pennsylvania
DEPARTMENT OF HEALTH

To: STD Clinical Providers

From: STD Program

Date: October 1, 2015

RE: Availability of Rapid Screening Test for Syphilis

The STD Program is pleased to announce the availability of the new Syphilis Health Check distributed from Trinity Biotech. The Syphilis Health Check is currently the only rapid syphilis test that has FDA Clearance and is CLIA waived. The test uses a finger-stick sample and will provide results within 10 minutes.

The Syphilis Health Check is ideally situated for use in outreach and other venues where syphilis testing is being offered to high-risk individuals and where the follow-up of those individuals who test positive is difficult.

We encourage providers to review the attached Syphilis Health Check Frequently Asked Questions and attached documents for more information.

If you have any questions regarding this new test or for ordering information, please contact Steve Kowalewski within the STD Program at 717-787-3981 or by email at c-skowalew@pa.gov.

Syphilis Health Check Frequently Asked Questions

Background

Late in 2014, the FDA granted it's first-ever waiver for a rapid syphilis screening test. This allows for the Syphilis Health Check test to be used in a variety of health care settings and help to achieve the mission of identification, treatment, and, ultimately, prevention of syphilis in high-risk populations. During the first half of 2015, the Pennsylvania Department of Health Sexually Transmitted Diseases (STD) Program piloted this new syphilis testing platform and is now making the test available to providers in our STD clinical network across the state.

What is the Syphilis Health Check?

The Syphilis Health Check is a very simple 10 minute, 2-step procedure utilizing a finger-stick; it affords the following features and benefits:

- 98 percent agreement with reference Treponemal assays;
- 100 percent agreement with clinically diagnosed samples;
- Detection of both IgG and IgM, enhancing detection with early syphilis;
- Utilization of multiple recombinant syphilis antigens (TP-15, TP-17, and TP-44 for optimized sensitivity and specificity);
- Room temperature kit storage;
- Only rapid syphilis test with FDA Clearance and CLIA-waived; and
- CPT code: 86780.

What are the venues where this test should be used?

The Syphilis Health Check is ideal for use in outreach and other venues where syphilis testing is being offered to today football predictions from the experts high-risk individuals and where the follow-up with those individuals who test positive is difficult. Specific venues include:

- Clinics designated for men who have sex with men (MSM);
- Outreach to commercial sex workers;
- Outreach to MSM venues such as gay pride events, gay book stores, bathhouses, and gay campgrounds;
- Testing sites performing rapid HIV testing; and
- Community-based testing in areas of high syphilis morbidity.

Who are the clients that should be offered the Syphilis Health Check?

- The Syphilis Health Check is not a test that should be offered to everyone.
- It is important that a detailed risk assessment be conducted prior to the offering of the test.
- Because the Syphilis Health Check is a Treponemal assay, individuals with a previous known syphilis history should not be offered this test. Individuals with a previous known syphilis history should instead have a routine serologic specimen drawn for the standard lab-based syphilis testing.

What do I need to do to start using the Syphilis Health Check?

- Sites wishing to use the Syphilis Health Check need to contact the STD Program. The STD Program can provide test kits at no cost or a significantly reduced cost to organizations that provide STD and/or HIV testing and outreach services.
- Trinity Bio-tech will provide training resources on the specifics of test storage and administration, as well as interpreting the Syphilis Health Check results. To arrange for training, please contact Christopher Gant:

  Trinity Biotech
  Christopher Grant
  National Account Manager
  609-578-7739
  Email: christopher.grant@trinityusa.com

What are the CLIA requirements for my organization to start using the Syphilis Health Check?

- If a facility already has a CLIA certificate and a Pennsylvania Department of Health, Bureau of Lab State permit, a Change of Status Form (Attachment 1) must be completed for each facility wishing to add the test.
- If a facility does not have a CLIA certificate and a Pennsylvania Department of Health, Bureau of Lab State permit, a CLIA 116 application and an In-State Clinical Lab Licensure application must be completed for each facility (Attachment 2).
- Since the Syphilis Health Check is a CLIA-waived test, organizations wanting to use this test should be familiar with the testing requirements under CLIA and should review the attached CLIA test booklet: "Ready? Set? Test!" (Attachment 3).
- The CLIA and Pennsylvania Department of Health, Bureau of Laboratory permit process can be confusing; organization with specific CLIA and lab permit questions should contact:

  Pennsylvania Department of Health
  Bureau of Laboratories
  Pam Groff, Administrative Assistant
  110 Pickering Way
  Exton, PA 19341
  Telephone: 848-870-6425
  Email: pgroff@pa.gov

How should the results of the Syphilis Health Check be interpreted?

The Syphilis Health Check is not recommended as a screening test for individuals with a past history of syphilis, whether or not they were appropriately treated. It is important to specifically ask individuals if they were previously diagnosed with syphilis prior to using this test. The STD Program in conjunction with Trinity Biotech has developed a testing algorithm for the suggested interpretation of the Syphilis Health Check and follow-up of individuals testing positive (Attachment 4).

Please Note:

Every individual and syphilis case is unique; as such, the individual's unique medical history, risk assessment, and circumstances must be thoroughly reviewed and evaluated prior to making a determination if the client is indeed infected with syphilis. The attached testing algorithm (Attachment 5) should be used to help in that decision-making process, but it should not be used exclusively to make a diagnosis. This algorithm is based on the guidelines established by the Centers for Disease Control and Prevention, published in MMWR 60(5), February 11, 2011, and it describes the "Reverse Algorithm" approach to syphilis testing, which begins with a direct T. Pallidum antibody test as the initial screening test. The STD Program requires that all positive Syphilis Health Check results be confirmed with a lab bench top test using this reverse algorithm.

Reporting Positive Syphilis Health Check Results

All positive Syphilis Health Check results are reportable. Reports can be made online at www.nedss.state.pa.us or by contacting the Pennsylvania Department of Health, STD Program 717-787-3981 between the hours of 8:00 AM – 5:00 PM

ATTACHMENT 1
BUREAU OF LABORATORIES CLIA CHANGE OF STATUS FORM

pennsylvania
DEPARTMENT OF HEALTH

Bureau of Laboratories
PO Box 500
Exton PA 19341-0500
Phone: 610-280-3464

Change of Status Form

This form is for **changes and updates only**. Please only provide the Bureau with information that is changing in the fields below along with the effective date of the change. Note that the name of the laboratory cannot exceed 32 characters including spaces so make any necessary abbreviations.

Changes will be made to both state permit and CLIA certificates (if applicable).

In order for the Department to qualify a director a copy of the curriculum vitae (CV) and medical license must be enclosed. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents are required. Please include a copy of any board certifications and a copy of any CEUs (continuing educational units).

State Lab ID # _____ (required) **Federal CLIA # 39D _____(required)**

Is this Clinical Laboratory Improvement Amendments number (CLIA) a multisite laboratory? Y N

Are you reopening a laboratory that was previously closed less than 6 months? Y N ***

Laboratory Name: _____ _____ **Effective Date:** _____

Owner: _____ **Effective Date:** _____

Tax ID #: _____ **Effective Date:** _____

Director: _____ _____ **Effective Date:** _____

Dr.'s Medical License: _____ **Effective Date:** _____

Physical Address: _____ **Effective Date:** _____

_____

Mailing Address: _____ **Effective Date:** _____

_____

Billing Address: _____ **Effective Date:** _____

_____

Telephone Number: _____ **Effective Date:** _____

Fax Number: _____ **Effective Date:** _____

Contact Name: _____ **Effective Date:** _____

Contact Phone #: _____ **Effective Date:** _____

Contact Email Address: _____ **Effective Date:** _____

Change my state Clinical Laboratory Permit to:

☐ **Physician's Office or Clinic** ☐ **Hospital** ☐ **Independent** ☐ **Nursing Home** ☐ **Mobile Lab** ☐ **Screening Site**

Effective Date: _____

State Lab ID # _____(required) **Federal CLIA # 39D _____(required)**

Please use the chart below and list the tests you are **adding or deleting** from your current test menu **as well as the laboratories' current test menu**. List the effective date of the change for the addition or deletion. For each test, indicate the instrument/kit and 510(k) Number. If your laboratory is adding moderate and/or high complexity testing, include the following documents: procedure, validation studies, training documentation and proof of proficiency testing enrollment.

Changes/Additions/Deletions to Test

Test Name	Kit/Instrument/510(k) Number	Add/Delete	Effective Date

If your laboratory is adding alcohol, drug, lead or EP testing, enrollment into the Pennsylvania Toxicology Proficiency Testing Program is a requirement for state licensure. Your lab will be contacted with details concerning this program.

Change my CLIA Certificate to:

☐ Waiver ☐ Compliance ☐ Provider-Performed Microscopic Procedures (PPMP)

☐ Accreditation-with which program? _____

Effective Date: _____

☐ **Our office has closed and/or discontinued all clinical testing.** **Effective Date:** _____

Print Laboratory Director Name Signature of Director Date

Print Owner/Corporation Name Authorized Signature Date

THIS FORM MUST BE SIGNED BY THE DIRECTOR/OWNER FOR ALL CHANGES TO BE VALID -

for director changes, the new director MUST sign this form.

Revised MAM 3/10/2014

INSTRUCTIONS FOR COMPLETING THE CHANGE OF STATUS FORM

Please provide only the information that is changing along with the current test menu.

Laboratory Name

This is the name that will be used for all aspects of the facility (billing, etc.). This name must be exactly the same as it appears on your CLIA certificate. Name may only be 32 characters including spaces.

Laboratory Address

This is the physical location of the laboratory where testing and treatment is performed. Use the mailing/billing address only if facility wants bills and other correspondence sent to separate address. Both physical and mailing/billing address(es) must be exactly as it appears on your CLIA certificate.

Laboratory Owner

Provide the name of the person(s) or corporation that owns the laboratory.

Contact Person

Provide the name of the person to contact in the event that there are questions about the changes.

Director

This must be a person who holds a doctorate and who qualifies under Section 5.21 of the Clinical Laboratory Regulations. The director must be the same for both State and CLIA purposes. Neither the state nor the federal government recognizes co-directors. In order for the Department to qualify a director, a copy of the curriculum vitae (CV), a copy of any board certifications and a copy of the director's medical license must be enclosed. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents are required. Please include a copy of any board certifications and a copy of any CEUs (continuing educational units).

Adding Tests

The following documents must be enclosed for the addition of all moderate, high complexity tests and lab-developed tests: procedure manual, validation studies, training documentation and proof of proficiency testing enrollment. The following documents must be enclosed for PPMP tests: list of testing personnel for PPMP tests and documentation of Quality Assurance plan two times per year (example: proficiency testing or split samples).

Change My Certificate To

Check the appropriate type of certificate if the addition or deletion of tests will change your certificate.

Laboratory Equipment/Kits Used for Testing

List all equipment used to perform laboratory tests including glucose meters, strep test kits, etc.

ALLOW 4-6 WEEKS FOR INITIAL REVIEW

*Initial review is defined as the time the application is first reviewed for completion of required documents.

****Laboratories closed 6 months or longer must submit a completed PA Dept. of Health Clinical Laboratory Application and Clinical Laboratory Improvement Amendments (CLIA) application. Indicate your existing State Laboratory identification number and Federal CLIA number on the appropriate application.

ATTACHMENT 2
CLIA 116 APPLICATION AND THE IN STATE CLINICAL LAB LICENSURE APPLICATION

pennsylvania
DEPARTMENT OF HEALTH

FOR DEPARTMENT USE ONLY

STATE ID # _____

LEVEL _____

CHECK REC'D Y OR N

CLINICAL LABORATORY APPLICATION

ALL SECTIONS MUST BE COMPLETED, please allow a minimum of 4-6 weeks for initial review*

NO PATIENT TESTING MAY BE PERFORMED UNTIL A PERMIT HAS BEEN GRANTED

LABORATORY NAME:			DIRECTOR:	
LABORATORY PHYSICAL ADDRESS:			IF M.D. OR D.O. GIVE MEDICAL LICENSE NUMBER:	
CITY:	STATE:	ZIP CODE:	TELEPHONE NUMBER:	FAX NUMBER:
LABORATORY MAILING ADDRESS:			FEDERAL TAX ID #	E-MAIL ADDRESS:
CITY:	STATE:	ZIP CODE:	OWNER NAME:	
LABORATORY BILLING ADDRESS:			CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) #: (IF PREVIOUSLY ASSIGNED OTHERWISE FOR DEPT USE ONLY): 39D	
CITY:	STATE:	ZIP CODE:	NAME OF CONTACT PERSON:	CONTACT PERSON TELEPHONE NUMBER:
TYPE OF CLIA CERTIFICATE REQUESTED (CHECK ONE) ☐ CERTIFICATE OF WAIVER ☐ PROVIDER-PREFORMED MICROSCOPY PROCEDURES (PPMP) ☐ COMPLIANCE ☐ ACCREDITATION				

Application is for (Check only one):

☐Hospital Laboratory ☐Independent Laboratory ☐ Physician Office/Clinic ☐Nursing Home

Before submitting the application, choose the kits/instruments your lab will use for testing. For Toxicology testing these kits/instruments must be available for pre-licensure testing.

List All Laboratory Equipment/Kits Used for Testing (e.g., 510(k) Number, name of glucose meter, strep test kit, etc.):

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

A check or money order for $100.00, payable to the "Pennsylvania Department of Health", must accompany this application.

-OVER-

Check ***all*** lab tests that are being performed by your facility. Also, check the proficiency testing program (if applicable) in which you have enrolled. If the testing you perform is not on this list, please describe those tests on a separate sheet.

☐BACTERIOLOGY
☐Gram Stain
☐GC Screen
☐Throat Screen (rapid strep)
☐Throat Screen (culture)
☐Urine Culture Screen (including colony counts)
☐Bacterial Susceptibility
☐Chlamydia Antigen
☐*H. pylori* (urease)

☐MYCOLOGY
☐Dermatophyte Screening
☐KOH Prep

☐PARASITOLOGY
☐Wet Mounts
☐Pinworms
☐Scabies

☐VIROLOGY
☐Tzanck Smears

☐SYPHILIS SEROLOGY

☐NON-SYPHILIS SEROLOGY
☐Pregnancy Testing
☐Infectious Mononucleosis
☐Rheumatoid Factor
☐HIV
☐Allergy Testing
☐Histocompatability
☐Chlamydia Antibody
☐ANA
☐*H. pylori* Antibody
☐Influenza A and/or B Screen
☐ HIV (Rapid)

☐HEMATOLOGY
☐Hemoglobin
☐Differential Smears
☐Prothrombin Time
☐Hematocrit
☐CBC
☐ACT
☐Centrifugal Hematology
☐Semen Analysis
☐Nasal Smears
☐Sedimentation Rate
☐Sickle Cell Screening
☐Manual Differential of Atypical Cells
☐Bleeding Time

☐IMMUNOHEMATOLOGY
☐Non Transfusion
☐Immuno-Group & RH Typing
☐RH Titers
☐Cross Matching
☐Transfusion Service

☐TISSUE PATHOLOGY
☐Pathology Frozen Section
☐Oral Pathology
☐Cytogenetics
☐Dermatopathology

☐EXFOLIATIVE CYTOLOGY
☐Histocompatibility
☐Gynecological
☐Non-Gynecological

☐RADIOISOTOPE TECHNIQUES

☐URINALYSIS
☐Dipstick Urinalysis
☐Microscopic Urinalysis
☐Automated Urinalysis

☐CLINICAL CHEMISTRY
☐Routine Chemistry
☐Endocrinology
☐Cholesterol
☐Fecal Occult Blood
☐Fecal Occult Blood Instrument
☐Blood Glucose (incl. Whole Blood)
☐Blood Gases
☐Therapeutic Drug Monitoring
☐PSA Testing
☐Synovial Fluid
☐Glycohemoglobin (A1C)
☐Theophylline
☐Electrolytes
☐Fructosamine
☐pH of Body Fluids
☐HDL Cholesterol
☐LDL Cholesterol
☐Triglycerides
☐TSH Rapid
☐BNP
☐ Bladder Tumor Antigen

☐TOXICOLOGY
☐Alcohol Analysis
  ☐Serum/Plasma
  ☐Blood
☐Drugs Blood and/or Serum
  ☐Drugs Blood Screening
  ☐Drugs Blood Confirmatory
  ☐Drugs Serum Screening
  ☐Drugs Serum Confirmatory
☐Drugs Urine
  ☐Drugs Urine Screening
  ☐Drugs Urine Confirmatory
☐ Limited Urine Drugs Survey
☐Blood Lead
☐Erythrocyte Protoporphyrin

Other Please list:

_____

_____

_____

_____

PROFICIENCY TESTING

All facilities performing tests on CLIA regulated anlytes are **required** to participate in a proficiency testing program. **Enrollment into the Pennsylvania Toxicology Proficiency Testing Program is a requirement for state licensure for Toxicology analytes.*** Unregulated analytes (those not regulated by CLIA or CLIA-waived) require the laboratory to take steps to assure the accuracy of testing in lieu of testing PT samples. CLIA requires that, at least twice annually, you verify the accuracy of any test or procedure that you perform. You must instruct the program to release results to 'The State Agency'. Listed below are the programs approved under the regulations of the Commonwealth and CLIA. Please check below the agency with which you have enrolled and send in proof of enrollment with this application.

☐College of American Pathologists (800) 323-4040
☐American Proficiency Institute (800) 333-0958
☐American Academy of Family Physicians (800) 274-2237
☐American Thoracic Society (Blood Gas Only) (212) 315-8808
☐American College of Physicians/Medical Laboratory Evaluation (MLE) (800) 523-1546
☐American Association of Bioanalysts (800) 234-5315
☐American Society of Internal Medicine (800) 338-2746
☐AccuTest (800) 665-2575
☐Pennsylvania Toxicology Program*

I hereby certify that the information stated herein is true and complete to the best of my knowledge and belief.

Print Laboratory Director Name | Signature of Director | Date

Print Owner/Corporation Name | Authorized Signature | Date

INSTRUCTIONS FOR COMPLETING THE CLINICAL LABORATORY APPLICATION

Laboratory Name

This is the name that will be used for all aspects of the facility (billing, etc.). This name must be exactly the same as it appears on your CLIA certificate. Name may only be 32 characters including spaces.

Laboratory Address

This is the physical location of the laboratory where testing and treatment is performed. Use the mailing/billing address only if facility wants bills and other correspondence sent to separate address. Both physical and mailing/billing address(es) must be exactly as it appears on your CLIA certificate.

Laboratory Owner

Provide the name of the person(s) or corporation that owns the laboratory.

Contact Person

Provide the name of the person to contact in the event that there are questions about the application.

Director

This must be a person who holds a doctorate and who qualifies under Section 5.21 of the Clinical Laboratory Regulations. The director must be the same for both State and CLIA purposes. Neither the state nor the federal government recognizes co-directors. In order for the Department to qualify a director, a copy of the curriculum vitae (CV), a copy of any board certifications and a copy of the director's medical license must be enclosed. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents are required. Please include a copy of any board certifications and a copy of any CEUs (continuing educational units).

Medical License Number

Indicate the medical license number for an M.D. or D.O.

Telephone/Fax Number

Provide telephone and fax number for the physical location.

CLIA Number

Fill in only if a number has been assigned by the Centers for Medicare and Medicaid Services (CMS) otherwise leave blank.

Application Type

Check the appropriate type of laboratory.

Laboratory Equipment/Kits Used for Testing

Check all tests that are being performed in your laboratory. Please do not include tests that are sent to reference laboratories.

List all equipment used to perform laboratory tests including glucose meters, strep test kits, etc. Please include 510(k) Number on all kits.

Proficiency Testing Program

Chose a proficiency testing program if applicable and send in proof of enrollment with this application (invoice or order confirmation).

APPLICATIONS MUST BE SIGNED BY DIRECTOR/OWNER. THE STATE AND CLIA APPLICATIONS MUST BE SENT IN TOGETHER WITH ALL SECTIONS COMPLETED.

ALLOW 4-6 WEEKS FOR INITIAL REVIEW*

***Initial review is defined as the time the application is first reviewed for completion of required documents.** OVER

Return both CLIA and Clinical Laboratory Application to:

Bureau of Laboratories

P.O. Box 500

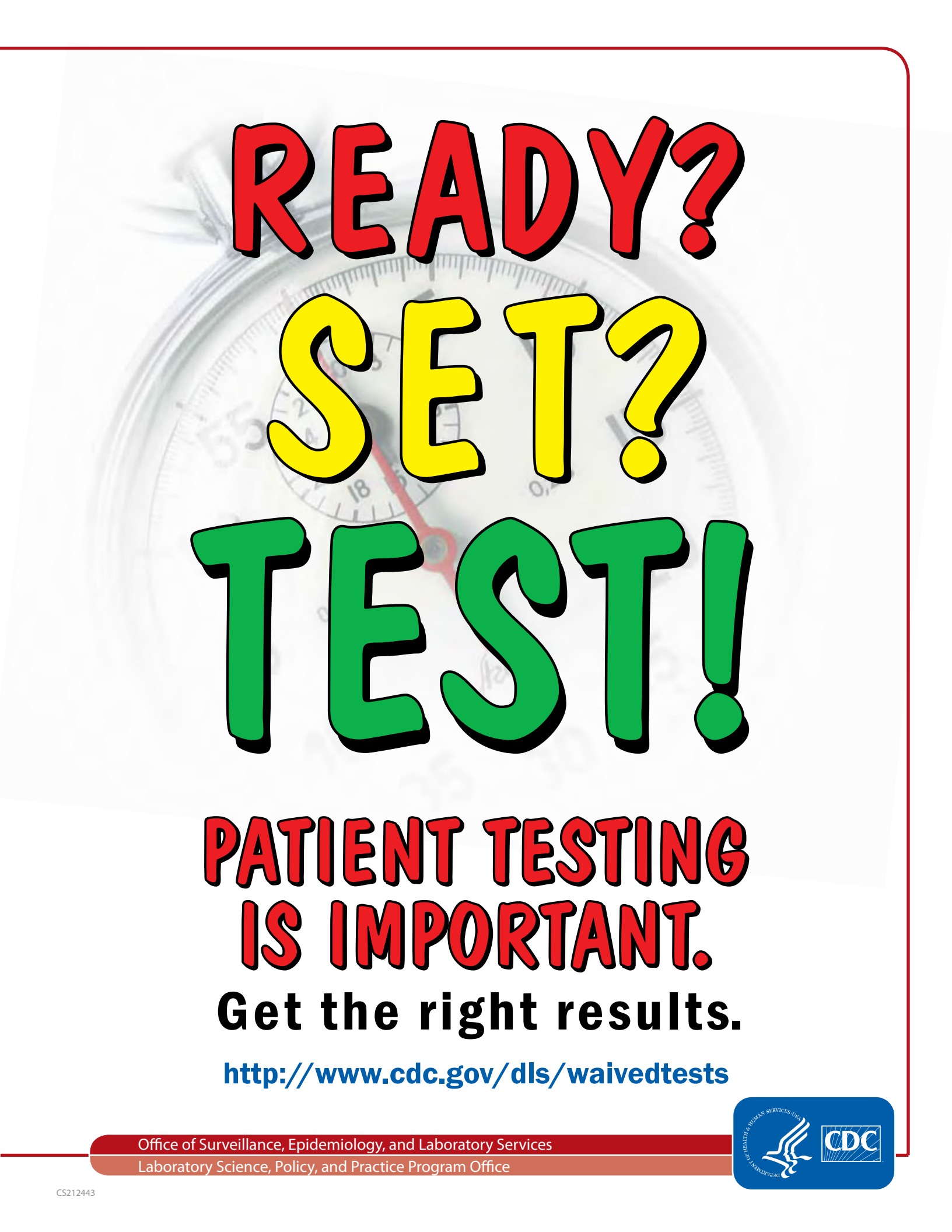
Exton, PA 19341

For overnight delivery services, our physical location is:

110 Pickering Way

Exton, PA 19341

ATTACHMENT 3
CLIA TEST BOOKLET:
“READY? SET? TEST!”


READY?
SET?
TEST!
PATIENT TESTING
IS IMPORTANT.
Get the right results.
http://www.cdc.gov/dls/waivedtests
Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office
CDC
CS212443

Introduction

Background

Health care providers use test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. Current practice shows an increased trend for medical decisions based on simple tests performed at the point of care. Many of these tests are called waived tests and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those tests approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) criteria. The FDA list of waived tests is continuously being revised as new tests are waived. The most current information on FDA cleared waived tests can be found at the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Purpose

CLIA requires that waived tests must be simple and have a low risk for an incorrect result. However, this does not mean waived tests are completely error-proof. To decrease the likelihood of incorrect results, waived testing needs to be performed correctly, by trained personnel and in an environment where good testing practices are followed.

Although not routinely done, the Centers for Medicare & Medicaid Services (CMS) will inspect waived testing sites under certain circumstances such as:

- if a complaint is made,
- to determine if the testing site is performing tests not permitted with a certificate of waiver,
- if there is risk of harm to a patient due to inaccurate testing, and
- to collect information about waived tests.

This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

The CLIA requirements for testing under a Certificate of Waiver can be found here: http://wwwn.cdc.gov/clia/regs/subpart_b.aspx

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

Contents

READY?

Overview

Certain steps need to be taken even before a test is begun to be sure results are accurate. Most importantly, follow the manufacturer's instructions throughout the testing process. Problems found in testing sites that perform waived tests are most often the result of not following this critical step.

Prepare for Testing

Testing should be performed in an area with adequate space to safely conduct testing while maintaining patient privacy. Testing and storage areas should be monitored to be sure they meet specific environmental requirements described in the manufacturer's instructions. Equipment used for testing should be maintained and calibration checks should be performed as directed in the manufacturer's instructions. Some important points to consider are:

- ✓ Clean work surfaces before and after testing.
- ✓ Perform testing in a well lit area.
- ✓ Check and record temperatures of the testing and reagent storage areas. See Appendix A for examples of daily temperature logs.
- ✓ Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
- ✓ Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- ✓ Check that all kit reagents came from the same kit lot. Do not mix reagents.
- ✓ Inspect reagents for damage, discoloration, or contamination, and discard if found.
- ✓ Prepare reagents according to manufacturer's instructions.
- ✓ Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
- ✓ Inspect equipment and electrical connections to be sure they are working.
- ✓ Perform equipment calibration checks, as needed, following the manufacturer's instructions.

The Test Instructions

Testing sites that perform testing under a CLIA Certificate of Waiver must follow the current manufacturer's test instructions. See Appendix B for an explanation of the common components found in a manufacturer's instructions. Keep in mind that manufacturer's instructions may be updated or changed and instructions from different manufacturers for the same type of testing, such as glucose, may not be the same. The following steps should be taken to be sure the current test instructions are being followed:

- ✓ 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 test kits to make sure there are no changes from the test kits being used.
- ✓ File the old manufacturer's instructions and replace with the new copy if there are changes.
- ✓ Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.

Some manufacturers provide quick reference instructions that can be posted in the testing area. If manufacturer's instructions are updated, the quick reference instructions may need to be updated as well. If your testing site has a procedure manual, the site specific procedure will need to be updated.

Know How to Do the Test the Right Way

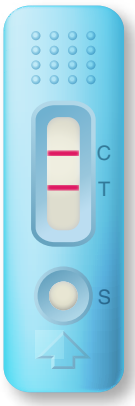
- ✓ Read and understand the manufacturer's instructions and/or site specific procedure.
- ✓ Follow safety precautions including Occupational Safety and Health Administration (OSHA) guidelines: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
- ✓ Practice all tests, while an experienced person watches, before testing patient samples and reporting patient results.
- ✓ Document training on all tests in staff personnel files.

Quality Control Testing

Quality control (QC) testing gives confidence that your results are accurate and reliable. The manufacturer's instructions or site specific procedure explain what the controls are checking, the steps for performing QC testing, and when to do QC testing. Incorrect QC results alert the user about potential problems such as reagent/test kit deterioration, equipment failure, environmental conditions, or human error.

What are the types of controls?

Two types of controls are generally found in waived tests:



- Internal controls (also referred to as built-in or procedural controls) evaluate whether:
  - the test is working as it should,
  - enough sample is added,
  - the sample is moving through the test strip correctly, and/or
  - the electronic functions of the instrument are working correctly.
- External controls evaluate whether:
  - the entire testing process is performed correctly, and
  - the control results are in the expected ranges or values as found in the manufacturer's instructions.

External controls are similar to patient samples but may need additional processing before use. Follow the manufacturer's instructions. External controls are not always included in the test kit and may need to be purchased separately.

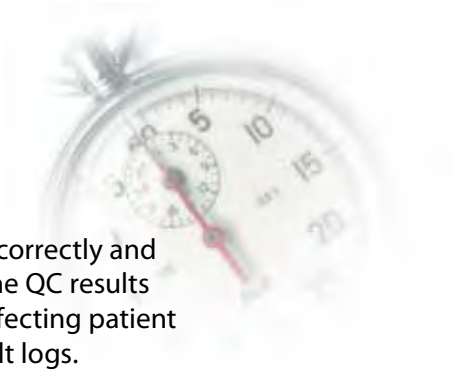
How often should QC testing be done?

Each testing site should have a policy for QC testing. When deciding on a control testing schedule, consider the:

- stability of the test (check expiration dates and storage requirements),
- environment (power outages or mechanical breakdowns of refrigerators can cause QC or testing material to go bad), and
- skills of the person performing the test (newly trained versus experienced).

Controls should be treated and tested in the same way as patient samples and by the same personnel who routinely perform patient testing. At a minimum, follow the manufacturer's instructions and test controls with:

- each new shipment of kits/reagents,
- a change in lot numbers, and
- each new operator.



Tracking of QC results

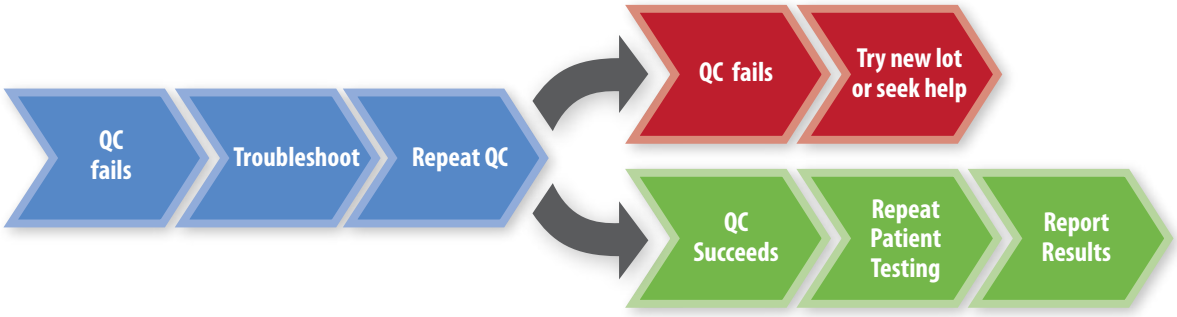
Documenting and tracking QC results can show whether a test is being performed correctly and if the test is working correctly. A periodic review of QC records can show whether the QC results are changing over time. This information can help identify problems that may be affecting patient testing and need to be addressed. See Appendix C for examples of QC logs and result logs.

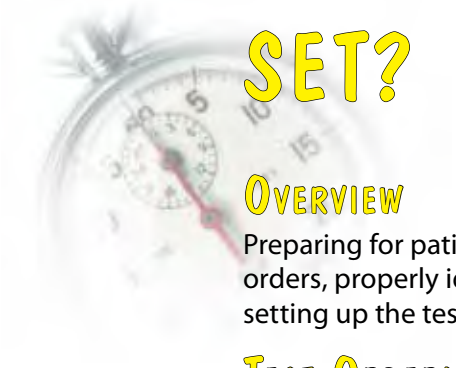
Actions for unexpected QC results

If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- ✓ Check to see if the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error such as outdated reagents or test devices.
- ✓ Check to see if reagents were stored correctly.
- ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching caps.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site specific procedure.
- ✓ For additional assistance, contact the manufacturer, technical representative, and/or the person who directs or supervises the testing.

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 acceptable results.





SET?

Overview

Preparing for patient testing is as important as performing the test. Paying attention to test orders, properly identifying and preparing the patient, collecting a good quality sample, and setting up the test system and testing area all contribute to quality test results.

Test Ordering

Before collecting a sample, confirm:

- ✓ The test order — if there is a question whether the order is correct, check with the individual who requested the test.
- ✓ Patient identification — because names can be similar and lead to confusion, use birth dates, middle initials, identification numbers or other ways to make sure the sample is collected from the correct patient.

Patient Preparation

Consult with the patient regarding:

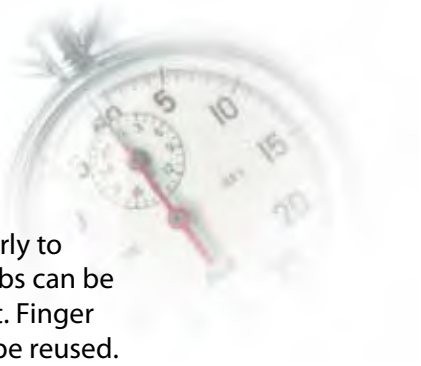
- ✓ Pretest instructions — some tests require preparation by the patient such as fasting for a glucose test. Verify these instructions were followed before collecting the sample.
- ✓ Pretest information — discuss factors such as medical indications, medications, or other interfering substances that can affect test results with the patient. This information can often be found in the *Limitations* section of the manufacturer's instructions.
- ✓ The test(s) — make sure the patient understands what the test(s) and result(s) will mean to their health.
- ✓ Patient counseling — some tests, such as HIV tests, benefit from counseling on what the test results will mean for the patient.

Sample Collection

Quality patient samples are critical for accurate and reliable test results. The person collecting the sample should have a good understanding of the type of sample needed for the test and how to collect it. The manufacturer's instructions have this information as well as directions for sample storage and handling. Do not test samples that are improperly collected or handled.

Caution: When a test is approved for both waived and non-waived testing, the manufacturer's instructions may include instructions that could be performed using more than one type of sample. 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, oral fluid, and
- gastric biopsy.



Collection Devices

Collection devices are an important part of sample collection and must be used properly to obtain good results. Do not substitute swabs that come in a sample collection kit. Swabs can be made of different material and using the wrong swab may interfere with the test result. Finger stick and venipuncture collection devices are for one-time use only and should never be reused. Finger stick devices come in various sizes from pediatric to adult. Be sure to use the appropriately sized device for your patient. Some collection devices ensure the delivery of the correct sample volume and some contain additives that are needed for the test to work correctly. Therefore, it is important to follow the manufacturer's instructions when using sample collection devices.

Sample Labeling

Be sure to label the sample as soon as it is collected with a unique identifier such as 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. For tests in which the sample is applied directly to the test device (for example: test strip or cassette), label the test device with the patient identifier before collecting the sample.

Safety Issues

- ✓ Follow OSHA safety guidelines for occupational exposure to bloodborne pathogens: http://www.osha.gov/SLTC/bloodbornepathogens/index.html and CDC's Exposure to Blood - What Health-Care Workers Need to Know: http://www.cdc.gov/ncidod/dhqp/pdf/bbp/exp_to_blood.pdf
- ✓ Wear appropriate personal protective equipment (PPE) such as gloves.
- ✓ Clean hands and change gloves between patients. See Appendix D for job aids on hand hygiene, exposure, and glove removal.
- ✓ 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 such as eyes, nostrils, and mouth,
  - wear goggles or face shields,
  - avoid the use of needles and lancets if safe and effective alternatives are available,
  - never re-use single-use devices such as needles and lancets,
  - avoid recapping needles, transferring a body fluid between containers, and opening blood tubes,
  - dispose of used sharps properly in puncture-proof sharps containers,
  - report all occupational exposures promptly to ensure that you receive appropriate follow-up care,
  - report any real or potential hazards you observe to the person who directs or oversees testing,
  - participate in training related to infection prevention, and
  - get hepatitis B vaccination.

Biohazardous Waste

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

- ✓ as close as possible to the immediate testing area,
- ✓ upright throughout use,
- ✓ replaced routinely, and
- ✓ not overfilled.

Containers for contaminated waste must be:

- ✓ constructed to contain all contents and prevent leakage of fluids during handling, storage, transport and/or shipping,
- ✓ labeled or color-coded to indicate biohazard material, and
- ✓ closed prior to removal to prevent spillage or protrusion of contents during handling.

Hazardous waste cannot be disposed of with regular trash. Use proper biohazard containers to dispose of waste and sharps. Each testing site should have site specific procedures that comply with local, state, and federal requirements for safe disposal of biohazardous waste generated from sample collection and testing. Local hospitals and/or clinics may be able to provide information about regulated waste disposal. Useful websites include:

- Federal website: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- State program site: http://www.osha.gov/dcsp/osp/index.html

Disinfecting Work Surfaces

- ✓ Disinfect surfaces before performing any test procedure, whenever contamination is visible, and before leaving the testing area. Bacteria and viruses can be present in very high concentrations in just a few drops of blood and some remain infectious for at least one week in dried blood on countertops and doorknobs.
- ✓ Use the appropriate disinfectant for decontaminating your work area. See Appendix E: Common Disinfectants and Antiseptics.

TEST!

Overview

Once the sample is collected, the testing phase begins. Test performance, result interpretation, recording, and reporting are activities involved in this phase.

Performing the Test

When performing a test, some important points to remember are:

- ✓ Follow the testing steps in the exact order as they are in the manufacturer's instructions.
- ✓ Test QC following the manufacturer's instructions.
- ✓ Have the manufacturer's instructions, site specific procedure, or a quick reference guide at the testing area.
- ✓ Use timers and follow the required timing intervals before reading test 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, or
    - invalid results – the reaction moves beyond a visible area.

Reading the Results

Interpret test results according to the manufacturer's instructions. Keep the quick reference guide or color charts available to help interpret results. Test results are either quantitative, qualitative, or a combination of the two with a number result that is interpreted into a non-numeric result.

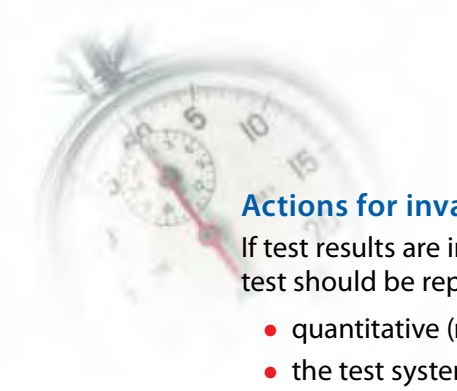
- ***Quantitative*** – number results produced by the test device or instrument. These results give the amount of substance being measured and are reported in specific measurement units.
- ***Qualitative*** – results are interpreted as positive, negative; reactive, non-reactive; or invalid. These results identify the presence or absence of a particular substance, condition, or microbial organism.

Resolving Problems

Problems that occur during the testing process or with equipment or material that are used during testing should be documented, reported to the person who directs or supervises the testing, and corrected. A few examples of problems include:

- improperly labeled samples,
- freezer or refrigerator failure,
- QC failure, and
- defective collection devices.

Trends can be identified by capturing and tracking this information and problems in the testing process can be identified as a result.



Actions for invalid or questionable test results

If test results are invalid, compromised, or disagree with the patient's clinical information, then the test should be repeated. Additionally, testing should be repeated when:

- quantitative (numerical) results have values beyond the measuring range of the instrument, or
- the test system gives an "invalid" result or prevents the display of the result.

The manufacturer's instructions for test performance should include steps for handling high or low results that cannot be accurately measured.

Test results should not be reported until the problem(s) are identified and corrected.

Recording Results

Record test results legibly in a log or following the testing site's policy and keep as a permanent record. These records should have enough detail for easy retrieval of information. Guidelines for recording results include:

- Quantitative (numerical) results should be recorded in the appropriate units of measurement.
- Qualitative results should be recorded using words or abbreviations rather than symbols. For example use:
  - "Positive" or "Pos", "Reactive" or "R" instead of "+", and
  - "Negative" or "Neg", "Nonreactive" or "NR" instead of "-".

Invalid or unacceptable results should also be recorded. If a test needs to be repeated, record the first result (invalid or unacceptable), resolve the problem, then record the repeated result(s). Report the final acceptable result only. See Appendix C for examples of QC logs and result logs.

Issuing Test Reports

Guidelines for issuing test reports:

- ✓ Patient test reports should be legible, standardized, and reported in a timely manner.
- ✓ Reports from tests conducted on-site should be easily distinguishable from referral laboratory test reports.
- ✓ Patient test reports should only be given to authorized persons.
- ✓ Verbal test reports should be documented and followed by a written test report.

Guidelines for critical values:

Critical values are test results that require immediate treatment or evaluation by the physician. The testing site 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 in a timely manner, and
- ✓ assuring that staff document 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 policies and 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, and
- ✓ transport or ship samples safely: http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/transporting_Infectious_Substances_brochure.pdf and http://www.iata.org/whatwedo/cargo/dangerous_goods/Pages/infectious_substances.aspx

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, and
- ✓ document when test results are received and the date of the final test report.

Public Health Reporting

Public health agencies require testing sites to report confirmed positive test results for certain infectious diseases. Testing sites should check with local public health agencies for the most current information on required reporting procedures, since diseases identified for reporting can change over time, and state requirements may vary.

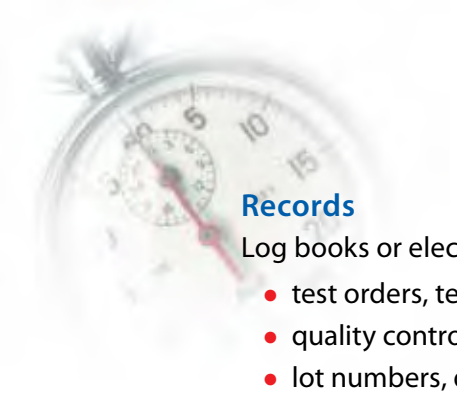
- National Notifiable Diseases Surveillance System: http://www.cdc.gov/ncphi/disss/nndss/nndsshis.htm
- Public Health Resources: State Health Departments: http://www.cdc.gov/mmwr/international/relres.html

Record Keeping

Document all steps of the testing process to assure quality testing. All equipment logs, maintenance records, QC documents, testing records, and test results should be kept for easy retrieval of information. The person overseeing testing and operations should periodically review records. Good record keeping is necessary to:

- ✓ retrieve and verify information,
- ✓ assess test performance,
- ✓ identify and resolve problems that could affect test results, and
- ✓ maintain patient and personnel information.

Check with your local/state public health department for record keeping requirements.



Records

Log books or electronic files can be used to maintain records. Examples of records include:

- test orders, test results, results from confirmatory or additional testing;
- quality control results;
- lot numbers, dates used and received, and expiration dates of reagents, kits and quality control material;
- 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; and
- results of proficiency testing or other external quality assessment activities.

Proficiency Testing

Although proficiency testing (PT) is not routinely required for waived testing, there are many benefits of participating in a PT program. PT provides:

- a regular, external check on quality of testing,
- motivation to improve performance,
- comparison of performance with that of other participating sites (peers),
- an opportunity to obtain feedback and technical advice from programs that offer PT,
- assistance in evaluating methods and instrumentation,
- assistance with staff education, training and competence monitoring, and
- opportunities for identifying areas needing improvement.

For information on programs that offer PT, refer to:
http://www.cms.hhs.gov/CLIA/downloads/ptlist.pdf

See also CMS brochure 'Proficiency Testing' available online:
http://www.cms.hhs.gov/CLIA/downloads/CLIAbrochure8.pdf

Tips, Reminders, and Resources

Ready?

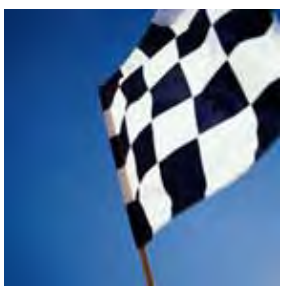
- ☐ Clean work surfaces before and after testing.
- ☐ Perform testing in a well lit area.
- ☐ Check and record temperatures of the testing and reagent storage areas.
- ☐ Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
- ☐ Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- ☐ Check that all kit reagents came from the same kit lot. Do not mix reagents.
- ☐ Inspect reagents for damage, discoloration, or contamination, and discard if found.
- ☐ Prepare reagents according to manufacturer's instructions.
- ☐ Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
- ☐ Inspect equipment and electrical connections to be sure they are working.
- ☐ Perform calibration checks, as needed, following the manufacturer's instructions.
- ☐ File the old manufacturer's instructions and replace with the new copy if there are changes.
- ☐ Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.
- ☐ Treat and test quality control (QC) samples the same as patient samples.
- ☐ Perform QC as recommended in the manufacturer's instructions.

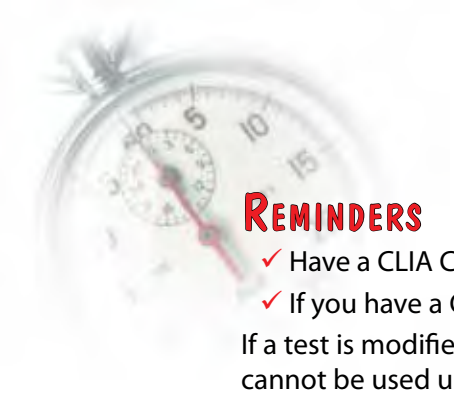
Set?

- ☐ Check patient identification and test orders.
- ☐ Discuss pretest instructions and counseling needs with the patient.
- ☐ Wear appropriate personal protective equipment (PPE) such as gloves.
- ☐ Collect and label a good sample for testing.
- ☐ Clean hands and change gloves between patients.
- ☐ Use the proper biohazard containers to dispose of waste and sharps.

Test!

- ☐ Do not test samples that are improperly collected or handled.
- ☐ Have the manufacturer's instructions or a quick reference guide at the work station.
- ☐ Follow the manufacturer's instructions in the exact order.
- ☐ Follow required timing for testing.
- ☐ Identify and correct problems before reporting test results.
- ☐ Identify and report critical values in a timely manner.
- ☐ Perform or refer confirmatory or additional testing, if needed.
- ☐ Make sure patient reports are legible and reported in a timely manner.
- ☐ Make sure reports are standardized and easily distinguishable from referral laboratory test reports.
- ☐ Report patient test results only to authorized persons.
- ☐ Document verbal reports, followed by a written test report.
- ☐ Report public health diseases.
- ☐ Dispose of biohazardous waste safely.
- ☐ Participate in proficiency testing (PT).





Reminders

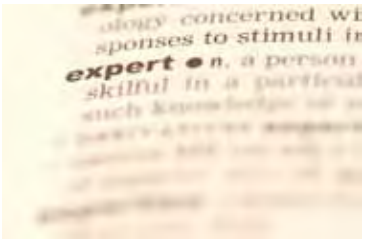
- ✓ Have a CLIA Certificate before testing patients.
- ✓ If you have a Certificate of Waiver (CW), use only waived tests or test kits.

If a test is modified by the testing laboratory in any way, it is no longer considered waived and cannot be used under a CLIA CW.

What is a modification? Any change made to the test, including:

- altering the timing of the test,
- physically modifying a component, such as cutting test cards or strips to increase the number of samples tested per kit,
- diluting a reagent, or
- testing a sample that is not indicated as an approved sample type or not collected using the appropriate device, kit or container per the manufacturer's instructions.

Resources



- Appendix F: Terms and Abbreviations
- "Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm
- "READY? SET? TEST!" poster http://wwwn.cdc.gov/dls/waivedtests/GoodLaboratoryPractices.pdf
- "Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988." http://www.cdc.gov/hiv/topics/testing/resources/guidelines/qa_guide.htm
- CLIA: http://www.cms.hhs.gov/CLIA/
- CLIA CW Application: http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf
- CLIA – State Agency Contacts: http://www.cms.hhs.gov/CLIA/downloads/CLIA.SA.pdf
- FDA's CLIA Waived Test List: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm
- Health Insurance Portability and Accountability Act (HIPAA): http://www.hhs.gov/ocr/hipaa
- For additional information: http://www.cdc.gov/dls/waivedtests

Safety Links

- The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) Biosafety link: http://www.cdc.gov/od/ohs/biosfty/biosfty.htm
- List of OSHA publications and links: http://www.osha.gov/pls/publications/publication.html
- State occupational safety and health programs: http://www.osha.gov/dcsp/osp/index.html

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. This includes instructions for reagents, controls, and patient specimen storage. The manufacturer's instructions will give storage conditions for the product and a temperature range for storing reagents, controls, and patient specimens.

Refrigerators and freezers are important for cooling or freezing the test reagents, controls, and patient samples for preservation. Typically, a refrigerator used to store patient samples is kept between +2 and +8 degrees Celsius. A freezer used for sample storage is often kept between -25 and -15 degrees Celsius. The acceptable temperature range for a freezer or refrigerator is determined by the temperature range indicated for the reagents, controls, and patient specimens that are stored in it.

In order to ensure that a refrigerator or freezer is maintaining the proper temperature, it is important to check and record the temperature daily. This applies whether or not the refrigerator or freezer has a temperature alarm, a chart recorder thermometer, or a digital data logger.

Contents:

There are many ways to log the temperature of a refrigerator or freezer. A blank log is included for your use, along with an example log that demonstrates how to correctly enter site specific information.

1. Example Temperature Log Completed.
2. Blank Temperature Log.
3. Example Temperature Log for Multiple Instruments Completed.
4. Blank Temperature Log for Multiple Instruments.

Instructions for Recording Temperatures:

1. Post a temperature log on the refrigerator and/or freezer door.
2. Read the thermometer(s) in the refrigerator and/or freezer daily.
3. Check for separated columns, gas bubbles, and cracks each time the thermometer is read, as applicable.
4. Record the temperature(s) of the refrigerator and/or freezer.
5. Date and initial/sign the temperature log.
6. If a temperature reading is missed, the blank log entry should remain blank. Do not make up or guess what the temperature was for that reading.
7. Document action when the temperature in the refrigerator and/or freezer falls outside the recommended range for storage.
8. The person who directs or supervises the testing should review and sign when the temperature log is completed for the month.

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 55555

TEMPERATURE LOG

Refrigerator/freezer Location lab refrigerator **Month/Year** June 2012

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:** 6/29/2012

Facility:

Location:

TEMPERATURE LOG

Refrigerator/freezer Location_____ **Month/Year** _____

Acceptable temperature range _____

Date	Temperature	Checked by:	Date	Temperature	Checked by:
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

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

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed by: _____ **Date:** _____

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 55555

Temperature Log for Multiple Instruments

Month_____ **Year** _____

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.

Reviewed by: Joe Smith, MD **Date:** 4/31/2012

Facility:

Location:

Temperature Log for Multiple Instruments

Month_____ **Year** _____

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°C Incubator/ (23 to 27°C)																															
37°C Incubator/ (35 to 39°C)																															
Refrigerator/ (2 to 8°C)																															
Freezer/ (-25 to -35°C)																															
Initials																															

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: _____

_____

_____

_____

_____

Reviewed by: _____ **Date:** _____

Appendix B

Common Components of a Manufacturer's Instructions

Component	Information Provided
Intended Use	Describes the test purpose, substance detected or measured, test methodology, appropriate specimen type and FDA cleared conditions for use. Additionally, might include if the test is diagnostic or for screening a target population and if it is intended for professional use or self-testing.
Summary	Explains what the test detects; a short history of the methodology, the disease process or health condition detected or monitored; the response to disease, symptoms and severity and disease prevalence and appropriate references.
Test Principle	A description of the test methodology and technical reactions of the test and the interactions with the sample to detect or measure a specific substance.
Precautions	Alerts the user of practices or conditions affecting the test, potential hazards and safety precautions (toxic reagents, handling infectious samples or biohazardous waste). Warnings to not mix components from different lot numbers or use products beyond the expiration date are often included.
Storage and Stability	The recommended conditions for storing reagents or kits; temperature ranges and other physical requirements (humidity, exposure to light) affecting the stability of reagents or test components.
Reagents and Materials Supplied	A list of reagents and materials included in the test kit, the concentration, and major ingredients in reagents.
Materials Required but Not Provided	A description of any additional materials necessary to perform the test that are not provided with the test kit.
Sample Collection and Preparation	A detailed procedure for collecting the appropriate sample including storage and handling instructions. Conditions affecting the acceptability of the sample may be described.
Test Procedure	Step-by-step instructions and information critical to correctly performing the test are provided in this section.
Interpretation of Results	An explanation of how to read or interpret the test results, often includes visual aids. Instructions for dealing with invalid results, precautions against reporting results when supplementary or confirmatory testing is required.
Quality Control	Instructions for performing QC, what aspects of the test are monitored by internal and/or external QC, and when to perform QC testing.
Limitations	Describes the conditions that can affect test results, or circumstances for which the test was not intended, such as: interference from medical conditions, drugs or other substances; limitations for testing with certain samples or populations; more specific testing may be required; warnings that the test does not differentiate between active infection and carrier states, or warnings that test results should be considered with clinical signs, history and other information.
Expected Values	Describes the test results normally expected, how results can vary with disease prevalence or seasonality. Studies leading to the expected results might be included.
Performance Characteristics	Details of the studies done to evaluate the overall performance of the test, including the data for determining accuracy, precision, sensitivity, specificity and reproducibility are present. Additional information from studies of cross-reactivity with interfering substances is included.

Note: Manufacturer's instructions vary in format and some information may be found in different sections than those described here. Testing site directors and testing personnel should read the information provided in the manufacturer's instructions for an understanding of the test and update their procedures, as needed, based on manufacturer's instructions updates.

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. This includes instructions for quality control (QC).

QC is designed to detect problems that might arise because of reagent or test kit deterioration, instrument malfunction, improper environmental conditions, or operator error. Performing QC testing procedures provides assurance that the test is performing 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 lots are changed,
- when test kit temperatures exceed the manufacturer's limits,
- after calibration, and
- when patient results seem questionable.

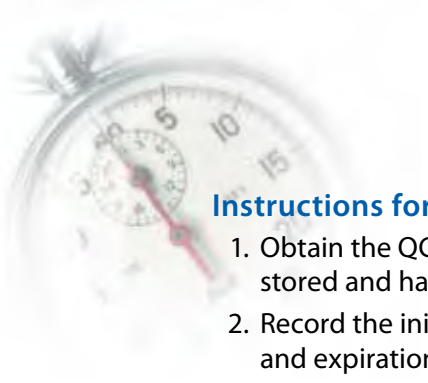
Refer to the manufacturer's instructions for specific QC requirements for each test that your facility performs. Each testing site should determine the appropriate QC frequency for each test system. Keep in mind that the frequency of QC testing cannot be less than what is specified in the manufacturer's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

Contents:

There are many ways to log QC results. A blank QC log is included for your use, along with an example log that demonstrates how to correctly enter site specific information.

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.

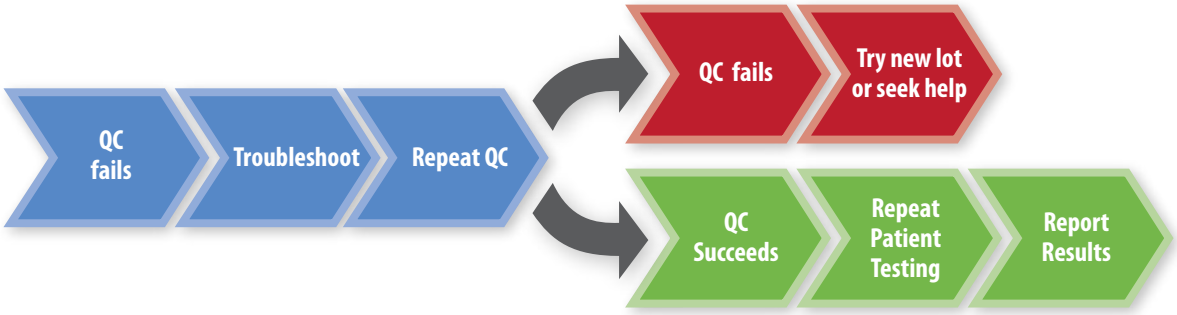
Note: Qualitative tests are interpreted as positive, negative; reactive, non-reactive; or invalid. Quantitative tests give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.



Instructions for Performing External Control Testing and Recording Results:

1. Obtain the QC material. Check the expiration date and check that the material has been stored and handled according to the manufacturer's requirements and instructions.
2. Record the initials of the person performing the test, test date, test name, lot number, and expiration date of the test on the QC Log.
3. Record the lot number for the QC material on the QC Log.
4. Test the QC material following the manufacturer's instructions and record the results on the QC Log.
5. If the results are acceptable, QC passes, and patient results can be reported.
6. If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- ✓ Check to see if the instructions in the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error such as outdated reagents or test devices.
- ✓ Check to see if reagents were stored correctly.
- ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching caps on kit or control vials.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site specific procedure.
- ✓ For additional assistance, contact the manufacturer, technical representative, and/or the person who directs or supervises the testing.
- ✓ Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient samples and report the final acceptable results.



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	5/5/2008	Occult Blood 1-2-3	Bjz-3 / 8-31-2008	lot #: 108-OCB result: Pos*	lot #: 108-OCB result: Pos	lot #: N/A result:	*possible sample mix-up, retest	Joe Smith 5/5/2008
2	CO	5/5/2008	Occult blood 1-2-3	Bjz-3 / 8-31-2008	lot #: 108-OCB result: Neg	lot #: 108-OCB result: Pos	lot #: N/A result:	QC passed and ready to use	Joe Smith 5/5/2008
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:		

Facility:

Location:

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					lot #:	lot #:	lot #:		
					result:	result:	result:		
2					lot #:	lot #:	lot #:		
					result:	result:	result:		
3					lot #:	lot #:	lot #:		
					result:	result:	result:		
4					lot #:	lot #:	lot #:		
					result:	result:	result:		
5					lot #:	lot #:	lot #:		
					result:	result:	result:		
6					lot #:	lot #:	lot #:		
					result:	result:	result:		
7					lot #:	lot #:	lot #:		
					result:	result:	result:		
8					lot #:	lot #:	lot #:		
					result:	result:	result:		
9					lot #:	lot #:	lot #:		
					result:	result:	result:		
10					lot #:	lot #:	lot #:		
					result:	result:	result:		

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	5/5/2012	XYZ ALT	C843 / 4-31-2012	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 5/5/2008
2	CO	5/5/2012	XYZ ALT	C978 / 8-31-2012	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 5/5/2008
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:		

Facility:

Location:

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					lot #:	lot #:		
					range:	range:		
					result:	result:		
2					lot #:	lot #:		
					range:	range:		
					result:	result:		
3					lot #:	lot #:		
					range:	range:		
					result:	result:		
4					lot #:	lot #:		
					range:	range:		
					result:	result:		
5					lot #:	lot #:		
					range:	range:		
					result:	result:		
6					lot #:	lot #:		
					range:	range:		
					result:	result:		
7					lot #:	lot #:		
					range:	range:		
					result:	result:		
8					lot #:	lot #:		
					range:	range:		
					result:	result:		
9					lot #:	lot #:		
					range:	range:		
					result:	result:		

Instructions for Logging or Recording Results

Purpose:

Recording test results legibly, completely, and filing records in an organized, easy to find manner are recommended practices for all testing.

Contents:

There are many ways to record results. A blank Results log is included for your use, along with an example log that demonstrates 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

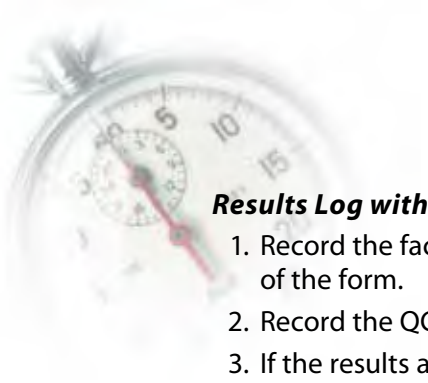
1. Record the facility information and test name on the top of the form.
2. Enter the date of the test, sample number, patient name or identification, test results, lot number and expiration date of test.
3. The person performing the test should initial the results after verifying all of the information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



Results Log with QC – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Record the QC material lot number, reportable range, and result.
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 taken.

Results Log for Multiple Tests

1. Record the facility information on the top of the form.
2. Record the date, sample number, patient identification, test name, reportable range (if applicable), test result, lot number, expiration date, and the initials of the individual performing the test.

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Location: 123 Main Street
Atlanta, GA 55555

Results Log – Qualitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2012	5/5/2018	Donald Smith	NEG	Bd-0679/ 11-30-2013	CO
2	5/6/2012	5/5/2019	Chris White	POS	Bd-0679/ 11-30-2013	CO
3	5/7/2012	5/6/1930	Sam Jones	NEG	Bd-0679/ 11-30-2013	CO
4						
5						
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7						
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9						
10						
11						
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14						
15						

Facility:

Location:

Results Log – Qualitative Test

Test Name:_____

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
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 ALT

Reportable Range: 5-400 U/L

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2012	5/5/2018	Steve Smith	Male: 30 u/L	Bd-0679/ 11-30-2013	CO
2	5/6/2012	5/5/2019	Chris White	Male: 22 u/L	Bd-0679/ 11-30-2013	CO
3	5/7/2012	5/6/1930	Sam Jones	Female: 14 u/L	Bd-0679/ 11-30-2013	CO
4						
5						
6						
7						
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** 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.*

Facility:

Location:

Results Log – Quantitative Test

Test Name:_____ Reportable Range:_____

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
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.*

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	5/5/2012	5-05-20 / Tom Jones	NEG	SH	Bd-0679/ 11-30-2013	108-OCB / 9-30-12	POS	NEG
2	5/6/2012	5-05-22 / Mattie Dunn	NEG	CO	Bd-0679/ 11-30-2013	108-OCB / 9-30-12	POS	NEG
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15								

Facility:

Location:

Results Log with QC – Qualitative Test

Test Name:_____

	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								
2								
3								
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 with QC – Quantitative Test

Test Name: XYZ ALT _____ Reportable Range: 5-400 U/L _____

	Date	Sample ID / Patient ID	Test Results	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1	5/5/2012	5/5/2018 / Steve Smith	Male: 30U/L	CO	C843/06-31-2013	lot #: 91750566 range: 43-78 U/L result: 57 U/L	lot #: 91750566 range: 132-242 U/L result: 203 U/L
2	5/5/2012	5/5/2019 / Chris White	Male: 22U/L	CO	C843/06-31-2013	lot #: 91750566 range: 43-78 U/L result: 58 U/L	lot #: 91750566 range: 132-242 U/L result: 221 U/L
3	5/7/2012	5/5/1930 / Sam Jones	Female: 14U/L	CO	C843/06-31-2013	lot #: 91750566 range: 43-78 U/L result: 57 U/L	lot #: 91750566 range: 132-242 U/L result: 221 U/L
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:

** 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.*

Facility:

Location:

Results Log with QC – Quantitative Test

Test Name:_____ Reportable Range:_____

	Date	Sample ID / Patient ID	Test Results	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1						lot #:	lot #:
						range:	range:
						result:	result:
2						lot #:	lot #:
						range:	range:
						result:	result:
3						lot #:	lot #:
						range:	range:
						result:	result:
4						lot #:	lot #:
						range:	range:
						result:	result:
5						lot #:	lot #:
						range:	range:
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6						lot #:	lot #:
						range:	range:
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7						lot #:	lot #:
						range:	range:
						result:	result:
8						lot #:	lot #:
						range:	range:
						result:	result:
9						lot #:	lot #:
						range:	range:
						result:	result:

** 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.*

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	5/5/2012	5/5/2018	Donald Smith	XYZ Strep	NA	NEG	Bd-0679/11-30-2012	CO
2	5/5/2012	5/5/2019	Chris White	XYZ Strep	NA	POS	Bd-0680/11-30-2012	CO
3	5/5/2012	5/5/2020	Tom Jones	Occult blood - 123	NA	NEG	Bjz-3/8-31-2013	SH
4	5/5/2012	5/5/2021	Pam Roberts	Urine HCG-ABC	NA	NEG	Trp-23/11-30-2012	CO
5	5/6/2012	5/5/2022	Mattie Dunn	Occult blood - 123	NA	NEG	Bjz-3/8-31-2013	CO
6	5/6/2012	5/5/2023	Steve Smith	XYZ ALT	5-400 U/L	Male : 33 U/L	C843/6-31-2013	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.*

Facility:

Location:

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								
2								
3								
4								
5								
6								
7								
8								
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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.*

Hand Hygiene Job Aid

The use of disposable gloves does not eliminate the need for cleaning hands. Likewise, handwashing does not eliminate the need for gloves. In order to ensure proper hand hygiene when performing testing, handwashing or alcohol-based gels should be used before and after each patient, just as gloves should be changed between each patient.

Hand Washing Steps

If a hand washing sink is available:

1. Wet hands with warm running water.

2. Apply soap and rub hands together, covering all surfaces of hands and fingers, for at least 20 seconds.

3. Rinse hands and dry with disposable towel.

4. Use disposable towel to turn off the faucet and discard in the regular trash.

If a hand washing sink is not available:

1. Use an alcohol-based gel.
2. Follow manufacturer's instructions to determine the amount of alcohol-based gel to use.
3. Apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.
4. Wash hands with soap and water as soon as possible.

Blood/Body Fluid Exposure

It is important to use universal precautions when cleaning up blood or body fluids. Always assume and act as if they are contaminated.

If your hands have been exposed to blood or body fluids:

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.
3. Rinse hands and dry with disposable towel.
4. Use disposable towel to turn off faucet.
5. Before leaving area, decontaminate sink and faucet handles using 10% bleach or Environmental Protection Agency (EPA) registered disinfectant effective against HBV, HIV, and other bloodborne pathogens.

If mucous membranes or eyes have been exposed to blood or body fluids:

1. Rinse mucous membranes (for example, nose or mouth) or eyes with large amounts of water or saline solution.
2. If running water is not readily available, use another source of water (for example, bottled water) to rinse.

If there is a puncture of skin from a sharp instrument or needle:

1. Wash the puncture with soap and water while encouraging the puncture to bleed (through squeezing if necessary).
2. Bandage the puncture when finished.

Report exposure:

1. Report any exposures to those responsible for managing exposures (for example, occupational health, infection control, management). Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and needs to 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.

Glove Removal Job Aid

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 requirements of the task being performed. Rings, long fingernails, and fingernail jewelry can make it more difficult to put the gloves on properly and can also cause gloves to tear more easily.

To help prevent allergic reactions to latex gloves:

- Do not use oil-based hand creams or lotions when wearing latex gloves.
- Wash hands with a mild soap and dry thoroughly after removing gloves.
- Do not use powdered latex gloves.

For additional latex allergy information: http://www.cdc.gov/niosh/topics/latex

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 as well as before leaving the work area.
- Remove contaminated gloves using a procedure that avoids contact with the outer surface of the glove.
- Dispose of contaminated gloves in infectious waste containers in the work area.
- Wash hands immediately or as soon as possible after removal of gloves.

Procedure for Removing Gloves Safely

1. With the right hand, pinch the palm of the left glove and pull left glove down and off your fingers.

2. Form left glove into a ball and hold it in the fist of your right hand. Insert two fingers of the left hand under the inside rim of your right glove on the palm side.

3. Push glove inside out down onto your fingers and over balled left glove. Grasp gloves, which are inside out and together, with your left hand and remove them from your right hand.

4. Discard gloves into infectious waste container and wash hands.

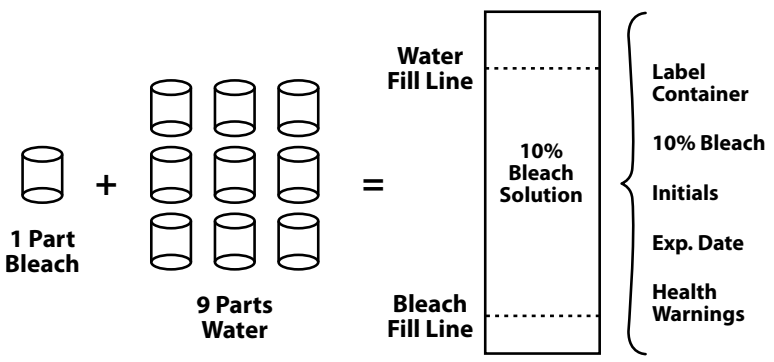
Appendix E

Common Disinfectants and Antiseptics

Note: Any mention of trade names is for identification purposes only and is not intended as an endorsement. Proprietary disinfectant products should be used in accordance with the manufacturer's instructions for concentration, contact time, or other conditions of use.

Selected EPA-registered disinfectants: A list of EPA's registered sterilizers, tuberculocides, and antimicrobial products against certain bacteria and viruses can be found at: http://www.epa.gov/oppad001/chemregindex.htm

1. **Chlorine compounds** are powerful disinfectants that are inexpensive and easy to obtain. Sodium hypochlorite or household chlorine bleach solutions possess intermediate-level disinfectant properties. 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 referred to as 1/10, 1:10 or 5,000 ppm bleach solution. The directions for preparation are:

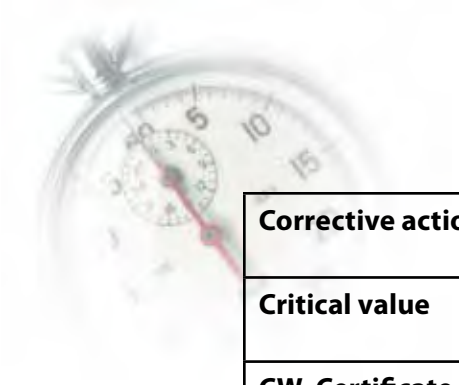


Note: bleach will corrode some equipment. Refer to manufacturer's recommendations for cleaning and disinfecting procedures.

2. **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.
3. **Commercial Products.** The EPA provides a list of 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).

Terms and Abbreviations

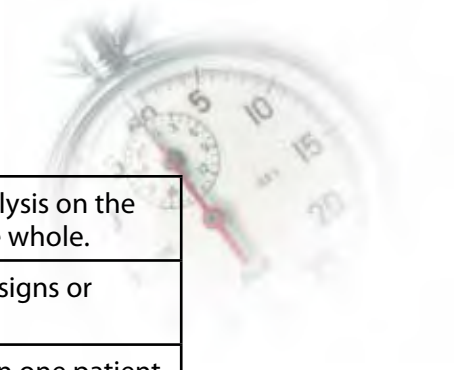
Anticoagulated blood	Blood that has been treated with an anticoagulant. Anticoagulant solutions are used for the preservation of stored whole blood and blood fractions and to keep laboratory blood specimens from clotting.
Biohazard	A biologic substance that can have harmful effects on humans.
Biohazardous waste	Biohazard or sharps waste and waste that is generated or produced as a results of the diagnosis, treatment, or immunization of humans. Environmental laws dictate appropriate, safe disposition of hazardous waste. Refer to applicable federal, state, and local laws.
Biosafety	The application of practices, procedures and safety equipment when working with infectious materials to prevent infection.
Bloodborne pathogens	Microorganisms that, when present in human blood, can cause disease in humans. Examples are hepatitis B and C viruses, and human immunodeficiency virus (HIV).
Calibration check	The process of testing and adjusting an instrument or test system to provide a known relationship between the value of the substance being measured by the test and the test system's measurement response. A calibration check is a mechanism to be sure the test system has remained stable and results remain accurate.
CDC, The Centers for Disease Control and Prevention	A federal agency under the department of Health and Human Services (HHS) that works with partners throughout the nation and world by collaborating to create the expertise, information, and tools that people and communities need to protect their health — through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.
CLIA, The Clinical Laboratory Improvement Amendments of 1988	United States federal regulatory standards that set forth the conditions that all laboratories must meet to be certified to perform testing on human samples.
CMS, The Centers for Medicare and Medicaid	A federal agency under HHS that has the administrative responsibility for the CLIA program.
Collection devices	A container or instrument used for the collection of samples for testing or analysis.
Competency assessment	The evaluation of a person's ability to perform a test and to use a testing device; this includes all aspects of testing, from sample collection to results reporting.
Confirmatory test	An additional more specific test performed to rule out or confirm a preliminary test result to provide a final result.
Control	A device or solution used to monitor a test system to ensure proper test performance and correct results.



Corrective action	A method used to remedy a situation, remove an error, adjust a condition, or prevent recurrence of a problem.
Critical value	A test result requiring immediate notification to the clinician for patient evaluation or treatment.
CW, Certificate of Waiver	A certificate issued or reissued by the Centers for Medicare & Medicaid Services to a testing site performing only waived tests.
Diagnostic test	Tests likely to provide information which aids in the making of a diagnosis.
Disinfectant	An agent that destroys microorganisms that may cause disease.
EPA, The Environmental Protection Agency	The United States government agency with the mission of protecting human health and the environment.
External control	Control materials that mimic patient samples and monitor the testing process from sample application to result interpretation.
External quality assessment	A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification, whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others.
False negative test result	A false negative result is when the test says the patient does not have a disease or condition but they do.
False positive test result	A false positive result is when the test says the patient does have a disease or condition but they do not.
FDA, The Food and Drug Administration	A federal agency under HHS that is responsible for regulating and supervising the safety of biological and medical products and devices as well as categorization of tests under CLIA, including waiver.
Fingerstick	A procedure in which a finger is pricked to obtain a small quantity of capillary blood for testing. Also called a finger prick.
Good laboratory practices	A technique, method, process, activity, incentive or reward that is believed to be more effective at delivering a particular outcome than any other technique, method, or process.
HHS, The Department of Health and Human Services	The United States government's principal agency for protecting the health of all Americans and providing essential human services.
HIPAA, Health Insurance Portability and Accountability Act of 1996	The Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes.
Interfering substance	Any substance in a sample, other than the one being measured or detected, whose presence affects the result of the test being performed.

Internal control	Procedural or built-in controls; controls that are built into a testing device and designed to verify that the test system is working as expected.
Kit	A packaged set containing test devices, instructions, reagents and supplies needed to perform a test and generate results.
Log	A record documenting the performance of a machine, the progress of an undertaking, or the results of a task.
Lot	A specific group of articles in a kit. Each article may have a number that can be used as a reference for manufacturing information.
Manufacturer's instructions	Written product information usually supplied by the manufacturer with each test kit or test system containing instructions and critical details for performing the test.
Nasopharynx	The area of the upper throat that lies behind the nose.
N, Neg, Negative	A result that indicates the absence of the substance a test is designed to detect.
Negative control	A device or solution used to monitor a test system for proper test performance and correct results. A negative control sample or reagent will produce a negative result on the test system.
NR, Nonreactive	A result that indicates the absence of the substance a test is designed to detect.
Order (test)	A written or verbal request by an authorized individual for a test or procedure to be performed on a patient.
OSHA, The Occupational Safety and Health Administration	The United States government agency with the mission to assure safe and healthful working conditions for all men and women. Workplace standards established and enforced to prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules for workplace safety and health.
POC, Point of Care	The analysis of clinical specimens as close as possible to the patient.
P, Pos, Positive	A result indicating the presence of a substance a test is designed to detect.
Patient identifiers	The method used to reliably identify the individual as the person for whom the service or treatment is intended, and to match the service or treatment to that individual. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier.
Positive control	A device or solution used to monitor a test system for proper test performance and correct results. A positive control sample or reagent will produce a positive result on the test system.
PPE, Personal protective equipment	Specialized clothing or equipment worn by an employee for protection against a hazard. Examples of PPE are gloves, respirators, lab coats, and safety glasses.

Pretest instructions	Information provided that should be read and followed before testing begins.
Procedure	A fixed, step-by-step sequence of activities or course of action (with definite start and end points) that must be followed in the same order to correctly perform a task.
Processing (sample)	Any type of treatment a sample undergoes before testing such as spinning of whole blood.
PT, Proficiency testing	An external quality assessment program in which samples are periodically sent to testing sites for analysis.
Public health reporting	A system to notify public health agencies and to monitor the incidence and distribution of communicable, environmental, occupational and other dangerous disease occurrences in populations, as well as factors determining that distribution.
QA, Quality assessment	A group of activities to monitor and evaluate the CW site's entire testing process to help ensure that test results are reliable, improve the testing process, and promote good quality testing practices.
QC, Quality control	The procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time.
Qualitative test	A test that detects the presence or absence of a substance or condition in a sample.
Quantitative test	A test that measures the concentration or amount of a substance present in a sample. Results are numerical.
Quick reference instructions	Cards or small signs containing diagrams or flow charts with essential steps for conducting a test that are often included with waived test systems.
R, Reactive	A result indicating the presence of a substance detected by a test.
Reagent	A substance that produces a chemical or biological reaction with the patient sample to detect or measure the substance or condition determined by the laboratory test.
Record	Anything (such as a document, form, log book) providing permanent evidence of or information about past events.
Referral laboratory	A laboratory that receives samples from CW sites (and other laboratories) to perform additional testing, often for follow-up confirmatory testing. The majority of referral laboratories perform nonwaived testing.
Report (test)	A document describing the result or findings of a test.
Reportable range	The span of test result values for which the instrument or test device can accurately measure.
Request (test)	A written or verbal order by an authorized individual for a test or procedure to be performed on a patient.



Sample	A specimen of fluid, blood or tissue collected for analysis on the assumption that it represents the composition of the whole.
Screening test	Tests used to detect a disease in individuals without signs or symptoms of that disease.
Single-use device	A device intended by the manufacturer to be used on one patient during one procedure.
Supplemental testing	A test performed that increases the reliability of reported test results or provides additional information about the sample.
Temperature range	The numerical difference between the minimum and maximum values of temperature observed in a system.
Test system	The instructions and all the instrumentation, reagents and supplies needed to perform a test and generate results.
Testing site	The location where testing is actually conducted. In some instances, laboratories do not stay at a fixed location (e.g., mobile units providing laboratory testing, health screening fairs, or other temporary testing locations). In these cases, the testing site for the laboratory is where the test is performed.
Universal Precautions	An approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bacteria and viruses.
Unprocessed samples	Samples that are not subjected to any type of treatment prior to testing such as centrifugation of whole blood.
Venipuncture	The puncture of a vein through the skin in order to withdraw blood for analysis.
Verbal report	An oral documentation describing the findings of a test or assay.
WT, Waived testing	Test systems, assays or examinations that have been cleared by the FDA for home use, or have been determined to meet the CLIA criteria of being a simple test with an insignificant risk for an erroneous result.
Whole blood	Blood containing all its cellular components that has not undergone centrifugation or had the plasma removed.

For additional information go to: www.cdc.gov/dls/waivedtests

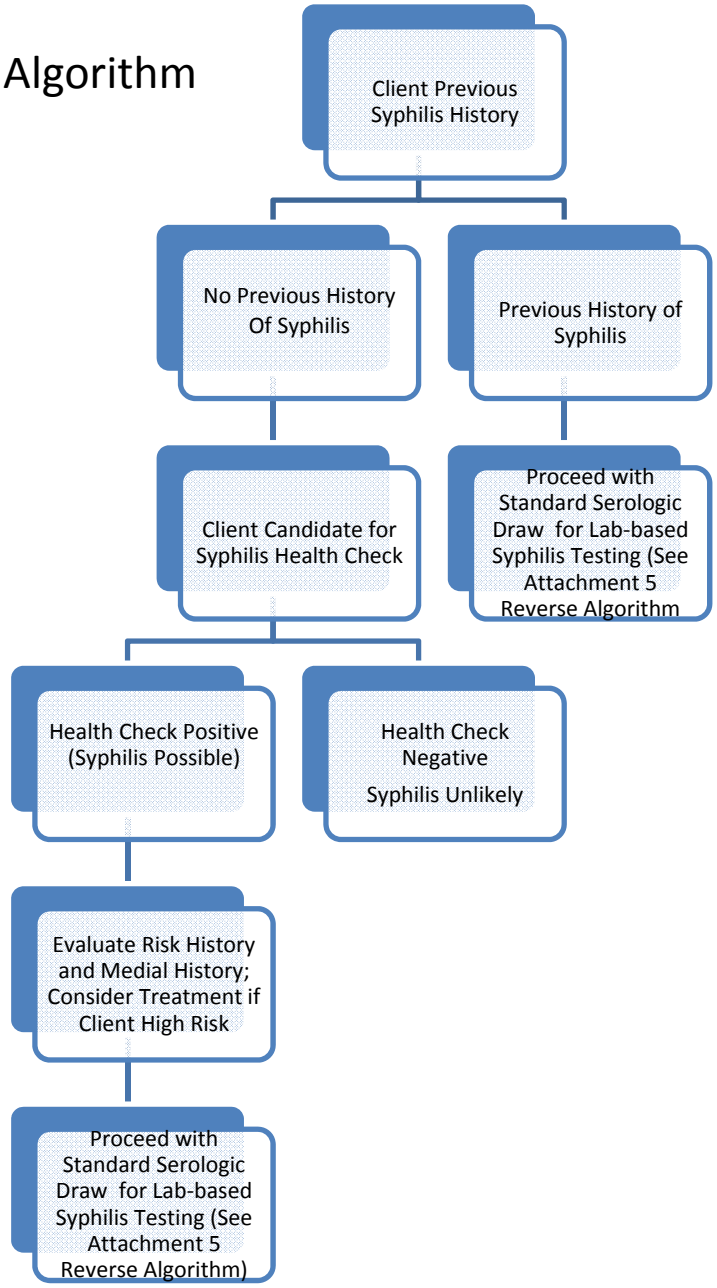
Contact the Division of Laboratory Science and Standards at WaivedTesting@cdc.gov

or by calling 404-498-2290.

March 2011

ATTACHMENT 4
SUGGESTED SYPHILIS HEALTH CHECK
TESTING ALGORITHM

Syphilis Health Check Test Algorithm

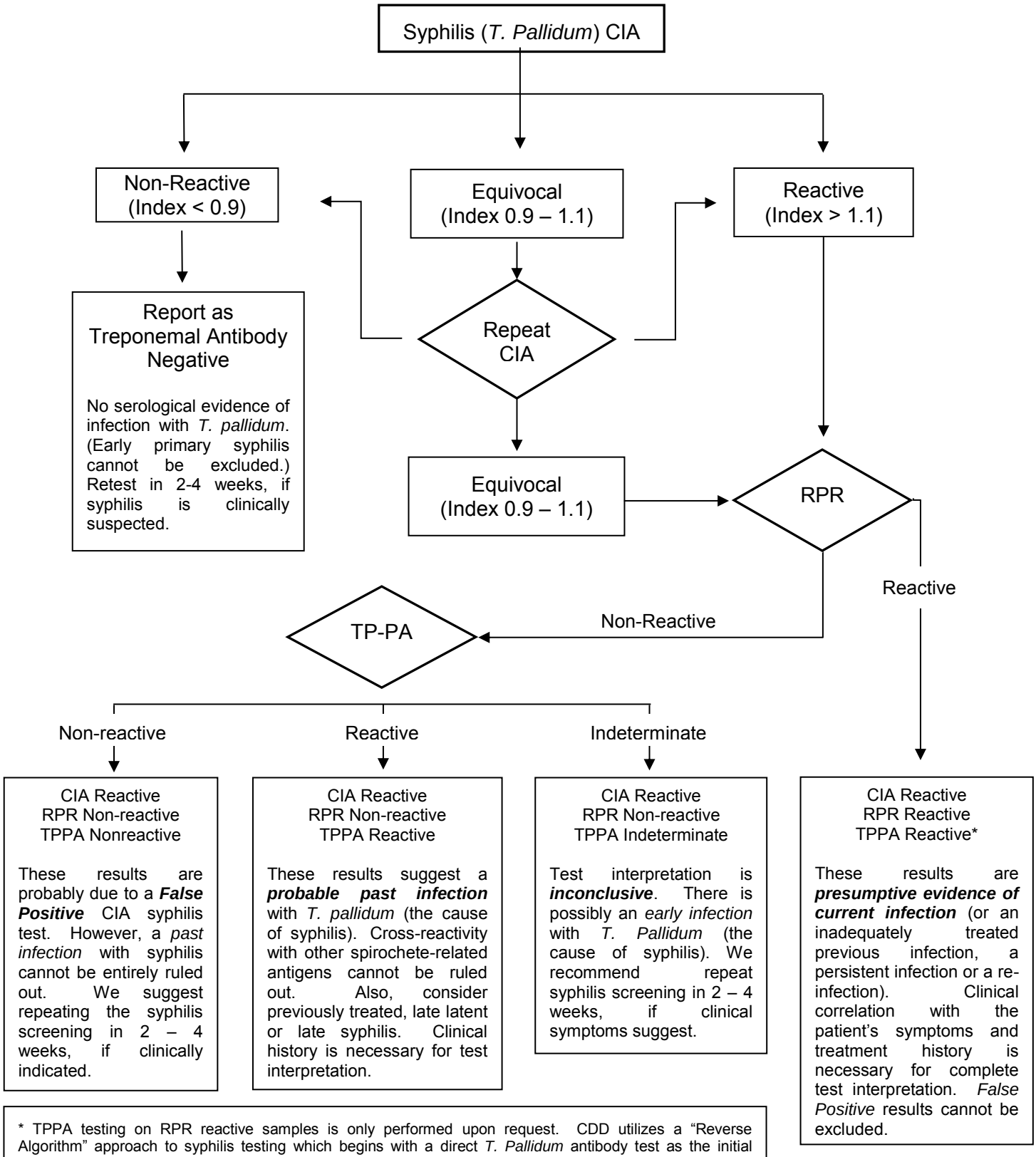


pennsylvania
DEPARTMENT OF HEALTH

Trinity Biotech

ATTACHMENT 5
LAB-BASED SYPHILIS
TESTING ALGORITHM (REVERSE ALGORITHM)

Title: Syphilis Testing Algorithm (Reverse Algorithm)	Number: AL0126.04.A



* TPPA testing on RPR reactive samples is only performed upon request. CDD utilizes a "Reverse Algorithm" approach to syphilis testing which begins with a direct *T. Pallidum* antibody test as the initial screening test. This algorithm is consistent with the guidelines established by the Centers for Disease Control and Prevention (CDC), published in MMWR 60(5), February 11, 2011