OneLab™

A Unified Response to Training Needs

Ready? Set? Test!

Patient Testing is Important. Get the Right Results.

Session 1

August 28, 2024

12pm – 1pm EST

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- *"Ready? Set? Test!" Patient Testing Is Important. Get the Right Result.*
- Q&A
- Upcoming Events

Participant Rules of Engagement for the Webinar Chat

Please keep the following in mind when using the chat feature:

- **Connect with others!** React to what you're hearing, share experiences, and ask questions of your fellow participants!
- **Have a question for the presenter?** Use the Q&A function, *not* the chat.
- **Show Respect and Professionalism.** Inappropriate language, improper conduct, or any form of discrimination may result in removal from the webinar.
- **Remain on Topic.** Ensure your comments are relevant to the topic.
- **Comply with Moderators' Guidance.** If a moderator gives direction regarding chat behavior, please comply accordingly.
- **Report Issues.** Notify moderators if you experience technical difficulties or observe any disruptive behavior.

OneLab **TEST**

OneLab TEST Job Aids

Personal Protective Equipment (PPE) Toolkit

The Laboratory Personal Protective Equipment (PPE) Toolkit is a guide to resources on using PPE.

PDF

Blood and Body Fluid Exposure

A list of standard precautions to take when cleaning up blood or body fluids.

PDF

Instructions for Performing External Control Testing

Instructions for performing external control testing including quality control log for qualitative and quantitative tests.

PDF

Today's Presenter

Theresia Snelling, BS, MBA, MPM, MT(ASCP)

Health Scientist
Quality and Safety Systems Branch (QSSB)
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Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control and Prevention (CDC)

Today's Presenter

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Centers for Disease Control and Prevention (CDC)

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Today we will be discussing:

- Waived Testing
- Educational Materials
- Ready?
- Set?
- Upcoming Events

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Learning Objectives

By the end of the presentation, the learner will be able to...

Objectives

1. Explain what a waived test is and what the CLIA regulatory requirements for waived testing are.
2. Identify the Ready? Set? Test! educational materials as resources for waived testing.
3. Describe best practices to follow when preparing for testing.
4. Describe test order, patient preparation, and sample collection considerations for testing.
5. Identify best practices to safely perform waived testing.

Waived Testing

What are Waived Tests?

- Simple tests with low risk for an incorrect result
- Often performed at the point-of-care
- Include test systems cleared by the FDA for home use and those tests approved for waiver under CLIA criteria.
- Performed without routine regulatory oversight.
- The FDA list of waived tests is continually revised as new tests are waived.
- The most current information on FDA-cleared waived tests can be found here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

CLIA Complexity Model

Type of Testing	Requirements
Waived	• Obtain a Certificate of Waiver • Pay applicable certificate fees biennially • Follow manufacturer's instructions for testing

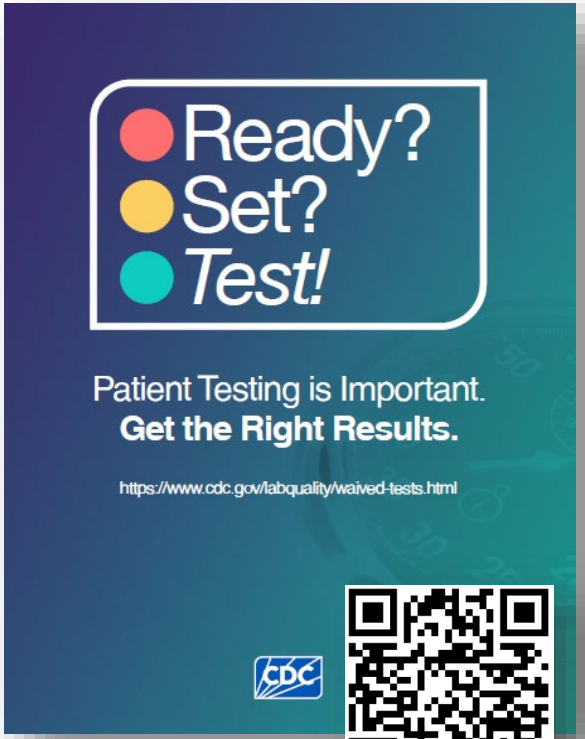
CLIA Brochure - How to Obtain a CLIA Certificate of Waiver
https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures

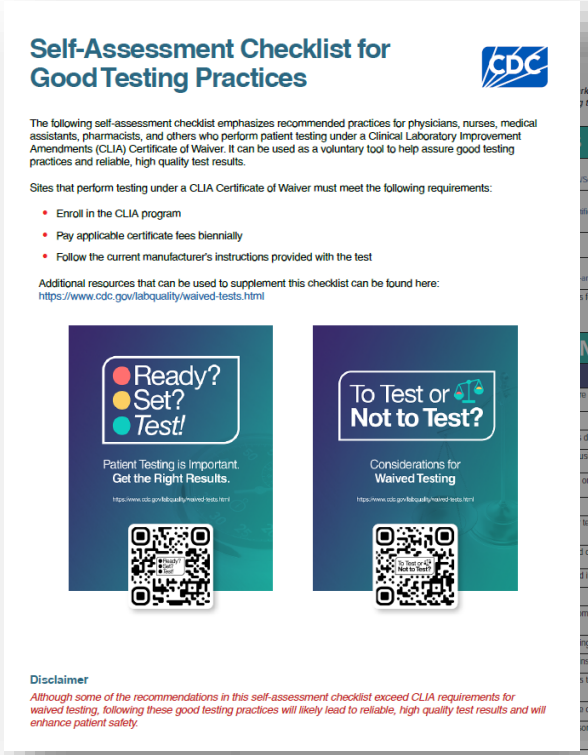
- Waived testing results are used to diagnose disease, determine prognosis, and monitor a patient's treatment or health status.
- Waived tests can be performed at non-traditional sites or settings (e.g., nursing homes, clinics, and jails).
- Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system.

Ready? Set? Test!
Educational Materials

https://www.cdc.gov/labquality/waived-tests.html

OneLab™ Ready? Set? Test! Educational Materials





To request hard copies:
https://www.cdc.gov/labquality/requests/waived-testing/index.html

Ready? Set? Test!

Online Course

Elearning Course

Ready? Set? Test! Patient Testing is Important. Get the Right Results (PACE)

CE
1.5 Hours P.A.C.E.® credit

Category

Duration
1.5 Hours

Course Number
1101900

P.A.C.E.® Certificate Number
288-032-24

https://reach.cdc.gov/course/146/1101900

Ready?

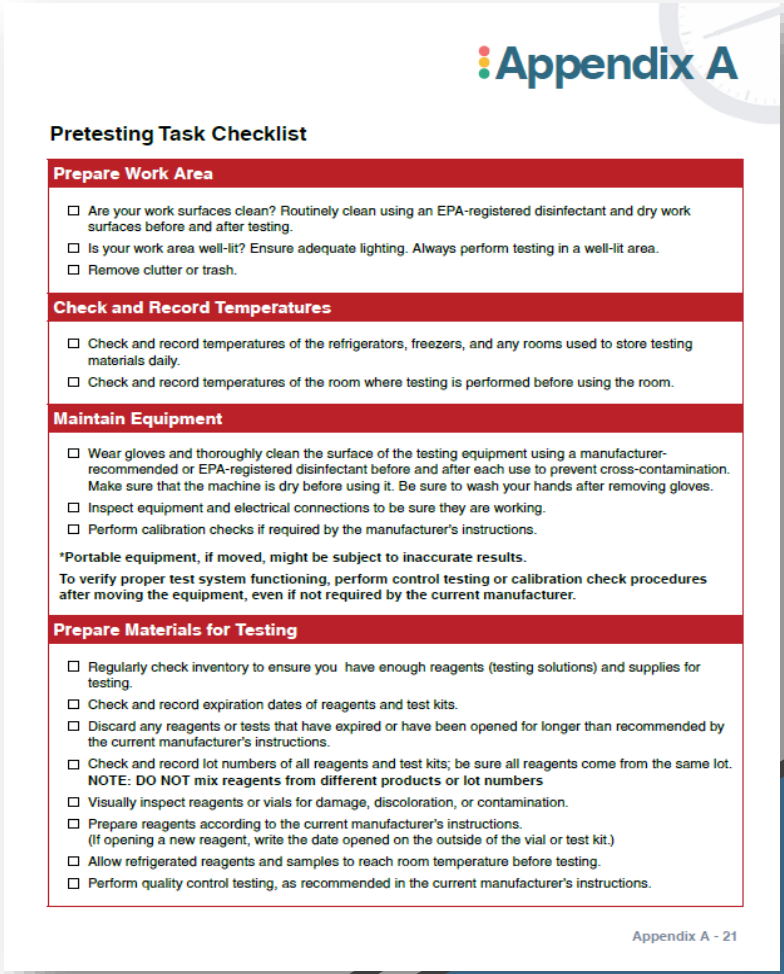
Prepare for Testing

Some best practices to follow when preparing for testing are:

- Routinely clean and dry work surfaces before and after testing.
- Perform testing in a well-lit, clean, and dry area. Placing test strips on a moist or newly cleaned surface may damage the strip and cause incorrect results.
- Check and record temperatures of the testing, reagent, and test kit storage areas.
- Check inventory regularly to ensure you have enough reagents, test kits, and supplies for testing.
- Check and record expiration dates of reagents and test kits. Discard any expired reagents or test kits.
- Ensure all test kit component reagents are from the same kit lot. Do not mix or combine reagents between different lot numbers.
- Inspect reagents or vials for damage, discoloration, or contamination, and discard if found.
- Prepare reagents according to the manufacturer's instructions.
- Allow time for refrigerated reagents, test kits, and patient samples to come to room temperature before testing.
- Perform equipment calibration checks, as needed, following the manufacturer's instructions.
- Disinfect surfaces before performing any test procedure, whenever contamination is visible, and before leaving the testing area.

Pretesting Task Checklist

Reviewing a pretesting task checklist before starting the testing process can be used as a voluntary tool to help ensure good testing practices.



Appendix A

Pretesting Task Checklist

Prepare Work Area

- ☐ Are your work surfaces clean? Routinely clean using an EPA-registered disinfectant and dry work surfaces before and after testing.
- ☐ Is your work area well-lit? Ensure adequate lighting. Always perform testing in a well-lit area.
- ☐ Remove clutter or trash.

Check and Record Temperatures

- ☐ Check and record temperatures of the refrigerators, freezers, and any rooms used to store testing materials daily.
- ☐ Check and record temperatures of the room where testing is performed before using the room.

Maintain Equipment

- ☐ Wear gloves and thoroughly clean the surface of the testing equipment using a manufacturer-recommended or EPA-registered disinfectant before and after each use to prevent cross-contamination. Make sure that the machine is dry before using it. Be sure to wash your hands after removing gloves.
- ☐ Inspect equipment and electrical connections to be sure they are working.
- ☐ Perform calibration checks if required by the manufacturer's instructions.

***Portable equipment, if moved, might be subject to inaccurate results.**

To verify proper test system functioning, perform control testing or calibration check procedures after moving the equipment, even if not required by the current manufacturer.

Prepare Materials for Testing

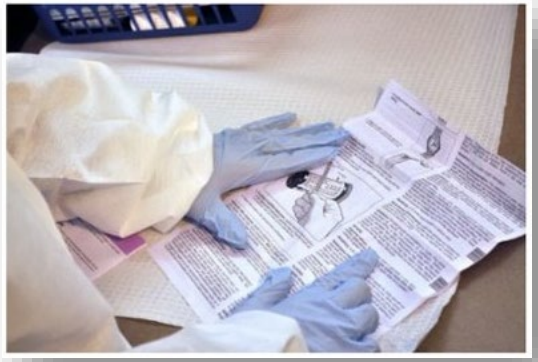
- ☐ Regularly check inventory to ensure you have enough reagents (testing solutions) and supplies for testing.
- ☐ Check and record expiration dates of reagents and test kits.
- ☐ Discard any reagents or tests that have expired or have been opened for longer than recommended by the current manufacturer's instructions.
- ☐ Check and record lot numbers of all reagents and test kits; be sure all reagents come from the same lot. **NOTE: DO NOT mix reagents from different products or lot numbers**
- ☐ Visually inspect reagents or vials for damage, discoloration, or contamination.
- ☐ Prepare reagents according to the current manufacturer's instructions. (If opening a new reagent, write the date opened on the outside of the vial or test kit.)
- ☐ Allow refrigerated reagents and samples to reach room temperature before testing.
- ☐ Perform quality control testing, as recommended in the current manufacturer's instructions.

Appendix A - 21

Following Manufacturer's Instructions

To ensure that the most current and appropriate test instructions are being used:

- **Keep a copy of the manufacturer's instructions on hand for easy reference.**
- **Check the manufacturer's instructions with each new lot and shipment of reagents or test kits to ensure they are unchanged from previous lots and shipments.**
- **Replace and file the old manufacturer's instructions when you discover changes.**
- **Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.**

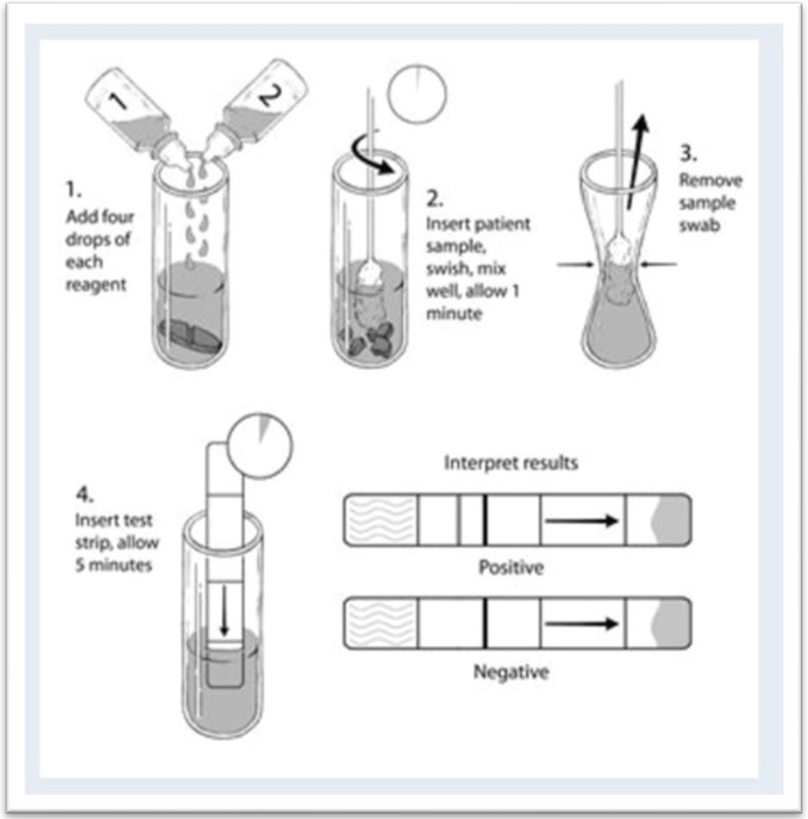


Remember it is not acceptable to make changes to the manufacturer's instructions that come with test system. If the testing site makes a change to the test, it is no longer considered waived.

Quick Reference Instructions

Some manufacturers provide quick-reference instructions to use during the testing process.

These instructions are intended to supplement the manufacturer's instructions.



Quality Control Testing

Quality control testing ensures the test performs as expected, alerts users when problems occur, and is required when indicated in the current manufacturer's instructions.

The manufacturer's instructions explain when, why, and how to perform QC testing. Incorrect QC test results alert users about potential problems with the test or testing process (e.g., reagent or test kit deterioration, equipment failure, environmental conditions, or human error).

Types of Quality Controls

Waived tests include two types of controls:

Internal controls (also referred to as built-in or procedural controls) determine whether:

- The test is working as it should.
- The test sample amount used was adequate for the test to perform properly.
- The sample is moving through the test strip correctly.
- Electronic functions of the instrument are working correctly.

External controls determine whether:

- The entire testing process is performed correctly, from sample application to interpretation of results.
- The control results are within the expected ranges or values printed on the controls or provided in the control manufacturer's instructions.

Who Should Perform QC Testing? & How Often Should It Be Done?

Waived tests include two types of controls:

Your testing site should perform QC testing at least as often as specified in the manufacturer's instructions and should test controls with:

Each new shipment of reagents or test kits	Any change in lot numbers	Each new tester

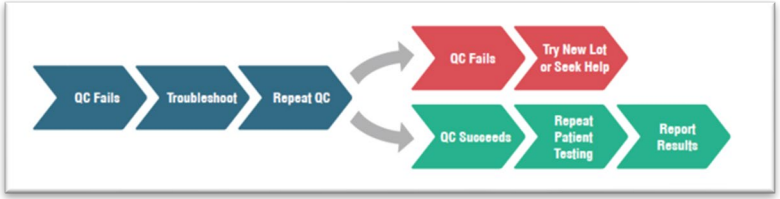
Additional considerations to help determine when and how often your site should perform QC testing:

Stability of the test (i.e., based on expiration dates and storage requirements)	Environmental changes (e.g., power outages, mechanical breakdowns, and extreme temperature changes	Can cause QC or testing material to spoil)	Competency and skills of the testers (i.e., based on if personnel are newly trained versus experienced

OneLab™ Actions for Unexpected Quality Control Results

If controls do not give the expected results, you should wait until the problem is identified and corrected before reporting patient results. This applies to both external and internal controls.

- Check to see if the manufacturer's instructions were followed correctly.
- Look for possible sources of error, such as outdated reagents, test kits, or control materials.
- Check whether reagents, test kits, and control materials were stored correctly.
- Ensure controls and reagents were not cross contaminated by accidentally switching caps.
- Follow the troubleshooting steps in the manufacturer's instructions or site-specific procedure.
- Contact the manufacturer, technical representative, or the person who directs or supervises the testing for additional assistance.
- Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient sample(s) and report the final results.



Knowledge Check

Scenario #1

You are working at a testing site that performs waived testing under a CLIA certificate of waiver. The manufacturer's instructions for one of the waived test systems used at your test site requires quality control testing daily. Before you begin testing for the day, you perform external quality control using quality control materials on the counter near the test system. The quality control results were unexpected. What next steps would you take?

A. Mix the quality control materials and immediately test them again.

B. Check the manufacturer's instructions to ensure the testing process was performed correctly.

C. Inspect the test kit and quality control materials for possible sources of error, such as outdated reagents, stored incorrectly, or cross-contamination.

✓ D. B & C

Set?

Test Order

Before collecting a sample, confirm:

The Test Order

If there is any question about whether the order is correct, check with the individual who requested the test.

Patient Identification

Patient names can be similar, which can lead to confusion. Using at least two unique patient-specific identifiers (e.g., patient name and date of birth) is good practice to ensure the test is ordered for and collected from the correct patient.

Preparing the Patient

Consult with the patient regarding:

Pretest Instructions

- Some tests require preparation by the patient (e.g., fasting for a glucose test). Verify that any recommended patient instructions were followed before collecting the sample.

Pretest Information

- Discuss factors such as medical indications, medications, or other interfering substances that could affect test results. This information can often be found in the Limitations section of the manufacturer's instructions.

The Test

- Make sure the patient understands the purpose of the tests being ordered and what the results will mean to their health.

Patient Counseling

- Some test results (e.g., HIV tests) may benefit from counseling on what the results will mean for the patient.

Collecting The Sample:

The manufacturer's instructions provide all necessary sample collection, handling, and storage information. Do not test samples that are improperly collected or handled.

When a test is approved for both waived and non-waived testing use, the manufacturer's instructions may include instructions for testing that could be performed using more than one sample type. However, waived tests may **only** be performed using unprocessed samples.

Examples of unprocessed samples include:

- Whole blood
  - (fingerstick or anticoagulated blood collected by venipuncture)
- Urine
- Throat swab, nasopharyngeal swab, nasal wash, or aspiration
- Stool
- Saliva or oral fluid
- Gastric biopsy

Labeling Samples

Always label the sample immediately after collection with at least two unique patient identifiers (e.g., name and date of birth) to prevent sample mix-up.

Sample labels may also include the date and time of collection and who collected the sample.

When a test requires the sample to be applied directly to the test device (e.g., test strip or cassette), label the test device with a patient identifier before collecting the sample.

Use Collection Devices

Swabs can be made of different materials, so substituting them may interfere with the test result.

Fingerstick and venipuncture collection devices are for one-time use only and should never be reused.

Be sure to use a device that is appropriately sized for your patient. Fingerstick devices come in various sizes, from pediatric to adult.

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Safety Considerations for Testing

Follow work practices that reduce the risk of exposure, including:

- Handle all blood and body fluids as if they are infectious.
- Use required PPE and safety devices.
- Do not eat, drink, or apply cosmetics in the testing area.
- Be cautious of exposure to mucous membranes (i.e., eyes, nostrils, and mouth.)
- Wear goggles or face shields to protect against aerosol and droplet exposure.
- Avoid using needles and lancets if safe and effective alternatives are available.
- Never re-use single-use devices (i.e., needles and lancets.)
- Avoid recapping needles, transferring a body fluid between containers, or opening blood tubes.
- Properly dispose of used sharps in puncture-proof sharps containers.
- Report all occupational exposures promptly to your supervisor or to the person who oversees or directs testing to ensure you receive appropriate follow-up care.
- Report any real or potential hazards you observe to the person who oversees or directs testing.
- Get hepatitis B vaccination.

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Biohazard Waste

During the testing process, the biohazard bags and containers used for disposal of contaminated materials should be:

- ✓ As close to the immediate testing area as possible
- ✓ Upright throughout use
- ✓ Routinely replaced and never overfilled
- ✓ Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, and shipping
- ✓ Labeled or color-coded to indicate biohazard material
- ✓ Closed before removal to prevent spillage or protrusion of contents during handling

Knowledge Check

Scenario #2

You are collecting a throat swab from a patient at your testing site. What best testing practices would you follow to ensure the sample is collected properly and from the correct patient?

A. Only use a swab from the test kit or sample collection kit for the test ordered.

B. Check at least two unique patient-specific identifiers to verify the patient and the test order.

C. Follow the test kit's manufacturer's instructions for sample collection.

D. All the above

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Summary

- Ready? Set? Test! educational materials are resources to provide testers the basic training necessary to safely and accurately perform waived patient testing.
- Prepare for testing by taking all necessary steps to ensure your results are accurate.
- Always follow the manufacturer's instructions.
- Reference the manufacturer’s instructions for when, why, and how to perform QC testing.
- Before collecting a patient sample, confirm the test order and verify the patient’s identification.
- Use the appropriate collection device for your test system and patient.
- Follow safe working practices to reduce the risk of exposure.

Let’s Discuss!

Q&A Session

Ready? Set? TEST! Session 2 Event

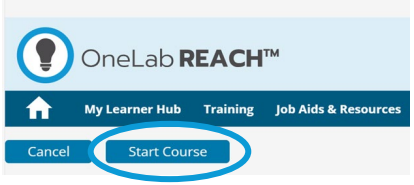
- "Ready? Set? Test!" Patient Testing Is Important. Get the Right Results. Session 2
- October 2, 2024, at 12 pm ET
- Will cover :
  - waived testing best practices to follow once the sample is collected and the testing phase begins
  - Ready? Set? Test! testing logs and resources.

OneLab TEST

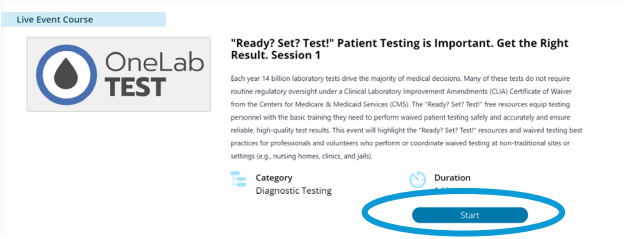
Share your feedback and training needs with us!

1. Log into your OneLab REACH account. **You must be logged into your REACH account to access the evaluation.**
2. Click on this link to take you to the survey.
3. Click "**Enroll**"

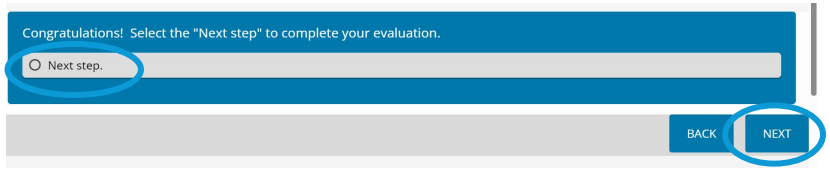
4. Select "**Start Course**".



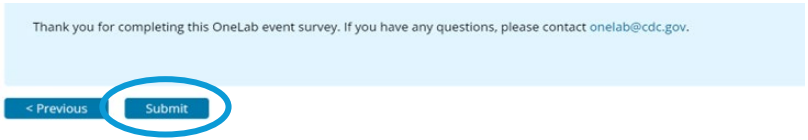
5. Select "**Start**".



6. Select "**Next step**" and "**Next**".



7. Complete the evaluation and click "**Submit**".



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