Division of Laboratory Systems

OneLab
A Unified Response to Training Needs

Waived Point-of-Care (POC) Testing Basics Virtual Training

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March 31, 2022

Agenda

- Introduction
  - Today's Presenters
  - OneLab Resources
- Waived Point-of-Care (POC) Testing Basics Virtual Training
- Q&A
- Upcoming Events

Presenters

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Mentimeter Instructions

- Open a new browser on your computer, tablet, or mobile device.
- Use the QR code or go to Menti.com to access Mentimeter
- Enter the code 3982 2502
- Keep this tab open throughout the presentation to interact with the knowledge checks
- Let's practice!

RELEVANT RESOURCES

CDC LOCS

(click to open)

Ready? Set? Test!

Register Now!

Waived Point-of-Care (POC) Testing Basics Virtual Training

Training Goal and Objectives

After completing this training, participants will be able to:

1. Describe basic safety procedures and the importance of quality in point-of-care (POC) settings performing CLIA-waived testing.

2. Identify the major considerations that impact workspace setup, testing workflow, and hazardous waste management at POC sites.

What are waived POC tests?

Tests performed at or near the place where a specimen is collected. They provide results within hours.

Some waived POC tests:

- Assess health

- Detect current infection/disease

- Detect previous infection

Where are waived POC tests performed?

- Physician offices

- Urgent care facilities

- Pharmacies

- School health clinics

- Long-term care facilities and nursing homes

- Temporary locations, such as drive-through sites managed by local organizations

Who* performs waived POC tests?

- Nurses

- Physicians

- Students

- Technical assistants

- Store clerks

- Others

*Some states and localities have specific regulations for testing, require licensure of personnel who perform testing, and have phlebotomy requirements.

Whenever state or local regulations are more stringent, they supersede the federal CLIA requirements.

Four Areas of Focus

Today we will focus on waived POC testing basics for four major areas:

- Safety and risk management
- The importance of quality control
- General workspace setup and testing workflow
- Managing waste at waived POC testing sites
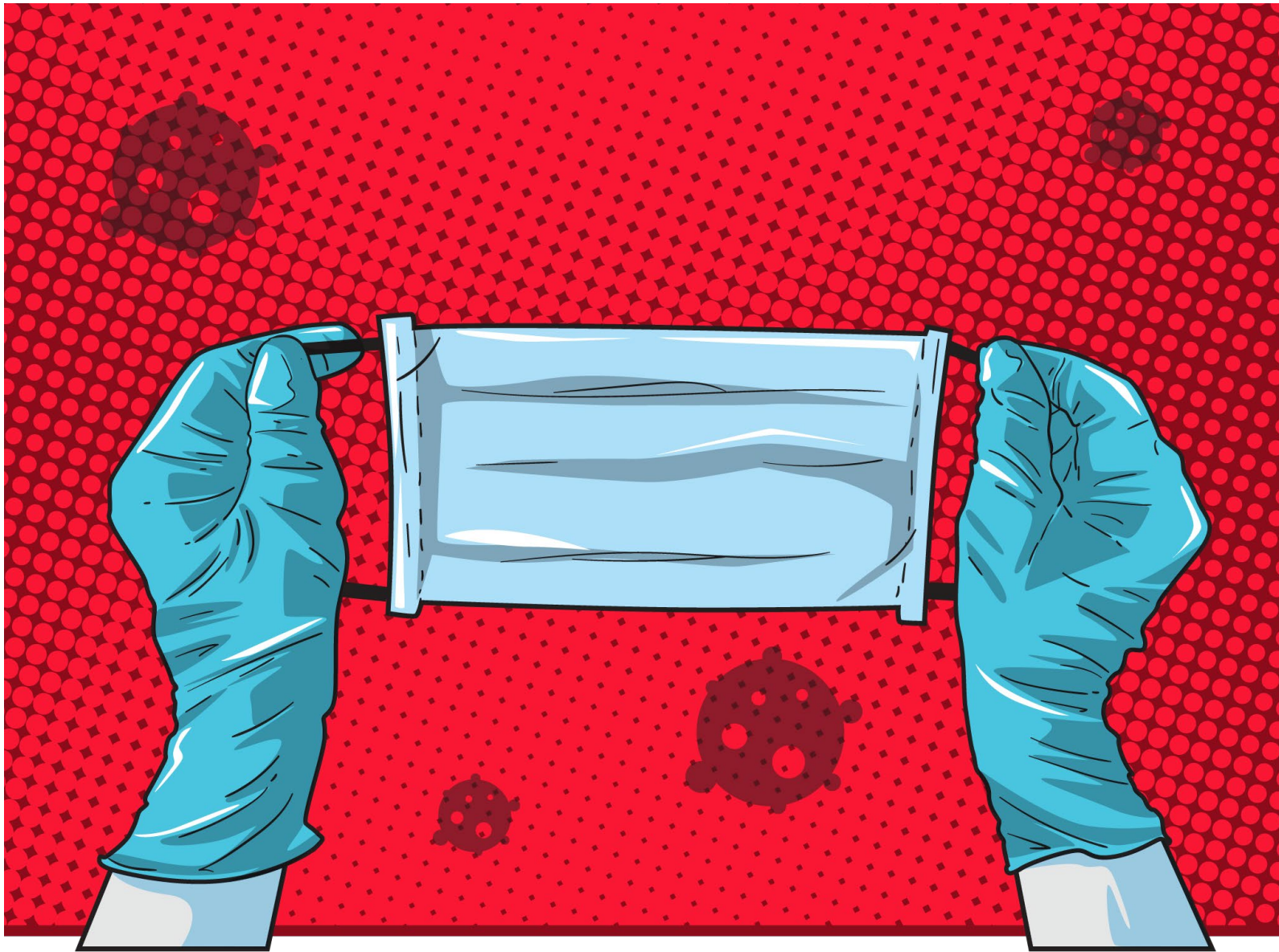
Waived POC Testing Safety and Risk Management

What is safety?

Safety can be defined as practices used to protect workers from harm.

Safety helps eliminate or reduce risks (potentially harmful events) to the individual and surrounding environment.

The Hierarchy of Controls shown here is used to help mitigate or manage risk.

Hierarchy of Controls
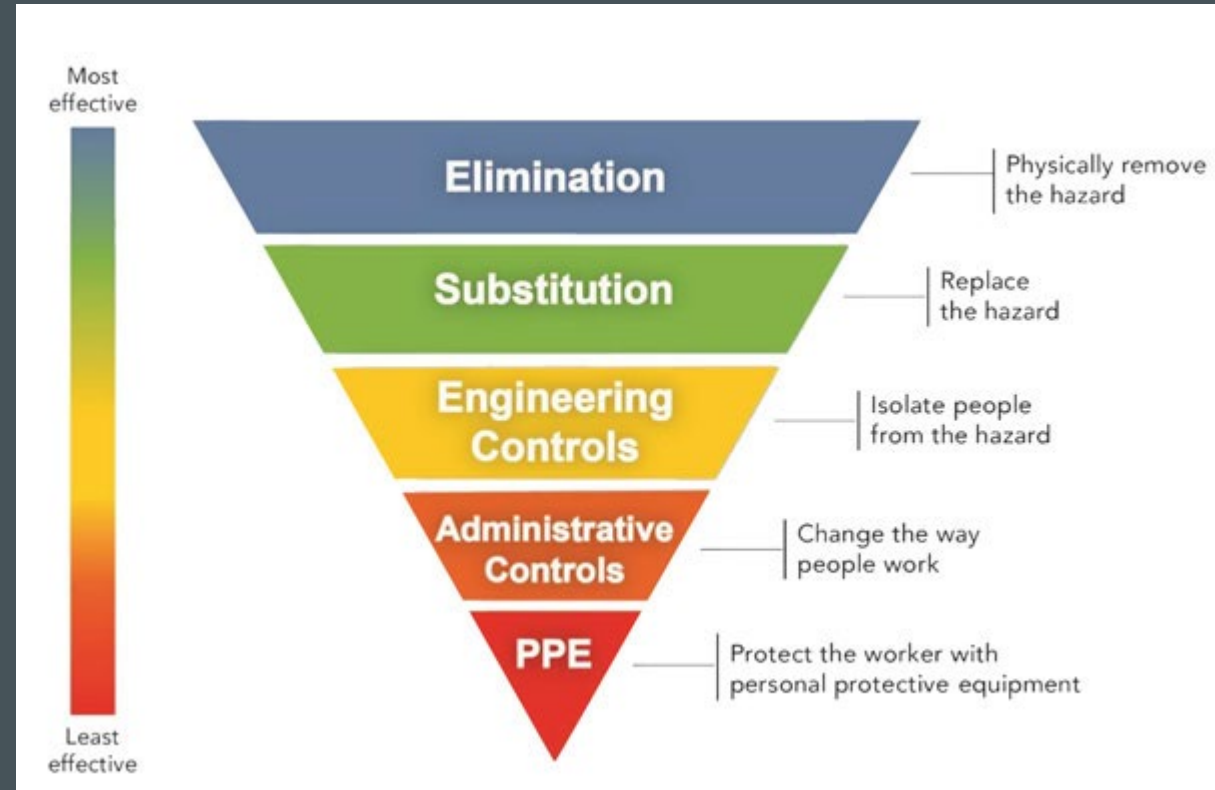
Why is this important?

Identifying safety concerns associated with testing helps to minimize the risk (or potential harm) to oneself and others.

All staff working at waived POC sites should have adequate training on safety precautions, standard operating procedures (SOPs), and testing processes.

What is risky about waived POC testing?

When performing testing there are many things that could go wrong, which may result in harm to the tester or those around them.

When waived POC testing you're handling something that may contain viruses and bacteria that can make people sick.

Viruses and bacteria are known as biological organisms.

Test components (e.g., chemicals, sharp edges) also pose risk.
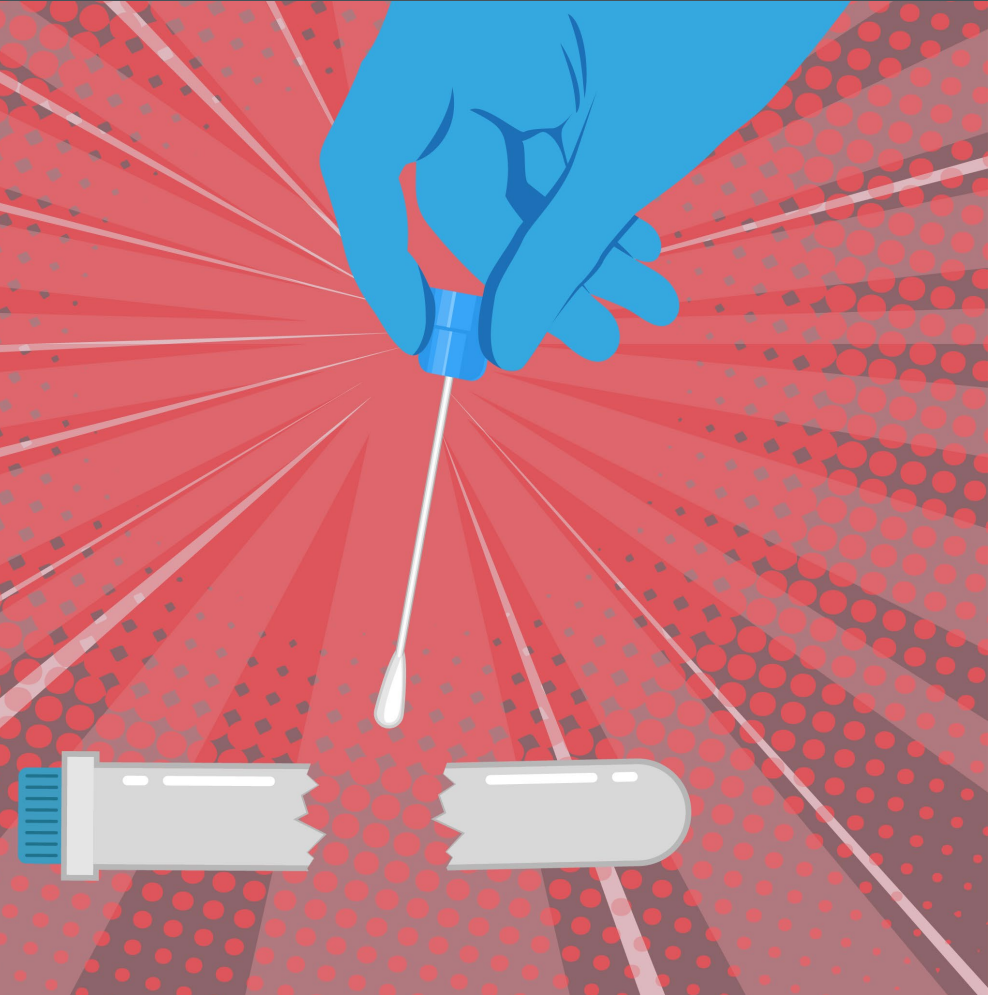
How is this done?

Risk assessments evaluate what could go wrong and identify the worst that could happen if something does go wrong.

Important questions to ask daily when performing waived POC testing include:

1. What can go wrong (risk)?

2. If something does go wrong, what is the worst that could happen?

3. How can this be prevented, and if it cannot be prevented, how can the impact be reduced?

Ways to Stay Safe When Testing

Using Personal Protective Equipment (PPE)

PPE is specific clothing and other equipment designed to protect the wearer from injury or the spread of infection or illness.

The National Institute for Occupational Safety and Health (NIOSH) develops and implements science-based national guidance for respiratory and other PPE.

The types of PPE you use can help protect your body from hazards encountered in the work environment.

Common Types of PPE Used at POC Test Sites

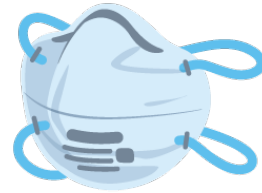**Eye and face protection**

- Safety glasses, goggles, disposable masks, and face shields

Respiratory protection

- N95 respirators

Hand protection

- Nitrile or latex gloves

Body Protection

- Gown

Foot Protection

- Closed-toe shoes

Understanding Different Types of PPE

Eye and Face Protection - helps protect your face and eyes from flying objects, droplets, and splashes.

Respiratory Protection - helps protect your respiratory system from droplets generated during routine procedures.

Hand Protection - helps protect your hands from exposure to hazardous materials and reduces risks associated with skin contact.

Body Protection - helps shield the body from hazards in the workplace, such as splashes, chemicals, infectious bodily fluids, and other hazardous materials.

Foot protection - helps protect your feet from splashes and chemicals.
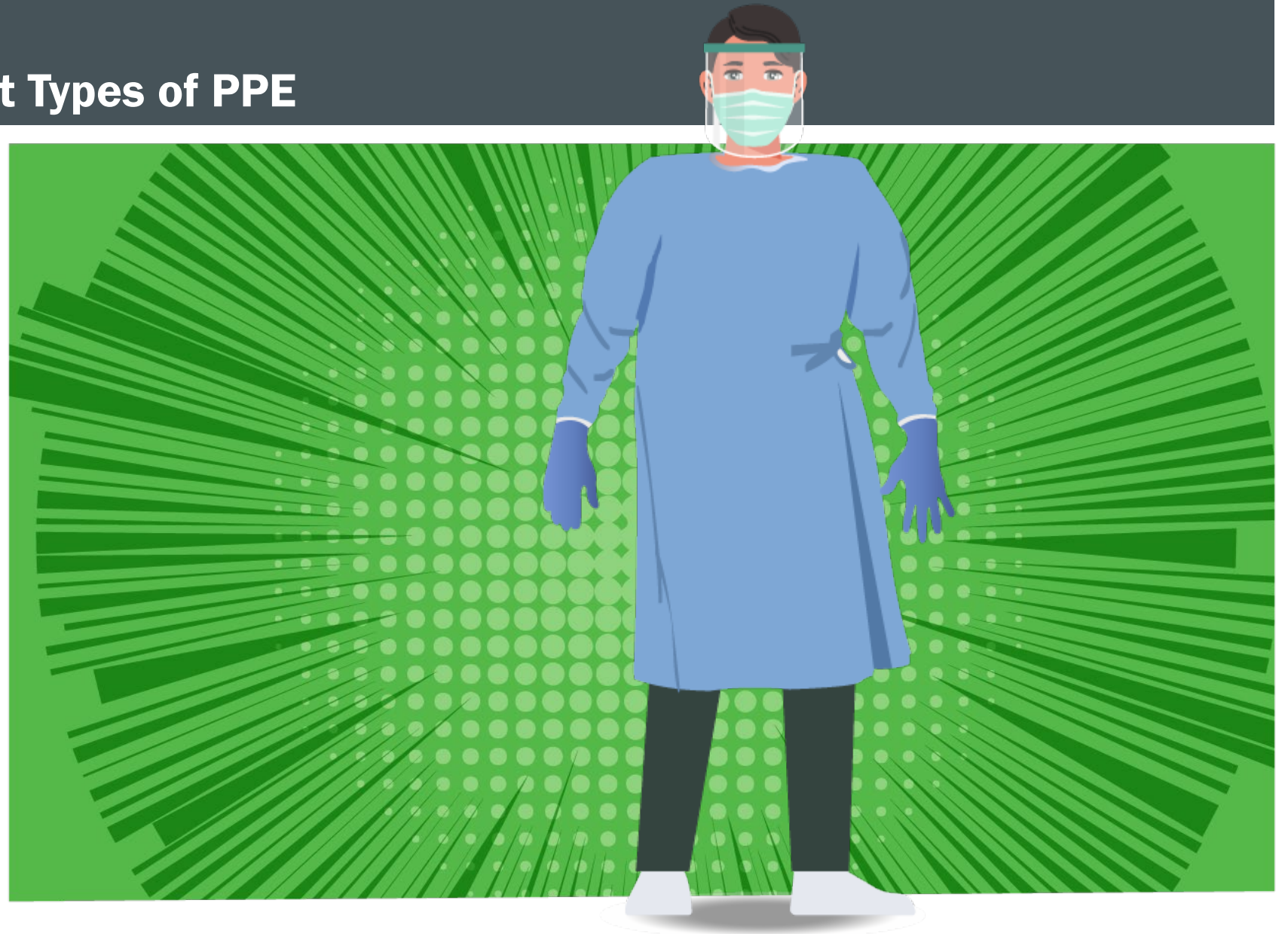
Safety Summary

- Safety can be defined as practices used to protect workers from harm.

- When performing testing there are many things that could go wrong, which may result in harm to the tester or those around them.

- It is important to identify the safety concerns associated with testing and implement safety precautions to minimize the risk (or potential harm) to oneself or others.

- PPE is one of the ways testers can protect themselves and others from serious workplace injuries or illnesses.

- PPE includes a variety of devices and garments such as goggles, gowns, gloves, and face masks.

- It is important to understand how to use PPE, recognize its limitations, put it on, take it off, and maintain it properly. Review your site-specific SOPs and check with your supervisor for additional details on PPE usage.

Safety Polls

Go to **menti.com** and use code **3982 2502** to interact with the poll questions

Safety Q&A

Remember to add any questions about safety and PPE to the Q&A forum in Zoom.

The Importance of Quality Control (QC)

Understanding QC
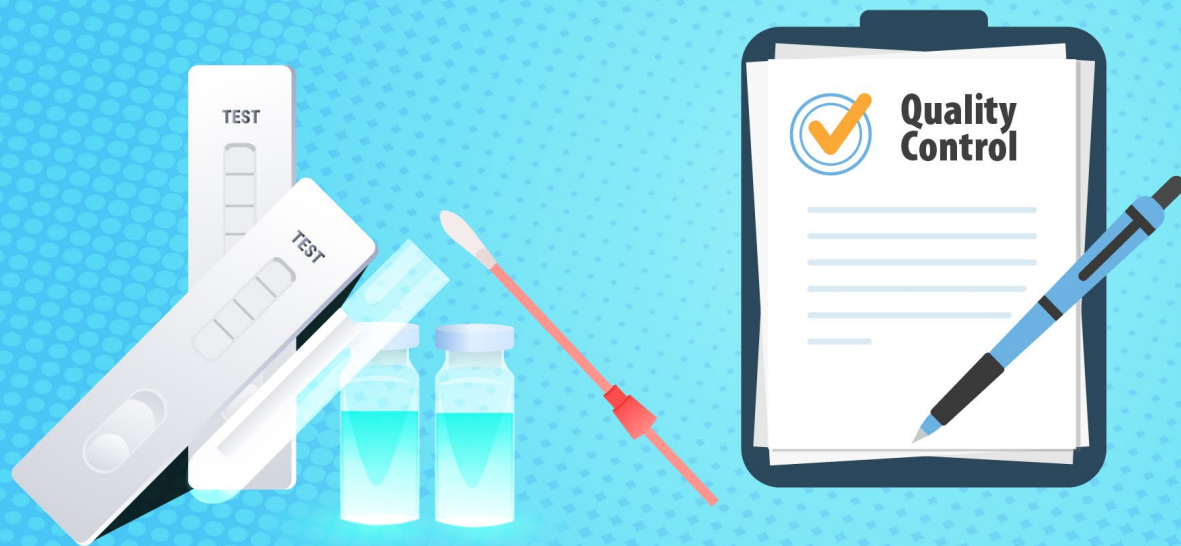
- QC monitors test performance to ensure that the results are accurate and are performed according to manufacturer instructions.

- The manufacturer's instructions explain what the controls are checking, the steps for performing QC testing, and when to do QC testing.

- Managing all components of the waived POC workflow is important.

When should QC be performed?

- In accordance with the manufacturer's instructions

- Test personnel is changed

- Reagent lots are changed

- Certain events occur (such as moving the instrument)

- Test kits are stored or used in temperatures that exceed the manufacturer's limits

- Test results seem questionable

QC Summary

- For waived POC tests that require it, QC helps achieve the highest level of test accuracy and reliability. Note: QC is not required for all waived POC tests.

- It is important to know when to test the positive and negative controls and events that require testing.

- Document control is a good practice. It involves tracking each new shipment of reagents or test kits/instruments and recording the positive and negative control results.

- If the correct control results are not obtained, do not perform tests or report results, review the manufacturer's instructions for the next steps and inform your supervisor.

QC Polls

Go to **menti.com** and use code **3982 2502** to interact with the poll questions

QC Q&A

Remember to add any questions about QC to the Q&A forum in Zoom.
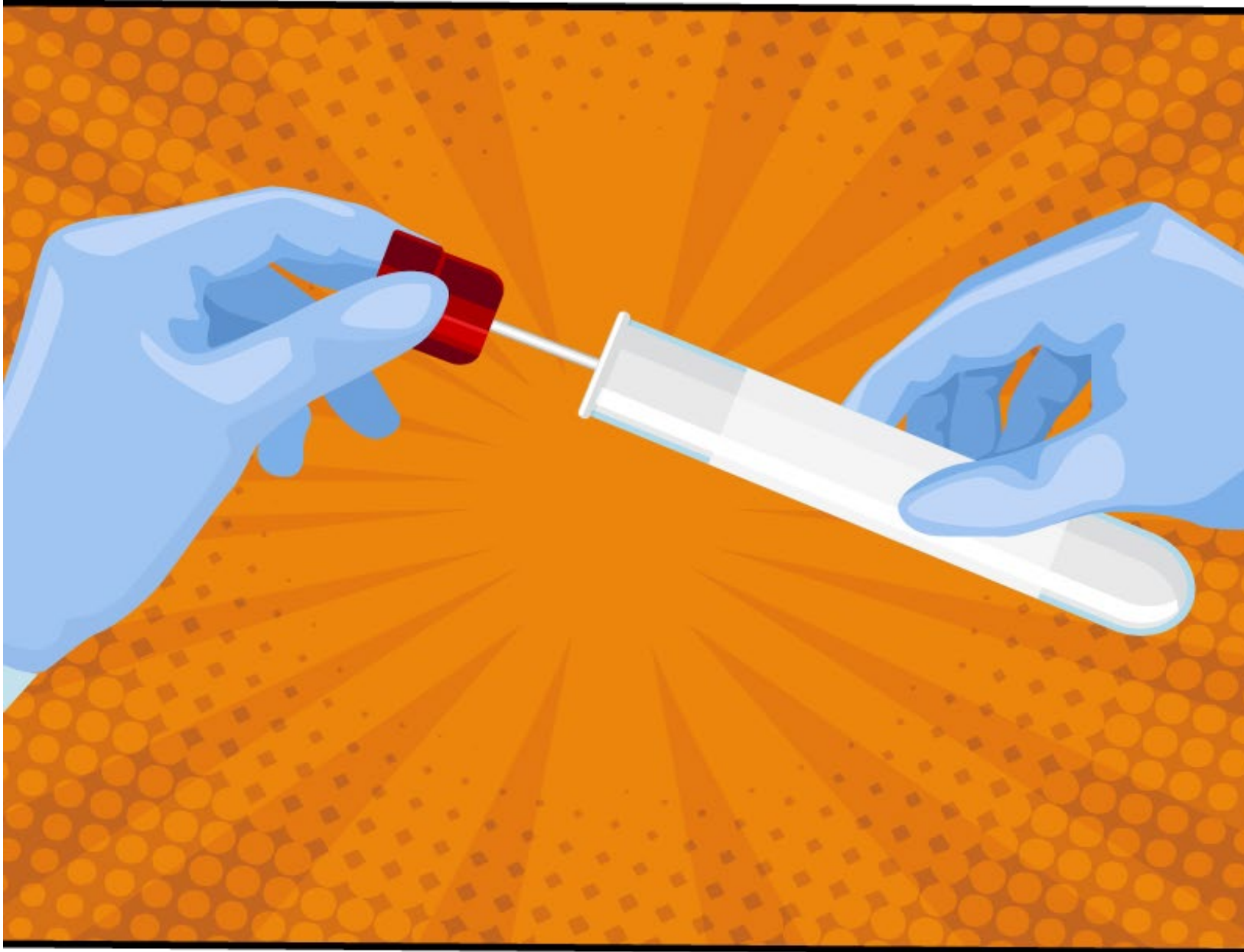
General Workspace Setup and Testing Workflow

Safety Considerations for Test Sites

- Adequate storage and space to perform work
- Manage access to the testing area
- Secure testing supplies

WORKSPACE SETUP

- Inspect the test kit material

- Layout testing supplies

- Ensure availability of appropriate PPE supplies

- Discard any damaged, discolored, or expired material and report to site coordinator/supervisor

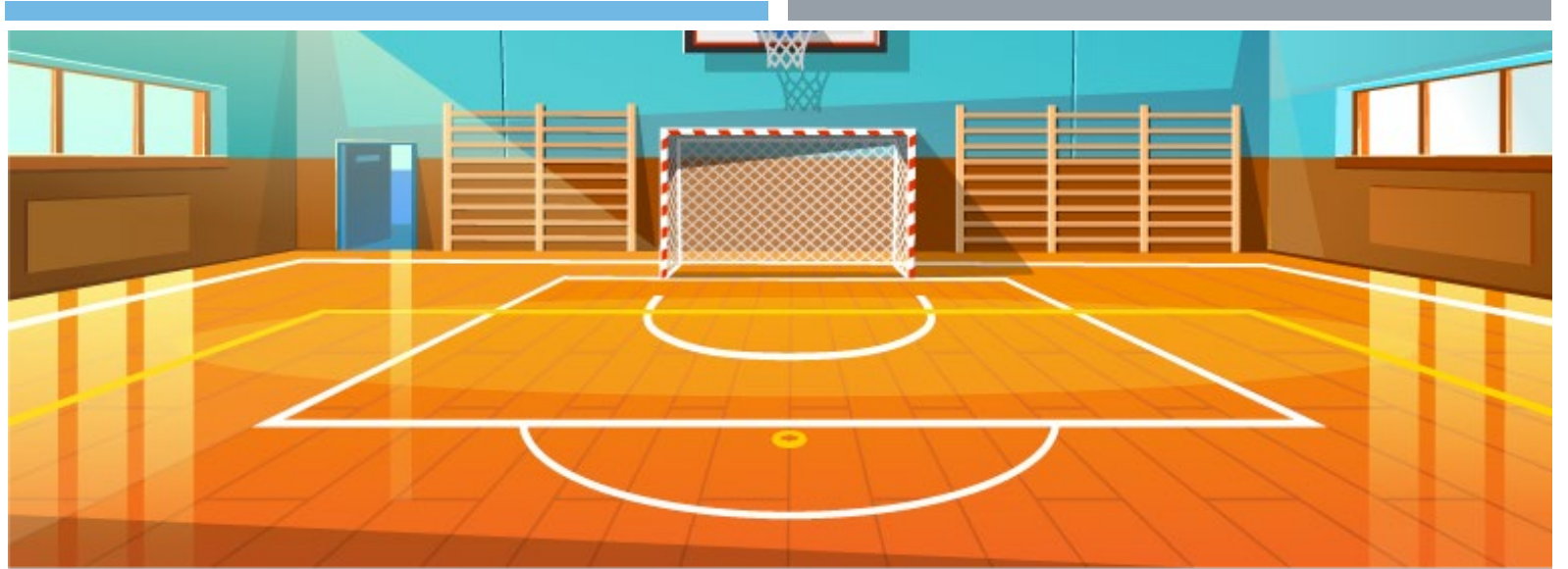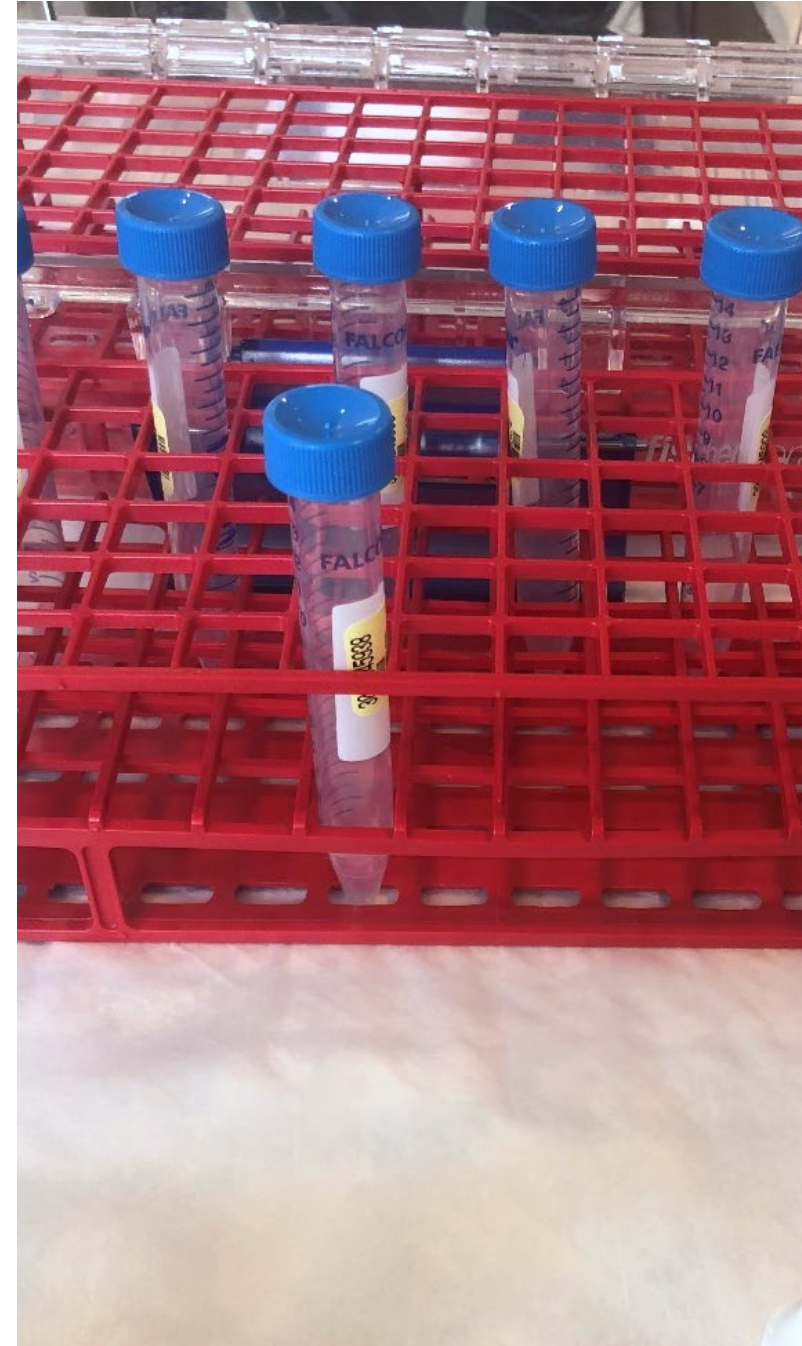# Preparing for the Test

Other things you should consider include:

- Follow manufacturer instructions for storing and preparing the test kit.
- Disinfect the surface.
- Have everyone who performs the test complete a QC test before testing a specimen and document it using a QC log.
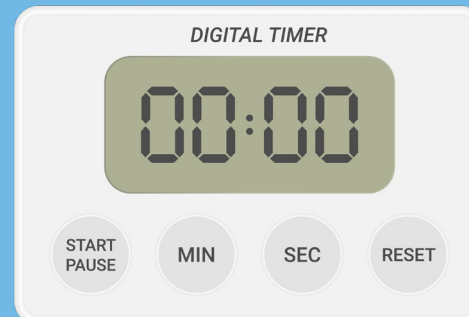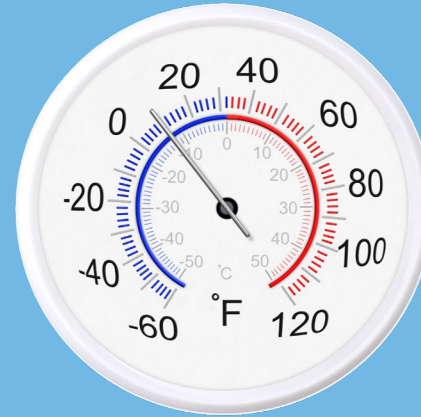
EXP DATE

MM 12	DD 30
YY 2022	

DIGITAL TIMER

00:00

START PAUSE   MIN   SEC   RESET

QUALITY CONTROL

Considerations for Specimen Collection Before Testing

- Identify the specimen type

- Put on and change PPE appropriately

- Collect the specimen within the manufacturer's collection and testing timeframe

- If testing immediately after specimen collection, place the collected specimen in a primary container

- Use a secondary container to store/transport specimens

- Refer to the manufacturer's instructions for specifics on specimen collection, handling, transport, and storage.
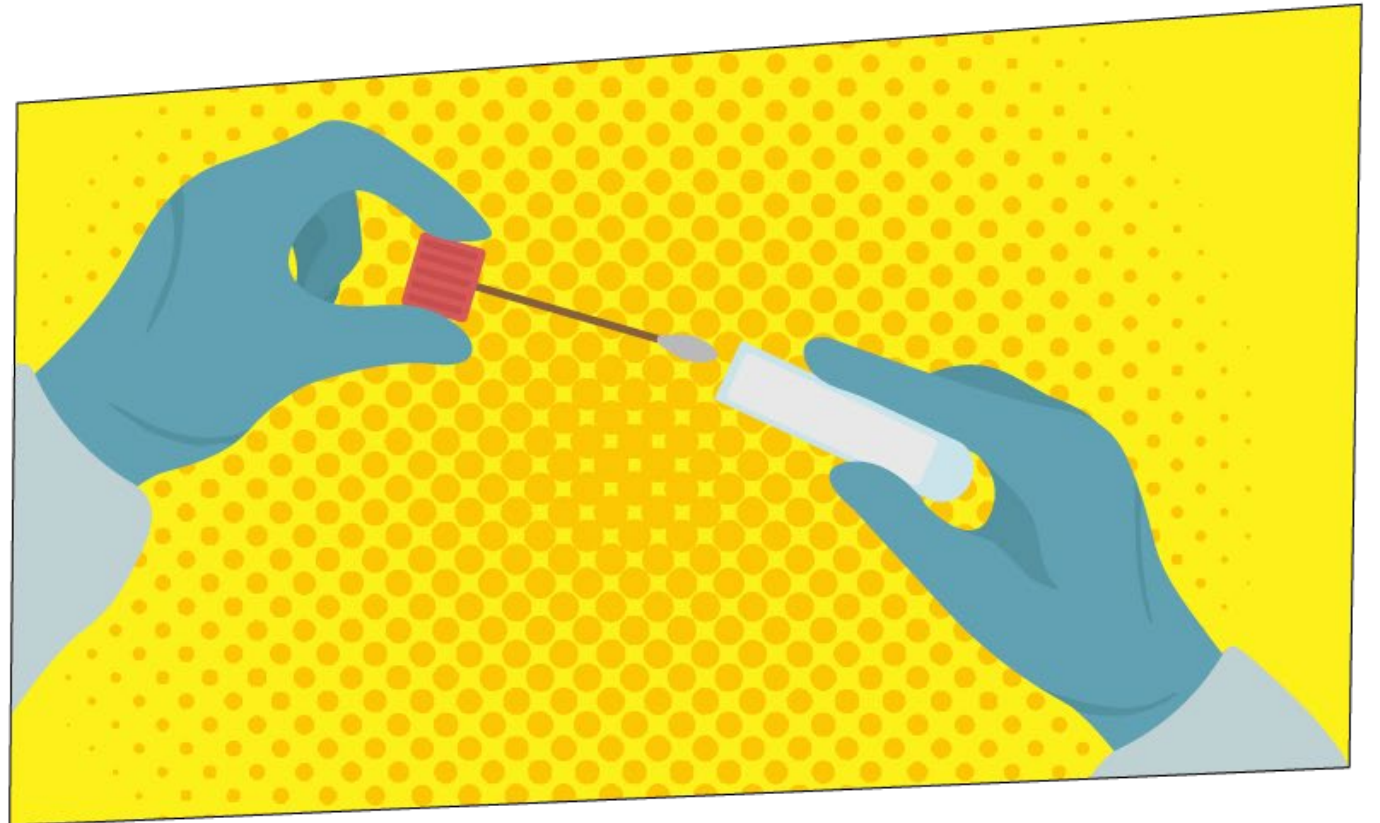
Things to Consider During the Test

- Do not open reagents, test devices, and cassettes until you are ready to start the testing process.

- Follow all manufacturer instructions for performing the test procedure.

- Perform regular quality control and instrument calibration, as applicable.

- When testing specimens individually, change gloves after testing each participant specimen, to avoid cross-contamination.
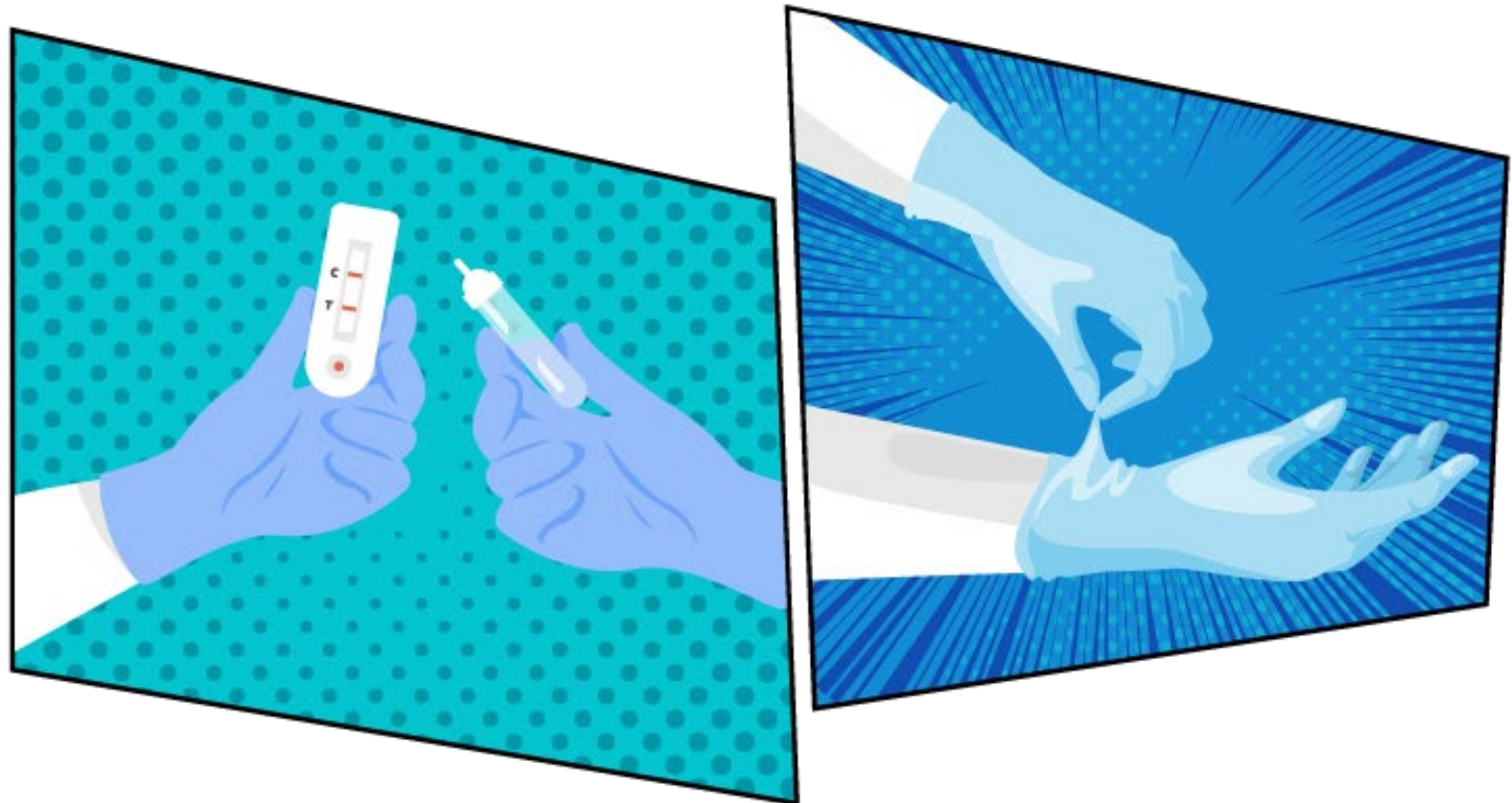
Things to Consider After the Test

- Discard used materials and do not reuse test devices, specimen collection tubes, swabs, lancets, or fingerstick collection devices.

- Read and record results only within the amount of time specified in the manufacturer's instructions.

- Decontaminate the testing area before testing another specimen.

- Follow the manufacturer's recommendations.

Testing Workflow Summary

- The physical environment must provide adequate workspace to support the POC test performed.

- Access to the area should be limited to essential staff and individuals to minimize the risk of exposure and cross-contamination.

- Make sure to have everything you need for testing readily available.

- Discard any damaged, discolored, or expired material and report it to the site coordinator/ supervisor.

- Use appropriate PPE based on your facility's SOPs

- Do not open reagents, test devices, and cassettes until you are ready to start the testing process.

- Follow site-specific SOPs and manufacturer's instructions when handling specimens, testing, and decontaminating work surfaces.

Testing Polls

Go to **menti.com** and use code **3982 2502** to interact with the poll questions

Testing Workflow Q&A

Remember to add any questions about the testing workflow to the Q&A forum in Zoom.

Managing Waste at Waived POC Testing Sites

What is hazardous waste?

- Hazardous waste, also commonly known as medical waste, is any item that has the risk of having infectious substances that can be transmitted.

- It includes but is not limited to all body fluids that could be potentially infectious, harmful chemicals, or any items that could damage the skin.

- Some waste generated during specimen collection and testing should be considered hazardous waste.

Waste Management Processes

- Waste disposal regulations vary at the state and local levels.

- Follow guidance according to federal, state, local, tribal, and territorial regulatory requirements.

WASTE MANAGEMENT SUMMARY

- It's essential to identify what is considered hazardous waste and the correct way to dispose of the materials.

- Some wastes generated during collection and testing should be considered hazardous waste.

Waste Management Polls

Go to **menti.com** and use code **3982 2502** to interact with the poll questions

Waste Management Q&A

Remember to add any questions about waste management to the Q&A forum in Zoom.

Waived POC Testing Virtual Training Review

Training Review and Summary

- It is important to identify the safety concerns associated with testing and implement safety precautions to minimize the risk (or potential harm).

- It is important to understand how to use PPE, put it on, take it off, and maintain it properly.

- For waived POC tests that require it, QC helps achieve the highest level of test accuracy and reliability.

- The physical environment or space must provide adequate workspace to support the POC test performed and access to the area should be limited to essential staff and participants.

- Some wastes generated during processing and testing including test kits, supplies, and disposable PPE worn during testing should be considered as hazardous waste.

SUMMARY

Waived Point-of-Care (POC) Testing Basics Q&A

1. What would have been helpful to know about waived POC testing before starting the process?

2. Do you have any additional questions or topics about waived POC testing not covered today?

Please input feedback in the chat and questions in the Zoom Q&A.

POC Training Resources

- [Ready? Set? Test! Patient Testing is Important. Get the Right Results | CDC](#)

- [Waived Tests | CDC](#)

- [MMWR: Good Laboratory Practices for Waived Testing Sites](#)

- [Point-of-Care Testing: Risk Assessment Basics | CDC](#)

- [COVID-19 Point-of-Care Batch Testing Tips (cdc.gov)](#)

- [COVID-19 Point-of-Care Diagnostics: Present and Future](#)

- [Biological Risk Management for Point-of-Care Testing Sites | CDC](#)

- [CDC's Biological Risk Management for Point-of-Care Testing Sites](#)

- [CDC's Guidelines for Handling and Processing Specimens Associated with COVID-19](#)

- [CDC's Laboratory Outreach Communication System (LOCS) | CDC](#)

POC Training Resources

- [Donning and Doffing PPE in Clinical Laboratories: Removing Gown First and Gloves Second - YouTube](#)

- [Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing | CDC](#)

- [Medical Waste | US EPA](#)

- [Results Log with QC – Quantitative Test (cdc.gov)](#)

- [Results Log with QC – Qualitative Test (cdc.gov)](#)

- [Nasal Mid-turbinate Specimen Collection Infographic 11-25-20 (cdc.gov)](#)

- [Nasopharyngeal Specimen Collection Infographic 11-25-20 (cdc.gov)](#)

- [Waste Management Guidance for SARS-CoV-2 Point-of-Care Testing (cdc.gov)](#)

CDC OneLab Virtual Summit 2022
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Tuesday, April 19 to Thursday, April 22 EDT

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