OneLab™

A Unified Response to Training Needs

“Ready? Set? Test!” Patient Testing Is Important. Get the Right Result.

Session 2

October 23, 2024

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- *"Ready? Set? Test!" Patient Testing Is Important. Get the Right Result. Session 2*
- Q&A
- Closing Remarks

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- **Have a question for the presenter?** Use the Q&A function, *not* the chat.
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- **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.

PPE Toolkit

Blood and Body Fluid Exposure

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

Blood and Body Fluid Exposure

Instructions for Performing External Control Testing

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

External Control Testing

Today's Presenter

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

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

Today's Presenter

Amanda Johnson, MHSc., MLS(ASCP)^{CM}

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

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A Unified Response to Training Needs

Ready? Set? Test!

Patient Testing is Important. Get the Right Results.

Session 2

October 23, 2024

12pm – 1pm

Today we will be discussing:

- Waived Testing
- Educational Materials
- **Test!**
- Checklists, Testing Logs, and Job Aids

Learning Objectives

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

Objectives

1. Identify the “Ready? Set? Test!” educational materials as resources for waived testing.
2. Describe best practices to follow when performing waived testing.
3. Describe how to read and record test results.
4. Identify actions to follow when problems (including questionable test results) occur during the testing process.
5. Recognize the “Ready? Set? Test!” educational material checklists, testing logs, and job aids available for use at testing sites.

Waived Testing

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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.
- View the most current information on FDA-cleared waived tests

OneLab™ CLIA Regulatory Requirements

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

Ready? Set? Test!
Educational Materials

Waived Testing Resources

Although some of the recommendations exceed CLIA requirements for waived testing, following these good testing practices will likely lead to reliable, high-quality test results and enhance patient safety.

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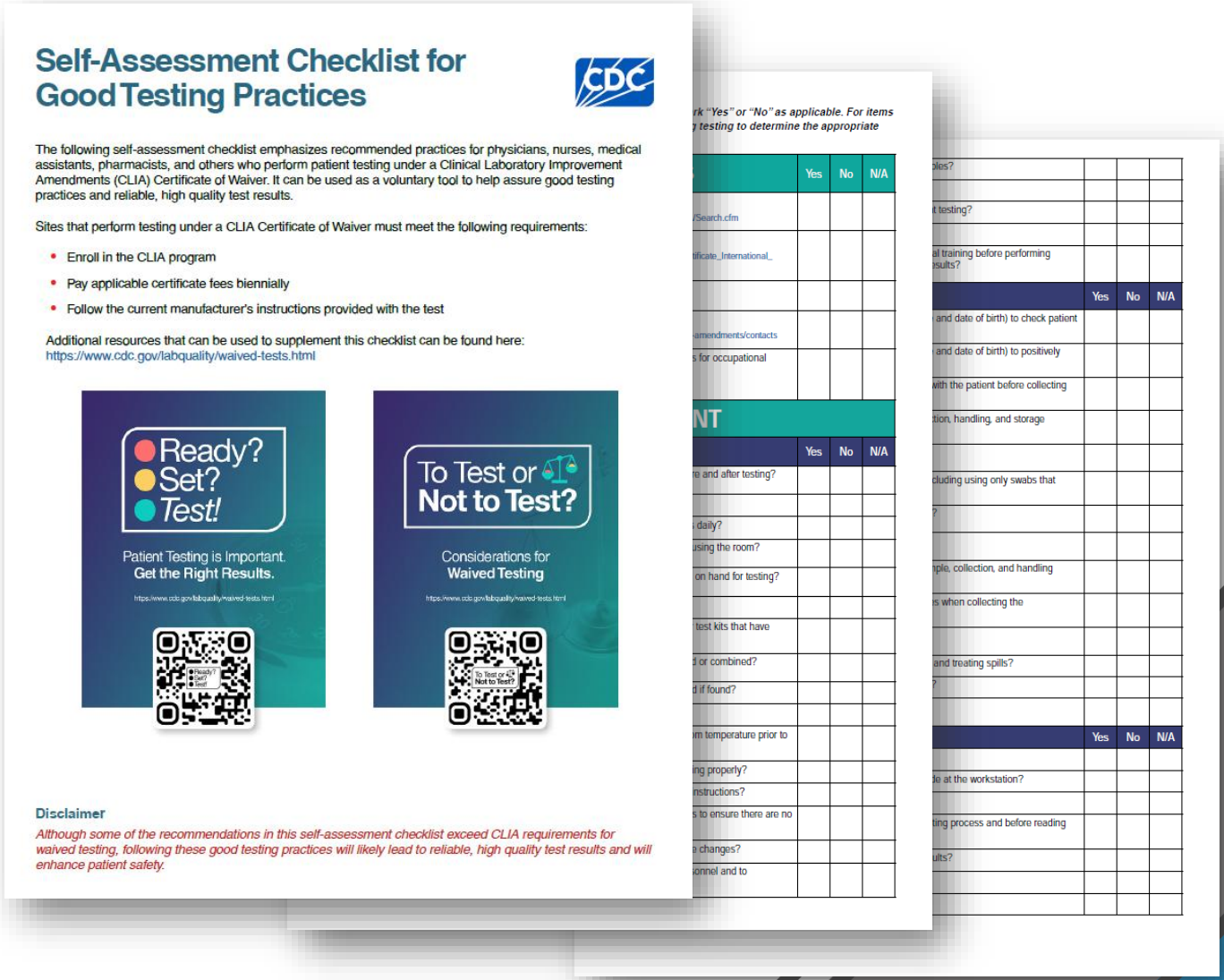
Educational Materials

[Laboratory Quality: Waived Tests]



To request hard copies visit [Waived Testing Booklet Request]

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

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

Test!

Performing the Test

When performing a test, be sure to:

Follow the proper testing steps according to the current manufacturer's instructions and in the exact order as they are listed.

Ensure QC is acceptable.

Have the manufacturer's instructions, the site-specific procedure, or a quick-reference guide in the testing area.

Quick reference guides or color charts can be useful resources when performing a test or interpreting results.

Use timers, if indicated, and follow the required timing intervals before reading test results.

Reading the Results

Reading the results too soon can cause invalid or false negative results due to incomplete reaction of the sample and reagents.

Reading a test after the time given in the manufacturer's instructions can lead to:

- **False-positive results – due to over-development of color**
- **False-negative results – fading of the reaction or color**
- **Invalid results – the reaction moves beyond a visible area**

Types of Test Results

Quantitative results:

- Numerical results a test produces
- Results indicate the amount of the measured substance reported in specific measurement units.

Qualitative results:

- Interpreted as positive, negative, reactive, nonreactive, or invalid.
- Identify the presence or absence of a particular substance, condition, or microbial organism.

Recording Results

Quantitative (numerical) results should be recorded in the appropriate units of measurement, and as described in the manufacturer's instructions.

Qualitative results should be recorded using words or abbreviations rather than symbols. For example, use:

- "Positive" or "Pos", "Reactive" or "R" instead of "+"
- "Negative" or "Neg", "Non-reactive" or "NR" instead of "-"

Be sure to record any invalid or unacceptable results. If you need to repeat a test, record the first result (invalid or unacceptable), resolve the problem, retest, and then record the repeated result. Only report the final acceptable result.

Resolving Problems

Problems should be documented, reported to the person who oversees or directs testing and corrected. Some examples of possible problems include:			
Improperly labeled samples	Freezer or refrigerator failure	QC failure	Defective collection devices

Actions for Invalid or Questionable Test Results:			
Repeat the test, request or collect a new sample if required	Refer to the manufacturer's instructions for next steps when higher or lower than reportable range results are obtained.	Consult the person who oversees or directs testing.	Report test results after all problems are identified and corrected.

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Issuing Test Results

Guidelines for Issuing Test Reports:

- Patient test reports should be legible, standardized, and promptly issued according to site-specific procedures.
- Reports from on-site tests should be easily distinguishable from referral laboratory test reports.
- Only give patient test reports to authorized persons, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- Verbal communication of test results should be documented and followed by a written test report.
- Follow site-specific policies and procedures when using electronic medical record systems or laboratory information systems to issue test reports.

Guidelines for Critical Values

Critical values are test results that require immediate treatment or evaluation by the physician.

Testing sites should establish a system to ensure critical values are addressed by:

- Defining which tests have critical values
- Ensuring that staff are aware of the critical values and know how to alert the physician promptly
- Documenting when and to whom critical values are reported

Confirmatory or Supplemental Testing

The manufacturer's instructions should explain when additional testing is required. Each testing site should have written site-specific procedures to ensure confirmatory or additional testing is performed or referred, when needed.

Instructions should include how to:

- Order additional tests with examples of completed request forms.
- Contact the referral laboratory, if necessary.
- Collect and label the sample.
- Transport or ship samples safely.

Sites should maintain records of referred tests that:

- Link the referred sample to the original patient sample
- Document the referral laboratory, test name, and date referred
- Document when test results are received and the date of the final test report

Record Keeping

Good recordkeeping is necessary to:

- Retrieve and verify information
- Assess test performance
- Identify and resolve problems that could affect test results
- Maintain patient and personnel information
- Check with your local/state public health department for record keeping requirements

Examples of records to maintain for easy access and retrieval of information include:

- Test orders, test results, confirmatory or additional testing results
- Quality control results
- Reagents, test kits, quality control material lot numbers, dates received and used, and expiration dates
- Daily temperature checks, test system or equipment function checks and maintenance
- Test system failures, troubleshooting, and corrective action taken when problems have been identified
- Test or product recall notices
- Personnel training and competency assessments
- Results of proficiency testing (PT) or other external quality assessment activities

Quality Testing

Voluntarily options to verify and maintain testing quality:

Proficiency Testing

Benefits to participating in a PT program:

- Regular, external checks on the quality of testing
- Motivation to improve performance
- Comparison of performance with that of other participating sites
- Feedback and technical advice from PT programs
- Assistance in evaluating methods and instrumentation
- Assistance with staff education, training, and competence monitoring
- Opportunities to identify areas needing improvement

Quality Assessments

Internal assessments:

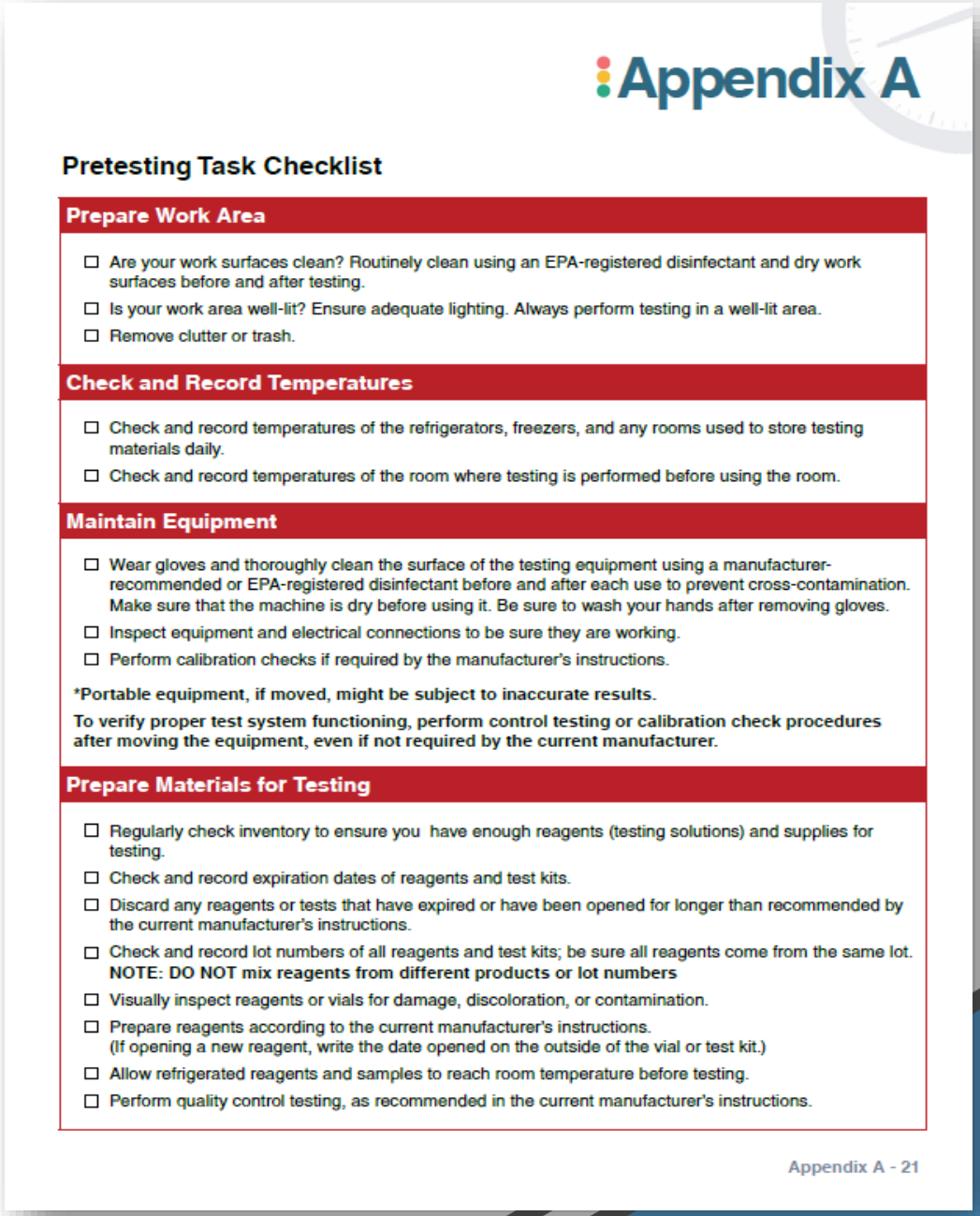
- Performing and documenting QC procedures and results
- Reviewing QC records and test results
- Reviewing room and refrigerator temperature log sheets for complete documentation
- Documenting and reviewing problems and establishing a plan to improve processes
- Documenting and reviewing injury/incident reports

External assessments:

- Undergoing voluntary inspections by peers or consultants
- Subscribing voluntarily to PT programs

Checklists
Testing Logs

Pretesting Task Checklist



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.

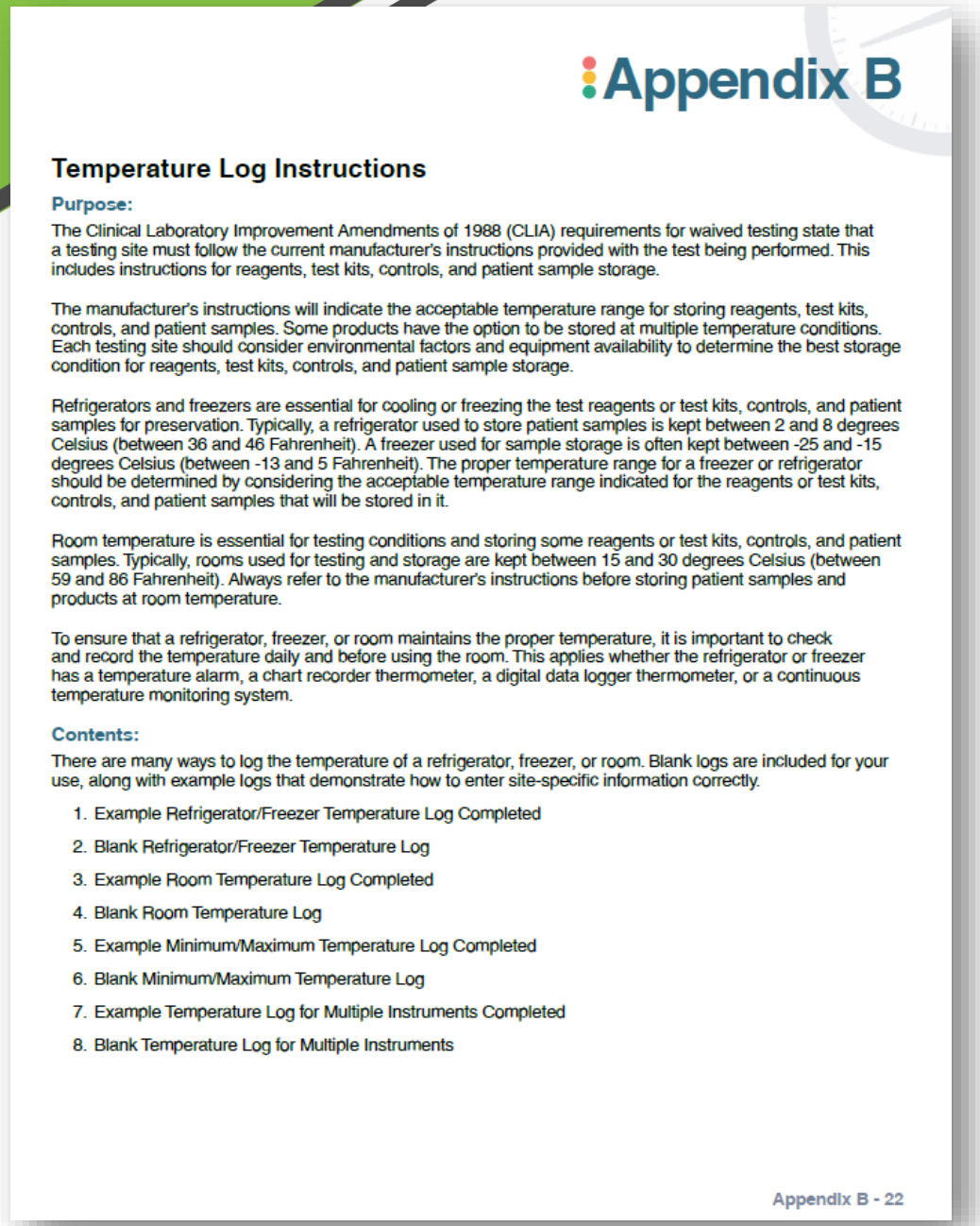
***Portable equipment, if moved, might be subject to inaccurate results.**

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



Appendix B

Temperature Log Instructions

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test being performed. This includes instructions for reagents, test kits, controls, and patient sample storage.

The manufacturer's instructions will indicate the acceptable temperature range for storing reagents, test kits, controls, and patient samples. Some products have the option to be stored at multiple temperature conditions. Each testing site should consider environmental factors and equipment availability to determine the best storage condition for reagents, test kits, controls, and patient sample storage.

Refrigerators and freezers are essential for cooling or freezing the test reagents or test kits, controls, and patient samples for preservation. Typically, a refrigerator used to store patient samples is kept between 2 and 8 degrees Celsius (between 36 and 46 Fahrenheit). A freezer used for sample storage is often kept between -25 and -15 degrees Celsius (between -13 and 5 Fahrenheit). The proper temperature range for a freezer or refrigerator should be determined by considering the acceptable temperature range indicated for the reagents or test kits, controls, and patient samples that will be stored in it.

Room temperature is essential for testing conditions and storing some reagents or test kits, controls, and patient samples. Typically, rooms used for testing and storage are kept between 15 and 30 degrees Celsius (between 59 and 86 Fahrenheit). Always refer to the manufacturer's instructions before storing patient samples and products at room temperature.

To ensure that a refrigerator, freezer, or room maintains the proper temperature, it is important to check and record the temperature daily and before using the room. This applies whether the refrigerator or freezer has a temperature alarm, a chart recorder thermometer, a digital data logger thermometer, or a continuous temperature monitoring system.

Contents:

There are many ways to log the temperature of a refrigerator, freezer, or room. Blank logs are included for your use, along with example logs that demonstrate how to enter site-specific information correctly.

1. Example Refrigerator/Freezer Temperature Log Completed
2. Blank Refrigerator/Freezer Temperature Log
3. Example Room Temperature Log Completed
4. Blank Room Temperature Log
5. Example Minimum/Maximum Temperature Log Completed
6. Blank Minimum/Maximum Temperature Log
7. Example Temperature Log for Multiple Instruments Completed
8. Blank Temperature Log for Multiple Instruments

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Temperature Logs

Examples and blank templates included:

1. Refrigerator/Freezer Temperature Log
2. Room Temperature Log
3. Minimum/Maximum Temperature Log
4. Temperature Log for Multiple Instruments

Example Temperature Log

Facility: Dr. Smith's Office
Location: 123 Main Street
Atlanta, GA 55555

TEMPERATURE LOG

Refrigerator/Freezer Location Lab refrigerator **Month/Year** June 2024
Acceptable Temperature Range 4-8°C

Date	Temperature	Checked By	Date	Temperature	Checked By
1	4°C	Sara	17	#	#
2	#	#	18	4°C	Sara
3	#	#	19	4°C	Sara
4	4°C	Sara	20	4°C	CO
5	4°C	Sara	21	4°C	Sara
6	8°C	CO	22*	24°C	Sara
7*	15°C	Sara	23	#	#
8	4°C	Sara	24	#	#
9	#	#	25	4°C	Sara
10	#	#	26	4°C	Sara
11	4°C	Sara	27	4°C	CO
12	4°C	Sara	28	4°C	Sara
13	4°C	CO	29	4°C	Sara
14	4°C	Sara	30	#	#
15	4°C	Sara	31	#	#
16	#	#			

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
*6/7	Refrigerator door was ajar. Closed door, check in 30 minutes. Temp at 6°C - OK	Sara
*6/22	Refrigerator not staying in range. Called for service. Door seal replaced. QC'd kits stored in refrigerator. Continue to QC and monitor for problems.	Sara

Reviewed By: Janice Smith, office mgr. **Date:** 6/29/2024

Facility: Dr. Smith's Office
Location: 123 Main Street
Atlanta, GA 55555

ROOM TEMPERATURE LOG

Room Location Lab **Month/Year** June 2024
Acceptable Temperature Range 15-30°C

Date	Temperature	Checked By	Date	Temperature	Checked By
1	20°C	Sara	17	#	#
2	#	#	18	19°C	Sara
3	#	#	19	18°C	Sara
4	20°C	Sara	20	18°C	CO
5	18°C	Sara	21	19°C	Sara
6	20°C	CO	22	21°C	Sara
7*	40°C	Sara	23	#	#
8	18°C	Sara	24	#	#
9	#	#	25	18°C	Sara
10	#	#	26	19°C	Sara
11	18°C	Sara	27	20°C	CO
12	19°C	Sara	28	20°C	Sara
13	18°C	CO	29	20°C	Sara
14	19°C	Sara	30	#	#
15	20°C	Sara	31	#	#
16	#	#			

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
*6/7	Unexpected power outage. Temp rechecked when power restored. Temp at 20°C - OK. QC'd room temp kits. Continue to QC and monitor for problems.	Sara

Reviewed By: Janice Smith, office mgr. **Date:** 6/29/2024

Facility: Dr. Smith's Office
Location: 123 Main Street
Atlanta, GA 55555

MINIMUM/MAXIMUM TEMPERATURE LOG

Refrigerator/Freezer Location Lab refrigerator **Month/Year** June 2024
Acceptable Temperature Range 4-8°C

Date	Min Temperature	Max Temperature	Checked By:	Date	Min Temperature	Max Temperature	Checked By
1	2°C	6°C	Sara	17	2°C	6°C	Sara
2*	#	9°C	Sara	18	2°C	6°C	Sara
3	2°C	6°C	CO	19	2°C	6°C	CO
4	2°C	6°C	Sara	20	2°C	6°C	Sara
5	2°C	6°C	Sara	21	2°C	6°C	Sara
6	2°C	8°C	CO	22	2°C	6°C	CO
7	2°C	8°C	Sara	23	2°C	6°C	Sara
8	2°C	8°C	Sara	24	2°C	6°C	Sara
9	2°C	8°C	CO	25	2°C	6°C	CO
10	2°C	8°C	Sara	26	2°C	6°C	Sara
11	2°C	8°C	Sara	27	3°C	6°C	Sara
12	2°C	8°C	Sara	28	3°C	8°C	Sara
13	2°C	8°C	Sara	29	3°C	8°C	Sara
14	2°C	8°C	CO	30	3°C	8°C	CO
15	2°C	8°C	Sara	31	3°C	8°C	Sara
16	2°C	8°C	Sara				

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
*6/2	Refrigerator not staying in range. Called for service. Door seal replaced. QC'd kits stored in refrigerator. Continue to QC and monitor for problems.	Sara

Reviewed By: Janice Smith, office mgr. **Date:** 6/29/2024

Example Temperature Log

Facility: Dr. Smith's Office
Location: 123 Main Street
Atlanta, GA 55555

Temperature Log for Multiple Instruments

Month July Year 2024

Temp/ Acceptable Range	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Room temp/ (18 to 30°C)	25	26	24	22	27	#	#	26	22	20	19	29	#	#	22	23	25	26	22	#	#	23	27	28	25	22	#	#	24	22	26
25°C Incubator (23 to 27°C)	25	25	25	25	25	#	#	25	26	25	25	25	#	#	25	25	26	25	25	#	#	25	25	24	25	25	#	#	26	25	25
37°C Incubator (35 to 39°C)	37	38	37	36	37	#	#	37	38	38	36	37	#	#	38	35	30*	36	35	#	#	36	37	38	35	36	#	#	38	37	37
Refrigerator (2 to 8°C)	5	6	4	5	6	#	#	6	5	4	6	5	#	#	6	6	6	5	5	#	#	6	6	5	6	4	#	#	5	5	6
Freezer (-25 to -35°C)	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30
Initials	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO

Temperatures should be read first thing in the morning.
Record temperature in degrees Celsius for all equipment requiring temperature monitoring. Enter # for weekends and holidays when temperature is not monitored.

Report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate corrective action.

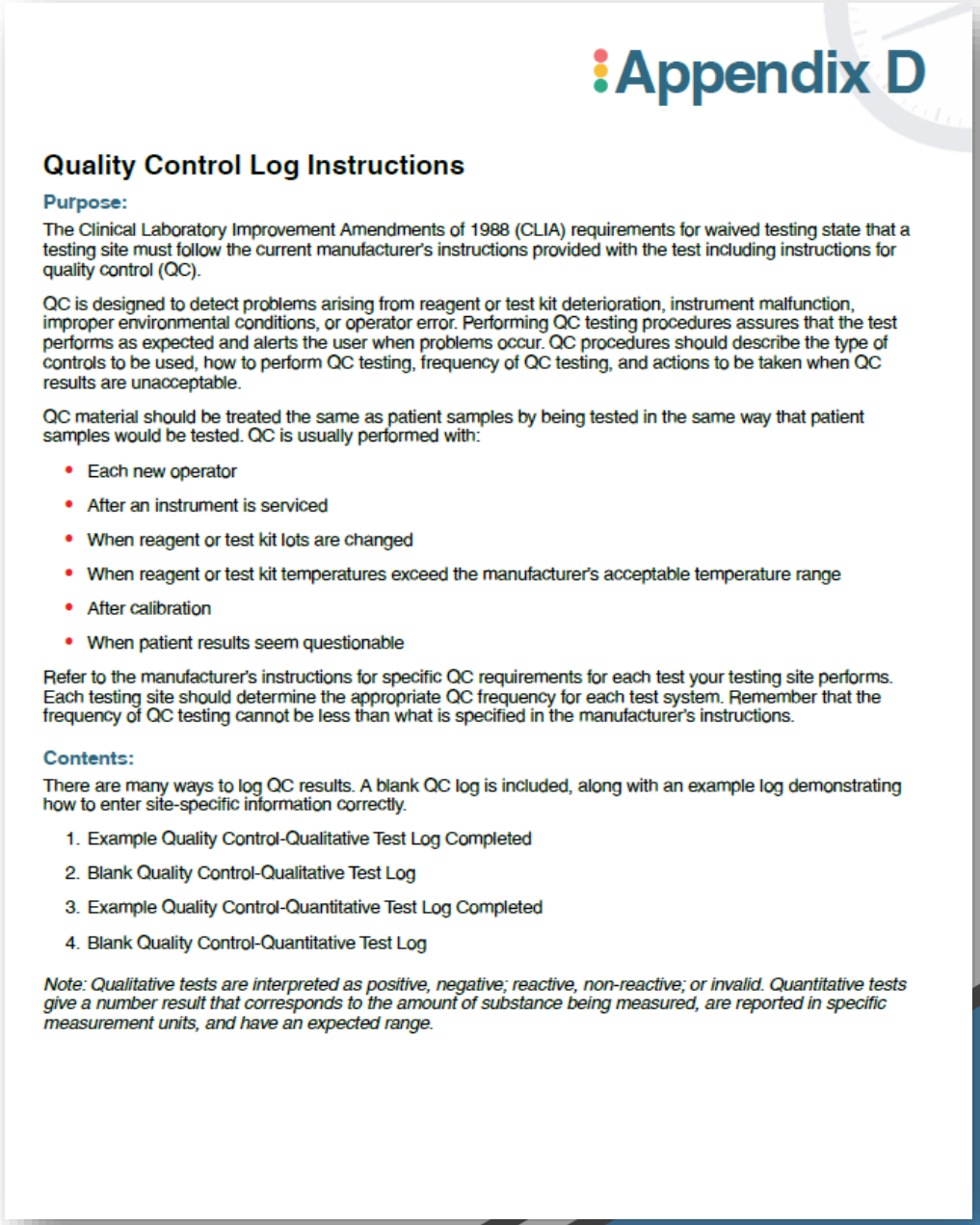
Comments: *Incubator door left open. Closed door and checked temperature prior to using for testing purposes. Temp was 35°C.

Reviewed By: Joe Smith, MD **Date:** 8/01/2024

Quality Control Logs

Examples and blank templates included:

1. Quality Control-Qualitative Test Log
2. Quality Control-Quantitative Test Log



Appendix D

Quality Control Log Instructions

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test including instructions for quality control (QC).

QC is designed to detect problems arising from reagent or test kit deterioration, instrument malfunction, improper environmental conditions, or operator error. Performing QC testing procedures assures that the test performs as expected and alerts the user when problems occur. QC procedures should describe the type of controls to be used, how to perform QC testing, frequency of QC testing, and actions to be taken when QC results are unacceptable.

QC material should be treated the same as patient samples by being tested in the same way that patient samples would be tested. QC is usually performed with:

- Each new operator
- After an instrument is serviced
- When reagent or test kit lots are changed
- When reagent or test kit temperatures exceed the manufacturer's acceptable temperature range
- After calibration
- When patient results seem questionable

Refer to the manufacturer's instructions for specific QC requirements for each test your testing site performs. Each testing site should determine the appropriate QC frequency for each test system. Remember that the frequency of QC testing cannot be less than what is specified in the manufacturer's instructions.

Contents:

There are many ways to log QC results. A blank QC log is included, along with an example log demonstrating how to enter site-specific information correctly.

1. Example Quality Control-Qualitative Test Log Completed
2. Blank Quality Control-Qualitative Test Log
3. Example Quality Control-Quantitative Test Log Completed
4. Blank Quality Control-Quantitative Test Log

Note: Qualitative tests are interpreted as positive, negative; reactive, non-reactive; or invalid. Quantitative tests give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.

Example QC Log

Facility: *Dr. Smith's Office*
Location: *123 Main Street, Atlanta, GA 55555*

Quality Control Log - Qualitative Test

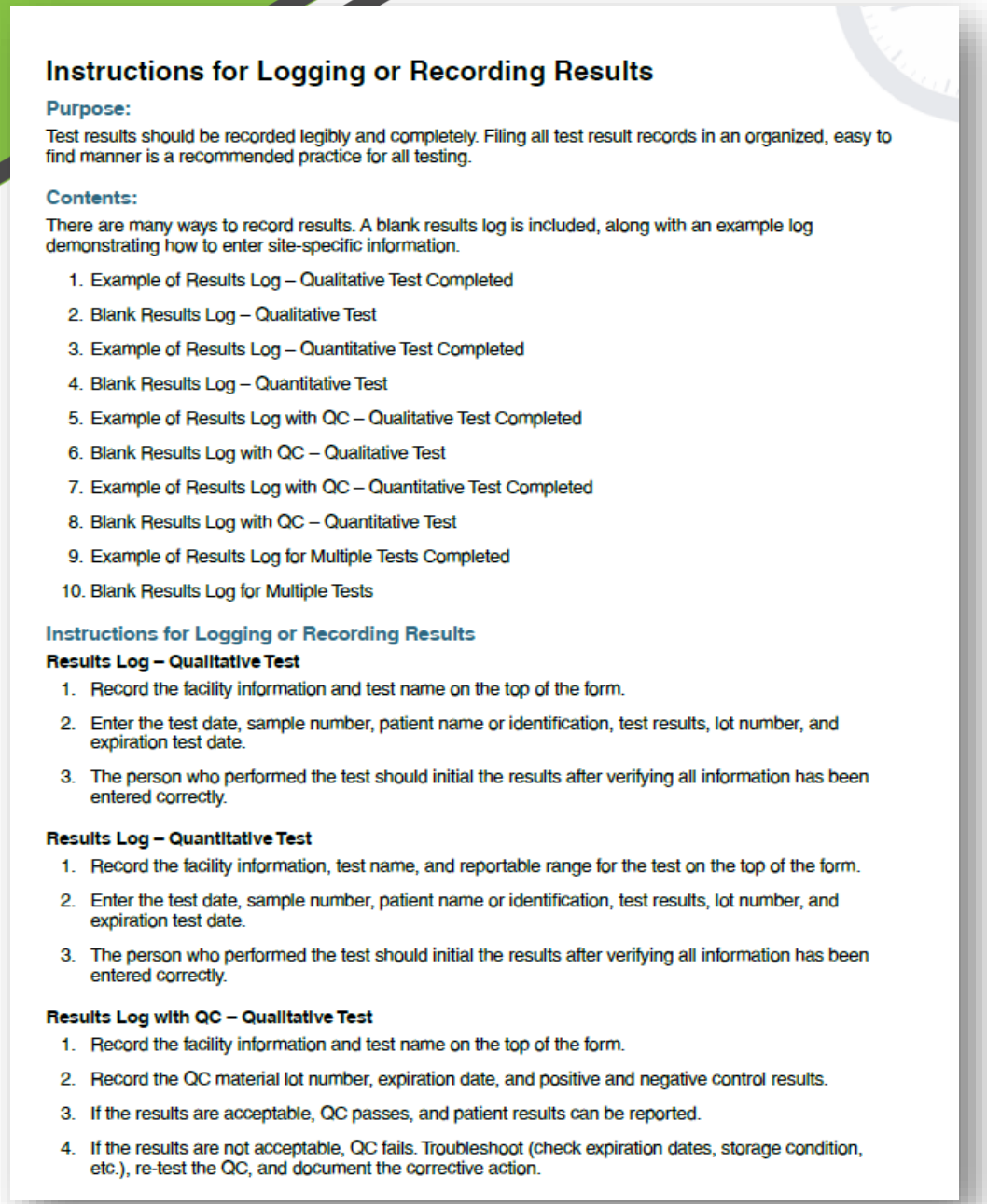
	Tech Initials	Date	Test Name	Test Lot number/ Test Exp. Date	Negative Control	Positive Control	Mid-Range Control (if applicable)	Comments	Reviewed by Initials/Date
1	CO	5/5/2024	Occult Blood 1-2-3	BJZ-3 / 8/31/2025	lot #: 108-OCB result: Pos*	lot #: 108-OCB result: Pos	lot #: N/A result:	*possible sample mix-up, retest	Joe Smith 5/5/2024
2	CO	5/5/2024	Occult Blood 1-2-3	BJZ-3 / 8/31/2025	lot #: 108-OCB result: Neg	lot #: 108-OCB result: Pos	lot #: N/A result:	QC passed and ready to use	Joe Smith 5/5/2024
3					lot #: result:	lot #: result:	lot #: result:		
4					lot #: result:	lot #: result:	lot #: result:		
5					lot #: result:	lot #: result:	lot #: result:		
6					lot #: result:	lot #: result:	lot #: result:		
7					lot #: result:	lot #: result:	lot #: result:		
8					lot #: result:	lot #: result:	lot #: result:		
9					lot #: result:	lot #: result:	lot #: result:		
10					lot #: result:	lot #: result:	lot #: result:		

Example QC Log

Facility: *Dr. Smith's Office*
Location: *123 Main Street, Atlanta, GA 55555*

Quality Control Log - Quantitative Test

	Tech Initials	Date	Test Name	Test Lot number/ Test Exp. Date	Level 1 Control	Level 2 Control	Comments	Reviewed by Initials/Date
1	CO	5/5/2024	XYZ ALT	C843 / 4/31/2025	lot #: 91750566 range: 43-78 U/L result: 31 U/L*	lot #: 91750566 range: 132-242 U/L result: 203 U/L	*Level 1 Control value too low, Kit was expired. Discard Kit	Joe Smith 5/5/2024
2	CO	5/5/2024	XYZ ALT	C978 / 8/31/2025	lot #: 91750598 range: 43-78 U/L result: 55 U/L	lot #: 91750598 range: 132-242 U/L result: 221 U/L	New lot. QC passed and ready to use	Joe Smith 5/5/2024
3					lot #: range: result:	lot #: range: result:		
4					lot #: range: result:	lot #: range: result:		
5					lot #: range: result:	lot #: range: result:		
6					lot #: range: result:	lot #: range: result:		
7					lot #: range: result:	lot #: range: result:		
8					lot #: range: result:	lot #: range: result:		
9					lot #: range: result:	lot #: range: result:		



Instructions for Logging or Recording Results

Purpose:

Test results should be recorded legibly and completely. Filing all test result records in an organized, easy to find manner is a recommended practice for all testing.

Contents:

There are many ways to record results. A blank results log is included, along with an example log demonstrating how to enter site-specific information.

1. Example of Results Log – Qualitative Test Completed
2. Blank Results Log – Qualitative Test
3. Example of Results Log – Quantitative Test Completed
4. Blank Results Log – Quantitative Test
5. Example of Results Log with QC – Qualitative Test Completed
6. Blank Results Log with QC – Qualitative Test
7. Example of Results Log with QC – Quantitative Test Completed
8. Blank Results Log with QC – Quantitative Test
9. Example of Results Log for Multiple Tests Completed
10. Blank Results Log for Multiple Tests

Instructions for Logging or Recording Results

Results Log – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Enter the test date, sample number, patient name or identification, test results, lot number, and expiration test date.
3. The person who performed the test should initial the results after verifying all information has been entered correctly.

Results Log – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Enter the test date, sample number, patient name or identification, test results, lot number, and expiration test date.
3. The person who performed the test should initial the results after verifying all information has been entered correctly.

Results Log with QC – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Record the QC material lot number, expiration date, and positive and negative control results.
3. If the results are acceptable, QC passes, and patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition, etc.), re-test the QC, and document the corrective action.

Test Result Logs

Examples and blank templates included:

1. Results Log – Qualitative Test
2. Results Log – Quantitative Test
3. Results Log with QC – Qualitative Test
4. Results Log with QC – Quantitative Test
5. Results Log for Multiple Tests

Example Result Logs

Facility: *Dr. Smith's Office*
Location: *123 Main Street, Atlanta, GA 55555*

Results Log - Qualitative Test

Test Name: *XYZ Strep antigen*

	Date	Sample ID / Patient ID
1	5/5/2024	05052018
2	5/6/2024	05052019
3	5/7/2024	05061930
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		

Facility: *Dr. Smith's Office*
Location: *123 Main Street, Atlanta, GA 55555*

Results Log - Quantitative Test

Test Name: *XYZ Strep antigen* **Reportable Range:** *5-400 U/L*

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2024	05052018	Steve Smith	Male: 30 U/L	Bd-0679/ 11/30/2025	CO
2	5/6/2024	05052019	Chris White	Male: 22 U/L	Bd-0679/ 11/30/2025	CO
3	5/7/2024	05061930	Sam Jones	Female: 14 U/L	Bd-0679/ 11/30/2025	CO
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

**Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Example Result Logs

Facility: Dr. Smith's Office
Location: 123 Main Street, Atlanta, GA 55555

Results Log With QC - Quantitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID
1	5/5/2024	5/05/2018 / Steve Smith
2	5/6/2024	5/05/2019 / Chris White
3	5/7/2024	5/05/1930 / Sam Jones
4		
5		
6		
7		
8		
9		

* Reportable Range is the range of results for which a test system ha

Facility: Dr. Smith's Office
Location: 123 Main Street, Atlanta, GA 55555

Results Log With QC - Qualitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Lot / Exp. Date	Positive Control Results	Negative Control Results
1	5/5/2024	5/05/20 / Tom Jones	NEG	SH	Bd-0679/ 11/30/2025	108-OCB / 9/30/2025	POS	NEG
2	5/6/2024	5/05/22 / Mattie Dunn	NEG	CO	Bd-0679/ 11/30/2025	108-OCB / 9/30/2025	POS	NEG
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

Example Result Log

Facility: Dr. Smith's Office
Location: 123 Main Street, Atlanta, GA 55555

Results Log for Multiple Tests

	Date	Sample Number	Patient Name or ID	Test Name	*Reportable Range	Test Result	Test Lot Number / Test Exp. Date	Initials
1	5/5/2024	05052018	Donald Smith	XYZ Strep	NA	NEG	Bd-0679 / 11/30/2025	CO
2	5/5/2024	05052019	Chris White	XYZ Strep	NA	POS	Bd-0680 / 11/30/2025	CO
3	5/5/2024	05052020	Tom Jones	Occult Blood - 123	NA	NEG	Bjz-3 / 8/31/2025	SH
4	5/5/2024	05052021	Pam Roberts	Urine HCG-ABC	NA	NEG	Trp-23/11-30-2025	CO
5	5/6/2024	05052022	Mattie Dunn	Occult blood - 123	NA	NEG	Bjz-3/8-31-2025	CO
6	5/6/2024	05052023	Steve Smith	XYZ ALT	5-400 U/L	Male: 33 U/L	C843/6-31-2025	CO
7								
8								
9								
10								
11								
12								
13								
14								
15								

* Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.

Job Aids & Other Waived Testing Resources

Appendix E

Safety: Blood and Body Fluid Exposure

It is important to use standard precautions when cleaning up blood or body fluids. **Always assume they are infectious and act accordingly**.

If a hand washing sink is available:

1. Wet hands with warm running water.
2. Apply soap and vigorously scrub all surfaces of hands and fingers, using large amounts of soap and water for at least 15 seconds.
3. Rinse hands and dry with disposable towels.
4. Use a disposable towel to turn off the faucet.

Before leaving the area, decontaminate the sink and faucet handles using 10% bleach, or an Environmental Protection Agency (EPA) registered disinfectant effective against HBV, HIV, and other bloodborne pathogens. See Appendix F: for Common Disinfectants and Antiseptics.

If mucous membranes or eyes have been exposed to blood or body fluids, follow the steps below.

1. Rinse mucous membranes (i.e., eyes, nostrils, and mouth) with large amounts of water or saline solution.
2. If running water is not readily available, use another water source, such as bottled water, to rinse.

If there is a puncture of skin from a sharp instrument or needle, follow the steps below.

1. Wash the puncture with soap and water while encouraging the puncture to bleed by gently squeezing it, if necessary.
2. Bandage the puncture when finished.

Report exposure

1. Report any exposures to those responsible for managing exposures. Prompt reporting is essential, as post-exposure treatment that might be recommended, in some cases, should be started as soon as possible.
2. Discuss the possible risks of acquiring hepatitis B, hepatitis C, and HIV and the need for post-exposure treatment with the provider managing your exposure.

Blood and Body Fluid Exposure Job Aid

Safety: Gloves Job Aid

Safety: Gloves

Disposable Gloves (latex, vinyl, nitrile)

Disposable gloves reduce hand contamination, prevent cross-contamination, and protect from infection. Gloves should fit properly, not restrict hand coordination, accommodate individual requirements such as allergy to latex, and meet the task's requirements. Rings, long fingernails, and fingernail jewelry can make it more challenging to put the gloves on properly and cause gloves to tear more easily.

To help prevent allergic reactions to latex gloves, use appropriate work practices.

- Do not use latex gloves. If you choose latex gloves, it is recommended to opt for powder-free gloves that have a lower protein content.
- Do not use oil-based hand creams or lotions when wearing latex gloves.
- After removing gloves, wash hands with a mild soap for at least 15 seconds, and then rinse and dry them thoroughly.
- Familiarize yourself with the signs of latex allergy, which may include symptoms such as a skin rash, hives, flushing, itching, nasal congestion, eye irritation, sinus problems, asthma, and in rare cases, even shock.

For more information on how to protect yourself from latex exposure and allergy in the workplace, visit: https://www.cdc.gov/niosh/docs/98-113/.

All employees using disposable gloves must observe the following precautions.

- Cover open sores, dermatitis, cuts, etc., with a dressing or bandage.
- Wash hands before putting on gloves.
- Never wash or reuse disposable gloves.
- Remove gloves after they become contaminated and before leaving the work area.
- Remove contaminated gloves using a procedure that avoids contact with the glove's outer surface.
- Dispose of contaminated gloves in infectious waste containers in the work area.
- Wash hands immediately or as soon as possible after removal of gloves.

Instructions on how to safely remove gloves:

https://www.cdc.gov/vhf/ebola/resources/pdfs/poster-how-to-remove-gloves-p.pdf

Appendix F

Common Disinfectants and Antiseptics

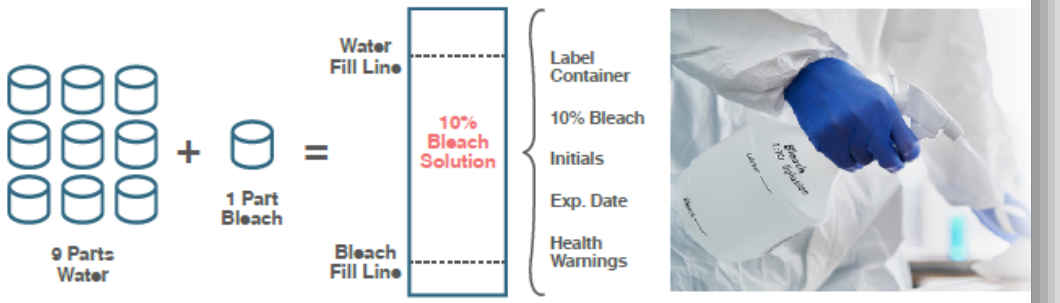
Note: Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services. Proprietary disinfectant products should be used in accordance with the manufacturer's instructions for concentration, contact time, or other conditions of use.

Disinfectants

Selected EPA-registered disinfectants: A list of EPA's registered sterilizers, tuberculocides, and antimicrobial products against certain bacteria and viruses can be found at: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.

Chlorine compounds are powerful disinfectants that are inexpensive and easy to obtain. Sodium hypochlorite or household chlorine bleach solutions possess intermediate-level disinfectant properties and are commonly used to disinfect lab surfaces. For maximum potency, the working solution should be prepared fresh at the time of use or daily as needed, but studies show that weekly preparations work, too. A 10% bleach solution is also called 1/10, 1:10, or 5,000 ppm bleach solution.

The directions for preparation are:



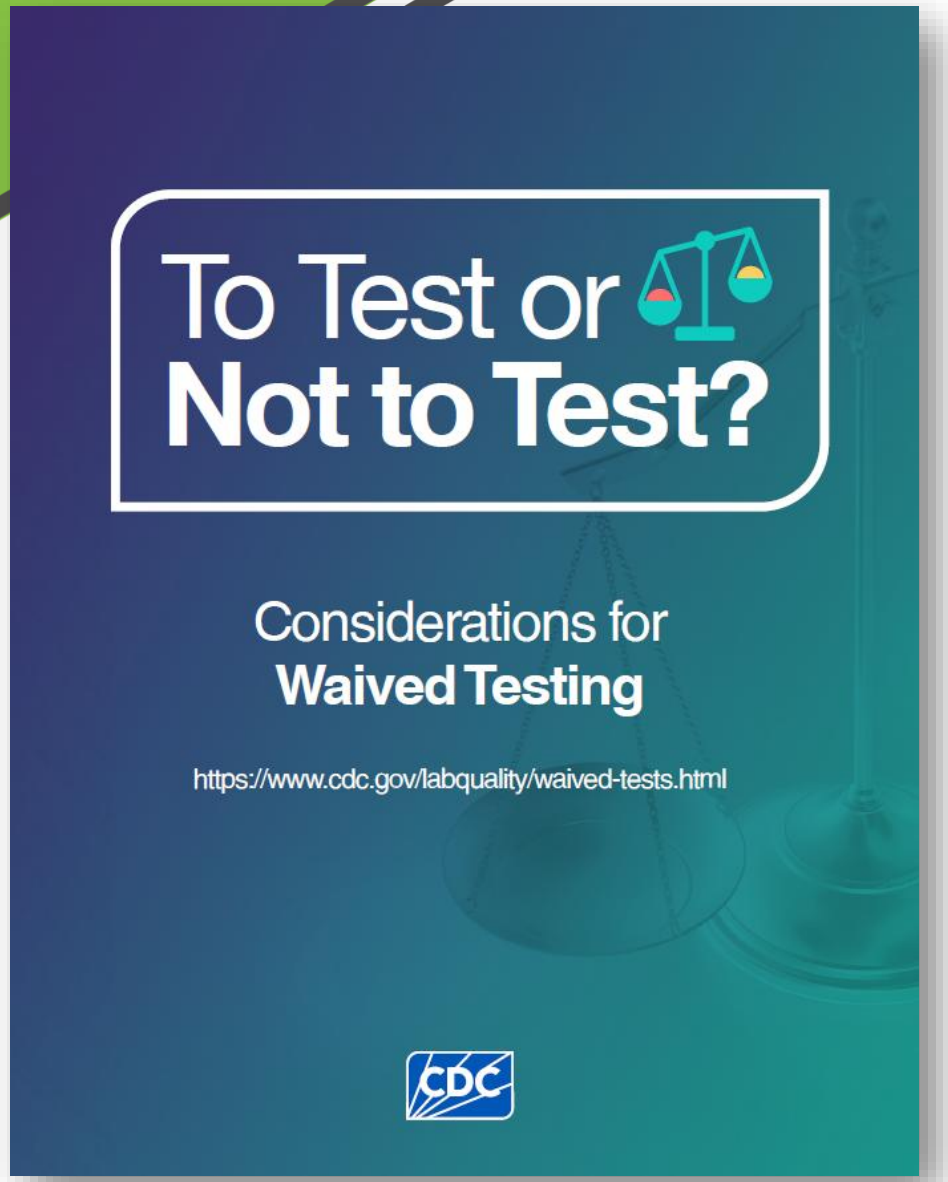
Note: Bleach will corrode some equipment. Refer to the manufacturer's instructions for alternatives and recommendations for cleaning and disinfecting procedures.

Commercial Products. The EPA lists registered commercial products that are effective against certain bacteria and viruses. Examples are 'Lysol' (cresol and soap solution) and 'Stericol' (xylenol-rich cresylic acid and soap solution).

Antiseptics

Alcohols are considered intermediate-level disinfectants. Alcohol solutions are often used as a skin antiseptic. Alcohols, such as isopropyl (rubbing) alcohol, are well suited to rapidly kill bacteria on the skin surface in preparation for fingerstick or venipuncture.

Common Disinfectants and Antiseptics Job Aid



Lab Quality: Waived Tests

To Test or Not to Test booklet describes considerations and preparations needed prior to performing waived testing. This resource is intended to assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver.

To request hard copies visit Waived Testing Booklet Request

Summary

- Ready? Set? Test! educational materials free resources equip testers with good testing practices that help improve the quality of test results and enhance patient safety.
- Follow best practices when performing waived testing.
- Always follow the manufacturer's instructions.
- Record test results accurately and according to the testing site’s policy for reporting results.
- When problems occur during the testing process, document and report to the person who oversees or directs testing.
- In the event of questionable test results, repeat the test with a new sample if required.
- Ready? Set? Test! checklists, testing logs, and job aids are available for use at testing sites.

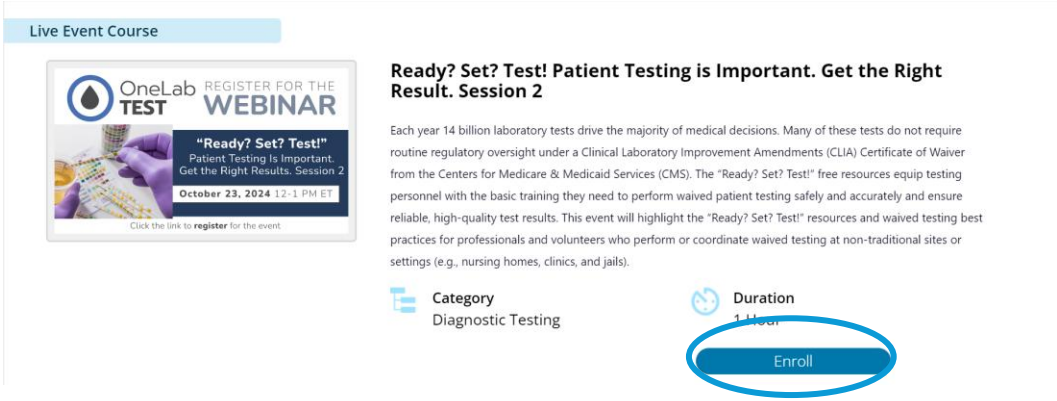
Let’s Discuss!

Q&A Session

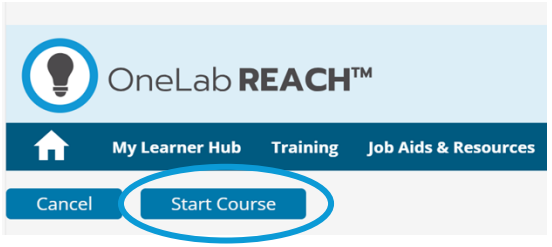
OneLab TEST

Share your feedback and training needs with us!

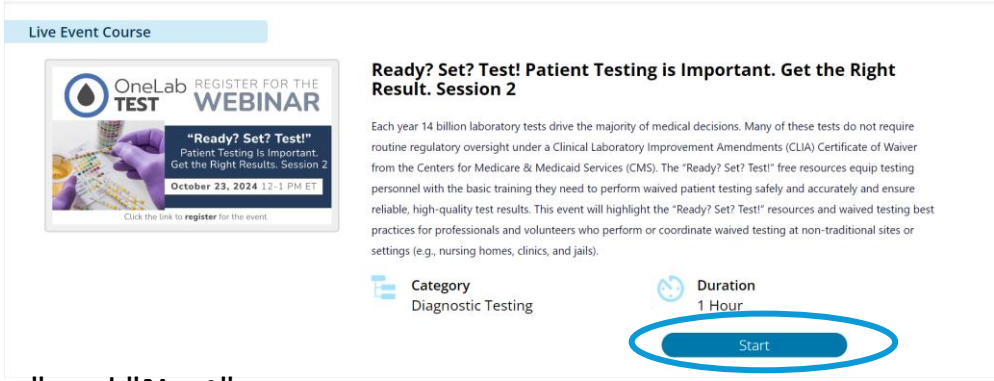
1. Log into your OneLab REACH account. **You must be logged into your REACH account to access the evaluation.**
2. Click on "Ready? Set? Test!" Patient Testing is Important. Get the Right Result. Session 1 to take you to the survey.
3. Click "**Enroll**"



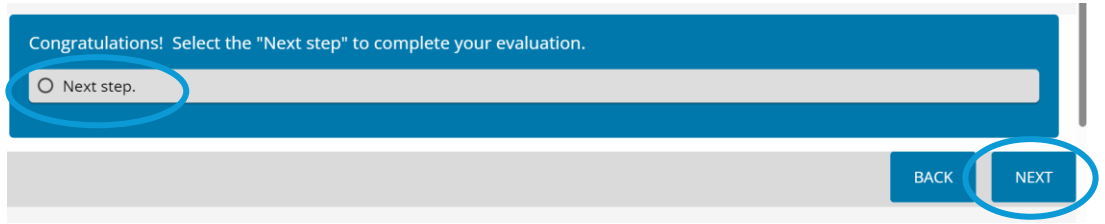
4. Select "**Start Course**".



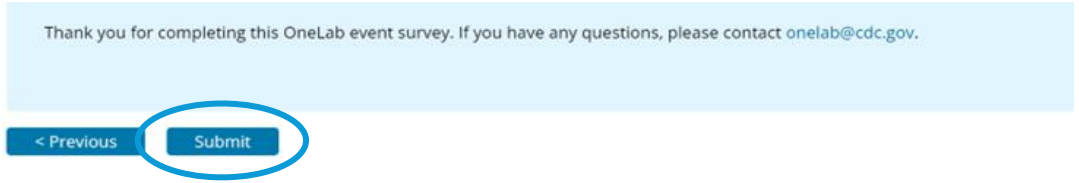
5. Select "**Start**".



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



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



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

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

OneLab **Assessments**

Share your feedback and testing training needs with us!

Email OneLab@CDC.gov