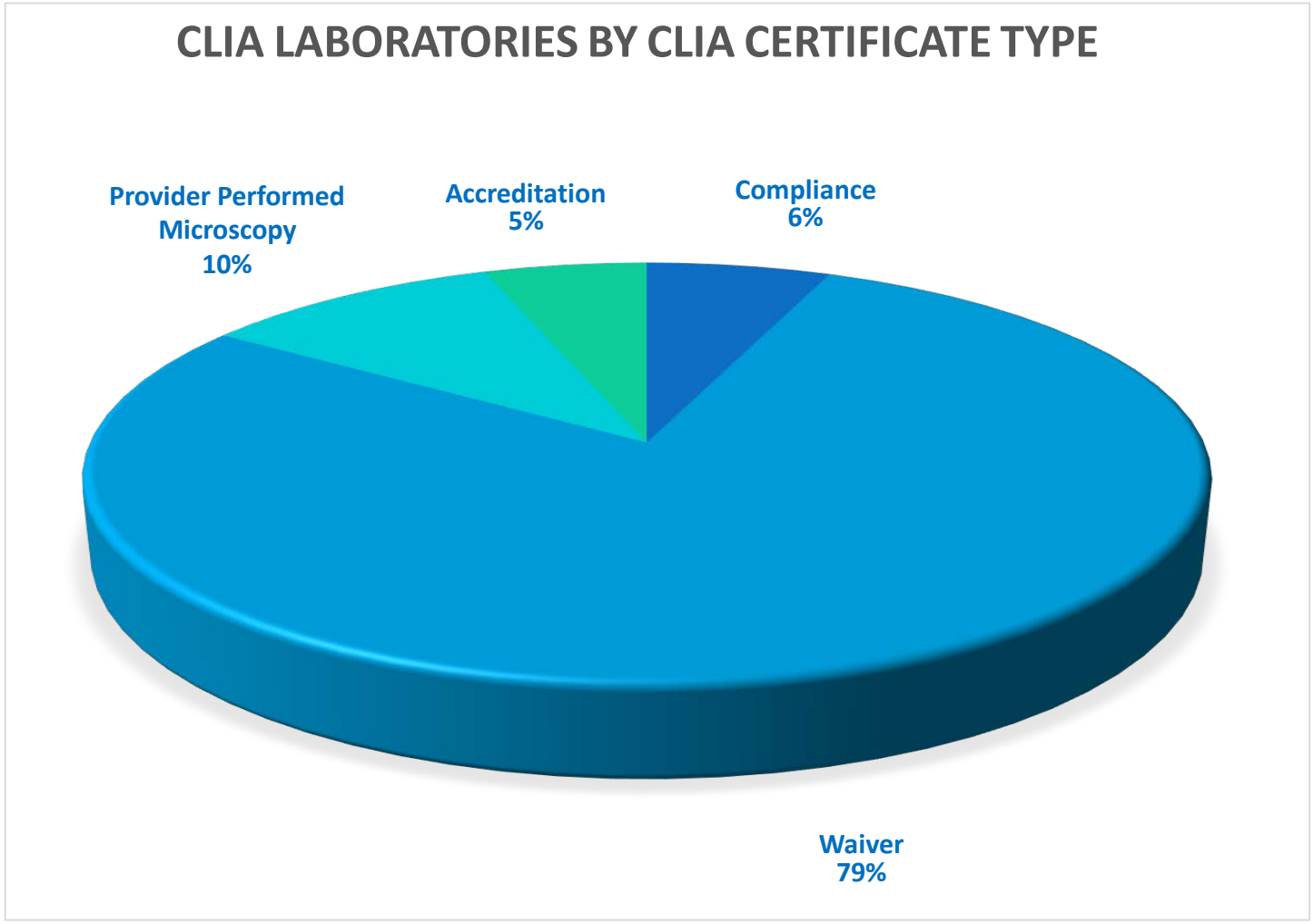
Current Statistics – Enrollment

- N

Total Number of CLIA Laboratories	309,914
Total Exempt States (NY & WA)	12,553
Total Non-Exempt	297,361
• Certificate of Waiver	233,540
• Provider Performed Microscopy	29,840
• Certificate of Compliance	18,039
• Certificate of Accreditation	15,942

Source: CMS database - August 2021

Certificate Type by Percent of Total



Current Laboratory Enrollment Since March 2020

Laboratory Types	Number of Laboratories Enrolled Since March 2020
Total Number of Laboratories Enrolled	45,974
Certificate of Waiver	32,399
Physician Office Laboratories	11,410
Pharmacy Laboratories	8,481
Assisted Living facilities	4,978
Nursing Facilities/Skilled Nursing Facilities	542
Home Health Agencies	1,472
CMS Database August 2021	

COVID-19 Public Health Emergency

- CMS, FDA, and CDC worked together to facilitate the availability of diagnostic tests
- FDA announced the Emergency Use Authorization for many Point of Care (POC) tests
- CMS developed several immediate initiatives to help relieve some burdens for clinical laboratories

CMS CLIA Immediate Process Changes

- Changes to the CMS 116 Application process resulted in immediate issuance of CLIA numbers to laboratories performing SARS-CoV-2 testing when a all of the information is provided on the application

- Pathologists could utilize temporary testing sites for remote review and reporting of slides or images under specific criteria

CMS Temporary Enforcement Discretion-Temporary Testing Site

- CMS has permitted a laboratory to extend its existing CLIA Certificate to operate a COVID-19 temporary testing site in a “designated overflow location” that is off-site.
- These overflow sites may include schools, churches, or parking lots

CMS Temporary Enforcement Discretion- EUA tests

- CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of molecular and antigen POC SARS-CoV-2 tests on asymptomatic individuals.

- Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver laboratories when SARS-CoV-2 POC tests are performed on asymptomatic individuals.

Individualized Quality Control Plan Temporary Enforcement Discretion

CMS has determined that IQCP is an option for EUA tests classified as non-waived (authorized for use in moderate or high complexity settings) when manufacturers' QC is less stringent than the CLIA quality control requirements.

Expired Reagents/Test Kits Temporary Enforcement Discretion

Expired Reagents/Test Kits

- During the COVID-19 public health emergency, in order to address the concern over COVID-19 reagent and swab supply problems, CMS will allow laboratories to use expired COVID-19 test kits, reagents, and swabs.

- Laboratories may use expired supplies until non-expired supplies become available provided that they put policies and procedures in place to ensure the reagents are performing as expected (e.g., ensuring that any expired supplies pass quality control tests with each assay run).

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CMS Temporary Enforcement Discretion- Surveillance Testing

- CMS is exercising enforcement discretion under CLIA for SARS-CoV-2 surveillance testing.
- Specifically, CMS will not cite non-CLIA certified facilities, such as university laboratories, that are performing such testing, provided that the facility **does not** report actual test results, but only **refers** an individual with a presumptive positive or inconclusive test result to a CLIA-certified laboratory for further testing.
- If at any time a patient specific result is to be reported by a facility, a CLIA certificate must be obtained, and the facility must meet all requirements to perform testing.

CMS Temporary Enforcement Discretion- Surveillance Testing

SARS-CoV-2 Variant Testing - Non-CLIA Certified Facilities

- CMS will not take action against non-CLIA certified facilities that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific results to State or local Public Health Departments, provided that the facility only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

CLIA

CMS Temporary Enforcement Discretion- Surveillance Testing

SARS-CoV-2 Variant Testing - CLIA Certified Laboratories

- CMS will not cite CLIA certified laboratories that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific variant results to State or local Public Health Departments without establishing performance specifications as required by §493.1253(b)(2), provided that the laboratory only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment.
- If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA-certified laboratory and in compliance with all applicable CLIA regulations.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

CLIA

Contact Information

CLIA Website: www.cms.hhs.gov/clia/

CLIA Headquarters/Baltimore: 410-786-3531

CLIA Mailbox: LabExcellence@cms.hhs.gov

Q&A

October OneLab Network Event

Affects of COVID-19 on Supply Chain and Lessons Learned

Registration coming soon!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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