Provider Performed Microscopy Procedures

A Focus on Quality Practices

https://www.cdc.gov/lab-quality/php/ppmp/index.html

CDC

For additional information go to:
https://www.cdc.gov/lab-quality/php/ppmp/index.html

Contact the Division of Laboratory Systems at PPMP@cdc.gov. The findings and conclusions in this booklet are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

May 2025

Introduction

Background

Healthcare providers use laboratory test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. While laboratory diagnostic testing is historically performed off-site, recent years have shown a marked increase in the availability and use of testing materials that can be performed by clinical staff at the point of care. Current practice shows a corresponding increase in point-of-care testing informing medical decisions.

Point-of-care testing is a valuable option for healthcare providers to perform certain microscopic examinations during patient visits using specimens that may quickly deteriorate or are difficult to transport. However, it is vital for patient safety and care that these procedures meet the same quality standards as any other moderately complex test performed in a clinical laboratory setting. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate for Provider-Performed Microscopy (PPM) procedures issued by the Centers for Medicare & Medicaid Services (CMS) permits a laboratory or testing site to perform a limited list of moderate complexity microscopic tests, as well as any waived tests.

Purpose

Forethought, planning, and careful preparation are critical considerations for administrators deciding whether to begin testing or expand an existing testing menu at their laboratory, physician's office, or other point-of-care location. This booklet describes regulatory requirements and recommended practices for licensed physicians, midlevel practitioners (nurse midwives, nurse practitioners, nurse anesthetist, clinical nurse specialist, or physician assistants), and dentists who perform patient testing under a CLIA Certificate for PPM procedures or who serve as laboratory directors at laboratories or testing sites that perform PPM procedures. The CLIA requirements for testing under a Certificate for PPM can be found at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-A/section-493.19.

An online course titled "Clinical Laboratory Improvement Amendments (CLIA) and Provider Performed Microscopy (PPM) Procedures: An Introduction" is also available at https://reach.cdc.gov/course/clinical-laboratory-improvement-amendments-clia-and-provider-performed-microscopy-ppm.

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

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Overview

PPM procedures are a select group of moderately complex microscopy tests that healthcare providers commonly perform during patient office visits. Because these tests are not simple and require training and specific skills, they do not meet the criteria for a waiver. Healthcare providers must obtain a CLIA Certificate for PPM procedures to allow licensed physicians, midlevel practitioners, and dentists to perform certain moderately complex microscopic examinations during a patient visit.

Characteristics of PPM procedures include:

- The specimen requires limited handling, transport, or processing.
- Any delay in performing the test could compromise the accuracy of the result (e.g., the specimen is liable to deteriorate or be easily altered).
- Control materials are generally not available to monitor the complete testing process.

Testing under a CLIA Certificate for PPM procedures is restricted to nine specific microscopic examinations using bright-field or phase-contrast microscopy:

- ✓ All direct wet-mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ✓ All potassium hydroxide (KOH) preparations
- ✓ Pinworm examinations
- ✓ Fern tests
- ✓ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ✓ Urine sediment examinations
- ✓ Nasal smears for granulocytes
- ✓ Fecal leukocyte examinations
- ✓ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Under a CLIA Certificate for PPM procedures, the laboratory or testing site may also perform all waived tests.

Laboratories or testing sites performing PPM procedures are not subject to routine biennial inspection. Because controls are generally unavailable to monitor the complete testing process for these procedures, only limited activities are suitable for inspection. However, laboratories and testing sites must have a CLIA certificate to perform these procedures and meet the CLIA quality standards for moderate complexity testing.

CLIA Certificate for Provider-Performed Microscopy Procedures

Obtaining a CLIA Certificate for PPM Procedures


CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
LABORATORY
12345 MAIN STREET
SPRINGFIELD, ST 67890

CLIA ID NUMBER
22D0981035

EFFECTIVE DATE
12/02/2018

LABORATORY DIRECTOR
JACOB LEE Ph.D.

EXPIRATION DATE
12/01/2020

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

Federal regulations require testing sites wishing to perform PPM procedures to file for and obtain a separate CLIA Certificate for PPM procedures for each testing location before testing patient specimens commences. Your site can obtain a CLIA Certificate for PPM procedures by completing the CMS-116 form located on the CMS website (https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms012169).

Your completed CMS-116 form must:

- ✓ Be signed by the owner or authorized representative attesting that the laboratory or testing site will be operated per CLIA requirements.
- ✓ Describe the characteristics of your operation and the examinations and other testing procedures your facility will perform, including:
  - The facility name, address, type, and hours of testing
  - The name and total number of testing procedures and examinations your facility performs annually [excluding tests for quality control, quality assurance, or proficiency testing (PT) purposes]
  - The methodologies for any testing procedure or examination your facility performs
  - The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory or testing site and performing the examinations and testing procedures

Send your completed CMS-116 form to the address of your site's local CMS state agency. You should contact the state agency for any additional forms necessary to complete the registration process. The CMS state agency contacts can be found at https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/contacts. Further information on how to apply for a CLIA certificate, including information for exempt states and international laboratories, is available at https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/apply.

For additional information on obtaining a Certificate for PPM procedures, refer to the CMS brochure *CLIA Certification*, available online at: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures.

Once your site has obtained a CLIA Certificate for PPM procedures, requirements for testing include:

- ✓ Paying the certificate renewal fee every two years.
  - Effective March 1, 2026, paper CLIA certificates and paper fee coupons will no longer be available. https://www.cms.gov/files/document/clia-transition-paperless-toolkit.pdf
  - All laboratories or testing sites can pay their CLIA certification fee online though a secure platform hosted by the U.S. Treasury Department. Paying online is the quickest option – your payment gets processed overnight. It is much faster than mailing hard-copy checks, which can take up to 10 business days. https://www.pay.gov/public/form/start/55598674
- ✓ Notifying your state agency of any changes in the laboratory's or testing site's ownership, name, address, or director within 30 days or if you wish to add tests that are not categorized as PPM procedures or waived.
- ✓ Allowing announced or unannounced on-site inspections by a CMS representative.

Facility Administration

To perform PPM testing, you need a location with adequate space, an appropriate physical environment, and accommodations for proper disposal of biohazardous waste. Your testing site must have suitable and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. Safety procedures must be clearly established, easily accessible, consistently followed, and reviewed to ensure compliance and protection. Your laboratory or testing site must retain records and, as applicable, slides for easy retrieval of information, and you must comply with applicable federal, state, and local laboratory requirements.

Participation in Proficiency Testing

Laboratories or testing sites performing PPM procedures must meet the general CLIA requirements for participation in proficiency testing (PT) for laboratories performing nonwaived testing as described in CLIA Subpart H. PT is only required for the limited number of tests found in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. While the CLIA regulations do not require participation in a PT program for PPM procedures, CLIA does require that laboratories performing PPM procedures take steps to assure the accuracy of testing. To comply with CLIA requirements, you must verify the accuracy of any test or procedure you perform at least two times each year. Participation in a clinical microscopy or PPM PT module from an HHS-approved PT program will satisfy this biannual PT performance assessment requirement. If laboratories or testing sites enroll in PT, they are subject to all requirements for PT, including the prohibition of PT referral.

Quality System

Every laboratory or testing site that performs PPM testing must establish and maintain written policies and procedures for a quality system covering all phases of the total testing process. Your laboratory or testing site's quality system should include an ongoing quality assessment component that monitors, identifies, evaluates, and resolves problems as appropriate for PPM testing.

Inspection

CMS does not routinely inspect PPM sites; however, site inspections may occur under certain circumstances:

- ✓ If a complaint is made.
- ✓ To determine if the laboratory or testing site is performing tests not permitted with a Certificate for PPM procedures.
- ✓ If there is a risk of harm to a patient due to inaccurate testing.
- ✓ To collect information about PPM procedures.

Enforcement

If your laboratory or testing site fails to comply with the applicable CLIA requirements, CMS may impose alternative and/or principal sanctions. Alternative sanctions include:

- ✓ Directed plan of correction
- ✓ Directed portion of a plan of correction
- ✓ State on-site monitoring
- ✓ Civil money penalty

Principal sanctions include suspension, limitation, or revocation of the CLIA Certificate for PPM procedures. Failure to meet CLIA requirements may also result in suspension of all or part of Medicare and Medicaid payments. The overall compliance history of your laboratory or testing site and the deficiencies' nature, severity, and duration would be considered when choosing sanctions.

Performing Waived Testing Under a Certificate for PPM Procedures

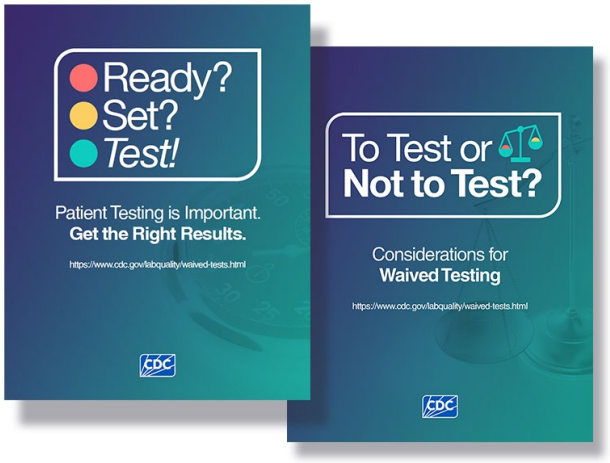
Laboratories or testing sites with a CLIA Certificate for PPM procedures may also perform waived testing. Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those approved for waiver under CLIA criteria. FDA continually updates its list of waived tests. The most current information on FDA-cleared waived tests can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

Requirements to perform waived testing include:

- ✓ Following the current manufacturer's instructions for the waived tests you perform without any changes.
- ✓ Paying the certificate renewal fee every two years.
- ✓ Notifying your state agency of any changes in ownership, name, address, or director within 30 days or if you wish to add tests that are not waived.
- ✓ Allowing announced or unannounced on-site inspections by CMS representatives.

Free educational products are available describing good laboratory practices for waived testing. These materials can be found at https://www.cdc.gov/lab-quality/php/waived-tests/index.html:

- ✓ The "***READY? SET? TEST!***" booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver. The booklet contains tips, reminders, resources, forms, and examples for use in your testing site.



- ✓ The "***READY? SET? TEST!***" online training provides resources to promote reliable, high-quality testing and enhance patient safety by explaining the steps of the waived testing process. This course offers continuing education credits.
- ✓ The "***To Test or Not to Test?***" booklet describes considerations and preparations needed before performing waived testing. It may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver. The booklet contains tips, reminders, resources, forms, and examples for use in your testing site.

Confidentiality and Patient Privacy

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) addresses the privacy rights and protection of personal health information. Laboratories and testing sites must establish policies and procedures to protect the confidentiality of health and personal information about their patients, including patient identification, test results, and all records of testing throughout the entire testing process. Several states have medical privacy laws that apply to laboratories and testing sites. All personnel should receive training on maintaining the confidentiality of patient information. You can find more information on HIPAA at https://www.hhs.gov/hipaa/for-professionals/index.html.

See Appendix A for an example of a Security and Confidentiality Agreement form.

Personnel

Overview

Site personnel must meet role-specific licensing, training, and competency assessment guidelines for the laboratory or testing site to perform testing under a CLIA Certificate for PPM procedures.

Laboratory Director

In states requiring a license, laboratory directors must possess a current, state-issued laboratory director's license. They must also be licensed physicians, midlevel practitioners, or dentists.

PPM Testing Personnel

Healthcare providers performing testing under a CLIA Certificate for PPM procedures must personally perform testing during a patient visit and within the context of a physical exam. Testing personnel are responsible for specimen processing, test performance, and reporting test results. They must also meet the following requirements, depending on their role:

- **Physicians** include individuals with a doctorate in medicine, osteopathy, or podiatric medicine who are licensed to practice medicine, osteopathy, or podiatry in the state where the laboratory or testing site is located. The physician may test specimens obtained from their patient or the patient of another physician or midlevel practitioner in their group medical practice during the patient visit.
- **Midlevel practitioners** are nurse midwives, nurse practitioners, nurse anesthetist, clinical nurse specialist, or physician assistants who, in some states, must be licensed. A midlevel practitioner may perform PPM procedures either under the supervision of a physician or on their patient or the patient of a clinic, group medical practice, or other healthcare provider in which the midlevel practitioner is a member. Some states authorize midlevel practitioners to perform PPM procedures in an independent practice.
- **Dentists** are doctors of dental medicine or dental surgery licensed to practice dentistry in the state where the laboratory or testing site is located. Dentists may test specimens obtained from their patients or their group dental practice patients during a patient's visit.

If the personnel performing microscopy testing at your laboratory or testing site do not meet these criteria, you must obtain a CLIA Certificate of Compliance or a Certificate of Accreditation. For details on CLIA certificate types, refer to the CMS brochure *CLIA Certification*, available online at: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures.

CLIA Requirements for Personnel

Laboratory directors and testing personnel performing PPM procedures must meet CLIA personnel requirements for their roles. A single, qualified individual may serve in both roles.

The laboratory director:

- ✓ Must also be eligible to operate a laboratory or testing site per CLIA requirements.
- ✓ Must possess a current license as a laboratory director issued by the State where the laboratory or testing site is located if licensing is required.
- ✓ Must be authorized to practice independently in the state of the laboratory or testing site.
- ✓ Is responsible for the overall operation and administration of the laboratory or testing site, including the prompt, accurate, and proficient reporting of test results.
- ✓ Must direct no more than five laboratories.
- ✓ Must be a physician, midlevel practitioner, or dentist.
- ✓ Must ensure that a qualified individual performs PPM procedures following applicable requirements.
- ✓ Must evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently.
- ✓ Must ensure all state and local requirements for testing are met.

Training

PPM procedures are nonwaived moderately complex and require the attention of highly skilled and well-trained personnel to protect patient care by ensuring quality testing. In addition to the established education requirements, PPM testing personnel should receive adequate training to meet the qualifications required to perform testing and report patient results.

A qualified person should have knowledge of:

- ✓ Microscope use and maintenance
- ✓ Accurate performance of tests
- ✓ Good laboratory practices
- ✓ Safety practices, such as:
  - Standard precautions: https://www.cdc.gov/infection-control/hcp/basics/standard-precautions.html
  - Handling and disposal of hazardous waste
  - Appropriate use of personal protective equipment (PPE)

You can access numerous online laboratory training courses free of charge at the Centers for Disease Control and Prevention (CDC) Laboratory Training website (https://www.cdc.gov/lab-training/php/courses/index.html). CDC designs these courses to assist public health and clinical laboratory professionals with their training needs and obtaining continuing education credits necessary to maintain certifications. Whether you are a laboratory director or a member of PPM testing personnel, these courses offer various opportunities to maintain the qualifications needed for your specific role. For example, a basic microbiology curriculum series, including a course on basic microscopy, is available to provide basic knowledge and understanding of the components, setup, procedures, and care and maintenance of a bright-field (compound) microscope.

Another useful resource for laboratory directors or PPM testing personnel is CDC's OneLab **REACH™** (https://reach.cdc.gov/training), a customized learning management system for laboratory professionals covering comprehensive training on laboratory preparedness, quality, safety, core sciences, and informatics. CDC OneLab **REACH™** also includes OneLab Network, which connects public and private laboratory professionals with CDC, and OneLab Test, a collaborative effort involving a collective of professionals and volunteers who perform testing.

Laboratory directors may find that a well-designed checklist can also be useful for you and your PPM testing personnel to work through the training agenda at your own pace. You may also find it valuable to request feedback from staff on different training modules to identify gaps in your training programs or other areas for improvement.

Examples of Training Checklist and Training Evaluation forms are available in Appendix B and Appendix C.

Other potential resources for training and educational materials include:

- ✓ Manufacturers and distributors
- ✓ Professional organizations
- ✓ State health departments or other government agencies

Competency Assessments

Training and education help develop the knowledge and skills needed to qualify staff to perform PPM procedures; however, they do not guarantee that all qualified staff will apply their knowledge, skills, and experience appropriately. By performing periodic competency assessments and remediation training when needed, you can ensure that your testing personnel fulfill their duties per applicable federal, state, and local requirements.

PPM testing personnel are required to undergo competency assessment to ensure accurate and reliable testing and reporting. If you are the laboratory director and are the only individual testing and reporting test results, you must establish and document a minimum proficiency level to maintain the required competency for accurate and reliable testing and reporting. Participating in PT or other external assessments is a common method to establish competency. All testing personnel must be assessed for each test they are authorized to perform.

As of December 28, 2024, CLIA regulation 42 CFR 493.1359 states laboratory directors are responsible for ensuring that testing personnel maintain their competency to perform PPM procedures. The laboratory director must evaluate and document the performance of individuals responsible for PPM testing at least twice during the first year they test patient specimens. Laboratory directors must repeat this evaluation and documentation process at least annually after the first year of testing. Laboratory directors can delegate the individual procedures of staff training and competency, in writing to other qualified PPM testing personnel.

The following five procedures are the minimum regulatory requirements for assessing the competency of all personnel performing PPM procedures:

1. Directly observe routine patient test performance, including, if applicable, specimen handling, processing, and testing.
2. Monitor the recording and reporting of test results.
3. Review test results or worksheets.
4. Assess test performance through testing internal blind testing samples or external PT samples.
5. Assess problem-solving skills.

Competency assessment for PPM may include:

- ✓ Observing routine patient test performance, including specimen handling, processing, and testing.
- ✓ Monitoring the recording and reporting of results according to the laboratory's or testing site's procedure.
- ✓ Reviewing testing documents such as worksheets, quality control (QC) records, PT results, and corrective action records.
- ✓ Observing microscope cleaning and maintenance procedures.
- ✓ Monitoring the number of procedural failures.
- ✓ Checking documents for accuracy and completeness.
- ✓ Participating in external assessment activities, such as PT programs.
- ✓ Monitoring the number of PT failures.

See Appendix D for an example Competency Assessment form.

The CMS brochure *Clinical Laboratory Improvement Amendments (CLIA) Assessing Personnel Competency* provides additional information on competency assessment. https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures

Safety

Overview

Every laboratory or testing site must comply with applicable federal and state safety regulations to ensure a safe environment for staff and patients.

Federal Regulations for Safety

The Occupational Safety and Health Administration (OSHA) requires employers to provide employees with a safe and healthy workplace. The OSHA brochure, *Medical & Dental Offices— A Guide to Compliance with OSHA Standards* (https://www.osha.gov/publications/publication-products?publication_title=3187), lists regulations applicable to most laboratories and testing sites. Other OSHA requirements for laboratories or testing sites include:

- ✓ Treating all human blood (and certain human tissues and body fluids) as infectious. Strictly enforcing the use of standard precautions and compliance with the bloodborne pathogens standard: https://www.osha.gov/bloodborne-pathogens/general.
- ✓ Providing safety training to employees on handling blood and other infectious materials. Safety training is required at the start of employment, at least annually thereafter, or sooner if conditions change. This training must be conducted during work hours, at no cost to the employee, and include guidance on responding to safety incidents.
- ✓ Using safer engineered needles, sharps containers, and personal protective equipment (PPE), such as gloves and protective eyewear: https://www.osha.gov/personal-protective-equipment/hazards-solutions.
- ✓ Implementing a sharps injury prevention program. Establish and maintain a sharps injury log to record any injuries from contaminated sharps. CDC provides a Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program: https://www.cdc.gov/infection-control/hcp/sharps-safety/program-workbook.html.
- ✓ Offering hepatitis B vaccination at no cost for employees with possible occupational exposure.
- ✓ Providing equipment for safe handling and disposal of biohazardous waste.
- ✓ Having a written plan for exposure control: https://www.osha.gov/sites/default/files/CPL_2-2_69_APPD.pdf.
- ✓ Maintaining records of occupational injuries and illnesses: https://www.osha.gov/recordkeeping/entry-faq.

For more information on standard precautions and infection control, refer to CDC's guidance Standard Precautions for All Patient Care: https://www.cdc.gov/infection-control/hcp/basics/standard-precautions.html.

State Regulations for Safety

Many U.S. states and territories provide OSHA-approved State Plans for workplace safety and health programs. If your laboratory or testing site is in one of these states or territories, you must comply with any regulations outlined for your state: https://www.osha.gov/stateplans.

General Safety Practices

In addition to applicable federal and state regulations, your laboratory or testing site should incorporate the following general safety practices into your standard operating procedures (SOPs):

- ✓ Do not eat, drink, or apply makeup in specimen collection or testing areas.
- ✓ Do not store food in refrigerators or freezers where testing supplies or specimens are stored.
- ✓ Refrigerators and freezers that store blood or other potentially infectious materials must display the biohazard symbol.
- ✓ Provide sinks for hand-washing or antiseptic hand-washing solutions for staff and patients. Staff should clean hands and change gloves between patients. Follow appropriate guidelines to ensure hand hygiene: https://www.cdc.gov/clean-hands/hcp/clinical-safety/index.html (for healthcare workers) and https://www.cdc.gov/Clean-Hands/About/Hand-Hygiene-for-Healthcare.html (for patients in healthcare settings).
- ✓ Ensure eye wash stations are operational by using a maintenance log (see Appendix E).
- ✓ Post safety information, including biohazard warning signs at all access points to alert employees and patients to potential risks.

Safety Plan

All laboratories and testing sites should develop site-specific safety plans describing policies, procedures, and work practices to protect employee safety. Your safety plan should inform testing personnel and staff about good laboratory practices and the health hazards associated with testing.

See Appendix F for an example Safety Plan, including a Safety Training Checklist and Incident Report.

Risk Management

Adhering to occupational safety regulations and establishing a strong safety plan will help reduce your laboratory's or testing site's risk, but they will not eliminate it. Risk management is an ongoing process that requires you to remain vigilant while identifying, assessing (evaluating), controlling, and monitoring risk. For detailed information on the overall risk management process, refer to the CDC Biological Risk Assessment Safe Labs Portal: https://www.cdc.gov/safe-labs/php/biological-risk-assessment/index.html.

To further ensure your staff's and patients' safety, conduct a biological risk assessment to evaluate the biological safety risks at your testing location and identify strategies for reducing them. Additional resources on performing risk assessments can be found at https://www.cdc.gov/safe-labs/php/biological-risk-assessment/process.html.

Testing Locations

The appropriate physical environment for testing is vital to achieving reliable test results. Your testing personnel should have a clean work area with space to ensure patient privacy and safety throughout the testing process. Your laboratory or testing site should also have procedures and materials necessary to properly dispose of hazardous waste.

Environment

Providing a physical space appropriate for testing requires you to consider many environmental factors. In conjunction with the test manufacturer's instructions, these factors will help you determine the best conditions for test performance and storage of reagents, test kits, controls, and patient specimens for your laboratory or testing site.

- **Workspace —** Testing workspaces should be stable and level, protect patient confidentiality, and allow for proper disinfection, specimen collection, testing, and storage of supplies and records.
- **Lighting —** Specimen collection and testing areas should be well-lit.
- **Ergonomics —** Evaluate work tasks for ergonomic stressors that could manifest into injuries or repetitive stress disorders. Major ergonomic issues in the laboratory setting include static or awkward postures and repetitive motions. The environment should also be free of trip hazards.
- **Safety labels —** Identify and clearly label all equipment and testing areas that present safety hazards.
- **Temperature range —** Follow the manufacturer's instructions for storage and testing and avoid temperature extremes, which can affect patient specimens, reagents, components, reaction times, and test shelf-life.
- **Humidity levels —** Relative humidity can affect reagents and test components, the rate of chemical reactions and specimen interaction, and test endpoints. Refer to the manufacturer's instructions for any applicable humidity level requirements.
- **Utilities —** Some testing devices and equipment may require a source of electricity or water.
- **Housekeeping —** Testing areas should be clean and organized. If applicable, ensure housekeeping staff are trained on the potential hazards of handling biological waste and have proper safety training to work with such material.

Biohazardous Waste Disposal

Laboratories and testing sites often generate hazardous waste, which cannot be mixed with regular trash. Use proper biohazard containers to dispose of waste and sharps. Your laboratory or testing site should have site-specific procedures that follow local, state, and federal requirements to safely dispose of biohazardous waste generated from specimen collection and testing. Local hospitals or clinics may be able to provide information about regulated waste disposal.

During the testing process, 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
- ✓ Not overfilled

Contaminated waste containers must:

- ✓ Be constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, and shipping.
- ✓ Display the biohazard symbol along with the word “biohazard” or ensure the background of the symbol is color-coded in red.
- ✓ Be closed before removal to prevent spillage or protrusion of contents during handling.

Disinfecting Work Surfaces

Bacteria and viruses can be present in very high concentrations in just a few drops of blood or other body fluids, and some remain infectious for at least one week in dried blood on countertops and doorknobs. Be sure to disinfect surfaces before you perform any test procedure, whenever contamination is visible, and before leaving the testing area. Use the appropriate disinfectant to decontaminate your work area.

See Appendix G for helpful information about common disinfectants and antiseptics.

Performing PPM Procedures

Overview

Preparing for patient testing is essential. Equipment used for testing should be maintained, with cleaning and servicing performed and documented as directed in the manufacturer's instructions.

Procedure Manual

Your laboratory or testing site must have written procedures for every PPM procedure you perform on-site that are easily accessible by all testing personnel. Textbooks may supplement but cannot replace your laboratory's or testing site's developed, approved, and updated written testing procedures. Appendix H (Procedure Contents and Tips) provides practical methods for writing your laboratory's or testing site's testing procedures.

Consider compiling testing procedures into a procedure manual that you can store in a central location to ensure QC for all documents, forms, and instructions at your laboratory or testing site. As laboratory director, you must approve and date procedure manuals before patient testing, and you should review and sign them annually and with every procedure change or revision. When your laboratory or testing site changes a testing procedure, you should remove the outdated versions from the active manual, clearly date and label them as inactive, and keep them on file for reference.

Procedure manuals should have instructions and forms for:

- ✓ Cleaning and maintenance of the microscope
- ✓ Patient identification and preparation
- ✓ Specimen collection and labelling
- ✓ Specimen acceptability and rejection criteria, including detecting inadequately prepared slides
- ✓ Preparation of slides, test reagents, controls, stains, and other test materials
- ✓ Storage of slides, test reagents, controls, stains, and other test materials
- ✓ Performing QC procedures
- ✓ Performing the test(s)
- ✓ Interpreting and recording the test result(s)
- ✓ Reportable range for test results, including normal values
- ✓ Entering test results in the patient record and reporting patient results
- ✓ Troubleshooting testing problems
- ✓ Recording temperatures of refrigerators and storage areas
- ✓ Keeping inventories and lot numbers of reagents
- ✓ Handling and disposal of hazardous waste

- ✓ Cleaning and disinfecting work areas and equipment
- ✓ Selecting and using personal protective equipment
- ✓ Performing work area environmental and ergonomic assessments
- ✓ Referring testing to outside laboratories

Prepare for Testing

Before testing, ensure your laboratory or testing site conforms to the physical environment criteria covered in the Testing Locations section and any applicable manufacturer's instructions. The laboratory or testing site must also have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed.

To ensure that your laboratory or testing site is always prepared for testing, you should:

- ✓ Inspect electrical connections to ensure they are functioning properly.
- ✓ Inspect all equipment, such as centrifuges, to ensure they are functioning properly.
- ✓ Clean work surfaces before and after testing.
- ✓ Inspect and clean the microscope before and after testing.
- ✓ Check inventory regularly to ensure you have enough unexpired reagents, stains, and supplies for testing.
- ✓ Verify proper storage of reagents, stains, and supplies.
- ✓ Check and record expiration dates of reagents and stains and discard any reagents or stains that have expired.

Testing Equipment

Your laboratory or testing site should have, and adhere to, a cleaning and maintenance procedure and policy for all testing equipment. Follow any professional servicing and documentation guidelines as directed by the equipment manufacturer.

Microscopes

Laboratories or testing sites performing PPM procedures need a bright-field and/or phase-contrast microscope. Bright-field microscopy illuminates the specimen with white light. The specimen absorbs some of the transmitted light, which creates contrast. The specimen retains much of its natural color in bright-field microscopy, though it appears darker on a bright background. Phase-contrast microscopy requires special phase-contrast objectives and a special phase-contrast condenser, which produces high-contrast images of transparent specimens. Phase-contrast microscopy reveals many cellular elements that are not visible with bright-field microscopy.

Microscopes used for testing must be maintained and serviced by a professional as directed by the manufacturer. Laboratories or testing sites must document all maintenance and professional service activities. See Appendix I for a Care and Maintenance of the Microscope job aid and Appendix J for a Microscope Maintenance Log.

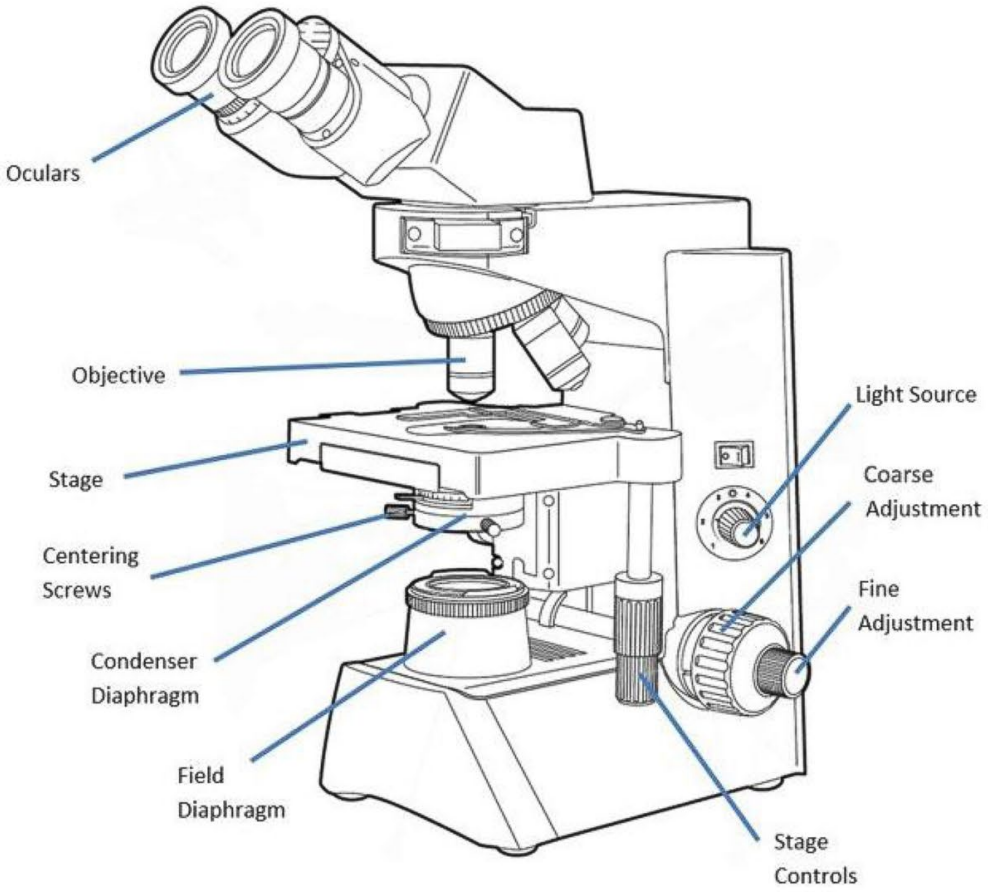
CDC DIVISION OF LABORATORY SYSTEMS

Sections of the Microscope

Introduction

Microscopy has a very important role in microbiology laboratories. A microscope is an essential tool for viewing microorganisms that are too small to be seen by the naked eye.

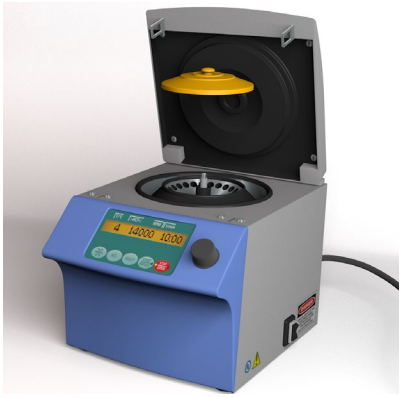
To use your microscope effectively and efficiently in your daily routine, it is necessary that you become familiar with the major sections of the microscope.



This job aid is a component of the free, on-demand CDC course Basic Microbiology Series: Basic Microscopy | CDC. Find the course at https://www.cdc.gov/lab-training/php/courses/basic-microscopy.html.

For information on the function of each microscope section, please visit CDC OneLab **REACH**™: https://reach.cdc.gov/jobaid/sections-microscope.

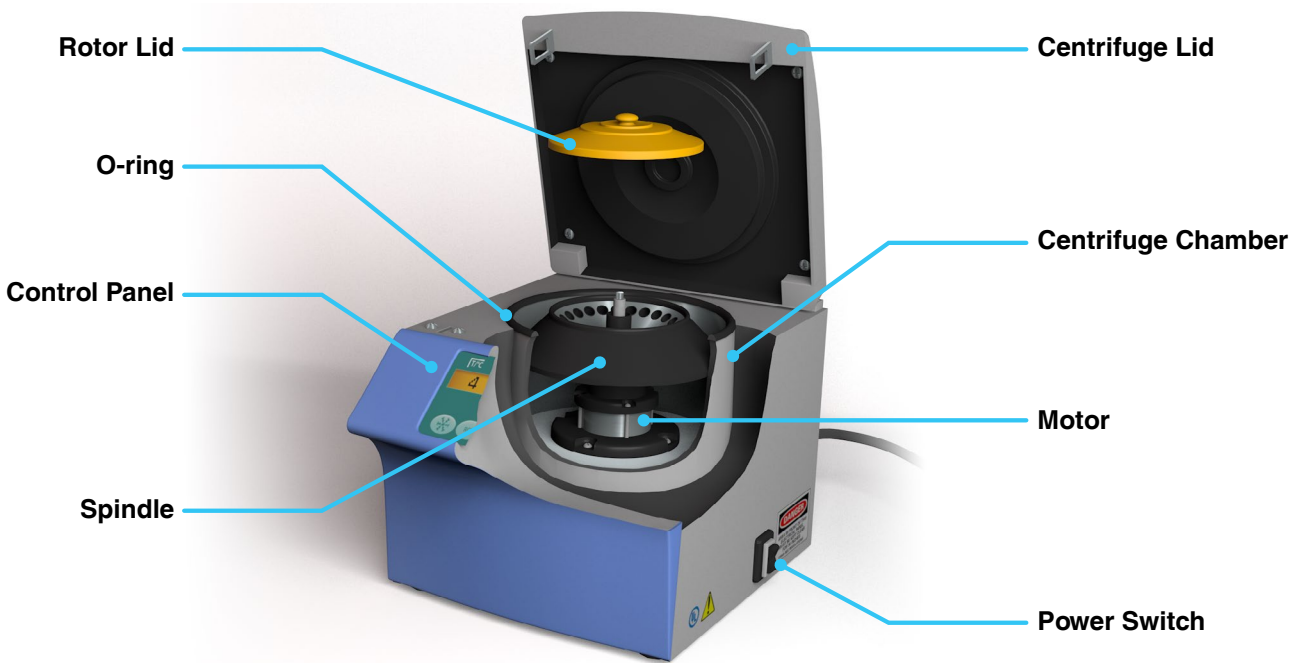
Centrifuges



Centrifuges are motor-driven instruments that spin specimen tubes at high speeds to apply outward force to the various materials inside the tube. The centrifugal force causes more dense materials inside the tube to separate from less dense materials, which settle at the bottom of the tube. In PPM procedures, your laboratory or testing site may use centrifugation as a pre-analytical step before performing the procedure. All testing personnel should be familiar with the key components of the centrifuge.

Components of the Centrifuge

- **Humidity levels —** Relative humidity can affect reagents and test components, the rate of chemical reaction
- **Centrifuge chamber —** The inside of the centrifuge where the rotor is contained.
- **Centrifuge lid —** A door that closes the centrifuge chamber and includes a lock system that latches while the rotor is spinning and unlatches when the rotor has stopped spinning.
- **Control panel —** Usually located on the front of the centrifuge for easy visibility and access, the control panel comprises indicators, control knobs, and switches which vary between models and styles.
- **O-ring —** A gasket located on the centrifuge lid or rim of the centrifuge chamber that creates a seal between the centrifuge lid and chamber. O-rings are also found inside fixed-angle rotors and buckets used with swing-arm rotors to create a seal to contain aerosols generated during spinning.
- **Rotor —** A fixed-angle vessel or swing arm attached to the spindle that spins/rotates the specimens.
- **Rotor lid —** A lid used primarily to close fixed-angle rotors. The lid is usually screwed in place.
- **Spindle —** Anchors and rotates the rotor within the centrifuge chamber.
- **Motor —** Drives the rotation of the rotor.
- **Power switch —** Turns the centrifuge on or off.



Centrifuge Maintenance and Safety

Regular maintenance of your laboratory's or testing site's centrifuge is essential for ensuring its optimal performance, longevity, and safety. Adhering to the manufacturer's specific maintenance guidelines helps prevent equipment failure and ensures compliance with safety standards. When cleaning your laboratory's or testing site's centrifuge, use an approved germicidal agent to wipe the chamber, rotor, rotor lid, and centrifuge housing before and after each use. You should document any maintenance activities.

For more information regarding the safe use of centrifuges, visit OneLab **REACH**™ "Fundamentals of Centrifuge Safety" continuing education course: https://reach.cdc.gov/course/fundamentals-centrifuge-safety.

Quality Control

QC testing gives confidence that your results are accurate and reliable. PPM testing personnel are expected to follow the manufacturers' directions for QC or follow good laboratory practices. QC materials are generally not available to monitor the complete PPM testing process, making it difficult to determine the accuracy of the results. Good laboratory practice dictates that quality controls be run whenever possible and that you document and review results for acceptability before reporting them. Your laboratory or testing site must document all QC testing performed, including errors and corrective actions taken.

Your laboratory or testing site should have a QC testing policy establishing the number and types of control materials needed and how often they should be tested. If available, two levels of controls should be performed with:

- ✓ Each day of testing
- ✓ Each new shipment of stains, reagents, or testing kits
- ✓ A change in lot numbers
- ✓ Each new operator

Test Request

Your laboratory or testing site must receive a written or electronic request for patient testing from an authorized person. Verbal requests may be accepted, but the PPM site must request a written or electronic authorization within 30 days of the verbal request and maintain the authorization or documentation of its efforts to obtain the authorization. The test request should contain the following information:

- ✓ Name and address or other suitable identifiers of the authorized person or laboratory requesting the test
- ✓ Patient's name and unique patient identifier
- ✓ Sex and age or date of birth of the patient
- ✓ Test(s) to be performed
- ✓ Source of the specimen
- ✓ Date and time of specimen collection
- ✓ Any additional information relevant for a specific test

Your laboratory or testing site may use the patient's chart or medical record as the test request or authorization; in this case, it must be available to you at the time of testing, and you must make it available to CMS upon request. If you enter the test requisition or authorization information into a record or laboratory information system, you must ensure the information is transcribed or entered accurately.

Before collecting a specimen, confirm:

- ✓ **The test order —** If there is a question about whether the order is correct, check with the individual who requested the test.
- ✓ **Patient preparation —** Ensure the patient understands the purpose of the tests being ordered and what the results will mean to their health.
- ✓ **Patient identification —** Patient names can be similar, which can lead to confusion. Using at least two unique patient-specific identifiers (e.g., patient name and date of birth) is a good practice to ensure the test is ordered for and collected from the correct patient.

Specimen Collection

PPM procedures involve the use of specimens, such as body fluids or skin scrapings. Properly collected patient specimens are critical for accurate and reliable test results. The person collecting the specimen should understand the type of specimen needed for the test and how to collect it. Do not test specimens that are improperly collected or handled. The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from collection or receipt of the specimen through completion of testing and reporting of results.

Remember, if your site performs waived testing in addition to PPM procedures, only unprocessed specimens can be used for waived tests. Specimens that require processing, such as centrifugation, dilution, or extraction, are not appropriate for waived tests.

Performing the Test

When performing a test, follow the testing steps in the exact order as they are in the procedure manual. Interpret and record results legibly in a log or following the testing site policy and keep results as a permanent record. These records should have enough detail for easy retrieval of information. Invalid or unacceptable results should also be recorded. If you need to repeat a test, record the first result (invalid or unacceptable), resolve the problem, and then record the repeated result(s). Report the final acceptable result only.

Appendix L provides examples of procedures that your laboratory or testing site may use. Each example includes specimen collection, procedures for slide preparation and microscopic examination, and images of common microscopic findings for the nine PPM procedures specified by CLIA.

Reporting Test Results

Your laboratory or testing site must have a system to ensure the timely reporting of test results and other patient-specific information.

The test report must include the following:

- ✓ Patient's name and unique patient identifier
- ✓ Name and address of the laboratory or testing site
- ✓ Test report date
- ✓ Test performed
- ✓ Specimen source
- ✓ Test result
- ✓ Information regarding the condition and disposition of specimens that do not meet the laboratory's or testing site's criteria for acceptability
- ✓ Pertinent "normal" values, as determined by the laboratory or testing site

Guidelines for issuing test reports:

- ✓ Patient test reports should be legible, standardized, and promptly issued according to site-specific procedures.
- ✓ Reports from on-site tests should be easily distinguishable from referral laboratory test reports.
- ✓ Only give patient test reports to authorized persons in compliance with HIPAA. https://www.hhs.gov/hipaa/for-professionals/index.html
- ✓ Verbal communication of test reports should be documented and followed by a written test report.
- ✓ Follow site-specific policies and procedures when using electronic medical record systems or laboratory information systems to issue test reports.

Proficiency Testing Requirements

Overview

PT for PPM procedures involve the periodic shipment of photographs or digital images by a CLIA-approved PT program to a laboratory or testing site for evaluation and submission of results back to the PT program. The PT program then compares the results with the correct result for that photograph or image and provides a report to the participating laboratory or testing site. PT is an excellent tool to verify the accuracy and reliability of testing.

Requirements

Laboratories or testing sites performing PPM procedures must meet the general CLIA requirements for participation in PT for laboratories performing nonwaived testing as described in CLIA Subpart H. PT is only required for the limited number of tests found in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. While the CLIA regulations do not require participation in a PT program for PPM procedures, CLIA does require that laboratories performing PPM procedures take steps to assure the accuracy of testing. To comply with CLIA requirements, you must verify the accuracy of any test or procedure you perform at least two times each year. Participation in a clinical microscopy or PPM PT module from an HHS-approved PT program will satisfy this biannual PT performance assessment requirement. If laboratories or testing sites enroll in PT, they are subject to all requirements for PT, including the prohibition of PT referral.

Participating in a PT program offers many benefits to your laboratory or testing site:

- ✓ A regular, external check on the quality of testing
- ✓ Motivation to improve performance
- ✓ Comparison of performance with that of other participating sites
- ✓ 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
- ✓ Opportunities for identifying areas needing improvement

Many PT programs offer modules for PPM procedures. Although the use of an HHS-approved PT program provider is not a requirement, a list of HHS-approved PT program providers can be found at https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing

See also the CMS brochure Proficiency Testing and PT Referral available online: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures

Quality System

Overview

CLIA regulations state every laboratory or testing site performing PPM testing must establish and maintain written policies and procedures for a quality system covering all phases of the total testing process. The quality system needs to include an ongoing quality assessment component for monitoring, identifying, evaluating, and resolving problems as appropriate for PPM testing.

Communications and Complaint Investigations

Communications

Your laboratory or testing site may experience challenges communicating with authorized persons who order tests or receive results. You must have a system to anticipate, identify, and document problems that occur because of a communication breakdown and to ensure documentation of all complaints and problems reported to the PPM site. Communication can refer to all types of inquiries, including positive feedback and complaints.

Complaint Investigations

Your laboratory or testing site must have a system to ensure documentation of all reported problems and complaints. You must also investigate complaints when appropriate.

Quality Assessment

Your laboratory or testing site must establish and follow written policies and procedures to continuously monitor, assess, and correct issues related to general laboratory systems. This quality assessment must include reviewing the effectiveness of corrective actions, revising policies and procedures to prevent recurrence, discussing findings with relevant staff, and documenting all quality assessment activities.

Depending on your laboratory's or testing site's needs, resources, and practices, you may choose to use both internal and external quality assurance mechanisms.

Internal assessments are processes for staff performing and overseeing testing to evaluate their current practices, including:

- ✓ Reviewing the procedure for patient preparation, specimen collection, specimen rejection, labeling, preservation, and transportation of specimens.
- ✓ Performing QC procedures and documenting results.
- ✓ Reviewing QC records and test results for completeness and accuracy.
- ✓ Documenting and reviewing problems that occur during QC testing and the testing process.
- ✓ Establishing a corrective action plan to improve processes.

- ✓ Monitoring to ensure correction.
- ✓ Reviewing policies and procedures for documenting competency of testing personnel.
- ✓ Documenting and reviewing injury/incident reports.
- ✓ Reviewing communication and complaint policies.

External assessments are typically performed by an outside party to evaluate current practices and offer education opportunities. Possible options for external review include:

- ✓ Undergoing voluntary inspections by peers or consultants who would evaluate testing practices and documentation systems and offer suggestions for improvement.
- ✓ Subscribing to PT programs.
- ✓ Exchanging samples with other laboratories or testing sites using the same test methodology to compare results.

Record Keeping

Laboratories or testing sites performing PPM procedures are required to follow CLIA record retention requirements. These requirements are crucial for maintaining the integrity and compliance of laboratory operations and apply to both records and specimens involved in testing processes. Your laboratory or testing site must preserve all relevant documentation within specified time frames. Adhering to these retention standards is essential for regulatory compliance, providing accurate and reliable test results, and upholding high standards of patient care.

Key records with a minimum of 2 years of retention are:

- Test requisitions, authorizations, and patient charts used in these procedures
- Documentation of PPM procedure methods and discontinued test procedures
- QC records, patient test results, and records of analytic system activities
- PT records and quality system assessments (internal or external)
- Specimen requisitions, authorizations, and any chain of custody

Your laboratory or testing site must maintain the following specimen information:

- ✓ The positive identification of the specimen
- ✓ The date and time of specimen receipt into the laboratory
- ✓ The condition and disposition of specimens that do not meet your laboratory's or testing site's criteria for specimen acceptability
- ✓ The records and dates of all specimen testing, including the identity of the personnel who performed the tests
- ✓ Any issues with specimen integrity or handling and the actions taken to resolve these issues must be documented as part of the laboratory's or testing site's records.

Tips

The following checklist summarizes the steps to implement and oversee PPM testing.

General Requirements

- ✓ Understand the procedures PPM laboratories or testing sites are allowed to perform.
- ✓ Obtain a CLIA Certificate for PPM before offering testing.
- ✓ Renew the Certificate for PPM every 2 years.
- ✓ Notify your state agency of any changes in ownership, name, address, or director within 30 days or if you wish to add tests that are not waived or PPM procedures.
- ✓ Allow announced or unannounced on-site inspections by CMS representatives.
- ✓ Follow all applicable CLIA requirements for testing:
  - Personnel
  - Facility Administration
  - Proficiency Testing
  - Quality System
  - Inspection
  - Enforcement
- ✓ Follow all applicable state and local requirements.
- ✓ Follow regulations for confidentiality and patient privacy.

Personnel

- ✓ Follow all applicable CLIA requirements for the laboratory director.
- ✓ Only perform testing if you are a physician, midlevel practitioner, or dentist during a patient visit within the context of a physical examination.
- ✓ Ensure that all testing personnel understand and can perform the test correctly before they report patient results.
- ✓ Periodically assess and document the competency of testing personnel, twice during the first year and at least annually thereafter.

Safety

- ✓ Follow regulations for safety.
- ✓ Conduct a site and activity-specific risk assessment to identify appropriate PPE.
- ✓ Collect and label a good specimen for testing.
- ✓ Clean hands and change gloves between patients.
- ✓ Use the proper biohazard containers to dispose of waste and sharps.
- ✓ Maintain records of occupational injuries and illnesses.

Location for Testing

- ✓ Perform testing in a stable and level area with adequate space for patient privacy while safely collecting specimens and performing testing.
- ✓ Consider environmental issues, such as temperature and humidity, especially in nontraditional test settings.
- ✓ Have clean work surfaces and good lighting for specimen collection and testing.
- ✓ Dispose of waste safely.

Performing PPM Procedures

- ✓ Provide a procedure manual with specific instructions for each PPM procedure for your testing site.
- ✓ Inspect equipment and electrical connections on the microscope to ensure they are functional.
- ✓ Check inventory regularly to ensure you have enough unexpired reagents, stains, and supplies for testing.
- ✓ Perform and document microscope maintenance.
- ✓ Perform QC as recommended in the laboratory's PPM procedure manual and policy.
- ✓ Verify the test request.
- ✓ Properly collect and label an appropriate specimen for testing.
- ✓ Do not test specimens that are improperly collected or handled.
- ✓ Perform PPM testing following the steps in the laboratory's PPM procedure manual.
- ✓ Make sure patient reports are legible and reported promptly.
- ✓ Report patient test results only to authorized persons.
- ✓ Document verbal reports, followed by a written test report.

PT Requirements

- ✓ Verify the accuracy of testing at least twice per year.
- ✓ PT can be used to routinely monitor performance.

Quality System

- ✓ Document communication and complaint issues.
- ✓ Establish written policies and procedures to monitor and evaluate the testing process.
- ✓ Perform assessments to improve your current practice.
- ✓ Follow record-keeping requirements.

Resources

CLIA and HIPAA Links

- CMS CLIA Home Page: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
- Clinical Laboratory Improvement Amendments of 1988. Title 42 United States Code § 263a. Public Law No. 100–578. https://www.govinfo.gov/app/details/USCODE-2023-title42/USCODE-2023-title42-chap6A-subchapII-partF-subpart2-sec263a
- CLIA Regulations (42 CFR 493): https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493
- CMS brochure "CLIA Certification": https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures
- CMS brochure "Assessing Personnel Competency": https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures
- CLIA requirements for testing under a Certificate for PPM: https://www.ecfr.gov/current/title-42/section-493.19
- CLIA Certificate of PPM Procedures Application: https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms012169
- CLIA State Agency Contacts: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/contacts
- FDA's CLIA Waived Test List: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm
- CDC's waived tests educational materials: https://www.cdc.gov/lab-quality/php/waived-tests/index.html
- HIPAA regulations: https://www.hhs.gov/hipaa/for-professionals/index.html
- CMS Approved PT Programs: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing
- CMS brochure "Proficiency Testing and PT Referral": https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures

Safety Links

- The Centers for Disease Control and Prevention (CDC) Biosafety Information for Laboratories and Testing Sites: https://www.cdc.gov/safe-labs/php/about/ and https://www.cdc.gov/safe-labs/php/biosafety-training/
- State Occupational Safety and Health Programs: https://www.osha.gov/stateplans
- Medical & Dental Offices—A Guide to Compliance with OSHA Standards at: https://www.osha.gov/publications/publication-products?publication_title=3187
- Bloodborne Pathogens Standard: https://www.osha.gov/SLTC/bloodbornepathogens/index.html
- OSHA's PPE Fact Sheet: https://www.osha.gov/personal-protective-equipment/hazards-solutions
- CDC Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program: https://www.cdc.gov/infection-control/hcp/sharps-safety/program-workbook.html

- Hand Hygiene in Healthcare Settings: https://www.cdc.gov/Clean-Hands/About/Hand-Hygiene-for-Healthcare.html
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition: https://www.cdc.gov/labs/bmbl/index.html

Training Links

- CDC Laboratory Training: https://www.cdc.gov/lab-training/php/courses/index.html
- CDC OneLab **REACH**™: https://reach.cdc.gov/training
- Clinical Laboratory Improvement Amendments (CLIA) and Provider Performed Microscopy (PPM) Procedures: An Introduction: https://reach.cdc.gov/course/clinical-laboratory-improvement-amendments-clia-and-provider-performed-microscopy-ppm

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- Versalovic J, Carroll KC, Jorgensen JH, Funke G, Landry ML, Warnock DW (ed), Manual of Clinical Microbiology, 10th ed, vol 2. ASM Press, Washington, DC, 2011.
- CLSI. Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline-Second Edition. CLSI document POCT10-A2, Vol. 31 No. 24. Wayne, PA: Clinical and Laboratory Standards Institute, 2011.

Acknowledgements

The Michigan Department of Community Health, Michigan Regional Laboratory Wet Mount Proficiency Program, and the Wisconsin State Laboratory of Hygiene Proficiency Testing Program generously provided many of the images in the booklet.

Appendix A

Security and Confidentiality Agreement Instructions

Purpose:

The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements. The Privacy Rule standards address the use and disclosure of individuals' health information—protected health information (PHI) by organizations subject to the Privacy Rule (called covered entities) and standards for individuals' privacy rights to understand and control how their health information is used.

The Privacy Rule protects all PHI held or transmitted by a covered entity or its business associate in any form or media, whether electronic, paper, or oral. PHI is information including demographic data that relates to:

- The individual's past, present, or future physical or mental health or condition
- The provision of health care to the individual
- The past, present, or future payment for the provision of health care to the individual
- Identification of the individual or for which there is a reasonable basis to believe the information can be used to identify the individual.

PHI includes many common identifiers (e.g., name, address, birth date, Social Security Number).

Good work practices should be in place to prevent PHI disclosure, and new employees should be trained in these practices. This Security and Confidentiality Agreement form documents the agreement of all employees to abide by HIPAA's Privacy Rule and prevent disclosure of patient PHI.

Contents:

There are many ways to document compliance training with HIPAA. A blank form and an example form that demonstrates how to enter site-specific information are included for your use.

1. Example Security and Confidentiality Agreement Form
2. Blank Security and Confidentiality Form

Instructions for Completing the Security and Confidentiality Agreement Form:

1. Train new employees on the work practices and the importance of HIPAA.
2. Employees should sign the Security and Confidentiality Agreement Form indicating their understanding and willingness to adhere to HIPAA.
3. File signed form with employee records.
4. When the Security and Confidentiality Agreement form is completed, the person who directs or supervises the testing should review and sign it.

EXAMPLE

Facility: *General Health Practice*
Location: *123 West Dr.*
Atlanta, GA 55555

Security and Confidentiality Agreement

1. I understand that the patient and organization information I will be able to access online, by voice transmission, and/or on paper is confidential and may be legally privileged. I have an obligation to protect data from loss, misuse, or unauthorized access or disclosure. The obligation to maintain confidentiality extends beyond work time to include personal time as well.

2. I acknowledge that patient information including demographics, patient care, and results, are confidential, and are protected by legal and regulatory guidelines. Further, this data should not be shared without appropriate consents authorization, or consideration. Accordingly, I understand that I am not allowed to share my password/ID access with others and that I have an obligation to close any computer session I open so that my access cannot be used by others.

3. I understand that improper access or disclosure of data may subject me to disciplinary and legal action. Similarly, if I exceed my computer system access authority or engage in conduct outside of the scope of my duties, I may be subject to disciplinary action.

4. I understand and agree to behave in a professional, ethical manner regarding patient and organizational confidentiality.

Employee Signature: *Thomas Smith, MD* **Date:** *6/15/2025*

Printed Name: *Thomas Smith, MD* **Facility:** *General Health Practice*

Facility:
Location:

Security and Confidentiality Agreement

1. I understand that the patient and organization information I will be able to access online, by voice transmission, and/or on paper is confidential and may be legally privileged. I have an obligation to protect data from loss, misuse, or unauthorized access or disclosure. The obligation to maintain confidentiality extends beyond work time to include personal time as well.

2. I acknowledge that patient information including demographics, patient care, and results, are confidential, and are protected by legal and regulatory guidelines. Further, this data should not be shared without appropriate consents authorization, or consideration. Accordingly, I understand that I am not allowed to share my password/ID access with others and that I have an obligation to close any computer session I open so that my access cannot be used by others.

3. I understand that improper access or disclosure of data may subject me to disciplinary and legal action. Similarly, if I exceed my computer system access authority or engage in conduct outside of the scope of my duties, I may be subject to disciplinary action.

4. I understand and agree to behave in a professional, ethical manner regarding patient and organizational confidentiality.

Employee Signature: _____ **Date:** _____

Printed Name: _____ **Facility:** _____

Appendix B

Training Checklist Instructions

Purpose:

All employees need to understand their role in the organization as a whole and learn the expectations of their supervisor while performing the basic elements of their job. Their experience in the first few weeks will have a significant effect on the level of commitment and ability to become productive quickly.

Checklists provide a structured approach to training new employees. Checklists allow new employees to work through the training agenda at their own pace, spending less time on issues with which they are already familiar and more time on those issues that are new or unfamiliar to them.

A well-designed training checklist can serve as a guide for new arrivals as they learn all the elements of their job.

Contents:

There are many ways to document training. A blank checklist is included for your use, along with an example checklist that demonstrates how to correctly enter site-specific information.

1. Example Training Checklist
2. Blank Training Checklist

Instructions for Completing the Training Checklist Form:

1. The employee should read the procedure that they will be trained to perform.
2. The trainer should review the procedure before beginning the training.
3. The trainer will demonstrate the procedure explaining each step as they perform it.
4. The trainee will perform the procedure and be able to explain key steps.
5. Upon completion, the trainer and trainee will document the training with the checklist and address any issues or concerns that arise. If re-training is necessary, this should be documented on the checklist.
6. The checklist should be filed with the employee's other records.

EXAMPLE

Facility: General Health Practice
Location: 123 West Dr.
Atlanta, GA 55555

Training Checklist

Trainee: Michelle Richards
Date: 06/03/2025 **Trainer:** Thomas Smith
Test: ABC Test Kit

The trainer should review all the material listed below and verify that the trainee has read and understood the appropriate procedures or manufacturer's instructions. Then, the trainer should file the completed form appropriately.

Objective	Date Completed	Trainee Initials	Trainer Initials
1. Trainee locates, reads, and understands policies and procedures for the PPM test(s).	06/03/2025	MR	TS
2. Trainer discusses principle of test procedure so that trainee understands scope and purpose of the test.	06/03/2025	MR	TS
3. Trainer identifies equipment, reagents, stains, and supplies to perform test and trainee knows location.	06/03/2025	MR	TS
4. Trainer demonstrates compliance with standard safety precautions including appropriate PPE and trainee understands the precautions.	06/03/2025	MR	TS
5. Trainee observes proper specimen collection, handling, and storage requirements for patient specimens.	06/03/2025	MR	TS
6. Trainee is able to reconstitute, prepare, and store reagents required for the PPM test.	06/03/2025	MR	TS
7. Trainee demonstrates knowledge of microscope components and proper microscope maintenance.	06/03/2025	MR	TS
8. Trainee observes test procedure performed by trainer.	06/03/2025	MR	TS
9. Trainee performs the procedure and should be able to: a. Identify proper specimen type, use of the appropriate collection device, labeling, handling, and storage of specimens b. Organize work area for testing including preparation of reagents c. Perform quality control (QC) samples, if available prior to performing patient specimen d. Set up timer and follow incubation times per the PPM procedure e. Interpret results f. Decontaminate and clean work area, including proper disposal of hazardous waste and sharps and microscope cleaning g. Document corrective action taken for errors in testing and unacceptable QC	06/06/2025	MR	TS
10. Data entry, recording, and reporting test results. Trainee demonstrates the ability to perform: a. Test order and accessioning b. QC and interpretation of results, if applicable c. Corrective action d. Report results	06/06/2025	MR	TS

Trainee Comments: Dr. Smith was clear in his explanations and knew the answers to my questions
Trainee Signature: Michelle Richards **Date:** 06/06/2025
Trainer Comments: Michelle was attentive and followed directions during the instruction
Trainer Signature: Thomas Smith **Date:** 06/06/2025

Facility:
Location:

Training Checklist

Trainee: _____

Date: _____ **Trainer:** _____

Test: _____

The trainer should review all the material listed below and verify that the trainee has read and understood the appropriate procedures or manufacturer's instructions. Then, the trainer should file the completed form appropriately.

Objective	Date Completed	Trainee Initials	Trainer Initials
1. Trainee locates, reads, and understands policies and procedures for the PPM test(s).			
2. Trainer discusses principle of test procedure so that trainee understands scope and purpose of the test.			
3. Trainer identifies equipment, reagents, stains, and supplies to perform test and trainee knows location.			
4. Trainer demonstrates compliance with standard safety precautions including appropriate PPE and trainee understands the precautions.			
5. Trainee observes proper specimen collection, handling, and storage requirements for patient specimens.			
6. Trainee is able to reconstitute, prepare, and store reagents required for the PPM test.			
7. Trainee demonstrates knowledge of microscope components and proper microscope maintenance.			
8. Trainee observes test procedure performed by trainer.			
9. Trainee performs the procedure and should be able to: a. Identify proper specimen type, use of the appropriate collection device, labeling, handling, and storage of specimens b. Organize work area for testing including preparation of reagents c. Perform quality control (QC) samples, if available prior to performing patient specimen d. Set up timer and follow incubation times per the PPM procedure e. Interpret results f. Decontaminate and clean work area, including proper disposal of hazardous waste and sharps and microscope cleaning g. Document corrective action taken for errors in testing and unacceptable QC			
10. Data entry, recording, and reporting test results. Trainee demonstrates the ability to perform: a. Test order and accessioning b. QC and interpretation of results, if applicable c. Corrective action d. Report results			

Trainee Comments: _____

Trainee Signature: _____ **Date:** _____

Trainer Comments: _____

Trainer Signature: _____ **Date:** _____

Appendix C

Training Evaluation Instructions

Purpose:

The individual overseeing testing advocates for employees by gathering and distributing the resources employees need to do a good job and by providing positive encouragement for a job well done. They should display the interpersonal skills required to engage employees and enhance their self-confidence.

Feedback from employees on the training experience provides valuable information to employers seeking to improve or identify gaps in their training programs. This method also opens communication between the employee and the employer.

Many training programs fail to deliver the expected organizational benefits. A well-structured measuring system can help you locate the problem.

Contents:

There are many ways to evaluate training. A blank evaluation form is included for your use, along with an example evaluation form that demonstrates how to correctly enter site-specific information.

1. Example Training Evaluation
2. Blank Training Evaluation

Instructions for Completing the Training Evaluation Form:

1. After training is completed, the trainee should complete the Training Evaluation.
2. The trainee should be honest and open about the training experience without fear of remedial action or other adverse reactions because of the evaluation.
3. Management should review and compile the results to assess the training program's effectiveness and make necessary improvements and changes to the program.

EXAMPLE

Facility: *General Health Practice*
Location: *123 West Dr.*
Atlanta, GA 55555

Training Evaluation

Date: *06/03/2025* **Trainee:** *Michelle Richards*

Item	Circle Y (Yes) or N (No)	Comments	Score 1= unsatisfactory 2= satisfactory 3= very good
1. Was the process clearly explained?	(Y) N		*3*
2. Was (were) the procedure(s) clearly demonstrated?	(Y) N		*3*
3. Were you shown where to get supplies and equipment?	(Y) N		*3*
4. Were you given enough time to practice?	Y (N)	*I felt rushed, and I could have used more time to read the fields.*	*1*
5. Was the trainer approachable?	(Y) N		*3*
6. Did you feel comfortable asking questions?	(Y) N		*3*
7. If the trainer did not know the answer, could they find the information?	(Y) N		*3*
8. When you did the procedure(s), were you corrected respectfully?	(Y) N		*3*
9. Did you get constructive, timely feedback?	(Y) N		*3*
10. Did you feel comfortable performing the procedure(s) on your own?	Y (N)	*I felt like I needed a few more times to identify the organisms prior to testing patient specimens.*	*1*
11. Were you asked questions to gauge your knowledge and understanding of the process or procedure(s)?	(Y) N		*3*
12. Do you know where to find safety information, including the exposure control plan?			

Trainer(s) being evaluated: *Thomas Smith, MD*

Facility:
Location:

Training Evaluation

Date: _____ **Trainee:** _____

Item	Circle Y (Yes) or N (No)	Comments	Score 1= unsatisfactory 2= satisfactory 3= very good
1. Was the process clearly explained?	**Y N**		
2. Was (were) the procedure(s) clearly demonstrated?	**Y N**		
3. Were you shown where to get supplies and equipment?	**Y N**		
4. Were you given enough time to practice?	**Y N**		
5. Was the trainer approachable?	**Y N**		
6. Did you feel comfortable asking questions?	**Y N**		
7. If the trainer did not know the answer, could they find the information?	**Y N**		
8. When you did the procedure(s), were you corrected respectfully?	**Y N**		
9. Did you get constructive, timely feedback?	**Y N**		
10. Did you feel comfortable performing the procedure(s) on your own?	**Y N**		
11. Were you asked questions to gauge your knowledge and understanding of the process or procedure(s)?	**Y N**		
12. Do you know where to find safety information, including the exposure control plan?			

Trainer(s) being evaluated: _____

Appendix D

Competency Assessment Instructions

Purpose:

The ability of each person to perform their duties should be assessed following training and periodically thereafter. Retain and reassess employee performance needs when problems are identified with employee performance. The training and assessment program should be documented and specific for each job description. Activities requiring judgment or interpretive skills need to be included in the assessment.

Competency assessment can

- Identify key training areas
- Identify processes that need improvement
- Provide supervisors and managers with data on employee performance
- Provide evidence to customers and management that the laboratory assures quality with trained staff.

Contents:

There are many ways to assess competency. A blank assessment and an example assessment demonstrating how to enter site-specific information are included.

1. Example Competency Assessment
2. Blank Competency Assessment

Instructions for Completing the Competency Assessment Form:

1. Record the facility name and location.
2. Record the employee's name and the procedure being observed.
3. Have the employee perform the procedure.
4. Record whether the steps completed were satisfactory or unsatisfactory, note any comments, and document any corrective action needed.
5. Sign and date the form.
6. Have the employee sign and date the form and provide comments.

EXAMPLE

Facility: *General Health Practice*
Location: *123 West Dr.*
Atlanta, GA 55555

Competency Assessment

Employee Name: *Michelle Richards*

Procedure to be Observed: *PPM Procedure: KOH Preparation*

Instructions to the Employee:

1. Review the procedure.
2. While being observed, perform the procedure, including collecting the specimen, maintaining equipment, and managing records.
3. Your performance will be based on how well you follow the procedure. You may refer to the written procedure while performing the procedure. If your performance evaluation is unsatisfactory, you will be given instructions for corrective action.
4. If you find the written procedure unclear or missing necessary information, please note it in the employee comments section below.

Instructions to the Observer:

1. Select previously analyzed specimens or samples with known results for the employee to demonstrate the procedure.
2. Directly observe the employee perform each step of the procedure. If any step of the procedure is performed incorrectly, please note this in the observer comments section.
3. Test the employee's problem-solving skills with a question or observe the employee resolving a problem.
4. If the procedure is followed correctly, mark it as satisfactory. If steps are not followed, mark unsatisfactory and describe the corrective action necessary to obtain a satisfactory rating.
5. Record your name and date on the 'observed by' line.
6. Ask the employee to sign and date the form and file it appropriately.

Assessment of Specimen Handling	**Satisfactory**	*X*	**Unsatisfactory**	
Assessment of Test Performance	**Satisfactory**	*X*	**Unsatisfactory**	
Assessment of Quality Control	**Satisfactory**	*X*	**Unsatisfactory**	
Assessment of Data Management	**Satisfactory**		**Unsatisfactory**	*X*
Assessment of Problem Solving	**Satisfactory**	*X*	**Unsatisfactory**	

Observer Comments: *Michelle did not know where to file completed result forms.*

Corrective Action Needed (if applicable): *We discussed the proper procedure and where to file result forms.*

Observed By: *Thomas Smith, MD* **Date:** *06/27/2025*

Reviewed by Employee: *Michelle Richards* **Date:** *06/27/2025*

Observer Comments: *I now understand the proper filing procedures*

Facility:
Location:

Competency Assessment

Employee Name: _____

Procedure to be Observed: _____

Instructions to the Employee:

1. Review the procedure.
2. While being observed, perform the procedure, including collecting the specimen, maintaining equipment, and managing records.
3. Your performance will be based on how well you follow the procedure. You may refer to the written procedure while performing the procedure. If your performance evaluation is unsatisfactory, you will be given instructions for corrective action.
4. If you find the written procedure unclear or missing necessary information, please note it in the employee comments section below.

Instructions to the Observer:

1. Select previously analyzed specimens or samples with known results for the employee to demonstrate the procedure.
2. Directly observe the employee perform each step of the procedure. If any step of the procedure is performed incorrectly, please note this in the observer comments section.
3. Test the employee's problem-solving skills with a question or observe the employee resolving a problem.
4. If the procedure is followed correctly, mark it as satisfactory. If steps are not followed, mark unsatisfactory and describe the corrective action necessary to obtain a satisfactory rating.
5. Record your name and date on the 'observed by' line.
6. Ask the employee to sign and date the form and file it appropriately.

Assessment of Specimen Handling	**Satisfactory** _____	**Unsatisfactory** _____
Assessment of Test Performance	**Satisfactory** _____	**Unsatisfactory** _____
Assessment of Quality Control	**Satisfactory** _____	**Unsatisfactory** _____
Assessment of Data Management	**Satisfactory** _____	**Unsatisfactory** _____
Assessment of Problem Solving	**Satisfactory** _____	**Unsatisfactory** _____

Observer Comments: _____

_____

Corrective Action Needed (if applicable): _____

_____

Observed By: _____ **Date:** _____

Reviewed by Employee: _____ **Date:** _____

Observer Comments: _____

Appendix E

Eyewash Station Weekly Maintenance Log Instructions

Purpose:

An eyewash station is an important safety device in a laboratory. Eyewash stations provide immediate flushing of the eyes after exposure to hazardous substances. There are two types of eyewash stations: plumbed and gravity-fed. Plumbed eyewash stations are permanently connected to a source of potable water and should be checked and flushed weekly to ensure proper functioning. This check should include a review of the following to ensure:

- Eyewash station is free from obstruction.
- Eyewash station is easily activated.
- Nozzles are equipped with protective covers.
- Covers are removed upon activation of the eyewash station.
- Water flows from both eyepieces.
- Flow of water is clear after flushing.
- Flow of water is steady

Contents:

There are many ways to document eyewash station maintenance. A blank log and an example log that demonstrates how to enter site-specific information are included.

1. Example Eyewash Station Weekly Maintenance Log
2. Blank Eyewash Station Weekly Maintenance Log

Instructions for Completing the Competency Assessment Form:

1. Post a weekly maintenance log near the eyewash station.
2. Perform a check of the eyewash station weekly.
3. Record the date of the eyewash station maintenance.
4. Record the initials of the person who performed the maintenance of the eyewash station.
5. Document action when the eyewash station requires any repairs or maintenance by a service professional.
6. The laboratory director should review and sign the eyewash station weekly maintenance log.

EXAMPLE

Facility: *General Health Practice*
Location: *123 West Dr.*
Atlanta, GA 55555

Eyewash Station Weekly Maintenance Log

Eyewash Station Location: *PPM/Microscope Room* **Year:** *2025*

Week	Date	Checked by
1	01/03/2025	MR
2	01/10/2025	MR
3	01/17/2025	MR
4	01/24/2025	MR
5	01/31/2025	MR
6	02/07/2025	MR
7	02/14/2025	MR
8	02/21/2025	MR
9	02/28/2025	MR
10	03/07/2025	MR
11	03/14/2025	MR
12	03/21/2025	MR
13	03/28/2025	MR
14	04/04/2025	MR
15	04/11/2025	MR
16	04/18/2025	MR
17	04/25/2025	MR
18	05/02/2025	MR

Week	Date	Checked by
19	05/09/2025	MR
20	05/16/2025	MR
21	05/23/2025	MR
22	05/30/2025	MR
23	06/06/2025	MR
24	06/13/2025	MR
25	06/20/2025	MR
26	06/27/2025	MR
27	07/03/2025	MR
28	07/11/2025	MR
29	07/18/2025	MR
30	07/25/2025	MR
31	08/01/2025	MR
32	08/08/2025	MR
33	08/15/2025	MR
34	08/22/2025	MR
35	08/29/2025	MR
36	09/05/2025	MR

Week	Date	Checked by
37	09/12/2025	MR
38	09/19/2025	MR
39	09/26/2025	MR
40	10/03/2025	MR
41	10/10/2025	MR
42	10/17/2025	MR
43	10/24/2025	MR
44	10/30/2025	MR
45	11/07/2025	MR
46	11/14/2025	MR
47	11/21/2025	MR
48	11/26/2025	MR
49	12/05/2025	MR
50	12/12/2025	MR
51	12/19/2025	MR
52	12/26/2025	MR

Problems encountered and corrective action taken:
**On 09/12/2025, the caps were off the eyepieces. I replaced the caps. -MR*

Reviewed by: *Thomas Smith, MD* **Date:** *12/30/2025*

Facility:
Location:

Eyewash Station Weekly Maintenance Log

Eyewash Station Location: _____ **Year:** _____

Week	Date	Checked by
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		

Week	Date	Checked by
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		
32		
33		
34		
35		
36		

Week	Date	Checked by
37		
38		
39		
40		
41		
42		
43		
44		
45		
46		
47		
48		
49		
50		
51		
52		

Problems encountered and corrective action taken: _____

_____

_____

_____

Reviewed by: _____ **Date:** _____

Appendix F

Laboratory Safety Plan

I. INTRODUCTION

The Laboratory Safety Plan (LSP) should outline the essential policies and procedures designed to ensure the safety of testing personnel. It is crucial that all laboratory staff actively participate in and adhere to these safety precautions to protect their health, that of their fellow workers, and that of the surrounding community.

Effectively developing the LSP should be based on site- and activity-specific risk assessments that identify hazards and risks within the workplace. The results from these assessments guide the creation of mitigation measures, including the safety policies and procedures within the LSP, engineering controls, and personal protective equipment (PPE).

The introduction to the LSP should address the following key elements:

1. Purpose: Clearly define the objectives of the LSP, emphasizing its role in mitigating workplace hazards and promoting a culture of safety.
2. Regulatory Standards: Identify relevant regulatory standards and guidelines that the laboratory must comply with, such as those set by OSHA, CLIA, and other governing bodies.
3. Scope: Specify the types of activities and personnel covered under the LSP to ensure comprehensive understanding and applicability.

For additional resources and guidance on laboratory safety practices, including how to conduct a risk assessment, refer to the following links: https://www.cdc.gov/safe-labs/php/biological-risk-assessment/index.html, https://www.cdc.gov/safe-labs/php/about/index.html and https://www.cdc.gov/safe-labs/php/biosafety-training/index.html.

II. PLAN AVAILABILITY:

The LSP should be readily available to all employees for review and reference. Each employee is expected to familiarize themselves with their specific safety responsibilities as outlined in the plan. A site-specific copy of the LSP should be prominently displayed in each testing area, ensuring that it is always easily accessible.

To further support safety awareness, regular training sessions should be conducted to review the plan and any updates. Digital copies of the safety plan could also be made available on the laboratory's internal network or shared drive, allowing for easy access by all staff members.

III. RESPONSIBILITIES

Implementation of the LSP is a shared responsibility among all personnel. The following outlines the specific roles and responsibilities of individuals overseeing testing and testing personnel:

A. Individual Overseeing Testing

1. Develop a comprehensive LSP that includes policies and procedures for employee safety.
2. Identify a designated area in each testing space for the storage and easy access to the site-specific LSP.
3. Ensure that all testing personnel and staff understand and adhere to the guidelines in the LSP.

4. Provide site-specific safety training to all new employees BEFORE they perform testing, with annual refresher training thereafter. Additional training should be conducted after any nonconformities are identified or after any changes in testing procedures to ensure all personnel remain informed and compliant with updated practices.
5. Document the completion of safety training for all employees, including housekeeping staff, and maintain training records.
6. Ensure each employee is competent after training, periodically re-evaluate competence, and retain documented information as evidence of ongoing competence.
7. Provide appropriate personal protective equipment (PPE) and implement engineering controls based on the site and activity-specific risk assessment. Ensure employees are trained on correct PPE use and maintenance.
8. Ensure all required and/or recommended immunizations are made available to employees and maintain immunization records.
9. If unsafe work practices are identified or reported, ensure immediate corrective actions are taken.
10. Review and update policies and procedures annually to reflect current practices and regulations.

B. Testing Personnel

1. Review and adhere to the policies and procedures outlined in the site-specific LSP.
2. Participate in site-specific safety training sessions.
3. Ensure training and competence is properly documented.
4. Complete the Appendix F1, the Safety Training Checklist, as part of the training documentation.
5. Use appropriate engineering controls and PPE as required for tasks.
6. Report all incidents, accidents, and potential exposures to the individual overseeing testing to facilitate timely investigation and corrective action.

IV. GENERAL SAFETY GUIDELINES

To ensure a safe work environment, all personnel should adhere to the following guidelines:

A. Conduct

1. Always maintain professionalism.
2. Avoid working alone, especially when performing hazardous procedures. If working alone is necessary, implement a buddy system or check-in protocol.
3. No horseplay or practical jokes in the workplace.
4. Learn the proper location, operation, and maintenance of safety equipment (i.e., fire alarms, fire extinguishers, eyewash stations, and safety showers).
5. Report all accidents, injuries, or near-misses, regardless of severity.

B. Avoidance of Routine Exposures

1. Ensure you are familiar with emergency and evacuation procedures.
    a. Participate in regular drills.
2. Read all warning labels and manufacturer instructions prior to operating ANY equipment.
    a. Do not use damaged equipment.
3. Be aware of potential hazards in the testing area by conducting risk assessments regularly.
4. Wear the appropriate PPE, ensuring it's properly fitted and in good condition.
5. Use engineering controls (e.g., fume hoods, biosafety cabinets) when necessary.
6. Report ALL exposures immediately to the individual overseeing testing or your supervisor.

C. Personal Hygiene

1. Smoking, drinking, eating, chewing gum, applying or removing contact lenses, and applying cosmetics are forbidden in the testing area.
2. Do not store food in freezers or refrigerators designated for testing.
3. Wash hands frequently and thoroughly, at minimum before and after each patient and when visibly soiled.
4. Use appropriate techniques when removing gloves to avoid contamination.
5. Wear footwear that completely covers the feet.
6. Tie or pin-up long hair while performing the testing procedures.
7. Keep fingernails trimmed and avoid wearing dangling jewelry or loose clothing that could interfere with equipment or procedures.
8. Be cautious of any unsafe conditions. Notify the individual overseeing the testing of any hazards.

D. Housekeeping Practices

1. Keep testing areas clean, organized, and free of clutter.
2. Clean spills efficiently and appropriately from the work area and floors. Notify the individual overseeing the testing of any spills immediately.
3. Do not impede or use doorways and walkways for storage.
4. Keep all exits, emergency equipment, and controls accessible.
5. Flush eyewash stations, if available, weekly; and emergency showers every six months. Keep documentation records of the maintenance history.
6. Label all containers, including those used for temporary storage.

E. Ergonomics

1. Perform an ergonomic assessment of the entire work area, including chairs, workstations, desks, and computer stations.
2. Provide an environment that limits ergonomic stress:
    a. Adjust chair height and monitor position for optimal posture.
    b. Use ergonomic keyboards and mouse devices.
    c. Take regular breaks and perform stretching exercises.
3. Implement proper lifting techniques and use mechanical aids for heavy loads.

V. SAFETY SIGNAGE AND LABELING

The individual overseeing testing is responsible for ensuring proper safety and hazard warning signs are posted and maintained, as necessary, for use by all employees. The following information should be prominently displayed in and around testing areas:

A. Emergency Information

a. Phone numbers of emergency personnel/facilities, such as the fire department, local security center, and Environmental Health and Safety department.

b. Contact information for the individual overseeing testing and alternate responsible personnel.

c. Evacuation routes and assembly points.

B. Hazard Labeling

a. Identity labels on all containers detailing contents and associated hazards.

b. Globally Harmonized System (GHS) pictograms and hazard statements where applicable.

c. Proper labeling of waste containers.

C. Safety Equipment Locations

a. Clear, visible signs indicating the location of safety showers, eyewash stations, other safety and first aid equipment, and exits.

b. Instructions for use of safety equipment.

D. Specialized Hazard Warning

a. Warnings at areas or equipment where special or unusual hazards exist (e.g., radiation hazards, biohazards, or magnetic fields [MRI]).

VI. SHARPS REDUCTION POLICY PRACTICES

The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard requires laboratories to institute practices that reduce injuries from needles and other sharp objects used at laboratory testing sites. All personnel who collect samples and perform testing must adhere to the following practices:

A. Use of Needleless Systems and Safety Devices

a. Implement needleless systems whenever possible.

b. When sharps are necessary, use safety-engineered devices such as retractable or shielded needles

c. Sharp objects (e.g., needles, glass pipettes) should be used only when no alternative is available.

B. Proper Handling and Disposal of Sharps

a. Do not resheath or recap needles; recapping of needles is prohibited.

b. Immediately after use, dispose of needles, syringes, slides, pipettes, capillary tubes, and scalpels in a rigid, puncture-resistant, labeled sharps container with a lid.

c. Never overfill sharps containers; replace when 3/4 full.

C. Safe Practices for Broken Glass

a. Do not touch broken glass with bare hands. Remove it mechanically using forceps, brush, dustpan, etc.

b. Deposit all broken glass into a designated sharps container.

D. Safe Practices for Broken Glass

a. Ensure sharps containers are readily accessible in all areas where sharps are used.

b. Regularly inspect and replace sharps containers to prevent overfilling.

VII. EMERGENCY DECONTAMINATION PROCEDURES

These procedures serve as a reference for preparing and responding to spills and personnel exposure incidents involving hazardous or infectious substances. However, it is crucial to note that each spill kit should be tailored to the specific testing area and the particular hazards in that environment.

A. Spill Kit

1. All laboratories and testing sites working with hazardous or infectious substances must maintain a readily accessible spill kit.
2. Biohazard Spill Kit Contents:
    a. Disinfecting solution (e.g., 10% bleach or EPA-registered disinfectant)
    b. Forceps or tongs, autoclavable broom and dustpan, or another mechanical device for handling sharps
    c. Absorbent materials (e.g., paper towels, absorbent pads)
    d. Biohazard bags
    e. PPE:
        1. Waterproof utility gloves and latex or nitrile gloves
        2. Face protection (e.g., face shield, splash goggles, disposable face mask)
        3. Disposable scrubs
    f. Spill sign to post on the door to the room
    g. Copy of your spill procedure

B. Biohazard Spill Procedure

1. Assess the spill:
    a. Determine the nature and extent of the spill.
        i. Evacuate the area if necessary and notify others.

b. If necessary, remove contaminated clothing, turn the exposed area inward, and place it in a biohazard bag.

   i. Wash exposed skin with antiseptic soap and water. Refer to Section C for more information on how to address personnel exposure.

c. Close the door and post with a warning sign.

2. Don appropriate PPE
3. Contain the spill:
   a. Use absorbent materials to prevent spread.
   b. Cover with paper towels or absorbent pads.
4. Decontaminate the area:
   a. Apply disinfectant, working from the outside towards the center.
   b. Allow appropriate contact time as per disinfectant instructions.
5. Clean up:
   a. Dispose of contaminated materials in biohazard bags.
   b. Use forceps to handle any sharps, placing them in a sharps container.
6. Final decontamination:
   a. Wipe the area again with disinfectant.
   b. Clean and disinfect utility gloves, face shields, goggles, and other reusable items.
   c. Remove the disposable PPE used in the spill clean-up carefully, disposing of it in biohazard bags.
7. Wash hands thoroughly with antiseptic soap and water.
8. Dispose of biohazardous waste following applicable regulations.
9. Notify the individual overseeing testing and document the incident accordingly.
10. Replenish or replace any items used in the spill kit.

C. Personnel Exposure Procedures

1. Splashes to face (eyes, nose, and mouth)
   a. Use the eyewash to flush the exposed area.
   b. Report to the individual overseeing testing immediately for prophylaxis, if necessary.
2. Hands or other exposed skin
   a. Remove contaminated clothing or PPE.
   b. Wash with antiseptic or soap.
   c. Report to the individual overseeing testing immediately for prophylaxis, if necessary.

3. Hands or other exposed skin
    a. Squeeze around the injury to encourage blood flow out of the wound.
    b. Wash needlesticks and cuts with soap and water.
    c. Report to the individual overseeing testing immediately for prophylaxis, if necessary.
    d. If applicable, follow the needle stick protocol for your organization and/or immediately seek medical treatment.

D. Training and Drills

1. Conduct regular training sessions on spill response procedures.
2. Perform periodic spill drills to ensure preparedness.

E. Documentation Procedures

1. Maintain records of all spills and exposure incidents.
2. The individual overseeing testing should review the incidents and implement work practices to prevent reoccurrence, if necessary. An example of incident report documentation is in Appendix F2: Example Incident Report.
3. Comply with OSHA injury and illness reporting.

VIII. ADDITIONAL RECOMMENDED SECTIONS FOR YOUR LSP

While this document provides a foundation for laboratory safety, your institution's LSP should be comprehensive and tailored to your specific needs. Consider including the following additional sections (if applicable):

1. Risk Assessment and Management

a. Detailed procedures for identifying, assessing, and mitigating biological risks.
b. Regular review and update of risk assessments.

2. Biosafety and Biosecurity Measures

a. Detailed standard operating procedures (SOPs) for specific laboratory tasks.
b. Access control and information security procedures.

3. Emergency Response and Contingency Planning

a. Detailed emergency procedures for various scenarios (e.g., power outages, natural disasters).
b. Business continuity plans.

4. Waste Management

a. Procedures for handling, treating, and disposing of biological and chemical waste.
b. Compliance with local and national regulations.

5. Equipment Maintenance and Calibration

a. Schedules and procedures for equipment maintenance.
b. Calibration protocols and record-keeping.

6. Personnel Management

a. Health surveillance programs.

b. Vaccination policies.

7. Training Program

a. Comprehensive training curriculum.

b. Competency assessment procedures.

8. Internal Audits and Inspections

a. Schedules and procedures for regular safety audits.

b. Non-conformity reporting and corrective action processes.

9. Management Review

a. Procedures for periodic biosafety and biosecurity management review.

b. Continuous improvement processes.

10. Communication and Reporting

a. Internal and external communication protocols.

b. Incident reporting and investigation procedures.

11. Procurement and Outsourcing

a. Safety considerations in purchasing decisions.

b. Management of external providers and collaborators.

IX. APPENDICES

F1. Safety Training Checklist

F2. Incident Report

Appendix F1

Safety Training Checklist Instructions

Purpose:

The purpose of this Safety Training Checklist is to ensure that all employees receive comprehensive training on the risks associated with bloodborne pathogens, such as hepatitis B, hepatitis C, and HIV. This training is essential for safeguarding the health and safety of workers in high-risk roles, including first aid team members, housekeeping personnel, nurses, and healthcare providers. By documenting training completion, we promote a culture of safety and compliance within the workplace.

Contents:

To facilitate effective safety training documentation, this appendix includes:

1. Example Safety Training Checklist: A model demonstrating proper completion with site-specific information.
2. Blank Safety Training Checklist: A customizable template for your specific workplace needs.

Instructions for Completing the Safety Training Checklist:

1. Review the example checklist to understand how to enter site-specific information.
2. Customize the blank checklist to reflect your workplace's unique hazards, procedures, and safety requirements.
3. Train new employees on work practices, safety procedures, and potential hazards.
    a. Cover all relevant topics, including but not limited to proper use of personal protective equipment, handling of hazardous materials, emergency procedures, and incident reporting.
    b. Use a combination of methods (e.g., lectures, demonstrations, hands-on practice) to ensure comprehensive understanding.
4. Have the trainer and employees sign the Safety Training Checklist.
    a. This includes filling in the date of completion and the initials of both the employee and the trainer. If necessary, provide any relevant comments in the designated section. Finally, ensure that both parties sign and date the checklist to confirm the completed training.
    b. The employee's signature should indicate their understanding and commitment to following established safety practices.
5. File the signed form in the employee's records.
6. Maintain these records in accordance with the institution's policies.
7. Ensure accessibility for audits or inspections.

EXAMPLE

Facility: General Health Practice
Location: 123 West Dr.
Atlanta, GA 55555

Safety Training Checklist

Purpose: To certify that new employees are properly informed of workplace hazards and trained on safety protocols relevant to their job duties. **Completion is mandatory before conducting any testing.**

Date	Date Completed	Employee Initials	Trainer Initials	Comments
1. Reviewed the institution's Laboratory Safety Plan and its locations for future reference.	06/01/2025	MR	TS	
2. Discussed the use of standard precautions when working with human blood or body fluids, including Bloodborne Pathogen training.				
3. Received appropriate immunizations as determined by the individual overseeing testing.	06/01/2025	MR	TS	
4. Discussed hazardous chemical inventory and safe use of hazardous chemicals at the laboratory testing site. Reviewed Safety Data Sheets (SDS).	06/01/2025	MR	TS	
5. Shown where First Aid Kits and automated external defribrillators (if available) are located.	06/01/2025	MR	TS	
6. Shown where Biosafety and Chemical Spill Kits (if applicable) are located.	06/01/2025	MR	TS	
7. Reviewed procedures for obtaining supplies.	06/01/2025	MR	TS	
8. Discussed and trained on the use of engineering controls, including proper operation and maintenance (e.g., BSCs).				
9. Discussed and trained on the required use, proper selection, and maintenance of personal protective equipment (PPE).	06/01/2025	MR	TS	
10. Provided appropriate PPE.	06/01/2025	MR	TS	
11. Shown where fire extinguishers are located.	06/01/2025	MR	TS	
12. Discussed ergonomics in the workplace.	06/01/2025	MR	TS	
13. Reviewed procedure on waste disposal: • Infectious • Non-infectious • Hazardous chemical • Sharps	06/01/2025	MR	TS	
14. Reviewed emergency response procedures. • Infectious material spill or release • Hazardous chemical spill or release • Fire or explosion • Medical emergency • Bomb threat • Shelter in place • Active Shooter	06/01/2025	MR	TS	
15. Provided instructions on Incident Reporting.	06/01/2025	MR	TS	

Trainee Comments: Michelle has previously worked in a CLIA-certified laboratory and is familiar with the appropriate safety requirements. I feel confident that she understands and will comply with our safety rules.

Trainer Signature: Thomas Smith, MD **Date:** 06/01/2025

Employee Signature: Michelle Richards **Date:** 06/01/2025

Supervisor Review: Joe Smith, MD **Date:** 06/01/2025

Facility:
Location:

Safety Training Checklist

Purpose: To certify that new employees are properly informed of workplace hazards and trained on safety protocols relevant to their job duties. **Completion is mandatory before conducting any testing.**

Date	Date Completed	Employee Initials	Trainer Initials	Comments
1. Reviewed the institution's Laboratory Safety Plan and its locations for future reference.				
2. Discussed the use of standard precautions when working with human blood or body fluids, including Bloodborne Pathogen training.				
3. Received appropriate immunizations as determined by the individual overseeing testing.				
4. Discussed hazardous chemical inventory and safe use of hazardous chemicals at the laboratory testing site. Reviewed Safety Data Sheets (SDS).				
5. Shown where First Aid Kits and automated external defribrillators (if available) are located.				
6. Shown where Biosafety and Chemical Spill Kits (if applicable) are located.				
7. Reviewed procedures for obtaining supplies.				
8. Discussed and trained on the use of engineering controls, including proper operation and maintenance (e.g., BSCs).				
9. Discussed and trained on the required use, proper selection, and maintenance of personal protective equipment (PPE).				
10. Provided appropriate PPE.				
11. Shown where fire extinguishers are located.				
12. Discussed ergonomics in the workplace.				
13. Reviewed procedure on waste disposal: • Infectious • Non-infectious • Hazardous chemical • Sharps				
14. Reviewed emergency response procedures. • Infectious material spill or release • Hazardous chemical spill or release • Fire or explosion • Medical emergency • Bomb threat • Shelter in place • Active Shooter				
15. Provided instructions on Incident Reporting.				

Trainee Comments: _____

_____

Trainer Signature: _____ **Date:** _____

Employee Signature: _____ **Date:** _____

Supervisor Review: _____ **Date:** _____

Appendix F2

Incident Report Instructions

Purpose:

The purpose of incident reporting is to ensure prompt response, thorough documentation, and systematic evaluation of workplace incidents. This safeguards employee health and safety while fostering continuous improvement in safety practices. This process is crucial because:

- Immediate action in response to injuries, exposures, or incidents can significantly mitigate risks to life and health.
- Comprehensive documentation ensures regulatory compliance and provides valuable data for analysis, leading to improved safety measures.
- Systematic evaluation of incidents reveals opportunities to enhance work practices and overall workplace safety.

This process is particularly vital in the context of patient testing, where exposure to various biological and chemical agents is possible. Workers must be familiar with all aspects of their work areas and the appropriate steps to take during a safety or medical incident. When an exposure or incident occurs, employees should follow site-specific guidelines for immediate intervention and consult the individual overseeing testing for further information.

Adhering to an incident reporting process protects the employees in the short term while also creating a safer work environment for the future through continuous learning and improvement.

Contents:

To facilitate effective incident reporting and documentation, this appendix includes:

1. Example Incident Report Form: A model demonstrating proper completion with site-specific information.
2. Blank Incident Report Form: A customizable template for your specific workplace needs.

Instructions for Completing the Incident Report:

1. Review the example Incident Report form to understand how to document incidents and include site-specific information.
2. Customize the blank Incident Report form to align with your workplace's unique hazards, protocols, and reporting requirements.
3. The employee involved in the incident should complete the Incident Report thoroughly and accurately.
    a. Include all relevant details about the incident, injuries, and immediate actions taken.
4. The individual overseeing testing should evaluate the incident to determine the necessary corrective actions.
5. Implement and document all corrective actions on the Incident Report.
6. The overseer should review the completed report for accuracy and completeness before signing it.
7. File the completed and signed report in accordance with the institution's policy.
8. Ensure accessibility for future reference and potential audits.

OSHA Recordkeeping and Reporting Requirements:

9. For sites with 10+ employees at any time during the last calendar year:
    a. Maintain the OSHA Injury & Illness Recordkeeping Forms, 300 series available at: https://www.osha.gov/recordkeeping/RKforms.html
10. For sites with consistently fewer than 10 employees:
    a. Utilize the OSHA forms only if OSHA explicitly instructs you to do so in writing.
11. Report immediately to the nearest OSHA office (by phone or in person) any workplace incident resulting in an employee fatality or the in-patient hospitalization of three or more employees due to a work-related event.

EXAMPLE

Facility: General Health Practice
Location: 123 West Dr.
Atlanta, GA 55555

Incident Report

Name of the person involved in the incident: Michelle Richards

Date of incident: 06/30/2025 **Time of Incident:** 2:30 PM

Location of incident: Well patient room 2

Description of incident: [Type of incident, e.g., illness, accident, injury. Indicate circumstances and who was involved. Indicate any substances (e.g., amount and kind of chemical) or object involved.]

Applied fingerstick device to self instead of patient and triggered the device. The device was held incorrectly, with the opposite end facing the patient's finger. When triggered, the device inserted the needle into Ms. Richards' finger instead of the patient's.

Action taken:

X **A.** First Aid: Wash, Burn, (Band-Aid), Eyewash, or other: _____

_____ **B.** Medical treatment beyond first aid: _____

_____ **C.** Clean-up or Spill _____ **D.** Fire _____ **E.** Evactuation

To be completed by the person involved in the incident:

Did your supervisor advise you on workplace hazards as part of training? (**Y**) / **N**

Were you wearing appropriate PPE (gloves, face shield, etc.) properly? (**Y**) / **N**

Did you read and sign the Safety Training Checklist before working in the lab? (**Y**) / **N**

What do you believe was the cause of the incident?

Not paying attention and making a mistake.

Preventive Measures to Prevent Reoccurrence (if applicable):

Re-trained personnel on the proper use and safety of fingerstick devices. Initial training was performed on 7/1/2025, documented, and filed.

Reviewed by: Thomas Smith, MD **Date:** 07/01/2025

Facility:
Location:

Incident Report

Name of the person involved in the incident: _____

Date of incident: _____ **Time of Incident:** _____

Location of incident: _____

Description of incident: [Type of incident, e.g., illness, accident, injury. Indicate circumstances and who was involved. Indicate any substances (e.g., amount and kind of chemical) or object involved.]

_____

_____

_____

_____

_____

Action taken:

_____ **A.** First Aid: Wash, Burn, Band-Aid, Eyewash, or other: _____

_____ **B.** Medical treatment beyond first aid: _____

_____ **C.** Clean-up or Spill _____ **D.** Fire _____ **E.** Evactuation

To be completed by the person involved in the incident:

Did your supervisor advise you on workplace hazards as part of training? **Y / N**

Were you wearing appropriate PPE (gloves, face shield, etc.) properly? **Y / N**

Did you read and sign the Safety Training Checklist before working in the lab? **Y / N**

What do you believe was the cause of the incident?

_____

_____

Preventive Measures to Prevent Reoccurrence (if applicable):

_____

_____

_____

Reviewed by: _____ **Date:** _____

Appendix G

Common Disinfectants and Antiseptics

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

Introduction: Disinfectants vs. Antiseptics

Disinfectants and antiseptics are both antimicrobial agents used to kill or inhibit the growth of microorganisms. However, they differ in their primary applications and concentrations:

- Disinfectants are chemical agents designed for use on inanimate objects and surfaces. They typically contain stronger concentrations of active ingredients and are not safe for use on living tissue. Disinfectants clean and sanitize countertops, medical equipment, and other non-living surfaces.
- Antiseptics are antimicrobial substances formulated for use on living tissue, such as skin and mucous membranes. They contain lower concentrations of active ingredients to ensure safety when applied to the body. Antiseptics are commonly used for wound care, surgical site preparation, and hand hygiene in healthcare settings.

Understanding this difference is crucial to properly select and apply these products in various settings.

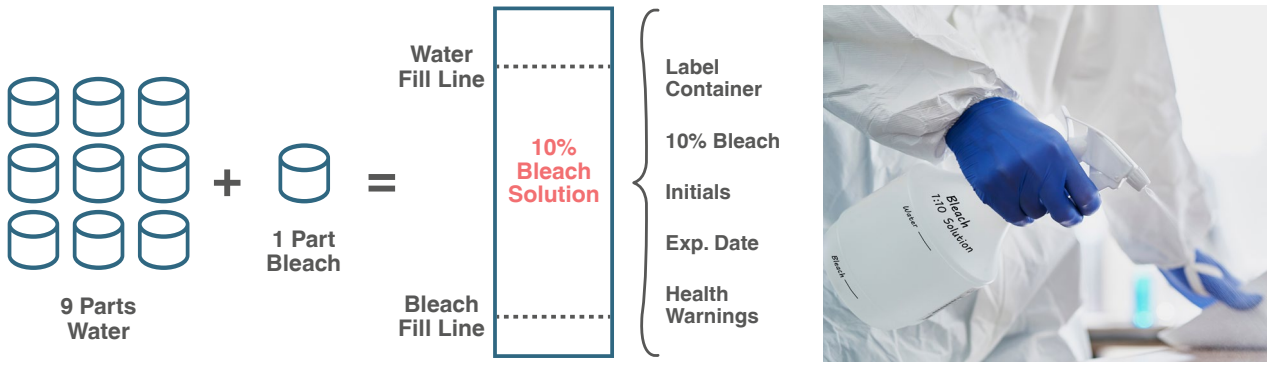
Disinfectants:

EPA's List S includes products registered for use against human immunodeficiency virus (HIV), Hepatitis B, and Hepatitis C. EPA has reviewed required laboratory testing data demonstrating that these products are effective.

Additional EPA-registered products can be found here: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.

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 also work. A 10% bleach solution is also called a 1/10, 1:10, or 5,000 ppm bleach solution.

   The directions for preparation are:



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

2. **Commercial Products.** EPA provides a list of registered commercial products that are effective against certain bacteria and viruses. Examples include 'Lysol' (a cresol and soap solution) and 'Stericol' (a xylenol-rich cresylic acid and soap solution).

Antiseptics

1. **Alcohols** are considered intermediate-level disinfectants. Alcohol solutions are often used as skin antiseptics. Alcohols, such as isopropyl (rubbing) alcohol, are well suited to rapidly kill bacteria on the skin surface.

Proper Storage and Handling of Disinfectants and Antiseptics

To ensure safety and effectiveness, follow these guidelines for storing and handling disinfectants and antiseptics:

- Store in a cool, dry, well-ventilated area away from direct sunlight and heat sources. Store in original containers with intact labels.
- Ensure products are out of reach of unauthorized personnel. Frequently used items should be easily accessible but not stored above eye level.
- Separate by hazard class and avoid overcrowding shelves. Use anti-roll lips to prevent spills.
- Always wear appropriate PPE when handling these products.
- Dispose of expired or unused products according to local regulations.

Appendix H

Procedure Contents and Tips

Procedure Contents:

Written procedures can be developed from the manufacturer's instructions, including specific instructions for your laboratory or testing site. When writing procedures, using a general template with standard headings is helpful. Headings that are often used for writing procedures are:

- ✓ **Title (Test Name)** — The title should clearly state the intent of the procedure.
- ✓ **Purpose —** States what the test measures and the clinical use of the result.
- ✓ **Patient Preparation —** Describes the requirements for patient preparation or any patient pre-test information to ensure the patient understands the purpose of the tests being ordered and what the results will mean to their health.
- ✓ **Materials —** Lists all materials and supplies, including slides, reagents, stains, and equipment used in testing and how to prepare them.
- ✓ **Specimen —** Describes the type of specimen and how to collect, label, store, and process it.
- ✓ **Special Safety Precautions —** Indicates any safety requirements that are unique to this procedure or need to be highlighted.
- ✓ **Quality Control (QC) —** Describes the types of controls for the test, steps to perform QC, how often to test, interpreting the results, and how to recognize and correct problems.
- ✓ **Procedure —** Use the manufacturer's instructions or the laboratory or testing site's procedures for:
  - Step-by-step instructions for performing PPM procedures, including QC.
  - Examinations, including the detection of inadequately prepared slides.
  - Course of action to take if test procedures or equipment becomes inoperable.
- ✓ **Method Performance Specifications —** This section should include information about precision, accuracy, specificity, and the reportable range for the test. This section should also include information on interfering substances or other methodology limitations that can affect the test result.
- ✓ **Expected Values**
  - The reference range for the test based on specimen type, age, sex, or race, if applicable.
- ✓ **Interpreting, Recording, and Reporting Results**
  - How to read and interpret test results (photos or diagrams from the manufacturer's instructions are especially useful).
  - Comparison of the results to the expected values or diagnostic findings to determine if the result is normal, abnormal, or indeterminate.
  - Follow-up for indeterminate results.
  - Criteria for referral of specimens, including procedures for specimen submission and handling.
  - How to report results in the patient record.
  - Actions to take if results cannot be reported (invalid or out-of-range values). Include contact information for the manufacturer and the individual overseeing testing.

- Follow up for results exceeding critical limits and considered life-threatening or panic (critical) values.

✓ **References —** List any references used in writing the procedure, such as the manufacturer's instructions for the test.

✓ **Signature —** The individual overseeing testing should sign and date after reviewing and approving the contents before the start of a new procedure and after each procedure revision.

✓ **Date procedure put into use —** Record the date the procedure became effective or the date each revision was made.

Tips for a Useful Procedure Manual:

✓ Use a three-ring or similar binder to maintain the manual in an easily reviewed and updated format.

✓ Provide electronic versions, if available. If electronic versions are available, ensure all manual copies are updated and consistent with the electronic version.

✓ Use tabs or a table of contents for easy reference.

✓ Use plastic sheet protectors to extend the "shelf-life" of the manual.

✓ Write each procedure at a level that all testing personnel can understand.

✓ Keep a copy of the manual in the work area.

✓ If there is more than one copy of the manual, ensure they are all current and include the same information.

✓ Include a page at the front of the manual where personnel can "sign off" when they read it.

✓ All staff who oversee and perform testing should review the manual annually.

Appendix I

Care and Maintenance of the Microscope

CDC DIVISION OF LABORATORY SYSTEMS

Care and Maintenance of the Microscope

Introduction

Regular maintenance of your microscope will improve its performance. You should have a professional maintain your microscope each year. In addition, you should clean the base and frame of your microscope by lightly wiping with a damp cloth or wet wipe after each use. Follow the instructions in this job aid regularly to clean the glass parts of your microscope.

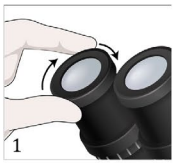
Avoid wearing eye makeup when using your microscope — especially mascara. It can leave debris that is hard to remove.

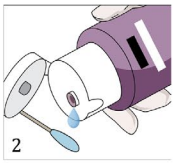
Supplies

- Commercial lens paper, cotton swabs, or other soft tissue
- Commercially available lens cleaner

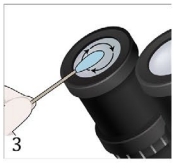
Instructions

1. To determine if your oculars are clean, rotate each one between your fingers to identify debris.
2. Moisten the tip of a swab or a piece of lens paper with lens cleaner.





3. Working from the center out, in a circular motion, gently clean the oculars and objectives.
4. Dry with a clean, dry swab or lens paper.



This job aid is a component of the free, on-demand CDC training course "Basic Microscopy." Find the course at https://reach.cdc.gov/training.

For more resources on microscope care, maintenance, and basic techniques, please visit CDC OneLab **REACH**™: https://reach.cdc.gov/jobaid/care-and-maintenance-microscope.

Appendix J

Microscope Maintenance Log Instructions

Purpose:

Microscopes used for testing must be maintained and serviced by a professional as directed by the manufacturer. Testing sites must document all maintenance and professional service activities. Maintenance may include:

- Clean dust in the microscope area
- Clean oculars
- Clean stage
- Clean condenser

Procedure Contents:

There are many ways to document microscope maintenance. A blank log and an example log demonstrating how to enter site-specific information are included for your use.

1. Example Microscope Maintenance Log
2. Blank Microscope Maintenance Log

Instructions for Completing the Microscope Maintenance Log:

1. Post a microscope maintenance log near the microscope.
2. Perform microscope maintenance weekly.
3. Record the date of the microscope maintenance.
4. Record the initials of the person who performed the maintenance.
5. Document action taken when the microscope requires any repairs or maintenance by a service professional.
6. The laboratory director should review and sign the microscope maintenance log.

EXAMPLE

Facility: General Health Practice
Location: 123 West Dr.
Atlanta, GA 55555

Microscope Maintenance Log

Microscope Location: PPM/Microscope Room **Year:** 2025

Week	Date	Checked by
1	01/03/2025	MR
2	01/10/2025	MR
3	01/17/2025	MR
4	01/24/2025	MR
5	01/31/2025	MR
6	02/07/2025	MR
7	02/14/2025	MR
8	02/21/2025	MR
9	02/28/2025	MR
10	03/07/2025	MR
11	03/14/2025	MR
12	03/21/2025	MR
13	03/28/2025	MR
14	04/04/2025	MR
15	04/11/2025	MR
16	04/18/2025	MR
17	04/25/2025	MR
18	05/02/2025	MR

Week	Date	Checked by
19	05/09/2025	MR
20	05/16/2025	MR
21	05/23/2025	MR
22	05/30/2025	MR
23	06/06/2025	MR
24	06/13/2025	MR
25	06/20/2025	MR
26	06/27/2025	MR
27	07/03/2025	MR
28	07/11/2025	MR
29	07/18/2025	MR
30	07/25/2025	MR
31	08/01/2025	MR
32	08/08/2025	MR
33	08/15/2025	MR
34	08/22/2025	MR
35	08/29/2025	MR
36	09/05/2025	MR

Week	Date	Checked by
37	09/12/2025	MR
38	09/19/2025	MR
39	09/26/2025	MR
40	10/03/2025	MR
41	10/10/2025	MR
42	10/17/2025	MR
43	10/24/2025	MR
44	10/30/2025	MR
45	11/07/2025	MR
46	11/14/2025	MR
47	11/21/2025	MR
48	11/26/2025	MR
49	12/05/2025	MR
50	12/12/2025	MR
51	12/19/2025	MR
52	12/26/2025	MR

Problems encountered and corrective action taken: _____

_____

_____

_____

Reviewed by: Thomas Smith, MD **Date:** 12/30/2025

Facility:
Location:

Microscope Maintenance Log

Microscope Location: _____ **Year:** _____

Week	Date	Checked by
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		

Week	Date	Checked by
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35		
36		

Week	Date	Checked by
37		
38		
39		
40		
41		
42		
43		
44		
45		
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49		
50		
51		
52		

Problems encountered and corrective action taken: _____

_____

_____

_____

Reviewed by: _____ **Date:** _____

Appendix K

Care and Maintenance of the Centrifuge

Introduction:

Centrifuges used for testing must be maintained and serviced by a professional as directed by the manufacturer. Poor centrifuge maintenance results in inefficient lab operations and can cause various physical and biological exposure hazards. Proper servicing and routine cleaning based on the manufacturer's recommendations are vital in maintaining a safe working environment for laboratory personnel.

The following general recommendations may be used as a starting point for scheduled centrifuge maintenance. For specific pertinent details, please refer to the original equipment manufacturer.

Description of Task to Perform	Maintenance Before Using	Maintenance After Using	Maintenance As Needed	Yearly Maintenance
Check if all components of the unit are clean and damage-free	✓			
Cleaning of unit exterior, rotors, and accessories		✓		
Cleaning and disinfection of unit interior in case of biological spillage			✓	
Removal of adherent dust from the ventilation slots of the centrifuge			✓	
General inspection				✓
Testing of speed				✓

Appendix L

PPM Procedure Examples

Purpose:

These procedures are provided as a guide and should not take precedence over established laboratory or testing site procedures. Procedures were developed using the cited references below.

Contents:

CLIA specifies nine PPM procedures. This appendix includes specimen collection, slide preparation, and microscopic examination procedures, as well as images of common microscopic findings for each procedure. Most images provided were identified using the high-power (40X) objective.

In addition to the procedures used in your laboratory or testing site, it is recommended that reference texts, atlases, and posters are available for reference when performing PPM testing.

References:

- Bauer JD, Clinical Laboratory Methods. 9th ed. St. Louis, MO; CV Mosby Co; 1982.
- Versalovic J, Carroll KC, Jorgensen JH, Funke G, Landry ML, Warnock DW (ed), Manual of Clinical Microbiology, 10th ed, vol 2. ASM Press, Washington, DC, 2011.
- CLSI. Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline- Second Edition. CLSI document POCT10-A2, Vol. 31 No. 24. Wayne, PA: Clinical and Laboratory Standards Institute, 2011.

Appendix L1

Wet Mount

A wet mount is a microscopic procedure used to examine material collected from a specimen suspended in a drop of liquid on a glass slide. It is used to view cells and organisms for motility, morphological characteristics, and identification. Specifically, it is used to determine the presence or absence of bacteria, fungi, parasites, and human cellular elements.

Specimen Collection

Before collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or other body fluid specimens.

1. Collect a sampling of material with a sterile cotton swab passed through and along the area of concern.
2. For vaginal specimens, test the specimen for pH and document results before adding it to the tube, if needed.

   Note: A pH greater than 4.5 is generally associated with bacterial vaginosis or trichomoniasis.
3. Place the swabs in a clean test tube containing 0.5 mL of normal (0.9%) saline.

   Note: Ensure that the specimen tube has at least 0.5 mL of saline and no more than 1.0 mL, or as indicated in your laboratory's or testing site's procedure. Sample dilution may affect identification.
4. Label the tube with patient identifiers, date, and time of collection.
5. Gently twist the swabs in saline to dislodge particles from the swab tip.
6. Reseal the tube to preserve the specimen.
7. Do not refrigerate the specimens.
8. Perform testing immediately or transport to the laboratory for testing as soon as possible.
9. Examine the specimens within two hours of collection.

Wet Mount Slide Preparation

1. Label a clean microscope slide with specimen identification.
2. Using a sterile transfer pipette or dropper, gently mix the specimen with the pipette.
3. Remove a specimen from the tube and place one drop (10 µL) on the labeled microscope slide.
4. Immediately put a coverslip over the specimen for examination.
5. Examine the slide to verify it is not overfilled and leaking once the coverslip is in place.

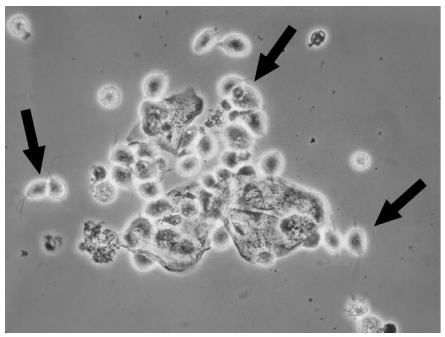
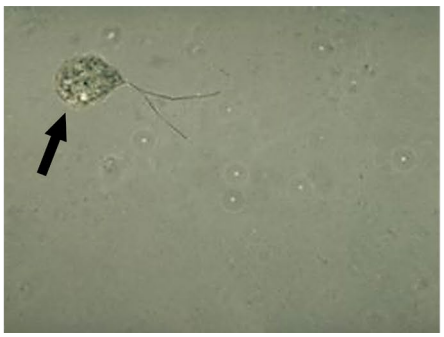
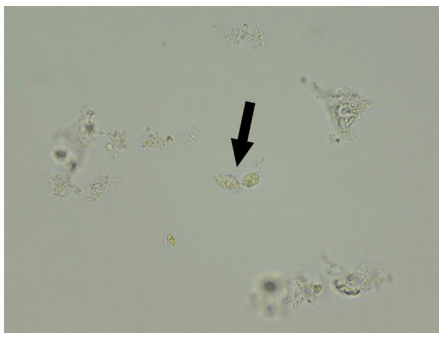
Wet Mount Slide Preparation

1. Place the slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Identify objects using high power (40X).
5. Read at least 10 fields using an "S" shaped viewing pattern.
6. Record findings.

Common Wet Mount Microscopic Findings

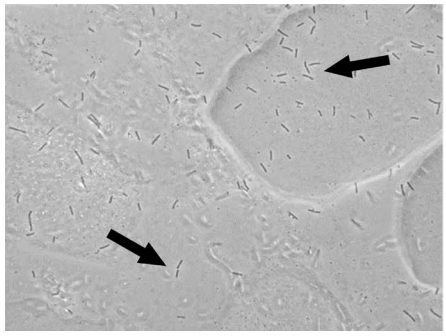
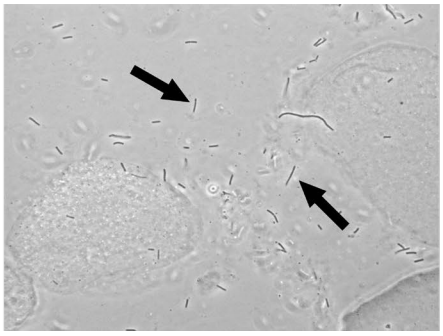
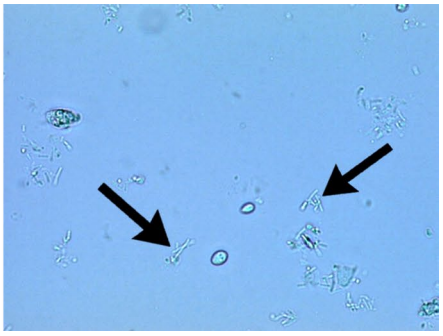
Trichomonas vaginalis

Trichomoniasis is a sexually transmitted infection caused by the parasite *Trichomonas vaginalis*, a motile pear-shaped protozoan. Trichomoniasis causes a vaginal discharge that is yellow-green, foamy, with an odor. In the images below, the arrows indicate examples of the *Trichomonas vaginalis* parasite.

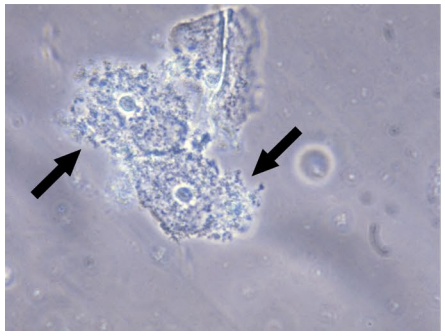
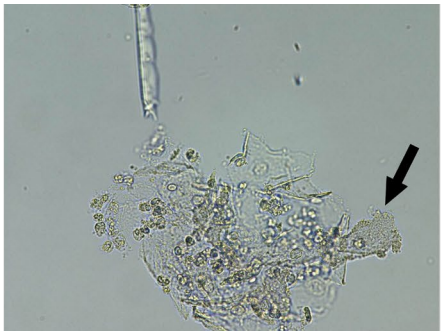
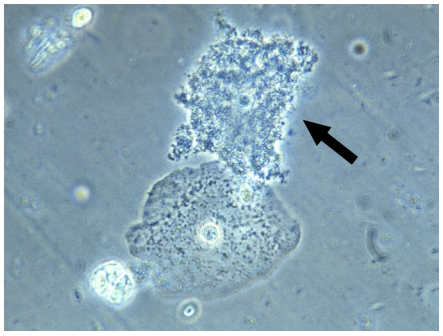
Bacteria

Bacterial vaginitis is often associated with a thin, gray-white, or milky vaginal discharge adhering to the vaginal wall to give a fishy smell. Bacterial vaginitis is caused by high concentrations of *Gardnerella vaginalis*, *Mycoplasma hominis*, and anaerobic bacteria such as *Prevotella sp*. and *Mobiluncus sp*. In the images below, the arrows indicate examples of bacteria.

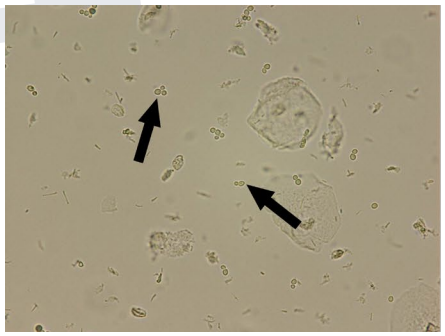
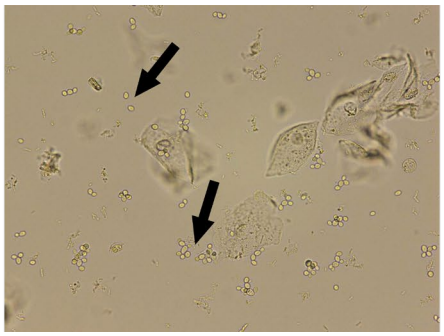
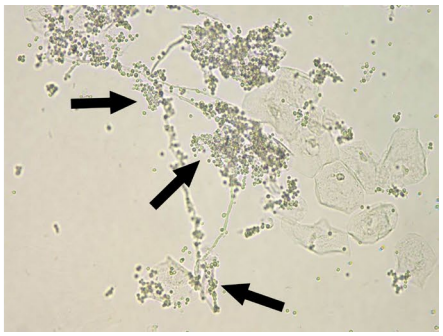
Clue Cells

Clue cells are epithelial cells of the vaginal wall. They often appear fuzzy, lacking distinct sharp borders due to being covered with bacteria. Clue cells are a sign of bacterial vaginosis caused by high concentrations of *Gardnerella vaginalis*, *Mycoplasma hominis*, and anaerobic bacteria such as *Prevotella sp*. and *Mobiluncus sp*. In the images below, the arrows indicate examples of clue cells.

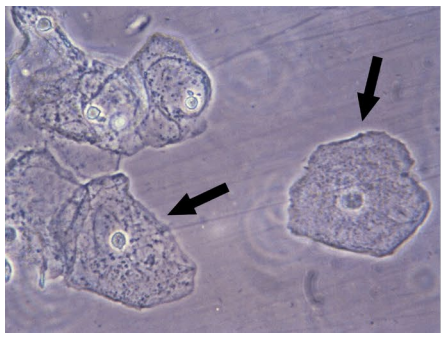
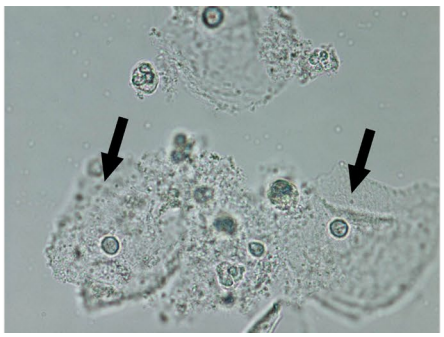
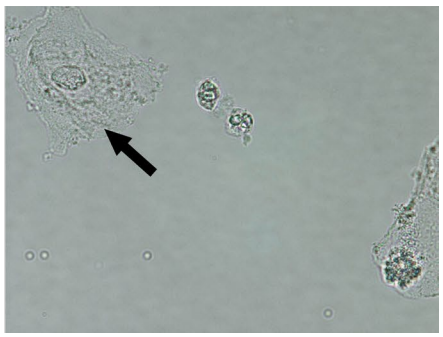
Yeast

Yeast are unicellular fungi that appear commonly in vaginal discharge wet mounts. Yeast can appear as budding yeast or yeast with pseudohyphae, an elongated filament-like string of attached cells. In the images below, the arrows indicate examples of yeast.

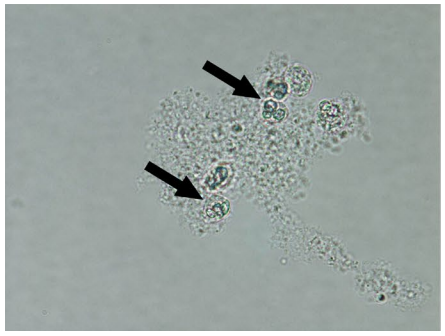
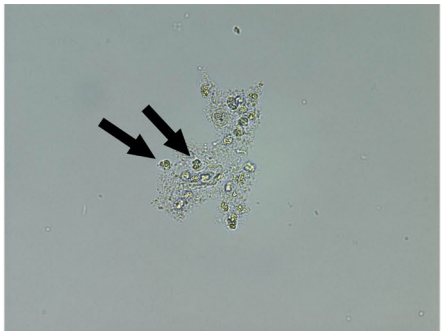
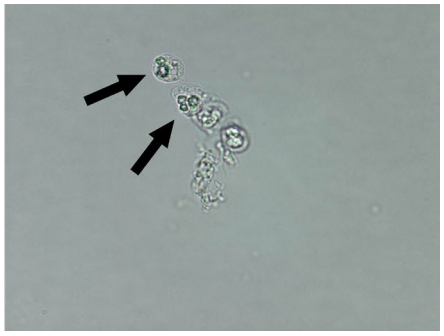
Squamous Epithelial Cells

Most cells observed in a normal vaginal wet prep will be vaginal epithelial cells. Squamous epithelial cells are large and flat with an irregular shape, distinct borders, and a single nucleus. In the images below, the arrows indicate examples of squamous epithelial cells.

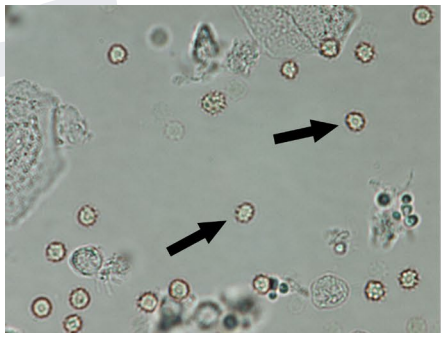
White Blood Cells

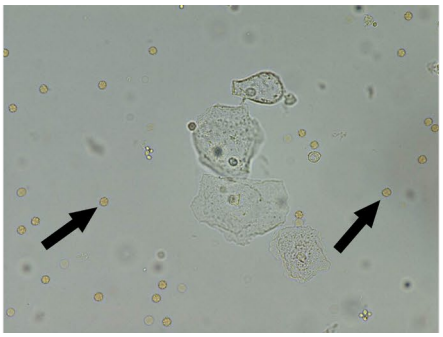
White blood cells (WBCs) are a common component of vaginal flora. WBCs are small, have a multi-lobed nucleus, and appear dark and granular. WBCs can be elevated in infections involving *Chlamydia*, *Trichomonas vaginitis*, herpes, and *Neisseria gonorrhoeae*. A ratio of one WBC for every epithelial cell is considered within normal limits. In the images below, the arrows indicate examples of white blood cells.

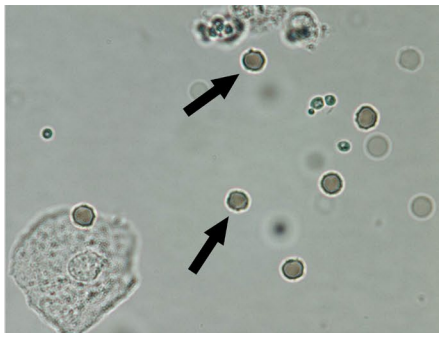




Red Blood Cells

The presence of red blood cells may indicate bleeding during the collection process. The arrows in the images below indicate examples of red blood cells.







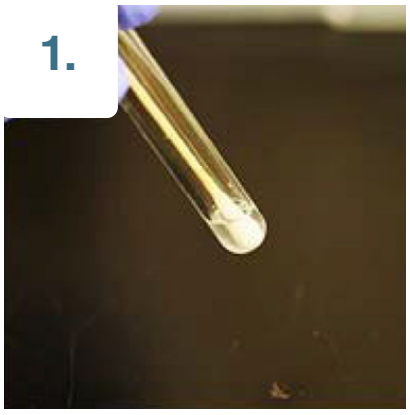
Preparing a Wet Mount

Introduction

The Wet Mount is a procedure performed in the laboratory to observe motile organisms. It is commonly used to examine material collected from the vaginal wall of a female patient.

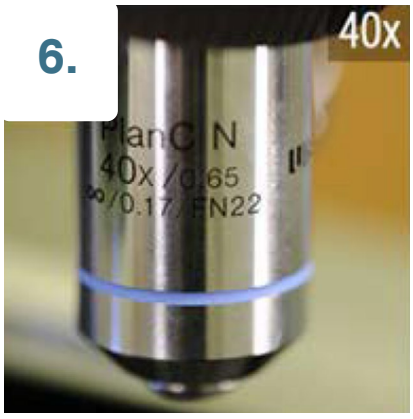
Supplies

1. Personal protective equipment
2. Sharps container
3. Biological waste container and bag
4. Sterile microscope slides
5. Sterile pipettes
6. Glass coverslips
7. Pencil



Instructions

1. Using a sterile dropper, gently mix and remove some of the specimen from the tube and place one drop (10µL) on a clean microscope slide with the patient's identification number/name.
2. Immediately put a coverslip over the sample for examination. A microscopic review of the slide should be performed as soon as possible to confirm the presence or absence of Trichomonads.
3. Focus with low power (10X), low light.
4. Scan the entire slide.
5. Read at least 10 fields.
6. Identify objects with higher power (40X).
7. Record results based on your laboratory's criteria.



Appendix L2

KOH Preparation

PPM laboratories and testing sites use KOH preparations to detect the presence or absence of fungi in vaginal or thick mucoid specimens or those containing keratinous material, such as skin, hair, and nails. KOH digests cellular components of the host cells and other contaminants, leaving the fungal cell wall intact, allowing the fungal elements to be clearly observed. Tinea species, Trichophyton rubrum, and Candida albicans commonly cause fungal infections of the skin, hair, and nails.

Specimen Collection

Before collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or body fluid specimens.

Vaginal Specimens

1. Collect vaginal specimens as described in the Wet Mount procedure section.

Skin Scrapings

1. Scrape the surface of the skin. Be careful not to contaminate scrapings with blood.
2. Place the skin scrapings between two clean glass slides or in a sterile container.

Hair

1. Collect at least 10–12 affected hairs with the base of the shaft attached.
2. Place in a sterile container.

Nail Scrapings

1. Collect a nail clipping.
2. Place nail clipping in a collection packet or sterile glass slide.
3. Cut nail clipping into small fragments.
4. Scrape the excess keratin produced under the nail.
5. Place in a sterile container.

Oral Scrapings

1. Gently scrape the tongue, buccal mucosa, or any other surface within the oral cavity suspected of harboring fungal infection with a sterile tongue depressor.
2. Place the mucosal scrapings between two clean glass slides or in a sterile container.

Sputum

1. Encourage the patient to collect sputum, free of saliva, into a sterile container after a deep, productive cough.

KOH Slide Preparation

Vaginal Specimens

1. Label a clean microscope slide with specimen identification.
2. Using a sterile transfer pipette or dropper, gently mix the specimen with the pipette.
3. Remove a specimen from the tube and place one drop (10 µL) on the labeled microscope slide.
4. Use a clean pipette and add one drop (10 µL) of 10% KOH directly on top of the specimen.

5. Check the slide for a “fishy” amine odor and note presence or absence. The odor indicates anaerobic bacteria overgrowth.
6. Wait up to 5 minutes to allow cellular tissue and debris to dissolve.
7. Immediately put a coverslip over the specimen for examination.
8. Examine the slide to verify it is not overfilled and leaking once the coverslip is in place.

Non-Vaginal Specimens

1. Label a clean microscope slide with specimen identification.
2. Place the specimen on the slide and add one drop (10 µL) of 10% KOH directly on top of the specimen.
3. Wait up to 30 minutes to allow cellular tissue and debris to dissolve. Alternatively, the slide may be heated by placing the specimen slide on a heating block.

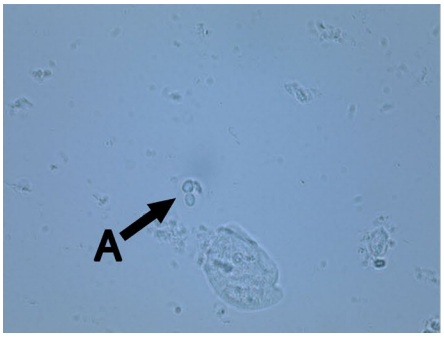
   Note: The exact time needed will depend on the thickness of the specimen fragments. Nail scrapings may require a 20% KOH solution.
4. Immediately put a coverslip over the specimen for examination.
5. Examine the slide to verify that it is not overfilled and leaking once the coverslip is in place.

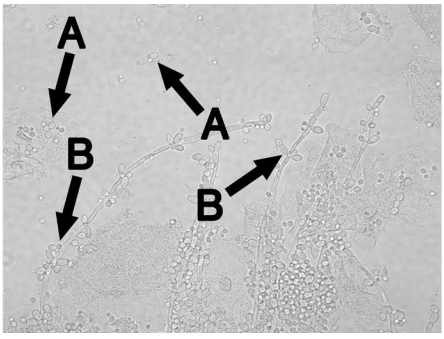
KOH Preparation Microscopic Examination

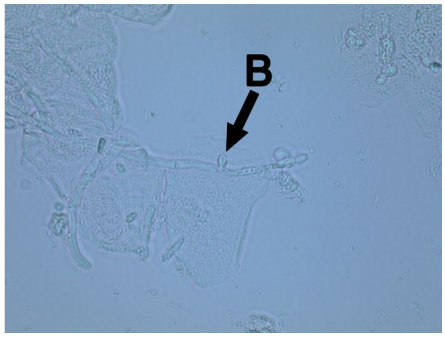
1. Place slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Identify objects using high power (40X).
5. Read at least ten fields using an “S” shaped viewing pattern.
6. Record findings.

KOH Preparation Microscopic Findings

Yeasts are unicellular fungi that appear commonly in vaginal discharge wet mounts. Yeasts are larger than bacteria, approximately the size and shape of the nuclei of epithelial cells. Individual cells of yeast propagate by budding out similar cells from their surface. In PPM observations, yeasts are indicated by a loose arrangement of budding cells. In many fungi, the budding cells remain attached to the parent cell resulting in an elongated filament-like string of attached cells, pseudohyphae, with a cell budding off the tubular structure. In the images below, the arrows indicated by “A” are examples of yeast and the arrows indicated by “B” are examples of pseudohyphae.







KOH Procedure

Introduction

The KOH (potassium hydroxide) procedure is a method used to examine specimens for yeast. KOH serves as an enzymatic agent that breaks down debris in a specimen, such as epithelial cells and WBCs, to view yeast or pseudohyphae.

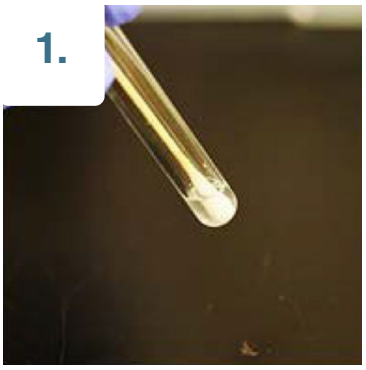
Supplies

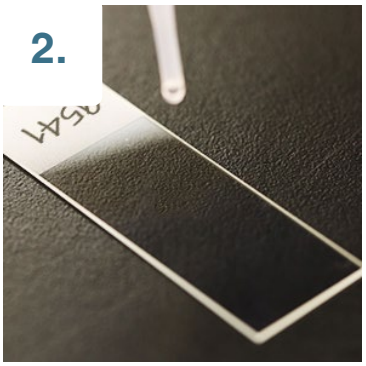
1. Personal protective equipment
2. Sharps container
3. Biological waste container and bag
4. Sterile microscope slides
5. Sterile pipettes
6. Glass coverslips
7. Potassium hydroxide (KOH)

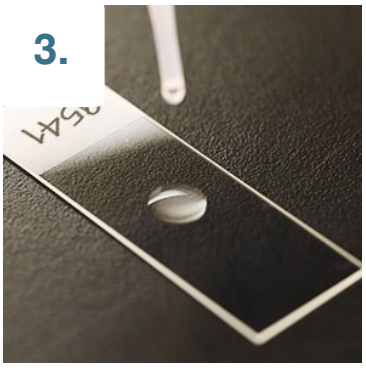
Instructions

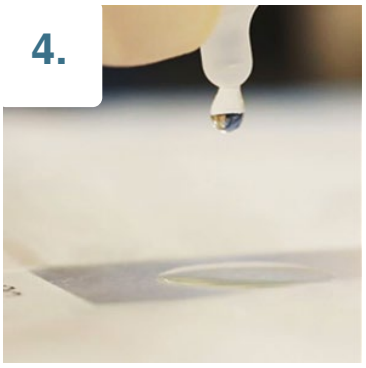
1. Mix the specimen and saline solution gently.
2. Transfer 10µL of specimen solution to a clean, labeled microscope slide.
3. Using a clean pipette, add one drop (10µL) of 10% KOH directly to the drop of specimen on the slide.
4. Hold the slide at room temperature for 5 to 30 minutes after the addition of KOH, depending on the specimen type, to allow digestion to occur.
5. Place a coverslip over the slide.
6. Focus the slide and scan at least 10 fields using low power (10X).
7. Examine detail with higher dry power (40X).

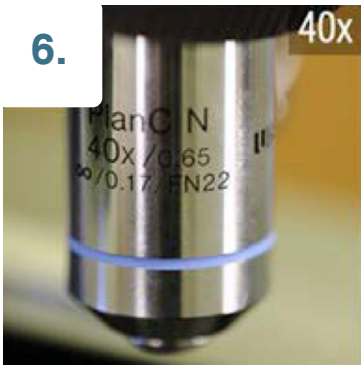
NOTE: This slide is held at room temperature for 5 to 30 minutes after the addition of KOH, depending on the specimen type and to allow digestion to occur. Low/brief heat can sometimes be added to speed up the action of the KOH on the specimen.

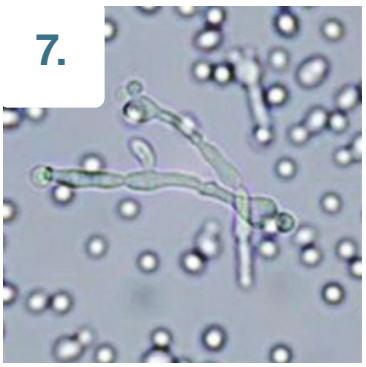












Appendix L3

Pinworm Examination

A pinworm examination is used to determine the presence or absence of the parasite *Enterobius vermicularis*. The adult female worm migrates out of the anus, usually at night, and deposits her eggs on the perianal area. PPM testing includes the collection of a specimen from the skin in the perianal area, followed by a microscopic examination to detect the presence of the pinworm eggs.

Pinworm Specimen Collection and Slide Preparation

Prior to collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or other body fluid specimens. Take specimens early in the morning, before the patient has bathed or used the toilet.

Paddle Method

1. Hold the paddle by the cap and remove it from the tube.
2. Press the sticky surface to the right and left perianal folds.
3. Replace the paddle in the tube until microscopic examination.
4. Place the paddle on a microscope slide labeled with patient identifiers

Cellulose Tape Method

1. Apply a strip of clear cellulose tape to the anal folds.
2. Place tape, sticky side down, on a microscope slide labeled with patient identifiers.

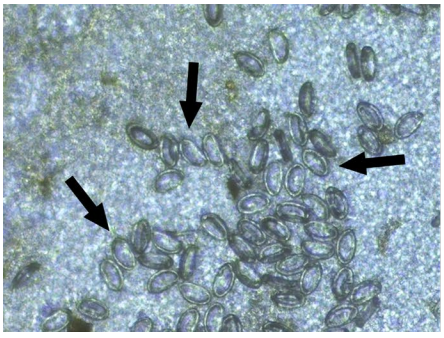
Note: (1) Visibility of eggs can be improved by lifting the tape from the slide, adding a drop of xylene or toluene, and pressing the tape back on the slide. This helps clear the preparation, and the eggs can be observed clearly. (2) By substituting xylene or toluene with safer and effective alternatives like mineral oil, glycerin, or isopropanol, the cellulose tape method can be performed effectively while minimizing health risks and any environmental impact.

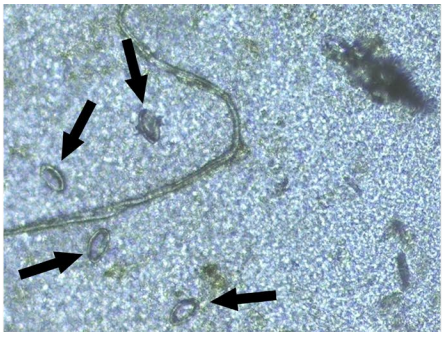
Pinworm Microscopic Examination

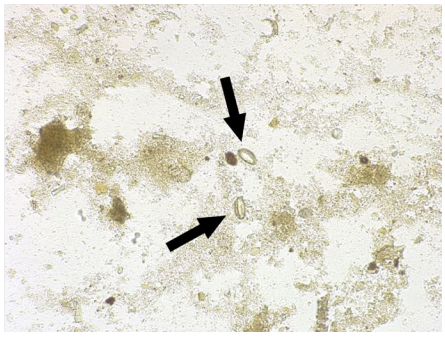
1. Place the slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Identify objects using high power (40X).
5. Read at least 10 fields using an “S” shaped viewing pattern.
6. Record findings.

Pinworm Preparation Microscopic Findings

E. vermicularis (pinworm) eggs are football-shaped, flattened on one side with a thick, colorless shell. The eggs are approximately 70-85 by 20-23 µm and may contain larvae. Movement of the larva may be observed. In the images below, the arrows indicate examples of pinworm eggs







Appendix L4

Fern Test

The Fern Test is used to detect amniotic fluid leakage from the membrane surrounding the fetus during pregnancy. If a membrane rupture occurs, evidence of amniotic fluid will be present. Amniotic fluid will crystallize when dried on a glass slide, forming a fern pattern due to the fluid's relative concentrations of sodium chloride, proteins, and carbohydrates. Normal vaginal secretions that do not contain amniotic fluid will not show the ferning pattern. The Fern Test may also be used to monitor fertility. Cervical mucus smears form a fern pattern when estrogen secretion is elevated.

Vaginal Specimen Collection

1. Before collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or other body fluid specimens.
2. Collect a vaginal secretion with a sterile cotton swab from the posterior vaginal pool during the sterile speculum exam.
3. Collect a sample from the external cervical os if a pool of fluid is not evident.

Fern Test Slide Preparation

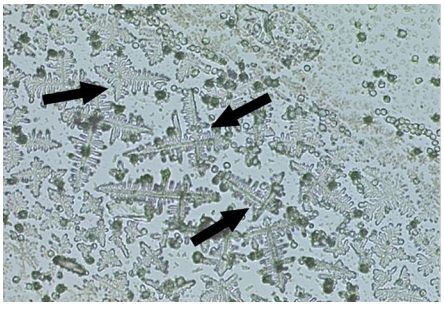
1. Label a clean microscope slide with specimen identification.
2. Roll the swab across the glass slide while applying pressure to express the fluid and create a thin smear immediately after collection.
3. Allow the slide to completely air dry (3-5 minutes).
4. Do not heat the slide or apply a coverslip.

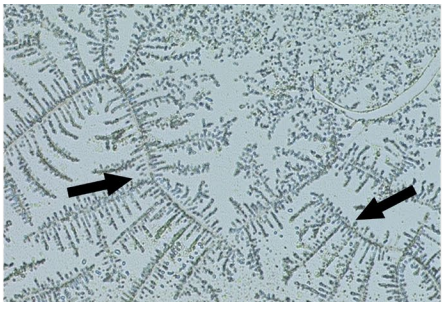
Fern Test Microscopic Examination

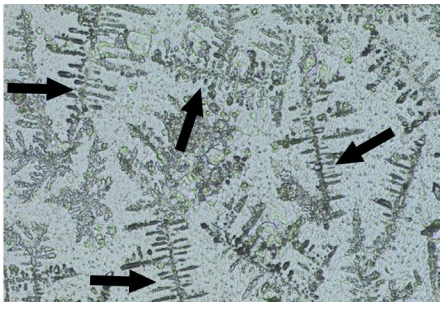
1. Place the slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Identify evidence of a fernlike pattern.
5. Observe the slide using high power (40X) to confirm the ferning pattern.
6. Examine the entire slide using an "S" shaped viewing pattern.
7. Record findings.

Fern Test Microscopic Findings

Visualization of a characteristic ferning pattern may provide evidence of membrane rupture. In the images below, the arrows indicate examples of positive ferning.







Appendix L5

Post-Coital Direct, Qualitative Examination of Vaginal or Cervical Mucus

The post-coital test involves direct, qualitative examination of vaginal or cervical mucus to evaluate factors that could affect fertility. The test involves the qualitative analysis of the mucus, including color, viscosity, and tenacity, and the determination of the presence and motility of sperm. The assessment provides information to determine the receptivity of cervical mucus and the ability of sperm to penetrate the mucus.

Patient Preparation

1. Patients should use an ovulation determination method.
2. When ovulation is detected, the patient and her partner should have intercourse.
3. The patient should remain in bed for 10 to 15 minutes following intercourse to allow the semen to contact the cervical mucus.
4. Testing should be performed within 2-12 hours following intercourse.
5. Upon arrival for testing, the provider should record the time since intercourse.

Post-Coital Direct, Qualitative Examination of Vaginal or Cervical Mucus Slide Preparation

Before collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or body fluid specimens. No lubrication should be used.

1. Remove excess vaginal secretions with a sterile cotton swab during the sterile speculum exam to prevent contamination.
2. Remove cervical mucus using a suction device on the cervical os.
3. Test the specimen as soon as possible after collection.

Post-Coital Direct, Qualitative Examination of Vaginal or Cervical Mucus Procedure

Qualitative Analysis of Cervical Mucus

1. Determine the volume of mucus in the syringe. Alternatively, expel the mucus from the syringe into a sterile Petri dish and estimate the amount of mucus (scant, moderate, or profuse).
2. Record the color and clarity of the mucus.
3. Label a clean microscope slide with specimen identification.
4. Remove a specimen from the Petri dish and place one drop (10 µL) on the labeled microscope slide.
5. Immediately put a coverslip over the specimen.
6. Pull the glass coverslip off the glass slide.
7. Determine the distance a thread of mucus remains attached to the glass slide when lifted. Alternatively, place a drop of mucus on a microscope slide and test tenacity by grasping a portion of the mucus with forceps and noting the distance at which it can be drawn without breaking.

Determination of Sperm Presence and Motility

1. Label a clean microscope slide with specimen identification.
2. Remove a specimen from the Petri dish and place one drop (10 µL) on the labeled microscope slide.
3. Immediately put a coverslip over the specimen.
4. Examine the slide immediately to prevent specimen drying, which may result in killing active spermatozoa.
5. Place the slide under the microscope for examination.
6. Focus using low power (10X) and low light.
7. Observe the slide using high power (40X).
8. Examine the entire slide using an “S” shaped viewing pattern.
9. Record the presence and motility of sperm for each high-powered field.
10. Use criteria for sperm motility assessment, for example:
    - Rapid Progressive Motility: Sperm moving swiftly in a straight line.
    - Slow Progressive Motility: Sperm moving slowly or in a curved line.
    - Non-Progressive Motility: Sperm moving but not advancing.
    - Immotile: Sperm not moving at all.

Determination of Sperm Presence and Motility

Normal mid-cycle mucus should be clear, with minimal viscosity, and profuse. A tenacity measurement of 6 to 10 cm is desirable. The normal number of sperm in a post-coital examination is not precise. Within 6-8 hours after coitus, at least five to ten motile sperm should be present per high-powered field.

Appendix L6

Urine Sediment Examination

Urine sediment examination is used to detect and identify formed elements in urine. The test involves collecting urine and microscopic examination of the urine sediment for formed elements such as cells, casts, crystals, and microorganisms. Specimens not obtained by "clean, catch midstream" methods often contain elements from sources other than the urinary tract. The microscopic examination is a valuable diagnostic tool for detecting renal and urinary tract disorders.

Patient Preparation

1. Provide patients with instructions on how to collect a "clean, catch midstream" urine specimen.

Urine Specimen Collection and Processing

Before collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or other body fluid specimens.

1. Label a clean, dry container free of lint and debris with patient identifiers, date, and time of collection.
2. Obtain a "clean, catch midstream" urine specimen. Concentrated first-morning specimens are preferred.
3. Examine the specimen within 2 hours of collection or 4 hours if refrigerated. Otherwise, bacteria may proliferate, casts and crystals may dissolve, and particulate matter may settle out.

   If planning to examine refrigerated collections longer than 24 hours, a specimen stability and interference study may be required to establish maximum storage time for a viable specimen. Consult your SOPs for specifics on maximum specimen stability durations.

4. Place 12-15 mL of urine in a conical centrifuge tube labeled with the patient identifiers.
5. Centrifuge at 400 x g for 5 minutes. To prevent re-suspension of urine sediment, do not apply brake at the end of centrifugation. Higher centrifugation rates and longer centrifugation times may result in denigration of cellular casts.
6. Carefully decant the supernatant into a biohazard-designated sink or receptacle, leaving approximately 1 mL in the tube.
7. Resuspend the sediment by gently tapping the bottom of the tube or using a pipet to mix.

Urine Sediment Microscope Slide Preparation

1. Label a clean microscope slide with specimen identification.
2. Gently mix the specimen using a sterile transfer pipette or dropper.
3. Remove the specimen from the tube and place one drop (10 µL) on the labeled microscope slide.
4. Immediately put a coverslip over the specimen for examination.
5. Allow urine to settle for 30-60 seconds before examination.
6. Examine the slide to verify it is not overfilled and leaking once the coverslip is in place.

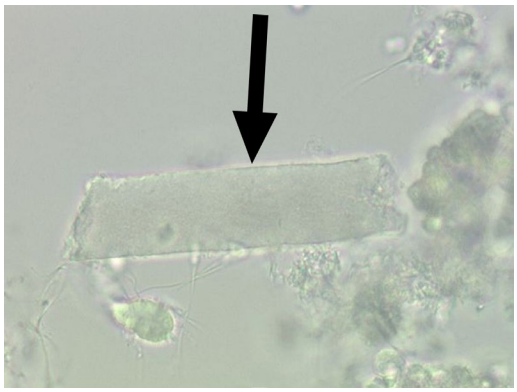
Urine Sediment Microscopic Examination

1. Place the slide under the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Read at least 10 fields using an “S” shaped viewing pattern.
5. Record the presence of crystals, casts, and squamous epithelial cells using semi-quantitative terms such as rare, few, moderate, or many and report results following laboratory procedure.
6. Identify objects using high power (40X).
7. Record the presence of red blood cells, white blood cells, and renal tubular cells. Quantitate the average number of elements per high-power field and report results following laboratory procedure.
8. Note the presence of bacteria, yeast, trichomonads, and mucus.

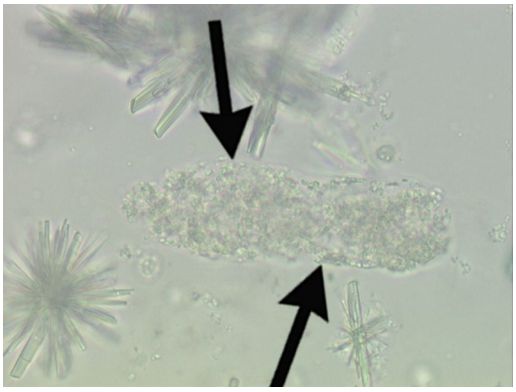
Common Urine Sediment Microscopic Findings

Casts

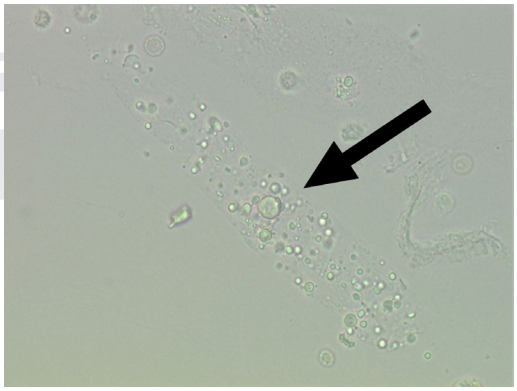
Urinary casts are small cylindrical structures that can be found in urine. Casts are formed by the solidification of proteins in the lumen of the kidney tubules and vary in size and shape according to the tubules where they were formed. The presence of casts in urine is associated with various pathologic conditions such as glomerular or tubular damage, renal inflammation, or infection.



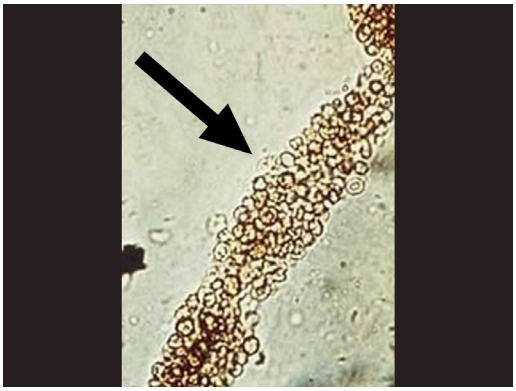
Hyaline casts are the most frequently seen urinary casts, and a few may be seen in healthy individuals. They have a smooth texture, and their refractive index is close to that of their surroundings. Increased numbers of hyaline casts are usually caused by dehydration, exercise, or diuretic medicines and may be associated with some renal diseases. The arrow indicates an example of a hyaline cast.



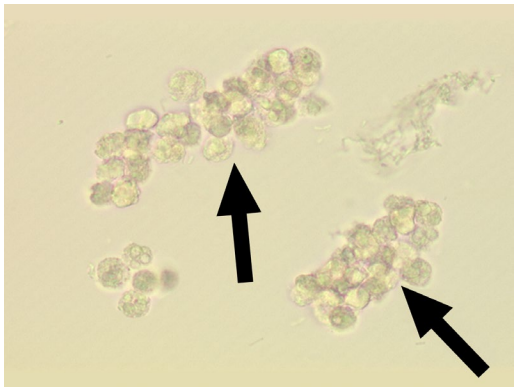
Granular casts may be coarse-to-fine in appearance. They are a sign of many types of kidney disease and may often indicate significant renal disease. The arrows indicate an example of a granular cast.



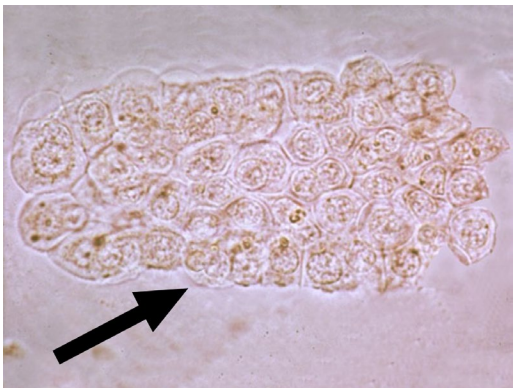
Fatty casts contain refractile liquid droplets within the cast. Fatty casts are seen in people who have lipids in urine, usually as a complication of nephrotic syndrome and diabetes mellitus. The arrow indicates an example of a fatty cast.



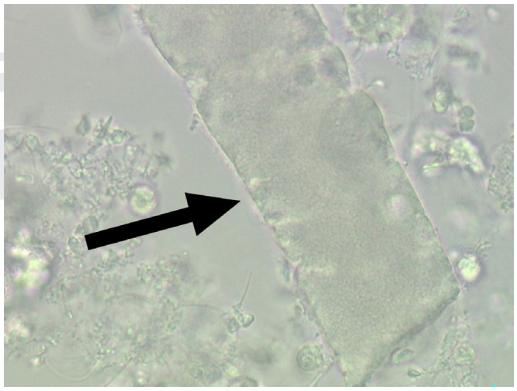
Red blood cell casts are granular cylinders composed of a matrix of red cells in various stages of degradation. Red blood cell casts are indicative of bleeding into the kidney and may be present in many kidney diseases, such as glomerulonephritis or vasculitis. Red blood cell casts may also be present in lupus nephritis, Goodpasture syndrome, and subacute bacterial endocarditis. The arrow indicates an example of a red blood cell cast.



White blood cell casts contain leukocytes in the cast matrix. They are common with acute kidney infections and may also be present in renal infection, glomerular disease, pyelonephritis, and interstitial nephritis. The arrows indicate examples of white blood cell casts.



Renal tubular epithelial cell casts contain renal tubular epithelial cells in the cast matrix. Individual cells may appear randomly in, or they can align as fragments of the tubular lining within the cast. These casts are seen in conditions such as renal tubular necrosis, viral disease (such as CMV nephritis), and kidney transplant rejection. The arrow indicates examples of renal tubular epithelial cell casts.

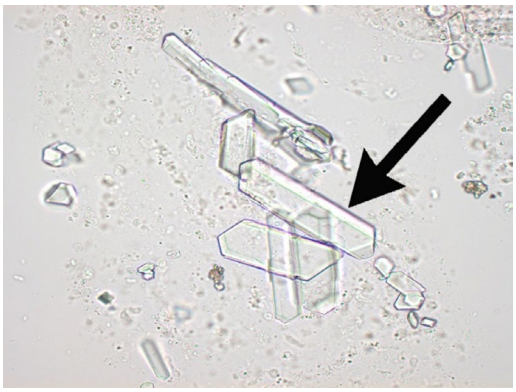


Waxy casts have smooth edges with squared-off ends and do not have inclusions present. Waxy casts can be found in persons with advanced kidney disease and chronic kidney failure. The arrow indicates an example of a waxy cast.

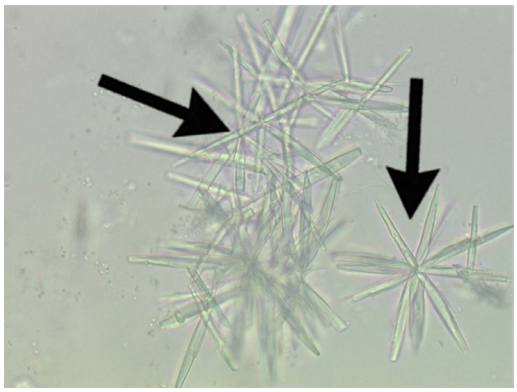
Crystals

The presence of trace crystals in urine is often of no clinical significance in healthy individuals. The presence of a large number of crystals may indicate underlying health issues. It is important to differentiate between crystals frequently found in the urine and abnormal crystals whose appearance is pathological. The pH of fresh urine aids in the identification of crystals. Crystals found in the urine at an alkaline pH are usually considered normal. Abnormal crystals precipitate in the urine at an acidic pH. Other biochemical tests may be needed to confirm the identification of abnormal crystals.

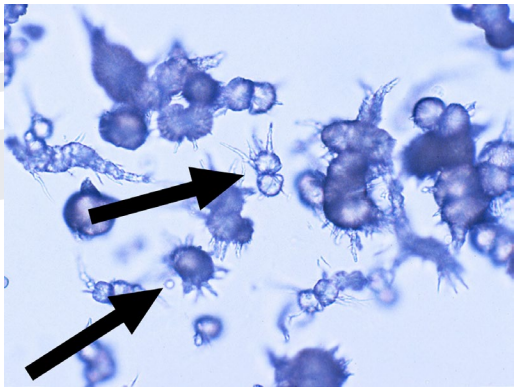
Alkaline Crystals



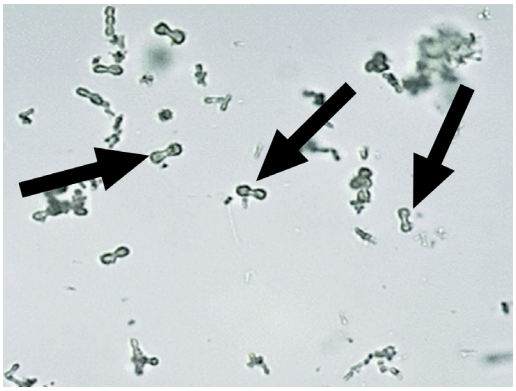
Triple phosphate crystals are colorless with a “coffin-lid” appearance. Although considered normal, they may be associated with urinary tract infections when found in freshly voided morning specimens. The arrow indicates an example of a triple phosphate crystal.



Calcium phosphate crystals are large wedge-shaped prisms that may appear as rosettes. They may be associated with kidney stone formation. The arrows indicate examples of calcium phosphate crystals.

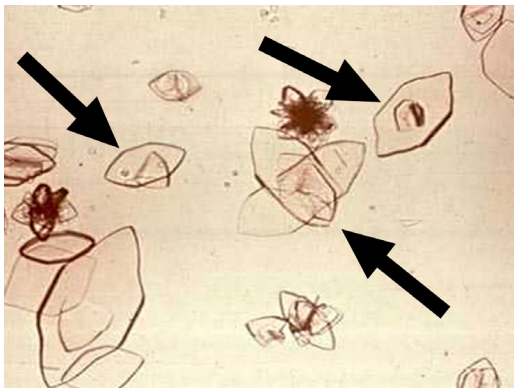


Ammonium biurate crystals often appear as a “thorn apple” shape. The presence of these crystals in urine with a pH 9.0 or higher usually indicates an old specimen. The arrows indicate examples of ammonium biurate crystals.

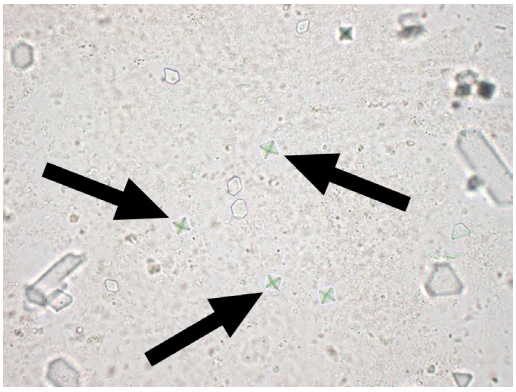


Calcium carbonate crystals appear small, colorless, and dumbbell-shaped. When dissolved in acetic acid, they give off bubbles of gas (effervesce). The arrows indicate examples of calcium carbonate crystals.

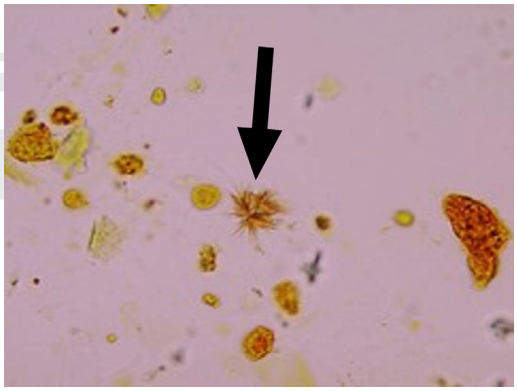
Acidic Crystals



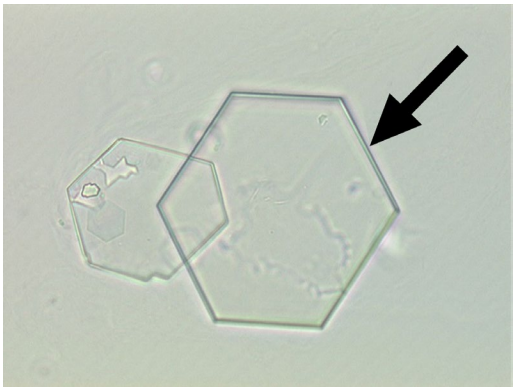
Uric acid crystals vary in size and shape and are often yellow brown in color. They may be associated with kidney stone formation and are often seen in patients with Gout, Lesch-Nyhan syndrome, and leukemia. The arrows indicate examples of uric acid crystals.



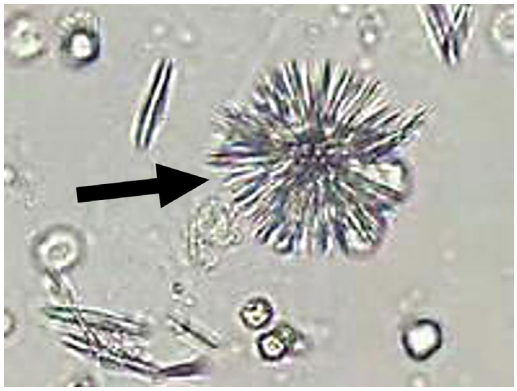
Calcium oxalate crystals are colorless and appear in many forms. The dihydrate form appears “envelope shaped,” with a highly refractile cross connecting the corners. The monohydrate form can appear as dumbbell, ovoid, or rectangular in shape. Calcium oxalate crystals are associated with kidney failure due to ethylene glycol (antifreeze) poisoning. The arrows indicate examples of the dihydrate form of calcium oxalate crystals.



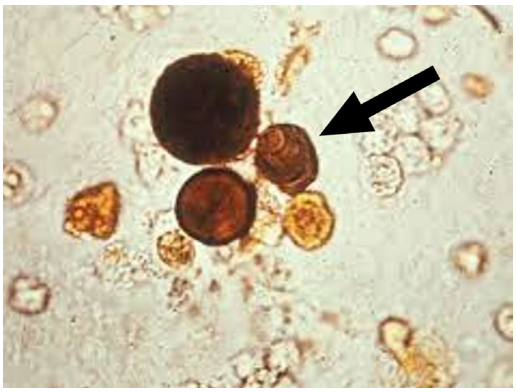
Bilirubin crystals appear as yellow-brown needles or granules. These crystals are considered abnormal in urine and may be associated with several hepatic disorders. The arrow indicates an example of a bilirubin crystal.



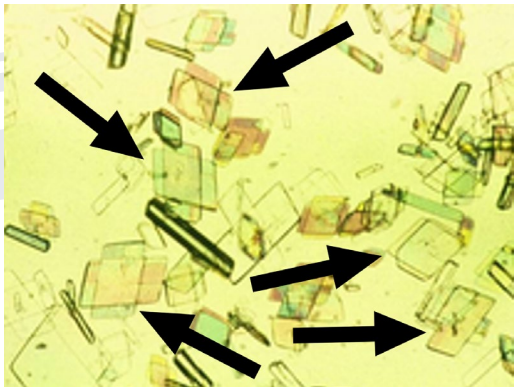
Cystine crystals appear as colorless, hexagonal plates. They are considered abnormal in urine and may be associated with cystinuria. Cystine crystals are a frequent cause of kidney stones in children. The arrow indicates an example of a cystine crystal.



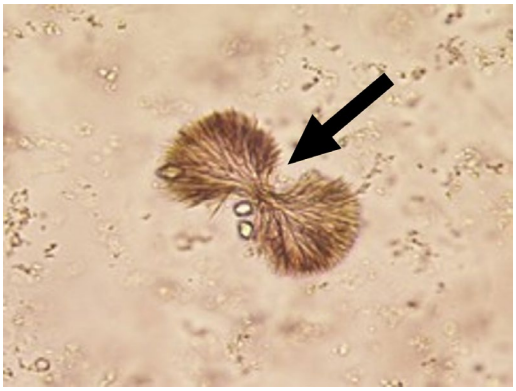
Tyrosine crystals appear as colorless to yellow-brown needles arranged in radiating sheaves. They are considered abnormal in urine and may be seen in tyrosinemia and in some liver disorders when amino acid metabolism is impaired. The arrow indicates an example of a tyrosine crystal.



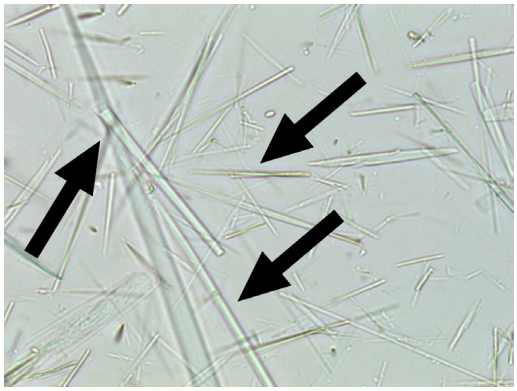
Leucine crystals appear as yellow-brown needles or granules. These crystals are considered abnormal in urine and may be associated with several hepatic disorders. The arrow indicates an example of a leucine crystal.



Cholesterol crystals appear as clear, flat plates with notched corners. These crystals are considered abnormal in urine and may be associated with nephrotic syndrome. The arrows indicate examples of cholesterol crystals.

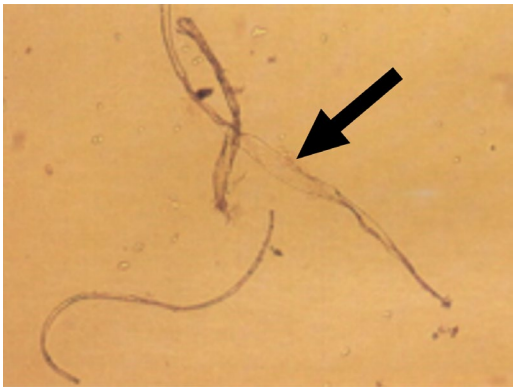


Sulfonamide crystals have a varied appearance including flat needles, sheaves of small needles, and spheres. These crystals are considered abnormal in urine and may indicate the presence of a sulfonamide drug and may be associated with kidney stone formation. The arrow indicates an example of a sulfonamide crystal.



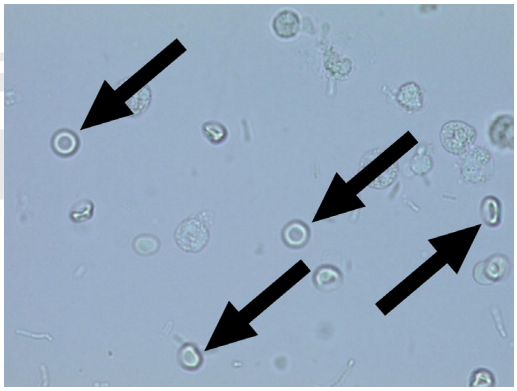
Radiopaque dye crystals appear as flat needles. These crystals are considered abnormal in urine and are associated with very high specific gravity results by refractometry. The arrows indicate examples of radiopaque dye crystals.

Other Microscopic Findings



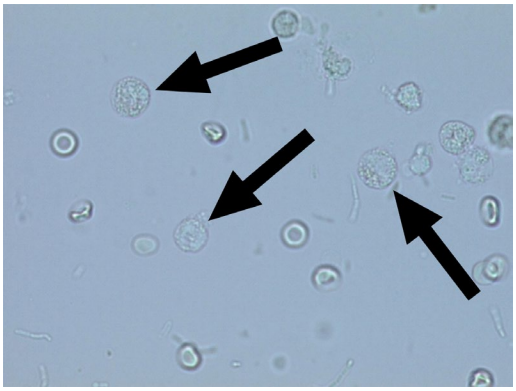
Mucus

The presence of mucus threads is often a benign situation. Large amounts of mucus in the urine most often indicates a urinary tract infection but may also be associated with irritable bowel syndrome, kidney stones, and some cases of malignant tumors of the urinary tract. The arrow indicates an example of a mucus thread.



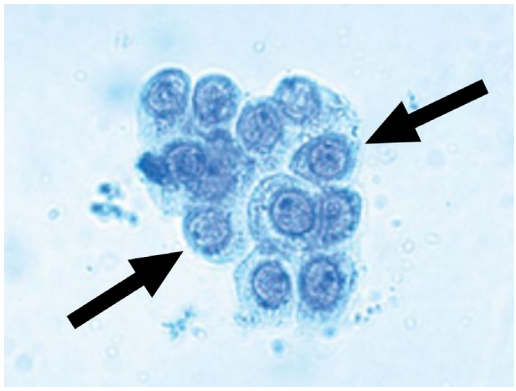
Red Blood Cells

In fresh urine, normal red blood cells appear as biconcave discs with distinct, dark, smooth cell walls. Red blood cells may be present in less than 5 cells per high-power field in normal urine. In hypotonic urine, the red blood cells swell and lyse, resulting in cells that appear as an empty shell. In hypertonic urine, the red blood cells crenate and form jagged cell walls. High red blood cell counts are associated with urinary tract disease, such as glomerulonephritis. The arrows indicate examples of red blood cells.



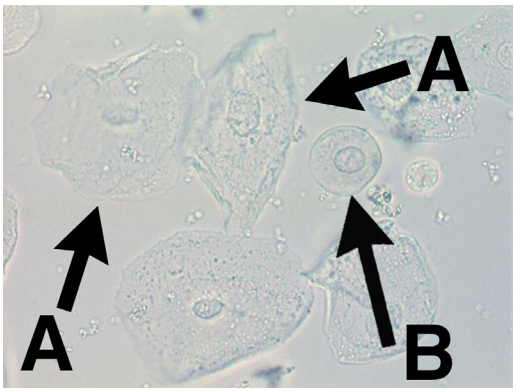
White Blood Cells

The presence of up to five white blood cells per high-powered field may be seen in normal urine. High neutrophil counts suggest inflammation or infection within the urinary tract. The arrows indicate examples of white blood cells.



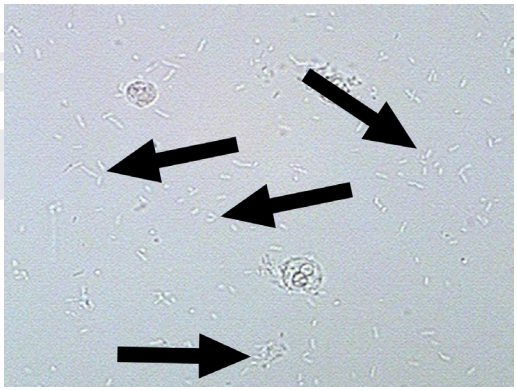
Renal Tubular Epithelial Cells

Renal tubular epithelial cells are large and have a distinct single round nucleus. The presence of more than 15 renal tubular epithelial cells per high-power field may indicate renal disease or tubular injury. The arrows indicate examples of renal tubular epithelial cells.



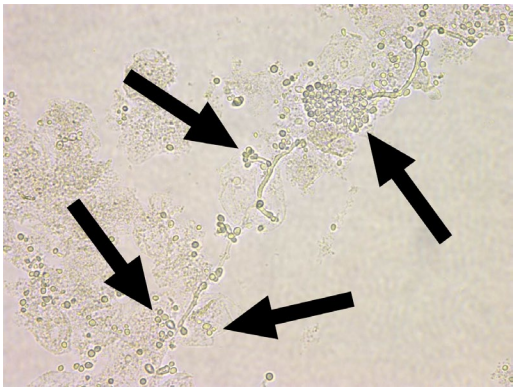
Epithelial Cells

Squamous epithelial cells (indicated by “A” in the image) are flat with an irregular border. A large number of squamous epithelial cells present may indicate a contaminated specimen. Transitional epithelial cells (indicated by “B” in the image) from the skin surface or the outer urethra can appear in normal urine. Increased numbers may indicate infection and transitional cell carcinoma.



Bacteria

Bacteria in urine usually indicates a contaminated specimen and is of little significance except in fresh catheterized specimens. The presence of high numbers of one organism with a high white blood cell count may indicate a urinary tract infection. The presence of bacteria without a high number of white blood cells may indicate a contaminated specimen.



Yeast

The presence of yeast in urine sediment of females is often a result of vaginal contamination from a yeast infection. Yeast is also associated with diabetes mellitus due to the presence of urinary glucose. The arrows indicate examples of yeast cells.

Appendix L7

Nasal Smear for Granulocytes

The examination of nasal smears for granulocytes is performed to detect eosinophils, a specific type of granulocyte, in nasal secretions as an indicator of allergic rhinitis.

Nasal Specimen Collection

Prior to collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or other body fluid specimens.

1. Collect a nasal discharge specimen onto a nonabsorbent material such as plastic wrap or wax paper.
2. Transfer a sample of the collected mucus with a sterile cotton swab.

Alternatively,

1. Collect a nasal secretion with a sterile nasopharyngeal swab by passing gently through the nostril into the nasopharynx.
2. Rotate the swab, applying gentle pressure to obtain a sufficient amount of specimen.
3. Repeat the process using the same swab on the other nostril.

Nasal Smear Slide Preparation

Before collecting specimens, perform hand hygiene and put on gloves. Take standard precautions when collecting and handling blood or body fluid specimens.

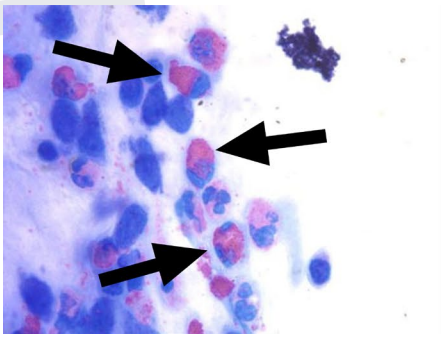
1. Label a clean microscope slide with specimen identification.
2. Gently roll the swab across the glass slide while applying pressure to express the fluid and create a thin smear immediately after collection.
3. Allow the slide to completely air dry (3-5 minutes).
4. Do not heat the slide or apply a coverslip.
5. Stain the smear using either a commercially prepared Wright-Giemsa stain or a Hansel stain following the manufacturer's procedure or documented laboratory procedures.

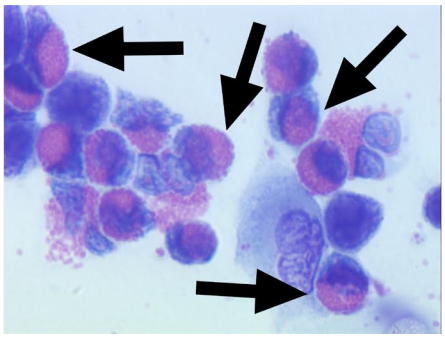
Nasal Smear for Granulocytes Microscopic Examination

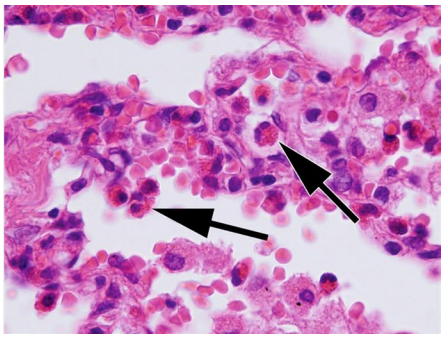
1. Place the slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Identify objects using high power (40X).
5. Read at least 10 fields using an "S" shaped viewing pattern.
6. Record details on the presence and quantity of eosinophils.

Nasal Smear for Granulocytes Microscopic Findings

Eosinophils stain to show bright red or reddish-orange granules in the cytoplasm, as indicated by the arrows in the images below. The presence of more than three eosinophils per high-power field may indicate allergic rhinitis.







Appendix L8

Fecal Leukocytes Examination

The fecal leukocyte examination is used to determine the presence of leukocytes in a fecal smear. Fecal leukocytes are indicators of bacterial infection such as shigellosis and can provide information to differentiate possible life-threatening inflammatory diarrheas from non-inflammatory diarrheas.

Fecal Specimen Collection

Prior to collecting specimens, perform hand hygiene and put on gloves. Standard precautions should be taken when collecting and handling blood or other body fluid specimens.

1. Label a clean, dry container that is sealable and leakproof with patient identifiers, date, and time of collection.
2. Obtain a stool specimen free of urine.
3. Store at room temperature. Do not place the specimen in the refrigerator.

Fecal Leukocyte Slide Preparation

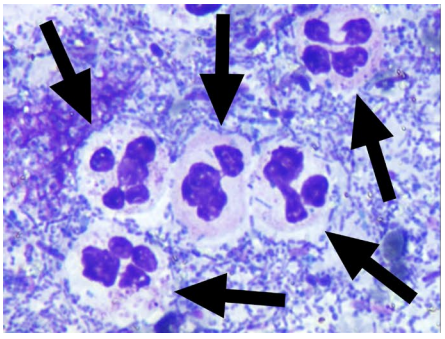
1. Label a clean microscope slide with specimen identification.
2. Use an applicator stick to apply a small amount of stool to the slide.
3. Stain slide with commercially prepared Loeffler's methylene blue or Wright-Giemsa stain following the manufacturer's procedure or documented laboratory procedures.
4. Apply a coverslip.

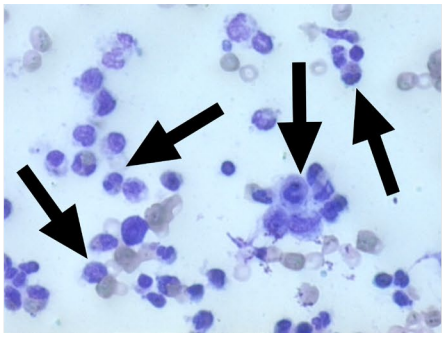
Fecal Leukocyte Examination Microscopic Examination

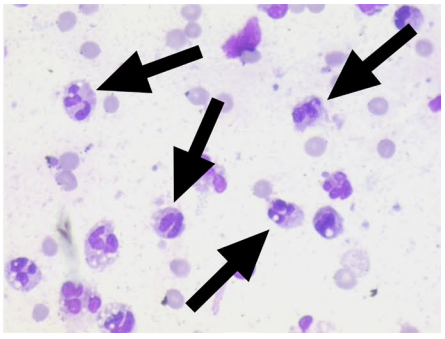
1. Place the slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Scan the entire slide.
4. Observe the slide using high power (40X).
5. Examine the entire slide using an "S" shaped viewing pattern.
6. Record details on the presence of fecal leukocytes.

Fecal Leukocyte Examination Microscopic Findings

The presence of fecal leukocytes as indicated by the arrows in the images below may indicate bacterial inflammatory enteritis condition associated with infection by Salmonella, Shigella, invasive Escherichia coli, or Yersinia. Fecal leukocytes may also be associated with infection by Entamoeba histolytica. The presence of fecal leukocytes may be indicators of inflammatory bowel diseases such as ulcerative colitis and Crohn disease, and fecal neutrophils occasionally can be present in cases of viral enteritis.







Appendix L9

Qualitative Semen Analysis

(limited to the presence or absence of sperm and detection of motility)

The qualitative semen analysis is limited to the determination of the presence/absence of sperm and sperm motility. Semen analysis may be performed to evaluate the effectiveness of a vasectomy procedure, evaluate infertility, or to determine the suitability of semen for use in artificial insemination.

Semen Specimen Collection

Prior to collecting specimens, perform hand hygiene and put on gloves. Standard precautions should be taken when collecting and handling blood or other body fluid specimens.

1. Label a clean, dry container that is sealable and leakproof with patient identifiers, date, and time of collection.
2. Collect semen in container.
3. Evaluate the specimen within 30 minutes of collection.
4. Store at room temperature. Do not place the specimen in the refrigerator. Do not use specimens older than 2 hours.

Qualitative Semen Analysis Slide Preparation

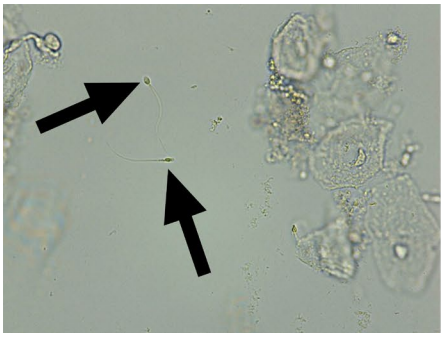
1. Label a clean microscope slide with specimen identification.
2. Using a sterile transfer pipette or dropper, gently mix the specimen with the pipette.
3. Remove a specimen from the tube and place one drop (10 µL) on the labeled microscope slide.
4. Immediately put a coverslip over the specimen for examination.
5. Examine the slide to verify that it is not overfilled and leaking once the cover slip is in place.

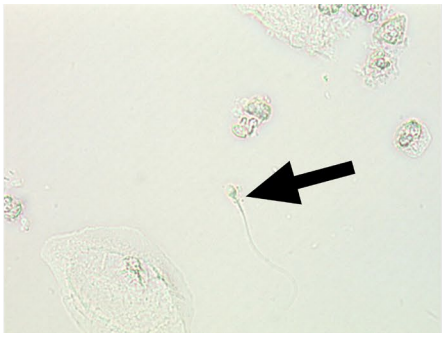
Qualitative Semen Analysis Microscopic Examination

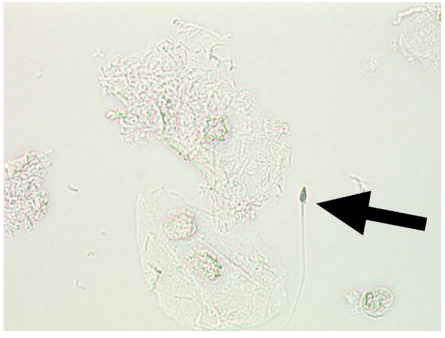
1. Place the slide on the microscope for examination.
2. Focus using low power (10X) and low light.
3. Observe the slide using high power (40X).
4. Examine the entire slide using an “S” shaped viewing pattern.
5. Record the presence/absence of sperm and detection of motility.

Qualitative Semen Analysis Microscopic Findings

The presence or absence of motile sperm is determined by of the identification of forward moving sperm. In post-vasectomy patients, centrifugation of the specimen into a pellet may be performed to assure a thorough analysis and confirmation of sperm absence. Examples of spermatozoa are indicated by the arrows.







Appendix M

Terms and Abbreviations

Biohazardous waste	Biohazard or sharps waste and waste that is generated or produced as a result of the diagnosis, treatment, or immunization of humans. Environmental laws dictate the 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	Bloodborne pathogens are infectious microorganisms that, when present in human blood, can cause disease in humans.
CDC, The Centers for Disease Control and Prevention	A federal agency under the Department of Health and Human Services (HHS). CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. In partnership with the Centers for Medicare & Medicaid Services and the Food and Drug Administration, CDC supports the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program and clinical laboratory quality.
CLIA, The Clinical Laboratory Improvement Amendments of 1988	The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.
CMS, Centers for Medicare & Medicaid Services	CMS is the federal agency that provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity, and outcomes in the health care system. CMS has administrative responsibility for the CLIA program including regulating all laboratory testing performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
Certificate of Provider-Performed Microscopy Procedures	A certificate issued or reissued by the Centers for Medicare & Medicaid Services to laboratories or testing sites performing Provider-Performed Microscopy Procedures, as well as any waived tests.
CoW, Certificate of Waiver	A certificate issued or reissued by the Centers for Medicare & Medicaid Services to a testing site performing only waived tests.
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 specimen collection to results reporting.
Compliance	The act of adhering to, and demonstrating adherence to, a standard or regulation.
Contamination	The accidental introduction of "foreign" material that can seriously distort the results of experiments where small samples are used.
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 the recurrence of a problem.
Decontamination	The removal or neutralization of toxic agents or the use of physical or chemical means to remove, inactivate, or destroy living organisms on a surface or item so that the organisms are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Disinfectant	An agent that destroys microorganisms that may cause disease.
Engineering controls	Controls (e.g., sharps containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.
Ergonomics	The science of fitting workplace conditions and job demands to the capabilities of the working population.
External assessment	A review that is typically performed by an outside party to evaluate current practices and offer opportunities for education.
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.
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	HIPAA is a federal privacy rule that provides protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. HIPAA permits the disclosure of personal health 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.
Infectious materials	Materials containing viable microorganisms, including bacteria, viruses, parasites, or fungi, that are known or reasonably believed to cause disease in humans or animals.
Internal assessment	A review that staff performing and overseeing testing perform to evaluate their current practices. The process of critical review of the laboratory.
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.
Occupational exposure	Reasonably anticipated skin, eyes, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
OSHA, The Occupational Safety and Health Administration	The United States government agency with the mission to assure safe and healthful working conditions for all people. OSHA establishes workplace standards to enforce and prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules for workplace safety and health.
Performance 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 specimen collection to results reporting.
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.
PPM, Provider Performed Microscopy Procedures	Provider-Performed Microscopy procedures are a select group of moderately complex microscopy tests commonly performed by health care providers during patient office visits.

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 (specimen)	Any type of pretreatment a specimen undergoes before testing. Examples include centrifugation or spinning down of whole blood.
PT, Proficiency testing	An external quality assessment program in which samples are periodically sent to testing sites for analysis. Proficiency testing involves a group of laboratories or analysts performing the same analyses on the same samples and comparing results. The key requirements of such comparisons are that the samples are homogenous and stable, and that the set of samples analyzed are appropriate to test and display similarities and differences in results.
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.
Quality assurance	Part of quality management focused on providing confidence that quality requirements will be fulfilled.
Sharps	Instruments, tools, or items that have rigid, acute edges, protuberances, or corners capable of cutting, piercing, ripping, or puncturing such as syringes, blades, and broken glass. Items that have the potential for shattering or breaking are also considered sharps.
Specificity (analyte)	The ability of a test to detect a particular substance or constituent without interference or false reactions by other substances.
Specimen	A substance collected for analysis on the assumption that it represents the composition of the whole.
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 should be treated as if known to be infectious for HIV, HBV, and other bacteria and viruses.
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.

For additional information go to:
https://www.cdc.gov/lab-quality/php/ppmp/index.html

Contact the Division of Laboratory Systems at PPMP@cdc.gov. The findings and conclusions in this booklet are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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