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SECTION 1: INTRODUCTION

Waived testing is an integral part of the everyday care for tens of thousands of our patients. Physicians, nurses, allied health professionals and even patients themselves use the results of these tests to monitor and screen for a variety of medical conditions including diabetes, hematology disorders and infectious diseases. In doing so, waived testing has allowed laboratory medicine to transcend its traditional setting and become a significant part of patient care.

Although the federal government has imposed requirements for facilities that perform waived testing, the findings from the CMS surveys and CDC-funded studies indicate that most laboratory directors and testing personnel did not have formal laboratory training or testing experience. In addition, there was a high turnover of personnel and some waived testing sites were determined to be performing testing that was an imminent and serious threat to the public’s health because they were performing non-waived testing in the absence of CLIA-required quality measures.¹

COLA developed this procedure manual for waived testing sites to help them understand and comply with CLIA regulations. This manual is intended to ensure the use of Good Laboratory Practices among all individuals performing waived testing. Whether you are teaching a patient to perform their own testing or performing the testing yourself, this manual will guide you through the fundamentals of waived testing. We will start by introducing you to government requirements, providing guidance for proper specimen collection and test performance and documenting inventory, quality control and patient results. Each section will identify specific statistics from the 2005 MMWR report and specify COLA resources to help you avoid those pitfalls.

By implementing these recommendations, waived testing sites can improve quality, reduce testing errors, and enhance patient safety. COLA believes that waived testing is an effective aid in patient care when correctly performed and recorded. Using the COLA Waived Procedure Manual is the first step to assure the public that your results can be used in determining the appropriate diagnosis and treatment. By following this simple approach, you will be making a significant difference in someone’s life.

Sincerely,

Douglas A. Beigel
Chief Executive Officer
COLA

SECTION 2: GOVERNMENT REQUIREMENTS AND GENERAL REQUIREMENTS

What are Waived Tests?
Laboratory tests are categorized as “waived” or “non-waived” by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These are the federal regulations that establish the minimum acceptable criteria that must be adhered to by medical laboratories.

Waived tests are laboratory tests that:
• Are simple to use
• Have easy to follow procedures
• Provide accurate results

The Food and Drug Administration (FDA) determines which tests are approved as waived. The list of waived tests continues to grow as new tests are developed and approved.

If you are unsure whether or not your test system is waived, then research the tests online at the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

Can Anyone Perform Waived Tests?
There are no personnel requirements to perform waived tests, but your facility must obtain a CLIA Certificate of Waiver before performing any testing. It is also important to assure competency of any individual performing waived testing. Using the current package insert and some simple processes can help assure competency of the individual performing waived testing.

Federal Regulations:
For waived testing, CLIA requires that you:
• Enroll in the CLIA program by obtaining a Certificate of Waiver;
• Pay the certificate fee every two years;
• Follow the manufacturers instructions for the waived tests you are performing;
• Notify your State agency of any changes in ownership, name, address and/or director within 30 days, or if you wish to add tests; and
• Permit inspections by a CMS agent, such as a surveyor from the State agency. These are random and generally unannounced.

STATE AND LOCAL REGULATIONS:
States and local jurisdictions vary as to the extent to which they regulate laboratory testing. Some states and localities have specific regulations for testing, some require licensure of personnel who perform testing, and some have phlebotomy requirements. State and local jurisdictions often regulate biohazard safety, including handling and disposal of medical waste. The person responsible for testing oversight should ensure that all state and local requirements are met. These requirements might be more or less stringent than federal requirements. When state or local regulations governing laboratory testing are more stringent than the federal CLIA requirements, they supersede what is required under CLIA.

The State Regulatory Database is available at COLAcentral.

JOINT COMMISSION REGULATIONS:
Some hospitals, practices associated with integrated healthcare delivery systems, clinics, and/or physician offices are accredited by The Joint Commission. COLA partners with The Joint Commission to improve laboratory medicine and patient care. You can find specific requirements for The Joint Commission in the current version of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing. The COLA Waived Procedure Manual will help any Joint Commission affiliated lab by supporting compliance with the following general guidelines:

• Lab Director ensures adequate policies and procedures to determine how waived testing will be used for patient testing.
• Lab Director determines the testing and supervisory staff.
• Staff complete orientation and training for testing, and are able to show that they have maintained competency.
• Policies and procedures are up-to-date, approved and available to staff.
• Quality Control is completed for each test procedure.
• All records for quality control and patient results are retained.

What Should I Do to Get Started?
In order to begin waived testing, laboratories must ensure the following conditions are met:

Certificate of Waiver
Laboratories must submit a completed CMS-116 form to the Centers for Medicare and Medicaid Services (CMS), including applicable fees, to apply for a Certificate of Waiver. The certificate is valid for two years and allows a laboratory to conduct only waived testing. CMS will bill your laboratory for certificate renewal fees every two years.

Manufacturer’s Instructions
It is a requirement for waived testing that laboratories follow the manufacturer’s instructions as written in the package insert, including all maintenance and quality control instructions. At times, this may include performing confirmatory testing for screening tests, such as Rapid Strep A. In order to ensure compliance with the manufacturer’s current instructions, it is important to review, maintain and follow the latest version of the package insert.
Proficiency Testing (PT)
Proficiency Testing (PT) is not a federal requirement for waived testing, but your state guidelines may require external validation, which includes enrollment in proficiency testing program. Contact your state survey agency to determine if any of the waived tests you perform require PT.

PT serves as an external check to verify the accuracy of your laboratory's test results by providing unknown specimens for you to analyze. It is an important aspect of a laboratory’s overall assessment of quality. While it is not a current requirement of the federal program, laboratories gain significant information about their performance as a result of participation in a proficiency testing program. Generally, proficiency testing is seen as an important part of a laboratory’s quality assessment program, and economical modules are available specifically for waived tests.

To perform proficiency testing, enroll with a PT provider and pay applicable fees. The PT provider will send specimens periodically throughout the year. These specimens are to be treated the same as patient specimens; however, it is important to ensure that all PT specimens are prepared, tested and reported according to the PT provider instructions which will accompany all shipments.

A list of PT providers is available at COLAcentral.

SECTION 3: TESTING CHECKLISTS
Any tests you perform deserve your best effort since the results of those tests may be used to make decisions about the patient’s diagnosis and/or treatment. We have already stated that federal regulations require that you follow all of the manufacturers instructions exactly. However, your efforts should not stop there. There are common practices utilized throughout laboratory medicine that help ensure accurate and reliable test results. These are known as Good Laboratory Practices (GLP) and are addressed in the following table. The table also identifies resources available through COLA to help you design a laboratory operations program which allows you to maintain compliance effortlessly.

<table>
<thead>
<tr>
<th>Good Laboratory Practice</th>
<th>COLAcentral Resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide initial and ongoing training to staff and maintain training records.</td>
<td>COLAcentral Education and Training</td>
</tr>
<tr>
<td>Evaluate the competency of staff and maintain competency assessment records.</td>
<td>COLAcentral Education and Training</td>
</tr>
<tr>
<td>Create an equipment/test kit list and maintain records according to the manufacturer’s</td>
<td>COLAcentral Lab Operations Module</td>
</tr>
<tr>
<td>instructions for maintenance logs, temperature logs and quality control.</td>
<td></td>
</tr>
<tr>
<td>Monitor compliance with applicable government requirements and Good Laboratory Practices</td>
<td>COLAcentral Lab Operations Module</td>
</tr>
<tr>
<td>through documented quality assessment reviews to evaluate and improve lab functions.</td>
<td></td>
</tr>
<tr>
<td>Consider enrolling in proficiency testing (PT) as an extra check for test accuracy.</td>
<td>COLAcentral Proficiency Testing</td>
</tr>
<tr>
<td>Report problems with reagents and tests to the manufacturer and/or the FDA.</td>
<td>COLAcentral FDA Reporting</td>
</tr>
</tbody>
</table>

The COLA Waived Procedure Manual
The COLA Waived Procedure Manual is a reference to help you maintain regulatory compliance as well as understand and follow Good Laboratory Practices. The COLAcentral website also acts as a great resource to maintain compliance with applicable regulations by providing a Document Repository to upload lab documents. It offers a Lab Operations module to record and monitor equipment, inventory, environmental conditions and quality control.

The following information will help support compliance with Good Laboratory Practices (identified by italicized font) for all testing phases, as well as CLIA regulations. By clicking on the information icons, you can review statistics from the 2005 MMWR report.

**Pre-Testing Checklist**

The pre-testing phase includes the test order, patient identification and preparation and the collection, labeling, handling, storage and transport of specimens prior to testing being performed.

<table>
<thead>
<tr>
<th>Pre-testing checklist</th>
<th>COLAcentral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Orders, Patient Identification, and Preparation</strong></td>
<td>Document Repository</td>
</tr>
<tr>
<td><strong>Test Orders:</strong></td>
<td>Specimen Collection Procedures</td>
</tr>
<tr>
<td>• Routinely confirm that the written test order is correct.</td>
<td></td>
</tr>
<tr>
<td>• If there is a question, check with the ordering clinician.</td>
<td></td>
</tr>
<tr>
<td>Standing orders for certain tests might apply, but they should be documented and confirmed.</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Identification:</strong></td>
<td></td>
</tr>
<tr>
<td>• Before collecting the specimen, confirm the test(s) ordered and the patient's identification.</td>
<td></td>
</tr>
<tr>
<td>Names can be similar and lead to confusion, use birth dates, middle initials, identification numbers, or other means to ensure the specimen is collected from the correct patient.</td>
<td></td>
</tr>
<tr>
<td>• Verify any pretest instructions or information such as fasting requirements and timed tests.</td>
<td></td>
</tr>
<tr>
<td>• Label all specimens with the patient's first and last name as well as another unique patient identifier.</td>
<td></td>
</tr>
<tr>
<td>• Ensure the patient’s specimen can be identified throughout all phases of testing, in order to prevent sample mix-ups.</td>
<td></td>
</tr>
<tr>
<td>• In other words, if the sample is transferred into an instrument cartridge or other device, or is placed on a slide, the cartridge or slide is labeled with the unique identifier.</td>
<td></td>
</tr>
<tr>
<td><strong>Specimen collection and handling:</strong></td>
<td></td>
</tr>
<tr>
<td>• The manufacturer’s procedures are included with each test procedure and are to be followed by all staff that perform these duties.</td>
<td></td>
</tr>
<tr>
<td>• Collect specimens in the correct containers.</td>
<td></td>
</tr>
<tr>
<td>• Follow the proper “order of draw” if more than one specimen is to be collected.</td>
<td></td>
</tr>
<tr>
<td>• If a delay in testing occurs or transport is necessary, follow the specified specimen storage/transport procedures written in the package insert.</td>
<td></td>
</tr>
<tr>
<td>• In the event that a specimen is unusable for the test ordered, immediately inform the physician so a decision to re-collect the specimen can be made in a timely fashion.</td>
<td></td>
</tr>
</tbody>
</table>

Supply Inventory:

- Keep track of the kits and supplies you have on hand and ensure that kits and reagents are not used beyond their expiration dates.

Lab Operations
Testing Checklist
The testing phase includes staff education and competency, laboratory policies and standard operating procedures, equipment maintenance and calibration, proficiency testing, quality control and specimen testing.

<table>
<thead>
<tr>
<th>Testing checklist</th>
<th>COLAcentral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff Education Training and Competency</strong></td>
<td>Education/Resources</td>
</tr>
<tr>
<td>• Ensure that all testing staff have read all current package inserts prior to performing any patient testing.</td>
<td></td>
</tr>
<tr>
<td>• Ensure that all testing staff are properly trained prior to performing any patient testing.</td>
<td></td>
</tr>
<tr>
<td>• Ensure that staff demonstrate competency. Competency should be assessed at least annually.</td>
<td></td>
</tr>
<tr>
<td><strong>Equipment Maintenance and Calibration</strong></td>
<td>Lab Operations, Document Repository</td>
</tr>
<tr>
<td>• Perform according to the manufacturer’s instructions.</td>
<td></td>
</tr>
<tr>
<td>• Document and retain maintenance and calibration records including any manufacturer-performed service records.</td>
<td></td>
</tr>
<tr>
<td><strong>Proficiency Testing</strong></td>
<td>Document Repository, PT Event Results</td>
</tr>
<tr>
<td>• Rotate among all staff.</td>
<td></td>
</tr>
<tr>
<td>• Treat PT specimens in the same way as patient specimens.</td>
<td></td>
</tr>
<tr>
<td>• Do not share PT specimens with other testing sites.</td>
<td></td>
</tr>
<tr>
<td>• Do not communicate results with other testing sites.</td>
<td></td>
</tr>
<tr>
<td>• Always submit results prior to the deadline.</td>
<td></td>
</tr>
<tr>
<td><strong>Package Insert: Each section of the Package Insert is described below.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Document Repository</td>
</tr>
<tr>
<td>Describes the test purpose, the substance being detected or measured, test methodology, appropriate specimen type and the FDA approved/cleared conditions for use. Might address whether the test is to be used for diagnosis or screening the test population and whether it is for professional use or self-testing.</td>
<td></td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td>Document Repository</td>
</tr>
<tr>
<td>Explains what the test detects and a short history of the methodology, including the disease process or health condition being detected.</td>
<td></td>
</tr>
<tr>
<td><strong>Test principle</strong></td>
<td>Document Repository</td>
</tr>
<tr>
<td>States the methodology used in the test. Details the technical aspects of the test and explains how components of the test system interact with the patient specimens to detect or measure a specific substance.</td>
<td></td>
</tr>
<tr>
<td><strong>Precautions</strong></td>
<td>Document Repository</td>
</tr>
<tr>
<td>Alerts the user of practices or conditions that might affect the test and warns the user of potential hazards. Document Repository</td>
<td></td>
</tr>
</tbody>
</table>

**Storage and stability**
Specifies conditions for storing reagents and test systems to protect their stability including recommended temperature ranges and physical requirements (i.e. protect from light). Also address the stability of reagents and test systems when opened or after reconstitution. Provides indications for reagent deterioration.

- Some tests have specific environmental requirements (described in the manufacturer’s product insert) that need to be met to ensure reliable test results. Meeting these environmental conditions can be challenging in nontraditional settings (e.g., health fairs or community outreach venues (e.g., shopping malls, meeting rooms, parks, parking lots, mobile vans, and buses). Factors to consider include:
  - Humidity: Unusually high, low, or extreme fluctuations in humidity can cause deterioration of reagents and test components, affect the rate of chemical reactions and specimen interaction, or make test endpoints blurred and difficult to read.
  - Temperature: Temperature ranges for storage of test components and controls and for test performance are defined by the manufacturer to maintain test integrity. Extreme temperatures can degrade reagents and test components, impact reaction times, cause premature expiration of test kits, and affect the test results.
  - Stability: Check and record expiration dates. Do not use expired reagents or kits.

**Reagents and materials included**
Lists reagents and materials supplied with the test system.
- Check and record lot numbers for test kits, test devices and controls.
- Do not mix reagents from different products or lot numbers.
- If using a new lot or shipment, set up quality control as needed and refer to product insert for any changes in control ranges.

**Reagents and materials needed**
Lists reagents and materials needed to perform the tests which are not included with the test system.

**Specimen collection and preparation**
Defines the specimen collection, handling, storage and stability instructions including appropriate collection devices. May address conditions for specimen acceptability.
**Test procedure**

Provides step by step instructions on how to perform the test.
- Use the current package insert. When each new lot or shipment is received, verify that the package insert has not changed.
- Testing should be performed in a separate designated area where adequate space is available. Work space should be adequate in size for patient confidentiality, ease of specimen collection, test performance, and storage of supplies and records.
- Clean work surfaces and remove clutter or trash. Work surfaces should be stable and level and be able to be adequately disinfected.
- Ensure adequate lighting. Inadequate lighting can negatively affect specimen collection, test performance, and interpretation of test results.
- Check the product insert and exterior labeling on kits and reagents for changes.
- Inspect equipment and electrical connections for integrity.
- If the test system incorporates internal calibration steps that need to be checked before testing, conduct the calibration check or set the test system as specified by the manufacturer.
- Visually inspect reagents or vials for damage, discoloration, or contamination.
- Prepare reagents according to instructions. If opening new reagents, write the date opened on the outside of the vial or test kit.

**Interpretation of results**

Describes how to read and interpret test results and often provides visual aids.
- Pay attention to timing for waived tests, particularly test devices that must be read during specific time intervals. Incorrect timing of these types of tests can give erroneous test results.
- Insufficient timing can result in false negative or invalid results because the specimen might not react completely with test system reagents.
- Time intervals longer than those specified in the product insert can result in false positive, false negative, or invalid results because of exaggerated color development, fading of reaction products, or migration beyond a visible range. Therefore, it is important to have a system established to read results during the correct timeframe, especially if conducting more than one test at a time.
- Suggestions for helping to ensure correct timing of tests include using timers that beep until turned off, using timers that can easily be worn or attached to clothing, using multiple timers when performing more than one test at a time, and maintaining extra timers and batteries.

**Quality Control**

Explains what aspects of the test system are monitored by QC procedures and how to perform QC tests.
- Test controls at the frequency determined by the manufacturer.
- Integrate control procedures with the steps for performing patient testing to assure control testing is performed.
- Evaluate quality control results for acceptability prior to performing patient tests.
- Take corrective action as indicated by the manufacturer to resolve unacceptable quality control results.
- Maintain documentation of all quality control results and corrective actions.

**Limitations**

Describes conditions that might influence the test results or for which the test is not designed. Limitations could include:
- Possible interferences from medical conditions, drugs, or other substances.
- Warning that the test is not approved for use with alternate specimen types or in alternate populations (e.g., pediatric).
- Indications of the need for additional testing that might be more specific or more sensitive.
- Warning that the test does not differentiate between active infection and carrier states.
- Statement that the test results should be considered in the context of clinical signs and symptoms, patient history, and other test results.

**Expected results**

Describes the test results the user should expect.
- Quantitative: Tests that provide numerical results generated by the test device or instrument. Numerical results are values corresponding to the concentration of the specific substance being measured. The value includes specific measurement units (e.g., such as a glucose result of 100 mg/dL). No interpretation is necessary to read the result.
- Qualitative: Tests that detect whether a particular substance, condition, or microbiological organism is present or absent. Results are interpreted as positive/reactive, negative/nonreactive, or invalid. Invalid results might indicate a problem with the specimen or the test system. Diagrams, color photographs, and color-comparison charts are often part of the product insert and quick references and serve as guides for interpretation.

**Performance characteristics**

Details the results of studies conducted to evaluate test performance including data used to determine accuracy, precision, sensitivity, specificity and reproducibility of the test results and cross reactivity studies with interfering substances.
Post-Testing Checklist

The post-testing phase includes result reporting, documentation and quality assessment activities.

**Post-testing checklist**

**Documentation of Patient and QC Results**
- Document all QC results, including at least once each day of testing that any built-in procedural controls worked as expected.
- Specify actions to take when test does not perform as expected.
- Re-confirm the patient’s identification prior to documenting the results.
- Include established reference intervals, critical values and units of measure for the test performed.
- Describe how to record and report results and how to handle critical values.
- Ensure results are reported to the ordering physician.
- Test records should include the name and location of the testing site.

**Quality Assessment**
- Evaluate quality control each day and over time, and resolve any discrepancies.
- Periodically review patient records to ensure that results are correctly recorded and reported to the ordering physician.
- If proficiency testing is performed, review results with staff and resolve failures promptly. If there are failures, determine if there may have been a problem with patient results during that timeframe and follow up, if necessary.
- Maintain proper documentation of all evaluations, reviews and other actions taken.

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**SECTION 4: LABORATORY SAFETY POLICY**

**PRINCIPLE:**
Eliminate or minimize staff and patient exposure to potentially infectious materials and occupational hazards.

**TERMINOLOGY:**
*Universal Precautions* assume that all specimens are potentially infectious and that all individuals coming into contact with these specimens should take appropriate precautions to avoid exposure. These specimens are known as regulated body fluids and include:
- Blood
- Semen
- Vaginal secretions
- Synovial fluid
- Amniotic fluid
- Cerebrospinal fluid
- Pleural fluid
- Pericardial fluid

*Personal Protective Equipment* is any barrier article used to avoid exposure to infectious agents. In the laboratory, these articles commonly include:
- Lab coats
- Gloves
- Gowns
- Face shields
- Safety eyewear

**GUIDELINES:**
1. Staff will be trained on safety procedures including the identification, location, and handling of biohazardous materials.
2. Staff will keep work areas clean and free from specimen spills.
3. Staff will wear appropriate Personal Protective Equipment.
4. Staff will wash their hands or use a sanitizer before and after patient contact and after removal of gloves.
5. Staff will observe Universal Precautions whenever there is anticipated exposure to regulated body fluids.
6. Staff will discard all disposable sharps, needles, and syringes in marked, impenetrable containers.
7. Staff will not eat, drink, smoke, or apply cosmetics in the laboratory and/or testing area.
8. Staff will not store food or drink in refrigerators used for storing reagents, controls, and/or specimens.
9. Staff will report needle sticks, biohazard spills and any other exposure to blood borne pathogens to their Supervisor and/or Lab Director.
10. Management will investigate and resolve all reported exposures.
SECTION 5: DRAFT SPECIMEN COLLECTION PROCEDURES

Draft Procedure:
Fingerstick Procedure for Waived Testing

PRINCIPLE:
This procedure is for waived test systems only. If you collect specimens to be sent out for non-waived testing, refer to and follow the collection procedures of the reference laboratory.

The finger puncture is the most common method used to collect whole blood for waived testing. It is also the preferred method to collect blood if the patient is a child, if the patient has scarred or damaged veins or if a desired vein cannot be accessed.

SUPPLIES NEEDED:
• Antiseptic swabs
• Sterile gauze pads
• Disposable sterile lancet
• Biohazard sharps container
• Gloves
• Band-aid

PROCEDURE:
1. Gather the supplies.
2. Put on gloves and any other appropriate Personal Protective Equipment (PPE).
3. Confirm the identity of the patient using two unique patient identifiers (full name, medical record number, birth date, etc.).
4. Check to see if the patient has allergies. Do not use betadine cleansers on patients that have allergies to iodine/shellfish.
5. Select a collection site. Avoid puncture sites which may show any of the following signs:
   a. Cyanosis (blue color)
   b. Swelling
   c. Rashes
   d. Scars (if possible)
6. If possible, warm the selected finger with a warm compress.
7. With your thumb and index finger, grasp the patient’s finger about three inches from the tip of the finger.
8. As indicated in the photograph, select a site slightly to the side of the fingertip, since it is not as sensitive as the center.
9. Cleanse the fingertip with an antiseptic swab.
10. Allow the finger to air dry.
11. Holding the finger firmly, puncture the skin with the sterile lancet. Be sure to follow the lancet manufacturer’s instructions.
12. Unless the manufacturer’s instructions state otherwise, wipe the first drop of blood using sterile gauze.
13. Collecting the blood:
   a. Follow the manufacturer’s instructions for the test if you are applying a drop of blood directly to a test device or test strip (cassette, pad, etc.).
   b. If using capillary tubes or capillary collection devices, such as shown in the illustration below, allow a drop of blood to form over the puncture site and gently touch the tip of the capillary tube to the drop of blood. The tube will fill by capillary action.
14. After the specimen has been collected, clearly label all specimens (devices) as appropriate.
15. Apply clean gauze and/or a band-aid to the collection site.
16. Discard used supplies in appropriate receptacles.

CAUSES OF INACCURATE TESTING:
1. Residual alcohol at the skin puncture site may cause hemolysis (destruction of red blood cells) in the sample.
2. Excessive squeezing of the tissue adjacent to the puncture site to stimulate blood flow may cause hemolysis in the sample or dilute the specimen with tissue fluid.
3. Scraping of the micropipettes or pediatric collection caps over the puncture site may cause trauma to the site and hemolyze the specimen.
4. Prolonged collection time or improper mixing of blood with anticoagulant can result in a clotted sample which may be unacceptable for desired tests.

REFERENCES:
Draft Procedure:  
Heel Puncture Procedure for Waived Testing

PRINCIPLE:

This procedure is for waived test systems only. If you collect specimens to be sent out for non-waived testing, refer to and follow the collection procedures of the reference laboratory.

Due to the fact that larger amounts of blood obtained during repeated venipuncture may cause anemia in infants, the heel puncture is the method of choice for infant patients.

SUPPLIES NEEDED:

- Antiseptic swabs
- Sterile gauze pads
- Disposable sterile lancet
- Heel warmer
- Biohazard sharps container
- Gloves
- Band-aid

PROCEDURE:

1. Gather supplies.
2. Put on gloves and any other appropriate Personal Protective Equipment (PPE).
3. Confirm the identity of the patient using two unique patient identifiers (full name, medical record number, birth date, etc.).
4. Position the infant on his/her back taking care to ensure that the infant does not fall.
5. Select a collection site. Avoid puncture sites which may show any of the following signs:
   a. Cyanosis (blue color)
   b. Swelling
   c. Rashes
   d. Scars (if possible)
6. If possible, warm the selected heel with a heel warmer.
7. Select the puncture site. For infants this is the lateral or medial plantar heel surface (shown in the shaded area in the drawing). Do not use the posterior curvature of the heel or a previous puncture site.
8. Cleanse the puncture site with an antiseptic swab.
9. Allow site to air dry.
10. Hold the heel with the forefinger at the arch and the thumb next to the puncture site at the ankle.
11. Make a puncture with the sterile lancet using a single deliberate motion. Keep the lancet perpendicular to the skin surface.
12. Wipe away the first drop of blood with sterile gauze, unless stated otherwise in the manufacturer’s instructions. Initiate further blood flow by thumb pressure -- do not “milk” the site.
13. Collecting the blood:
   a. Follow the manufacturer’s instructions for the test if you are applying a drop of blood directly to a test device or test strip (cassette, pad, etc.).
   b. If using capillary tubes or capillary collection devices, such as shown in the illustration below, allow a drop of blood to form over the puncture site and gently touch the tip of the capillary tube to the drop of blood. The tube will fill by capillary action.
14. After the specimen has been collected, clearly label all specimens (devices) as appropriate.
15. Apply clean gauze and/or a band-aid to the collection site.
16. Discard used supplies in appropriate receptacles.

CAUSES OF IMPROPER SPECIMEN COLLECTION:

1. “Milking” the puncture site may cause a hemolyzed specimen and/or erroneous results due to the excessive tissue fluid which may dilute the specimen.
2. Inadequate punctures cause a slow blood flow which can cause clotted specimens, particularly when using micro collection containers containing anticoagulants.

REFERENCES:


Draft Procedure: Venipuncture

PRINCIPLE:
This procedure can be used to collect specimens for waived and non-waived testing. Refer to the manufacturer instructions to ensure specimens are collected in tubes with the proper additives.

Venipuncture, or phlebotomy, is the puncture of the vein for any purpose. Collecting a venous blood sample requires the phlebotomist to pierce the vein with a hypodermic needle and draw blood into vacuum tubes specifically designed for collecting venous blood.

SUPPLIES NEEDED:
• Tourniquet
• Sterile gauze
• Antiseptic swabs
• Adhesive bandage
• 20 or 22 gauge needle or butterfly
• Vacutainer holder
• Vacutainer tubes
• Biohazard sharps container
• Biohazard waste container
• Gloves

PROCEDURE:
1. Gather supplies.
   a. Attach needle or butterfly to the vacutainer holder.
2. Put on gloves and any other appropriate Personal Protective Equipment (PPE).
3. Confirm the identity of the patient using two unique patient identifiers (full name, medical record number, birth date, etc.).
4. Check to see if the patient has allergies. Do not use betadine cleansers on patients that have allergies to iodine/shellfish.
5. Select vein site.
6. Clean site.
   a. Always allow alcohol to dry.
7. Apply tourniquet.
8. Pull the skin taunt, ensure that the bevel is up, and enter the vein at a 45 degree angle.
9. To prevent cross contamination, collect specimens according to the order of draw.
   a. Blood culture bottles
   b. Light blue (citrate)
   c. Red top or Serum Separator Tube (SST, gold or tiger top)
   d. Purple top (EDTA)
   e. Gray (sodium fluoride or potassium oxalate)
   f. Dark blue (FDP)
10. Gently mix any anti-coagulated tubes by inverting the tube 8 to 10 times.
11. Apply clean gauze and/or a band-aid to the collection site.
12. Discard used supplies in appropriate receptacles.
13. Clearly label all patient specimens with two patient identifiers.

SPECIAL CONSIDERATIONS:
• Patients taking blood anticoagulant medication may require may require additional pressure time to ensure that bleeding has stopped.
• Remove the tourniquet within 1 to 2 minutes of application.
• Do not recap or bend needles before discarding.
• Use a new needle if a second venipuncture is required.

CAUSES OF INADEQUATE SPECIMEN COLLECTION:
• Traumatic punctures (where the needle is manipulated in and out of the vein repeatedly to complete the collection) will frequently result in a hemolyzed specimen and bruising at the draw site.
• An improper anticoagulant to blood ratio can cause erroneous results with some tests either because of anticoagulant action or blood dilution.
• Tourniquets on for a prolonged timeframe (> 2 minutes) may result in falsely increased Potassium results.

REFERENCES:
West GR. The Learning Laboratory Series; Phlebotomy. Augusta GA: Medical College of Georgia, 1989.
Draft Procedure: Urine Specimen Collection for Waived Testing

PRINCIPLE:
This procedure is for waived test systems only. If you collect specimens to be sent out for non-waived testing, refer to and follow the collection procedures of the reference laboratory.

Urine is tested for its chemical and microscopic composition to determine if a disease state exists in a patient. Depending upon the testing being performed, urine must be obtained according to special methods which allow clinicians to maximize the usefulness of the specimen for testing purposes. Refer to the specific test procedure for more information.

SUPPLIES NEEDED:
• Non-sterile or sterile urine container
• Biohazard waste container

PROCEDURE:
A random "midstream" specimen is the preferred method of collection for routine urinalysis testing. It can also be used for pregnancy testing, but the first morning void is the preferred specimen for most pregnancy test kits.

1. Gather supplies.
2. Give the patient a urine specimen collection cup.
3. Direct the patient to obtain the urine specimen in the following manner:
   a. Urinate a small amount of urine into the toilet.
   b. Stop the urine flow and obtain urine specimen cup.
   c. Start urine flow directly into the urine specimen cup.
   d. Fill the urine specimen cup to appropriate level.
   e. Set the cup on a flat surface.
   f. Finish urinating into the toilet.
   g. Place the urine specimen lid onto the urine specimen cup and close tightly to avoid spilling its contents.
4. Label the cup with two patient identifiers.
5. Return specimen to the lab.

REFERENCES:
Addison LA and Fischer PM. The Office Laboratory. 2nd ed. Norwalk, CN: Appleton & Lange, 1990.

National Committee for Clinical Laboratory Standards. Physician’s Office Laboratory Guidelines.


SECTION 6: APPENDIX
Example of Package Insert

TABLE 7: Components of the manufacturer’s product insert

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>INFORMATION PROVIDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Describes the test purpose, the substance being detected or measured, test methodology, appropriate specimen type and the Food and Drug Administration-cleared conditions for use. Might address whether the test is to be used for diagnostic or screening the target population and whether it is for professional use or self-testing.</td>
</tr>
<tr>
<td>Summary</td>
<td>Explains what the test detects and a short history of the methodology, including the disease process or health condition being detected or monitored. Might include the response to disease (e.g., development of IgM antibodies), the symptoms and their severity, and the disease prevalence. Includes literature citations as applicable.</td>
</tr>
<tr>
<td>Test Principle</td>
<td>States the methodology used in the test. Details the technical aspects (chemical, physical, physiologic, or biologic reactions) of the test, and explains how the components of the test system interact with the patient specimen to detect or measure a specific substance.</td>
</tr>
<tr>
<td>Precautions</td>
<td>Alerts the user of practices or conditions that might affect the test and warns of potential hazards (e.g., handling infectious specimens or toxic reagents). Frequent precautions include directions to not mix components from different lot numbers, to not use products past expiration dates, and the need for safe disposal of biohazardous waste. Might address conditions for specimen acceptability.</td>
</tr>
<tr>
<td>Storage/Stability</td>
<td>Specifies conditions for storing reagents and test systems to protect their stability. Includes recommended temperature ranges and, as applicable, physical requirements (e.g., protection from humidity and light). Also addresses the stability of reagents and test systems when opened or after reconstitution and/or mixing. Describes indicators of reagent deterioration.</td>
</tr>
<tr>
<td>Reagents and materials supplied</td>
<td>Lists the reagents and materials supplied in the test system kit and the concentration and major ingredients used to make the reagents.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>INFORMATION PROVIDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials required but not provided</td>
<td>Lists materials needed to perform the test but not provided in the test system kit.</td>
</tr>
<tr>
<td>Specimen collection and preparation</td>
<td>Details the procedures for specimen collection, handling, storage, and stability, including, as applicable, instructions for performing a fingerstick, appropriate anticoagulant or swab type, and directions for specimen preparation. Might address conditions for specimen acceptability.</td>
</tr>
<tr>
<td>Test procedure interpretation of results</td>
<td>Provides step-by-step instructions for performing the test and frequently includes visual aids (e.g., pictures or graphs). Critical information (e.g., the order of reagent addition, timing of test steps, mixing and temperature requirements, and reading of the test results) is included. Describes how to read and interpret the test results and often includes visual aids. Alerts the user when the results are invalid and gives instructions on what to do when the results cannot be interpreted. Might include precautions against reporting results unless supplementary/confirmatory testing is performed.</td>
</tr>
<tr>
<td>Quality control (QC)</td>
<td>Explains what aspects of the test system are monitored by QC procedures and provides instructions on how to perform QC. Includes recommendations on how frequently QC should be performed, acceptable QC results, and what to do when QC values are not acceptable. Might include specific information about external QC and, as applicable, internal procedural QC.</td>
</tr>
</tbody>
</table>
| Limitations                                  | Describes conditions that might influence the test results or for which the test is not designed. Limitations could include:  
  • possible interferences from medical conditions, drugs, or other substances.  
  • warning that the test is not approved for use with alternate specimen types or in alternate populations (e.g., pediatric).  
  • indications of the need for additional testing that might be more specific or more sensitive.  
  • warning that the test does not differentiate between active infection and carrier states.  
  • statement that the test result should be considered in the context of clinical signs and symptoms, patient history, and other test results. |
### COMPONENT INFORMATION PROVIDED

| Expected values | Describes the test result the user should expect (positive/negative or within/outside of a reference interval). Explains, as applicable, how results can vary depending on disease prevalence and the season of the year. Might include a brief description of studies conducted to derive this information. |
| Performance characteristics | Details the results of studies conducted to evaluate test performance. Included are data used to determine accuracy, precision, sensitivity, specificity, and reproducibility of the test and results of cross-reactivity studies with interfering substances. |

* Product inserts vary in format, but the majority contains the information described above. Some information might appear in different sections than listed above because of format variations between manufacturers. Certificate of Waiver site directors and testing personnel should read this information for a complete understanding of each test.

### QUALITY DEFICIENCIES

<table>
<thead>
<tr>
<th>QUALITY DEFICIENCIES</th>
<th>NO. OF SITES</th>
<th>(% OF SITES)</th>
<th>PHASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Following manufacturer’s instructions†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The site did not</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have current manufacturer’s instructions</td>
<td>485</td>
<td>(12)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Routinely check new product inserts for changes§</td>
<td>701</td>
<td>(21)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Based on manufacturer’s instructions, the site did not</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perform quality control testing</td>
<td>866</td>
<td>(21)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Report test results with terminology or units described in package insert</td>
<td>744</td>
<td>(18)</td>
<td>Post-testing phase</td>
</tr>
<tr>
<td>Adhere to proper expiration dates</td>
<td>267</td>
<td>(6)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Perform required confirmatory tests</td>
<td>265</td>
<td>(6)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Perform function checks or calibration</td>
<td>195</td>
<td>(5)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Adhere to storage and handling instructions</td>
<td>139</td>
<td>(3)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Perform instrument maintenance</td>
<td>126</td>
<td>(3)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Use appropriate specimen for each test</td>
<td>81</td>
<td>(2)</td>
<td>Testing phase</td>
</tr>
<tr>
<td>Add required reagents in the prescribed order</td>
<td>24</td>
<td>(1)</td>
<td>Testing phase</td>
</tr>
</tbody>
</table>

| Documentation The site did not | | | |
| Document the name, lot number, and expiration date for all tests performed§ | 1,493 | (45) | Post-testing phase |
| Maintain a quality-control log§ | 1,151 | (35) | Post-testing phase |
| Maintain a log of tests performed | 1,318 | (31) | Post-testing phase |
| Require test requisition (or patient chart) before performing a test§ | 304 | (9) | Pre-testing phase |
| Keep the test report in the patient’s chart§ | 56 | (2) | Post-testing phase |
| Check patient identification§ | 31 | (1) | Pre-testing phase |

* N = 4,214 sites.
† Required for waived testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
¶ Not required for waived testing under CLIA.

### TABLE 5: Number and percentage of quality deficiencies related to following manufacturer’s instructions and documentation in Certificate of Waiver sites, from the Centers for Medicare & Medicaid Services surveyed sites,* 2002–2004
ACRONYMS AND ABBREVIATIONS FOR THE CLINICAL LABORATORY

**BBP**  
Bloodborne Pathogen

**CDC**  
Centers for Disease Control and Prevention

**CLIA ’88**  
Clinical Laboratory Improvement Amendments of 1988

**CLIA**  
Clinical Laboratory Improvement Amendments

**CLSI**  
Clinical and Laboratory Standards Institute (formerly National Committee for Clinical Laboratory Standards)

**CMA**  
Certified Medical Assistant

**CMS**  
Centers for Medicare and Medicaid Services

**COLA**  
Formerly known as the Commission on Office Laboratory Accreditation

**CW**  
Certificate of Waiver (formerly COW)

**DO**  
Doctor of Osteopathy

**FDA**  
Food and Drug Administration

**HBV**  
Hepatitis B Virus

**LIS**  
Laboratory Information System

**MA**  
Medical Assistant or Master of Arts

**MSDS**  
Material Safety Data Sheet

**OSHA**  
Occupational Safety and Health Administration

**POL**  
Physician Office Laboratory

**PPE**  
Personal Protective Equipment

**PPM**  
Provider-Performed Microscopy

**PT**  
1. Proficiency Testing  
2. Prothrombin Time  
3. Physical Therapy

**PTM**  
Patient Test Management

**QA**  
Quality Assessment (formerly Quality Assurance)

**QC**  
Quality Control

GLOSSARY

**Acceptable limits**  
The expected range of results (above and below the target mean value) for the material. Obtaining results within the acceptable limits gives confidence that the test system is accurately measuring the analyte.

**Accreditation organization**  
A private entity deemed by CMS to have laboratory standards and requirements that meet or exceed the CLIA regulations. COLA, The Joint Commission (formerly JCAHO), and the College of American Pathologists (CAP) are examples of clinical laboratory accrediting agencies.

**Accuracy**  
How close a test result is to the true value.

**Analyte**  
The chemical substance being measured. Example: glucose.

**Analytic, Analytical**  
Processes that occur during the testing phase in the path of workflow.

**Calibration**  
The process of testing materials (standards or calibrators) of known value and adjusting the instrument readout to establish a correlation between the instrument’s measurement of the analyte being tested and the actual concentration of the analyte.

**CDC**  
The Centers for Disease Control and Prevention (CDC) is responsible for the CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAC), and providing scientific and technical support to CMS.

**Certificate, CLIA**  
A lab that possesses a valid CLIA certificate is CLIA certified. The CLIA law requires any laboratory performing testing on specimens derived from a human being for purposes of providing diagnosis, treatment, etc., to enroll with the CLIA program. This is regardless of whether or not the laboratory receives payment from Medicare, Medicaid or any other third party payor, or where the testing is performed.

Each certificate enables a lab to perform specific testing in each category. The certificates are:

1. Certificate of Waiver (CW) – may perform waived tests only (no inspection, personnel standards, or proficiency testing required)
2. Certificate for PPM (PPMP) – Provider Performed Microscopy Procedures
3. Certificate of Compliance (COC) – non-waived testing, lab is inspected by state CMS Surveyors
4. Certificate of Accreditation (COA) – non-waived testing, deeming agencies such as COLA inspect the lab

NOTE: Prior to inspection, COC or COA labs receive a Certificate of Registration (COR). The lab will operate under the COR until successfully completing the inspection process.
CLIA
The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

CMS
CMS is the Centers for Medicare & Medicaid Services. Formerly known as the Health Care Financing Administration (HCFA), CMS is the federal agency responsible for administering the Medicare, Medicaid, SCHIP (State Children's Health Insurance), HIPAA (Health Insurance Portability and Accountability Act), CLIA (Clinical Laboratory Improvement Amendments), and several other health-related programs.

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, certificate generation, surveys, surveyor guidelines development and training, enforcement, financial management, and finally, approvals of proficiency testing providers, accrediting organizations and exempt states. Additional information regarding CMS and the CLIA program is available at www.cms.hhs.gov/clia/

Comparative method
In proficiency testing, a widely accepted, reliable method.

Control material
A specimen with a known value or range of values that is tested like a patient sample to ensure the methodology is working correctly.

Control range
The allowable limits or acceptable range of values for a control material.

Corrective action
Steps taken to remedy an undesirable situation or quality problem. Examples of corrective actions are providing training, opening a new bottle of control, re-calibrating the instrument, or performing instrument maintenance.

Engineering controls
Safety devices (such as self-sheathing needles) or other products that act as controls to isolate or remove blood borne pathogen hazards and/or that reduce the likelihood of exposure the workplace.

FDA
The Food and Drug Administration (FDA) is responsible for laboratory test categorization. The FDA determines if the product is safe and effective as a condition of approval. The Centers for Medicare & Medicaid Services (CMS) determines if the product is reasonable and necessary as a condition of Medicare coverage. Any product regulated by the FDA must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage. FDA approval/clearance alone does not automatically entitle that device to coverage. There may be exceptions for IDE Category B devices.

Hemolysis
The rupturing of red blood cells that releases hemoglobin (and other intracellular substances) into the plasma or serum.

High complexity
CLIA has classified laboratory tests according to the difficulty of performance and interpretation. High complexity is the most complex level of lab testing as defined by CLIA. High complexity testing has the most demanding requirements, and includes manufacturer’s tests that have been classified as high complexity and any tests developed by the laboratory or modified by the laboratory.

Moderate complexity
CLIA has classified laboratory tests according to the difficulty of performance and interpretation. Approx. 75% of lab tests are classified as moderate complexity, including most routine tests such as automated blood cell counts and chemistry tests performed on automated analyzers.

Non-waived
Moderate or high complexity. The term non-waived is used to describe moderate and high complexity laboratory testing when the requirements are the same for both.

Package insert and operator manuals verbiage
• “Must” – a CLIA mandate
• “Recommendation” – not a CLIA requirement
• “Requirement” – a CLIA mandate
• “Should” – not a CLIA requirement
• “Suggestion” – not a CLIA requirement

Panic values
Laboratory test result values that demand attention by a clinician; also called alert values.

Personal Protective Equipment (PPE)
Specialized clothing or equipment worn by an employee for protection. The OSHA Blood borne Pathogen regulations specify that PPE is to be made available at no cost to the employee. This equipment should be: gloves, gowns, face shields, masks, eye shields, or other protective equipment.

Post-analytic, post-testing
Processes in the path of workflow that occurs after testing is complete, such as result transcription and reporting, and specimen retention after testing.

Pre-analytic, pre-testing
Processes in the path of workflow that occur before testing begins, such as test orders, patient identification, and specimen collection, labeling, receiving, and processing.

Proficiency testing (PT)
A means of verifying results of lab testing using an external testing company—often called external quality assessment. Unknown samples are sent from a PT program three times a year for analysis by the lab in the same manner as patient samples. The results are then compared to a known target value and reports are issued to the lab, CMS, and any accrediting agency.
PT provider
A business entity that operates a proficiency testing program.

Qualitative
A test that detects the presence or absence of a substance without providing a specific measure of “how much.” For example, some qualitative tests are reported as negative or positive, and others as reactive or non-reactive.

Quality
Degree to which a set of inherent characteristics meets requirements and the needs and expectations of customers.

Quality Assessment (QA)
An overall evaluation program which examines ALL of the activities in all phases of the path of workflow and operation of the laboratory. The essential elements are identified and efforts are then focused on improving performance and service. Formerly referred to as Quality Assurance, QA focuses on preventing errors, producing reliable results, and improved patient outcomes.

Quality Control (QC)
A set of activities or techniques that monitor processes to ensure that all quality requirements are being met. In the clinical laboratory, QC is the process of testing materials that have a known concentration of the substance being measured, prior to or concurrent with patient testing. QC can detect analytical errors related to the test system, environment, and operator. When QC results are within the expected target range for the control material, it gives confidence that the test system is accurately measuring the analyte.

Quantitative
A test result that gives a specific numerical measure of “how much” as opposed to simply detecting the presence or absence of the substance.

Reference laboratory
A large commercial laboratory where routine and complex laboratory tests can be performed. Reference laboratories perform tests on specimens from other sites, and are often used to perform more complex and unusual tests not performed in your own facility.

Regulated waste
In the OSHA Blood borne Pathogen regulations, liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other infectious materials when compressed; items that are caked with dried blood; contaminated sharps; and wastes containing visible blood or other potentially infectious materials. These must be disposed of in specially marked bags and/or containers.

Reliability
A method’s capacity to maintain both accuracy and precision.

Split samples
A specimen is divided into aliquots and sent to different laboratories or tested by different methods for the analyte. Results are then compared.

Test system
The test kit or method, including the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

Universal precautions
Mandates that all blood and other body fluids be treated as potentially infectious materials. Protect yourself with the use of gloves, lab coats, hand washing, and proper disposal procedures.

Waived
The least complicated level of testing as described by CLIA. Certificate of Waiver (CW) laboratories must enroll in the CLIA program, pay applicable certificate fees biennially, and follow manufacturers’ test instructions. No proficiency testing is required and there are no personnel standards. Waived tests are those tests that are determined by CDC or FDA to be so simple that there is little risk of error.

Work practice controls
As described in the OSHA Blood borne Pathogen regulation, these procedures and practices act as controls to reduce the likelihood of exposure by altering the manner in which a task is performed. For example, wearing PPE and prohibiting the re-capping of needles.
LABORATORY RESOURCES
Where can you find current information and topics of interest that relate to the clinical laboratory? In this section, we provide a partial listing of the websites, publications, and organizations that may be able to provide helpful information on laboratory compliance, operation, and management.

REGULATORY INFORMATION
There are both state and federal regulators who provide information about the Clinical Laboratory Improvement Amendments (CLIA) and related state laws. The Centers for Medicare and Medicaid Services (CMS) and individual state Health Departments are free sources for information on regulations and inspections.

Centers for Medicare and Medicaid Services (CMS)  www.cms.gov  877-267-2323
CLIA Program  www.cms.hhs.gov/clia
Occupational Safety & Health Administration (OSHA)  www.osha.gov  800-321-OSHA
Centers for Disease Control and Prevention (CDC)  www.cdc.gov  800-232-4636

Through its Office of the Federal Register (OFR), the National Archives and Records Administration provides ready access to federal regulations, public laws, and presidential documents.


EDUCATION AND INFORMATION SOURCES
There are many other publications and internet websites that focus on clinical laboratory topics. Here is a sampling of a few.

CodeMap (MCF Compliance)  www.codemap.com  847-381-5465
LabTestOnline  www.labtestsonline.org
LabUniversity® (COLA)  www.labuniversity.org  800-981-9883
OSHA Watch (Quality America)  www.quality-america.com  800-946-9956
PointofCare.net  www.pointofcare.net
The Help Book (Quality America)  www.quality-america.com  800-946-9956
The Safety Lady® LLC  www.safetylady.com  877-894-7004
Rapid near patient testing is an integral part of the everyday care of tens of thousands of our patients. From diabetes management and monitoring anti-coagulant therapies, to screening for infectious disease, there are hundreds of simple tests that, to date, have been largely free from federal and state regulation. Laboratory professional groups have long advocated for increased oversight of these “waived” tests, and unfortunately, evidence is mounting that significant quality problems exist in the largely unregulated labs relying on these tests. It is clear that the Federal Government is preparing to establish a new level of oversight in the practice of medicine.

Some examples of notable problems include that among the nearly 120,000 waived testing sites in the U.S.

- More than 20% do not routinely check the product insert or instructions for changes to the information; (consider the implications of an ignored new sampling technique for a Rapid HIV test)
- More than 20% do not perform Quality Control testing as specified by manufacturers instructions (consider the implications of an improperly controlled Prothrombin Time test)
- Nearly half do not document the name, lot number, and expiration dates for tests performed (consider the implications of massive recall of problematic test kits)

Evidence is growing that educational interventions and practical tools (e.g. logs for recording key data) have a significant impact on improving compliance with these important activities.

COLA, the nation’s largest physician-directed not-for-profit laboratory accrediting organization provides a private sector solution to the problems encountered by labs relying primarily on waived tests. This program blends education and key practice management tools, with recognition of achievement. Program participants and Federal Oversight agencies can be confident that these tests are being performed and managed properly.

COLA is leading the charge in ensuring that the voice of the primary care physician is represented to the oversight agencies considering increased regulatory oversight of waived testing and in the design of physician-centric alternatives with a focus on quality patient care.

Introduction
Laboratory testing plays a critical role in health assessment, treatment, monitoring, and ultimately, the public’s health. Test results contribute to diagnosis and prognosis of disease, monitoring of treatment and health status, and population screening for disease. Laboratory testing affects persons in every life stage, and almost everyone will experience having one or more laboratory tests conducted during each year of their life. An estimated 7.10 billion laboratory tests are performed each year in the United States and laboratory test results influence approximately 70% of medical decisions.

Increasingly, these decisions are based on simple tests performed at the point-of-care, using devices that are “waived” from most federal oversight requirements, and are thus designated as waived tests. These waivers include requirements for personnel qualification and training, quality control (QC) (unless specified as required in the test system instructions), proficiency testing (PT), quality assurance (QA), and the need for routine inspection.

The Rise in Waived Testing
Advances in technology have made tests simpler and more robust, and this has contributed significantly to the shift in testing from the more complex tests to the simpler waived methods. In the past, tests such as cholesterol and glucose used complex manual methodologies or were performed with instrumentation designed for use by highly trained personnel in traditional clinical laboratory settings. Many tests can now be performed using compact or hand held devices by personnel with limited experience and training. These advances have enabled more testing to be performed in emergency departments, hospital rooms, and physicians’ offices and in non-traditional testing sites such as community counseling centers, pharmacies, nursing homes, ambulances, and health fairs. Since the 1992 inception of the program implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the numbers of waived tests and the sites that perform them have increased dramatically. The list of waived test systems has grown to over 1,600. This trend is expected to continue as laboratory testing technology continues to evolve.

CLIA Requirements for Waived Testing
All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under CLIA. The three categories of testing for CLIA purposes are waived, moderate complexity, and high complexity. Waived tests are defined by law as simple laboratory examinations and procedures which:
Facilities performing only waived tests are only required to obtain a Certificate of Waiver (CW), pay biennial certificate fees, and follow manufacturers’ test instructions. However, they must agree to allow inspections, and some states do regularly inspect waived laboratories. Also, while CLIA’s technical requirements for personnel are less stringent for laboratories that perform waived testing than for those that perform moderately complex testing, some states set standards for both types of laboratories that are higher than the minimums required by CLIA.

Scope of Waived Testing
Since 1992, the number of CLIA-waived tests has increased from eight to over 100 tests, representing some 1,600 test systems. During this same period, the number of laboratories issued a Certificate of Waiver has grown exponentially from 20% to 60% of the more than 209,000 laboratory testing sites in the United States. These sites include pediatric, urology, family physician and internal medicine practices as well as urgent care clinics and other primary care sites.

Patient Safety Concerns Related to Waived Testing
While the law and the FDA assert that risk of harm to the patient is insignificant (from incorrect performance of test), these tests are not completely error-proof and are not always performed in settings that use a systems approach to quality and patient safety. Errors can occur anywhere in the testing process, particularly when the manufacturer’s instructions are not followed and when testing personnel are not familiar with all aspects of the test system and how testing is integrated into the facility’s workflow.

Indeed, some waived tests have potential for serious health impacts if performed incorrectly. For example, results from waived tests are used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy, and glucose monitoring in diabetics. In addition, erroneous results from diagnostic tests, such as those for human immunodeficiency virus (HIV) antibody, can have innumerable unintended consequences.

The lack of oversight and requirements for personnel qualifications and training for an increasingly large number of Certificate of Waiver sites is also a concern, and could contribute to errors and patient harm. Often, the personnel performing these tests do not understand the potential negative impacts of improper sampling and testing technique and its relation to accurate results.

In 2001, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) published a report that identified vulnerabilities in the program enrollment and certification process of the CLIA program, including oversight of Waived and Provider-Performed Microscopy Procedures (PPMP) labs, particularly due to the lack of routine inspection visits. It recommended several steps to improve testing at waived laboratories, including increased educational outreach, periodic self-assessment, and random surveys of some waived laboratories each year.

CMS, which had conducted its own on-site surveys of a representative sample of Certificate of Waiver sites in 10 states during 1999-2001 to assess the quality of testing in these sites, concurred with the OIG’s findings. In the case of 100 Certificate of Waiver and PPMP laboratories visited in 1999, for example, CMS had found that 50% had quality problems. During a 2000-2001 CMS Expanded Pilot Study, 32% of the 436 labs surveyed were determined to have quality problems.

As a result, during 2002-2004, CMS conducted nationwide on-site surveys of Certificate of Waiver facilities to collect additional data and simultaneously encourage improvement through educational outreach, promote good laboratory practices, and make recommendations on the basis of cumulative survey findings. The data collected from these surveys, along with data on waived testing practices gathered through CDC-funded studies conducted during 1999-2003 by several state health departments (collectively referred to as the Laboratory Medicine Sentinel Monitoring Network or LMSMN); support the initial CMS findings of gaps in good laboratory practices in these sites.

CMS and CDC Findings
The findings from the CMS 2002-2004 surveys and CDC-funded studies indicate that most laboratory directors and testing personnel did not have formal laboratory training or testing experience, and there was high turnover of personnel. Also, in some instances, Certificate of Waiver sites were determined to be performing testing that was an imminent and serious threat to the public’s health because they were performing non-waived testing in the absence of CLIA-required quality measures. The CMS surveys indicated that 5% of Certificate of Waiver sites were conducting tests that were not actually “waived”, and were therefore outside the scope of the laboratory.

Additionally, of the Certificate of Waiver facilities CMS surveyed:

- 12% did not have the most recent instructions for the waived test systems they were using
- 21% reported they did not routinely check the product insert or instructions for changes to the information
- 21% did not perform Quality Control testing as specified by manufacturers instructions

• Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible;
• Pose no reasonable risk of harm to the patient in the test is performed incorrectly.
18% did not use correct terminology or units of measure when reporting results
6% failed to adhere to proper expiration dates for the test system, reagents, or control materials
3% failed to adhere to the storage conditions as described in the product insert
6% did not perform follow-up confirmatory tests as specified in the instructions
5% did not perform function checks or calibration checks to ensure the test system was operating correctly

Although not usually specified in the product insert (and therefore not a CLIA requirement), proper documentation and recordkeeping of patient and testing information are also important elements of good laboratory practices. CMS surveys of the Certificate of Waiver sites indicated that:

45% did not document the name, lot number, and expiration dates for tests performed;
35% did not maintain logs with records of their Quality Control testing
31% did not maintain a log or record of tests performed
9% did not require a requisition or test orders be documented in a patient chart before performing a test.

The CDC-funded study also reported strikingly similar findings in its 2004 report. Among the waived laboratories surveyed, the study found:

• High staff turnover
• Lack of formal laboratory education
• Limited training in test performance & QA
• Lack of awareness concerning “good laboratory practice”
• Partial compliance with manufacturers’ Quality Control instructions (approx. 55-60%)

Study Conclusions and Marketplace Responses
CMS studies have demonstrated that a persistent percentage of Certificate of Waiver sites do not meet minimal requirements, and are not aware of recommended practices to help ensure quality testing. The studies indicate a need for educational efforts to Certificate of Waiver site directors and testing personnel about the importance of following manufacturers’ instructions, adhering to expiration dates, performing Quality Control testing, and proper documentation and recordkeeping.

The study findings have resulted in several industry responses to date. CMS continues to randomly survey 2% of all Certificate of Waiver sites as part of its ongoing nationwide study of waived testing facilities. Statistics suggest that this ongoing surveillance, combined with educational outreach is having an impact. For example, in fiscal year 2006, CMS data shows that nearly 85% of labs inspected and provided educational guidance showed at least temporary improvement upon revisit.

Nevertheless, industry experts argue, even these lowered rates are not low enough. In a 2008 presentation, “How to Avoid the Most Frequently Cited Deficiencies,” CMS indicated that as of December, 2007, there were 200,667 laboratories in the U.S. of which 119,839 were Certificate of Waiver sites. Stated another way, this means that nearly 80% of laboratories in the U.S. do not have any routine oversight, according to the laboratory quality consulting firm Westgard QC. While CMS noted some improvement in overall laboratory performance in leading deficiency areas, Westgard QC points out that even if only 5-6% of waived labs aren’t performing, for example, QC and QA properly, that can still translate into thousands of labs operating without proper quality control in place.

Good Laboratory Practices Recommendations
In response to the CMS and CDC survey findings, the Clinical Laboratory Improvement Advisory Committee (CLIAC) in 2005 developed and published a series of guidelines for good laboratory practices. These recommendations are intended to promote the use of good laboratory practices by physicians, nurses, and other providers of waived testing in a variety of Certificate of Waiver sites. They address decisions that need to be made and steps to be taken as a facility begins offering waived testing or adds a new waived test, develops procedures and trains personnel. They also describe recommended practices for each phase of the total testing process, including the important steps or activities before, during, and after testing, which are critical to providing quality testing.

By implementing these recommendations, Certificate of Waiver sites can improve quality, reduce testing errors, and enhance patient safety. The CDC also provided recommendations for good laboratory practices, which essentially follow the recommendations developed by CLIAC.

Government Oversight Imminent
In a February, 2009 presentation, “What’s New for CLIA at CMS for 2009,” Judith Yost, Director of the Division of Laboratory Services, re-emphasized the need for educating waived sites on good laboratory practices. To further this goal, CMS provides on its website a clearinghouse of available educational opportunities that are customized specifically for laboratories issued a Certificate of Waiver. CMS also is currently developing an issue paper on the waived testing issue with “multi-faceted recommendations for agency management.” Yost indicated that CMS intends to convene industry partners such as laboratory professional and accrediting organizations, manufacturers, states, the CDC, the FDA and the educational community to develop “long and short-term plans with related studies” regarding waived testing.
While stating that “education is effective” in improving Certificate of Waiver laboratories performance, CMS’s resources in this area are “lacking,” according to Yost. And meanwhile, the problem of unregulated waived testing is growing, as the number of both Certificate of Waiver labs and new waived test methods continue to increase exponentially.

It is clear, many industry experts agree, that government oversight will be required to fully address the problems caused by largely unregulated waived testing. Even a CDC expert group seems to acknowledge this in a recent report on proficiency testing, where it made the following recommendation: “Develop a process to assure that all clinical laboratories, including those that perform waived tests, participate in PT”. This recommendation requires a change in the CLIA statute (law) (Public Health Service Act: Section 353 [263a] [d] [2] [C]) that specifically exempts waived laboratories from standards (i.e., Quality Control programs, PT, and inspections). 1

The Changing Political Landscape
This drive towards increased regulation of waived laboratories is also being fueled by a philosophical shift by the new political administration, which is creating momentum toward fundamental change in the U.S. health care system.

According to a recent report by Deloitte LLP, health care issues such as “comparative effectiveness, evidence-based medicine, cost reduction, performance-based payments, consumerism, safety, quality and transparency...are all on the table as legitimate action items in the new political structure of Washington, D.C.” While waived testing is not at the top of this list, it is inevitable that an issue with such patient care quality implications as waived testing will be addressed by the Obama Administration -- sooner rather than later.

Proactive, voluntary initiatives to improve quality in waived testing bolster organized medicine’s strong focus on evidence-based practices, quality measures and indicators, and patient safety.

A Solution is Already at Hand
If legislative oversight of waived testing is imminent -- and governmental resources to help labs prepare are, by CMS’s admission, lacking -- what, then, can the industry do to prepare for this new environment?

In fact, a solution already exists in the form of COLA, a leading laboratory accreditation organization which is dedicated to “promoting excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation”. Based on its belief that education is the way to achieve excellence in healthcare, COLA has built an extensive library of tools that allow practices to improve their testing processes.

Backed by Experienced Staff and Management Expertise
COLA’s legacy was built by working with labs that were previously unregulated by providing an educational, user friendly, simple roadmap to compliance and lab quality. With an accreditation program that has helped over 35,000 laboratories maintain compliance with CLIA since 1993, COLA also has the knowledge, experience, and expertise to educate and provide assistance to Certificate of Waiver site personnel. COLA’s solutions provide accreditation, competency assessment and maintenance tools, and management services that support the physician’s role in quality management of waived testing.

Conclusion
The findings of multiple surveys of sites performing waived testing throughout the United States lead to similar and alarming conclusions about lapses in quality in Certificate of Waiver sites. The studies highlight the need for additional education and training related to waived testing for Certificate of Waiver site directors and testing personnel.

While CMS provides some educational resources and is preparing recommendations on the waived testing issue, the agency characterizes its resources in this area as “lacking.” In the meantime, the problem of unregulated waived testing continues to grow, with the number of both Certificate of Waiver labs and new waived test methods increasing dramatically. Many industry experts believe that government oversight of the waived testing sector is inevitable, especially as the new political administration seeks to make sweeping changes to the U.S. health care system.
COLA’s offers extensive tools that provide the laboratory industry a ready-made answer to the growing problem of how to provide oversight of waived testing. By encouraging the widespread use of these COLA tools by waived laboratories everywhere in the U.S., laboratory and medical industry leaders, manufacturers, states, the CDC, CMS and other stakeholders will be able to proactively manage this important health care issue, even in the face of emerging government reforms of waived testing practices.

For additional information or to comment on this report, please contact COLA, at 800.981.9883 or www.cola.org

(1) “Review of Proficiency Testing Services for Clinical Laboratories in the United States,” April, 2008, Prepared for the Division of Laboratory Systems, Centers for Disease Control and Prevention

(2) “The Realities of Health Care Reform: Consumers Want Change but Will They Pay the Price?” Paul Keckley, Executive Director, Deloitte Center for Health Solutions, Deloitte LLP

Some of the information in this report was gleaned from “Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing,” which appeared in the CDC’s MMWR, Reports and Recommendations, November 11, 2005. The material in the MMWR report originated in the Coordinating Center for Health Information and Service, Steven L. Solomon, MD, Director; National Center for Health Marketing, Jay M. Bernhardt, PhD, Director; and the Division of Public Health Partnerships, Robert Martin, DrPH, Director.

About COLA
In 1988, a group of physicians founded COLA as a private alternative to help Physician Office Laboratories (POLs) stay in compliance with newly enacted Clinical Laboratory Improvement Amendments (CLIA). In 1993, the Health Care Financing Administration (now CMS) granted COLA deeming authority in all 50 states under CLIA, and in 1997 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also recognized COLA’s laboratory accreditation program.

After 35,000 surveys in which COLA’s practical, educational accreditation methods helped physician office laboratories stay in compliance with CLIA; COLA expanded its program offerings to include hospital and independent laboratories.

Today, COLA is the premier independent laboratory accrediting organization, dedicated to promoting excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation. COLA offers a wide range of services designed to enable clinical laboratories and staff to meet U.S. CLIA and other regulatory requirements, act in accordance with quality systems, and provide the best possible patient care.