

TENNESSEE DEPARTMENT OF HEALTH

LABORATORY POLICIES AND PROCEDURES MANUAL FOR LOCAL HEALTH DEPARTMENTS



2015

TABLE OF CONTENTS

Page No.

I. GENERAL INFORMATION

LABORATORY CERTIFICATION (CLIA).....	1
POLICIES FOR LABORATORY	
Infection Control and Safety	2
Routine Cleaning.....	3
Cleaning Spills	3
Disposal of Liquid Wastes	3
QUALITY MANAGEMENT/QUALITY CONTROL	
Certification	4
Laboratory Inspection	4
Personnel	4
Training	5
Proficiency Testing or Comparison Testing.....	5
Competency Evaluation	5
Procedure Manual	6
Laboratory Testing.....	6
Record Keeping.....	6
Quality Control.....	6
1. Test kits and supplies.....	6
2. QC Testing Procedures	6
3. QC Schedule for Procedures.....	8
4. QC Model	9
5. Corrective action.....	10
Preventive Maintenance (PM).....	11
1. Instrument care	11
2. PM schedule.....	12

II. ON-SITE LABORATORY TEST PROCEDURES

HemoCue 201 Photometer	1
Hemocult Sensa	1
Hemocult ICT	1
True Track	1
Clinitek	1
LeadCare II.....	1
PT/INR Analyzer.....	1
Contour Blood Glucose	1
Vital Glucocard Meter.....	1
Stanbio True 20	1
QuickVue In-Line Strep	1
Newborn Screening	1
Urine Microscopy (PPM)	2
Wet Mount.....	4

III. SPECIMEN COLLECTION PROCEDURES

SPECIMEN/SAMPLE INTEGRITY	1
Basic Specimen/Sample Considerations	1
VENOUS BLOOD COLLECTION	4
Equipment and Supplies	4
Procedure	4
Serum Separation	5
Possible Causes of Hemolysis	5
Management Guidelines	5
SPECIMEN COLLECTION FOR STATE LAB PROCEDURES	6
AIDS Serology, Human Immunodeficiency Virus (HIV) Testing	6
Chlamydia & GC Screen – DNA Probe	6
Gonorrhea (GC) Culture	6
Handling of Neisseria Gonorrhoeae Cultures	6
Hepatitis B Surface Antigen (HBsAG) Testing	6
Mumps Titer	6
Rubella Titer	6
Rubeola Titer	6
Serological Test for Syphilis	6
Stool Specimens for OVA and Parasites	6
Stool Specimens and Rectal Swabs for Bacterial Cultures	6
Throat Culture for Group A Streptococcus	6

IV. APPENDICES

1a. Laboratory Services Contact Information Link	1
1b. Requisition For Laboratory Supplies Link	1
2. Laboratory Definitions	2
3. Product/Instrument Information Sheet	5
4a. Specimen/Quality Control Log	6
4b. Quality Control Corrective Action Log	7
4c. Instructions	8
5a. Fecal Occult Blood Specimen/Quality Control Log	10
5b. Quality Control Corrective Action Log	11
5c. Instructions	12
6a. Generic Laboratory Log for Mailed or Forwarded Specimens	14
6b. Instructions	15
7. Scheduled Preventive Maintenance Checklist	16
8a. Equipment Temperature Record	17
8b. Instructions	18

9.	Thermometer Calibration.....	19
10a.	Autoclave Quality Control – Attest	20
10b.	Autoclave Attest Log	22
11a.	Bacteriological Culture Media Quality Control Log	23
11b.	Bacteriological Culture Media Quality Control Log Instructions	24

V. PRODUCT INSERTS (Added by Region)

I. GENERAL INFORMATION

LABORATORY CERTIFICATION

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) OF 1988

All laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings must have a CLIA certificate. A laboratory is certified depending on the types of testing that it performs. CLIA awards certificates in the categories listed below:

- High complexity
- Moderate complexity
- Provider Performed Microscopy (PPM)
- Waived

A laboratory that has a certificate to perform high complexity tests can perform tests in all categories. A laboratory that has a moderate certificate can perform tests in the moderate, PPM, and waived categories. A laboratory that has a PPM certificate can perform tests in the PPM and waived categories. A laboratory that has a waived certificate can only perform waived tests. Most local health departments are PPM certified with recertification every two years.

The Department of Health and Human Services (HHS) determines the criteria used to categorize a test and in what category a laboratory test falls. Revisions to test categories are published in the *Federal Register*.

Laboratory procedures are categorized by seven criteria specified by the CLIA regulations. These criteria are: knowledge, training and experience; reagents and materials preparation; characteristics of operational steps; calibration, quality control, and proficiency testing materials; test system troubleshooting; equipment maintenance; and interpretation and judgment.

PPM procedures - CLIA has designated some moderate complexity procedure as PPM procedures. A physician, mid-level practitioner, or a dentist performs these procedures during the patient's visit. The primary instrument for performing these tests is the microscope. An unstable specimen or a delay in performing the test could compromise the accuracy of the test results. Control materials are not available to monitor the entire testing procedure. Limited specimen handling or processing is required. Employee competency checks and applicable quality control and proficiency tests should be performed for these procedures. If proficiency tests are not available, perform comparison testing twice a year. This can be done by having two people read the same slide. Comparison and competency testing can be done at the same time. Document comparison and competency testing activities.

Waived tests are simple laboratory examinations. These procedures are cleared by the Federal Drug Administration (FDA) for home use. Employee methodologies are simple and accurate enough to render the likelihood of erroneous results negligible, and pose no reasonable risk or harm to the patient if the test is performed incorrectly. Laboratories with a certificate of waiver must follow manufacturer's instructions for performing the test.

POLICIES FOR LABORATORY SERVICES

INFECTION CONTROL AND SAFETY

1. Follow the universal precautions of the Centers for Disease Control.
2. All specimens are to be treated as potential sources of infection.
3. Infection control and safety practices are followed as outlined in the most recent edition of the Tennessee Department of Health Infection Control Manual.
4. Handwashing is the basic and most important effective regular safety and infection control practice. Hands are washed before and after contact with each patient; after toileting and smoking; before and after eating; and before donning gloves if contact with patient, specimen, or contaminated objects has occurred, as well as after removal of gloves.
5. Contaminated needles, syringes, and sharps are discarded into sharps containers according to the most recent edition of the Infection Control Manual.
6. Disposable gloves are worn when drawing blood or handling other potentially infectious material.
7. Centrifuges are never to be opened while running nor slowed with the hand. Disinfect the centrifuge immediately if a tube breaks inside it or whenever it is visibly soiled.
8. Mouth pipetting is not allowed.
9. Food is not to be put in refrigerators used for specimens or reagents.
10. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not allowed in the laboratory area as hands can be contaminated with infectious organisms that can be spread to the worker's mouth or eyes.
11. Clean, buttoned lab coats are worn while performing lab procedures. If there is danger of splatter or soiling with blood or other potentially infectious material, a disposable impervious apron or lab coat is worn. These coats or aprons are only worn in the lab or clinic area, and are left there when one goes to break, lunch, or away from the lab or clinic area.
12. All health department staff exposed to potentially infectious materials will follow the Post Exposure Plan in the most recent edition of the Tennessee Department of Health Infection Control Manual.

ROUTINE CLEANING

Follow cleaning instructions in the most recent edition of the Infection Control Manual.

CLEANING SPILLS

Follow the procedure for cleaning spills in the most recent edition of the Infection Control Manual.

DISPOSAL OF LIQUID WASTES

Flush blood, urine, liquid body wastes, and reagents down a designated laboratory sink or commode if it is especially designated for that purpose. Use plenty of water to rinse the sink/commode after emptying the specimen or reagent down the drain. Avoid splashing while disposing of specimen and rinsing the sink/commode.

QUALITY MANAGEMENT/QUALITY CONTROL

The relative simplicity of laboratory tests performed in health department clinics does not negate the importance of assuring quality laboratory test results for patients. In addition to Community Health Services' obligation to provide quality laboratory results, federal regulations continue to have a significant influence in shaping and improving laboratory services in health department clinics.

The federal Clinical Laboratory Improvement Amendments and their revisions emphasize assuring quality laboratory services for patients. Appropriate quality control and quality assurance is integrated into health department clinic activities as a means to good laboratory practice and quality patient care.

Laboratory Services Standards in the Patient Risk Minimization Section of the most recent edition of the TDH Quality Improvement Guidelines must be met.

CERTIFICATION

The local health department clinic laboratory maintains a current CLIA certificate. The only testing performed in the clinic is testing that the facility is certified to perform.

The CLIA number and certificate expiration date is available for each referral laboratory.

LABORATORY INSPECTION

Local Health Departments may be inspected by:

1. Community Health Services Quality Improvement Program
2. CLIA program inspectors

PERSONNEL

Local health department laboratory services are under the direction of a designated Tennessee Department of Health physician qualified to manage and direct the laboratory personnel and the performance of procedures that the clinic is certified to perform. The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results.

The individual performing PPM procedures must be a physician, a dentist, a mid-level practitioner, or a registered nurse with expanded skills. PPM testing personnel are responsible for processing specimens, performing specimen testing, and reporting results of tests that are in the PPM and waived category.

The individuals performing waived test procedures are responsible for the processing of specimen, performing specimen tests, and reporting results of tests in the waived category.

All individuals performing laboratory tests are qualified and have the appropriate documentation. Education and training records and laboratory job descriptions must be available in the clinic files for the laboratory director and all testing personnel.

TRAINING

New staff receives on the job training and attends the Public Health Clinic Laboratory Practitioner Training Program provided by TDH Nursing Services and/or TDH Laboratory Services. All staff receives updated training from appropriate personnel when new or different materials, kits, or procedures are introduced.

PROFICIENCY TESTING OR COMPARISON TESTING

A clinic laboratory with a CLIA Provider Performed Microscopy (PPM) Certificate can perform urine microscopy and vaginal wet mount tests. These are moderately complex tests and regulations regarding competency evaluation and proficiency testing apply. If proficiency tests are not available, regulations regarding comparison testing apply.

COMPETENCY EVALUATION

Competency evaluation of personnel is done every six months during the first year of employment and annually thereafter by:

1. Direct observation of test performance.
2. Monitoring the recording and reporting of test results.
3. Review of worksheets, quality control records, and preventive maintenance records.
4. Direct observation of performance of instrument maintenance and function checks.
5. Assessment of problem solving skills.
6. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

Proficiency testing (PT) is used to monitor the performance and quality of laboratory testing. PT is a program in which samples are sent to a group of laboratories for analysis. The sample is tested in the same manner as a patient's specimen. Results are returned to the program sponsor for tabulation and grading. Results must be reviewed by the laboratory director, supervisor and individuals performing the tests. If one or more challenges are missed, corrective action must be taken.

If a proficiency testing program is not available, comparison testing can be done. This should be done twice annually. Comparison tests can be done by:

1. Use of a proficiency testing program that is not CLIA approved. Several PT providers have a program for urine microscopy and vaginal wet mounts. These provide slides to be viewed with a slide projector.
2. Work with another laboratory and test the same specimen. Compare results.
3. Have two people in the clinic read the same sample. Compare results.

Employee competency and comparison testing can be done at the same time. Documentation of these activities is required and must be retained for two years.

PROCEDURE MANUAL

A current copy of the Laboratory Policies and Procedures Manual for Local Health Departments is maintained at each site. The latest edition is on the Community Health Services website (<http://health.state.tn.us/lab/directory.htm>). This manual contains the laboratory procedures conducted in health department clinics. Product inserts for the test and quality control products used at each site are to be placed in the manual. Inserts for the control product may also be maintained in the control records. The insert is retained in the files for two years after the product is no longer used.

LABORATORY TESTING

Laboratory specimens are collected according to acceptable procedures.

Laboratory specimens are labeled and request forms, electronic or paper, completed accurately.

Specimens are stored appropriately before testing or mailing to a referral laboratory. Patient test results are to be entered into the patient's medical record.

RECORD KEEPING

All laboratory quality control logs, temperature logs and product inserts are retained for a minimum of two years after the product is no longer used.

Preventive maintenance and repair logs for equipment are kept for the life of the equipment.

QUALITY CONTROL (QC)

Quality control is the set of laboratory procedures designed to ensure that the test method is working properly and that the results meet the diagnostic needs of the physician.

1. Test Kits and Supplies

All test kits, reagents, and quality controls used in the clinic are in date. Expired laboratory supplies are discarded. Label test kits, reagents, and quality control materials with the date opened. Store at the temperature recommended by the manufacturer. Follow manufacturer's directions on storing.

Do not mix reagents from one kit with reagents from another kit unless the manufacturer's product insert states that it is acceptable to mix reagents from different kits. Never mix reagents from one manufacturer to another.

2. QC Testing Procedures

The reliability of laboratory test results is monitored by the concurrent analysis of known samples called "controls". These controls have expected results, such as positive and negative for pregnancy tests and established ranges for hemoglobin testing. Quality control tests are performed as defined by the specific laboratory procedure. All control results must be properly documented on the Specimen/Quality Control Log. The lot number, control results and tolerance limits are to be properly documented in the laboratory log.

As long as control results fall within the established ranges, the test may be considered valid and "in-control."

If the control results do not give the established ranges, the patient's specimen (test) result is not reported. The problem is identified and corrected (following the Laboratory Quality Control Model page 9) after which the patient's specimen is retested.

Quality control tests are documented according to the "Specimen/Quality Control Log" instructions (see Appendices) for tests completed in the health department. Since the controls and ranges vary from lot to lot, the product insert for each batch must be consulted for expected values.

A supervisor or designee will review and initial patient test results and quality control results weekly.

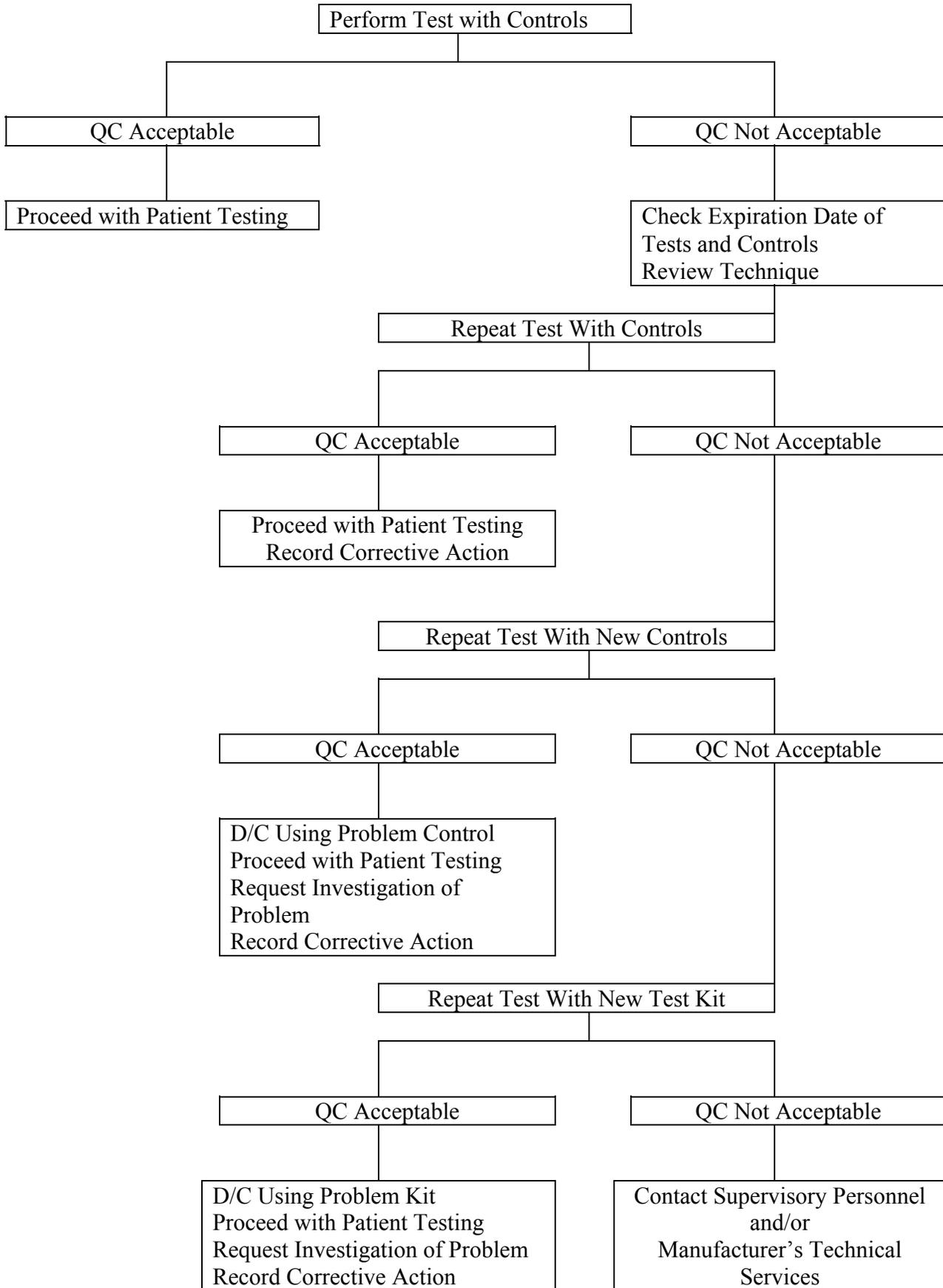
QUALITY CONTROL (QC) SCHEDULE FOR PROCEDURES

See specific package insert for details in performing quality control tests.

<u>Procedure</u>	<u>Known Controls</u>	<u>QC Frequency</u> *
Hemoglobin	Normal and Low Controls	Each day patient test is run New bottle of cuvettes
Urinalysis Dipstick	Positive or Negative	With each new bottle opened. Monthly if opened bottle is stored >30 days
Blood Glucose	Use 2 of 3 levels Normal, high, or low	Each day patient test is run With each new bottle
Streptococcus (Rapid)	Positive and Negative	New box
Pregnancy	Positive and Negative	New box
Fecal Occult	Positive and Negative	With each patient test slide
Lead II	Level 1 & 2	Each new lot. Monthly, as a check on continued storage conditions.
		When problems are suspected or identified.
Hemmocult ICT	Positive and Negative	With each patient test slide

*When a new kit or bottle of reagents is opened, run QC before using for patient's specimens

LABORATORY QUALITY CONTROL (QC) MODEL



EXPLANATION OF QUALITY CONTROL (QC) MODEL

CORRECTIVE ACTION

Quality control tests are performed according to procedure. If the control is "out of control," the patient's specimen is not reported, and the problem is identified and corrected following the Laboratory Quality Control Model. Usually the QC testing will give the expected results and the practitioner will proceed with patient testing. On those rare occasions when the QC tests do not yield expected values, steps must be taken to identify and correct the problem. When controls are "out of control," i.e., not yielding expected values, it is important to ask "why" and to document the steps taken to solve the problem.

As illustrated on the QC Model, corrective action behaviors include:

- Checking expiration date of test kits and reagents and controls.
- Reviewing testing technique.
- Repeating test with new controls.
- Repeating test with new test kit.
- Contacting supervisor.
- Contacting manufacturer's technical service.

Each corrective action, along with the QC test, is documented on the Specimen/Quality Control Log according to the instructions.

PREVENTIVE MAINTENANCE

Preventive maintenance ensures that all instruments and equipment function properly. Equipment is cleaned, inspected, worn parts replaced, and calibration checked according to the manufacturer's instructions. A record of these activities is kept on a log and should be reviewed by the supervisor. Preventive maintenance records are kept for as long as the equipment is used.

INSTRUMENT CARE

To care for instruments properly:

1. Select one person to be responsible for the instrument.
2. Read the instrument manual. The section on maintenance or routine care should be followed without exception.
3. Create a maintenance record form and note all maintenance actions when they occur. Use the "Scheduled Preventive Maintenance Checklist" form or the form provided by the manufacturer. The form should include the instrument name, installation date, equipment serial number, local health department number if applicable, and specific location in the health department. Keep the form with the instrument records, or post it as a reminder to do the maintenance and record it.
4. Record the date, type of maintenance done, and the name or initials of the person doing the maintenance. Maintain these logs for as long as the equipment is used.
5. Keep necessary spare parts on hand. The instrument manual will recommend the spare parts inventory.

PREVENTIVE MAINTENANCE SCHEDULE FOR EQUIPMENT

Refrigerator/Freezer/Incubator

- Daily - - Check temperature (exclude weekends and holidays).
- Yearly - - Check thermometers with a certified/calibrated National Institute of Standards and Technology (NIST) thermometer or a thermometer recently calibrated against a NIST thermometer.
- Yearly - - Check yearly unless using a lifetime calibrated thermometer.

Centrifuge*

- Monthly or more often if needed - - Clean with disinfectant.

*If centrifuge is used only to prepare specimens for a reference lab, calibration checks are not required on a routine schedule.

Autoclave

- Each Use - - Record information: date, time run completed, contents, initials of operator.
- Weekly when autoclave is used - - Spore test

II. ON-SITE LAB TEST PROCEDURES WEBLINKS

ON-SITE LAB TEST PROCEDURES WEBLINKS

This section is for examples only.

For any test being performed that is not included in this manual, the product insert must be added.

HemoCue 201 Photometer	http://www.hemocue.us/en-us/products/hemoglobin/hb-201-plus-system
Hemocult Sensa	Search: Hemocult Sensa, click on Beckman Coulter link, click Americas, Click on Region (U.S.), click on Technical Documents at bottom of right column
Hemocult ICT	Search: Hemocult ICT, click on Beckman Coulter link, click Americas, Click on Region (U.S.), click on Technical Documents at bottom of right column
True Track	http://www.niprodiagnostics.com/our_products/bgm_true_track.aspx
Clinitek	http://usa.healthcare.siemens.com/point-of-care/urinalysis/clinitek-status-analyzer
LeadCare II	http://www.leadcare2.com/Product-Support/Training-Tools or http://health.state.tn.us/MCH/lead.shtml
PT/INR Analyzer	http://www.alere.com/us/en/product-details/inratio-pt-inr-monitoring-systems.html
Contour Blood Glucose	http://www.bayercontour.com/Blood-Glucose-Monitoring/Contour#tab2
Vital Glucocard Meter	http://glucocardusa.com/vital_how.html
Stanbio True 20	http://www.ekfdiagnostics.com/Pregnancy_Testing_1122.aspx
QuickVue In-Line Strep	http://www.quidel.com/immunoassays/rapid-strep-tests/quickvue-in-line-strep-test
Newborn Screening	http://health.state.tn.us/lab/directory.htm or http://health.state.tn.us/MCH/NBS.shtml
Urine Microscopy (PPM)	See page 2
Wet Mount	See page 4

URINE MICROSCOPIC EXAMINATION (PPM)

Equipment and Supplies

- Gloves
- Antiseptic wipes or cotton balls moistened with warm water or antiseptic solution
- Urine specimen container
- Centrifuge tube
- Centrifuge
- Clean slide and cover slip
- Quality control samples
- Microscope

Quality Control Procedures

Follow directions according to QC product insert.

1. Record the log number and expiration date of the test kit and controls on the Specimen/Quality Control Log, PH-3237. Record given values of the controls.
2. Follow the patient test procedure substituting controls for the patient's urine sample.
3. Record the test results on the log.
4. Acceptable performance of the procedure is assured only when the control test falls within the range specified in the package insert. Follow corrective action procedures based on the Laboratory Quality Control Model if the controls do not fall within the given range. Record the corrective action steps taken to resolve the problem.

Patient Test Procedure

1. Collect a clean-catch, midstream urine specimen. Instruct patient:
 - a. Female - Separate labia majora, using the fingers on one hand. (Continue to separate as specimen is collected.)
 - Wipe three times from front to back, using a fresh antiseptic wipe or cotton ball for each stroke.
 - Begin to urinate. When the flow is well established, catch 1-2 ounces of urine in a specimen container.

- b. Male - Clean the distal urethra with water or antiseptic cotton balls.
 - Begin to urinate. When the flow is well established, catch 1-2 ounces of urine in a specimen container.
2. Label the specimen and examine it within one hour from collection time.
3. Mix specimen thoroughly. Transfer 10 ml to a centrifuge tube (properly labeled) and centrifuge at 2000 rpm for five minutes.
4. The sediment in the centrifuge is used for the microscopic examination. Pour off the urine and stand the tube upright. Mix the sediment by tapping hard against palm of your hand.
5. Place a drop of the sediment on a clean slide and cover with a cover slip.
6. Place immediately under a microscope. Scan on low power and then change to high power with constant up and down focusing with the fine adjustment. (See Appendix– Use & Maintenance of Microscopes)
7. Interpretation of Slide. Main pathologic elements are:
 - a. Red Blood Cells (RBC) - Pale, donut-shaped and slightly refractive but have no nucleus. Count under high power noting how many observed in each field.
 - b. White Blood Cells (WBC) - 1 1/2 times as large as RBC; usually granular in appearance but quite often with a visible nucleus; may be called “pus cells”; are greatly increased in bacterial infection. Count the same as for RBC’s.
 - c. Casts - Formed from protein material in the kidney tubule, cylindrical in shape, and indicate a pathological problem in the kidney which may be chronic or acute. Several types of casts depending on their composition are hyaline, coarsely granular, finely granular and waxy. Count on low power unless noted otherwise.
8. Reporting Results

Results are reported as per high power field or low power field. At least 10 fields must be studied and reported. In reporting RBC, WBC, and casts, an exact number per field is given. (Example: 2-4 RBC/hpf.) In reporting non-pathological elements, numbers are not given, only general terms such as rare, occasional, moderate, few, many and loaded. In counting RBC and WBC, if there are more than 50 cells, they may be too packed to count. The term TNTC (Too Numerous To Count) may be used.

VAGINAL WET MOUNT (PPM)

Equipment and Supplies

Speculum
Disposable gloves
Microscopic slides 1" x 3"
Cover slips 1" x 1"
Spatula or cotton swab
pH paper (optional)
Normal saline, non-bacteriostatic, in dropper bottle or tube (stored at room temperature)
Potassium hydroxide (KOH) (10% solution) in dropper bottle (stored at room temperature)
Microscope

Quality Control Procedure

There is no formal quality control check (positive and negative organism controls) for the vaginal wet mount. Qualified professionals should read the wet mount preparations.

Label the saline and potassium hydroxide solutions with name, date prepared, and expiration date. DO NOT use a solution after the expiration date. Both reagents should be clear. If cloudiness or turbidity is observed, discard the solution.

Patient Test Procedure

Wet smears are to be done before pelvic bi-manual examinations where lubricant is used and after the Pap smear, Gonorrhea culture, or *Chlamydia* culture.

1. Collect specimen
 - a. With patient in dorso-lithotomy position and draped appropriately, put on gloves.
 - b. Insert speculum into vagina, exposing cervix.
 - c. Using a spatula or wooden end of a cotton swab, collect specimen from the vaginal discharge pooled in the posterior fornix or in excess discharge accumulated on speculum blade.
 - d. Remove speculum and proceed with gynecological exam. Remove and discard gloves upon completion of examination of patient. Put on new pair of gloves for performing laboratory tests.

2. To check the pH of the vaginal discharge, touch a small amount of the discharge to pH paper and compare with the pH color chart.

3. Prepare slide

Note: Keep saline, slides, and cover slips at room temperature and out of drafts. Examine the slide immediately after the specimen is collected as trichomonads are very sensitive to decreased temperatures and rapidly lose their motility

- a. Place one drop of normal saline on one end of the slide and one drop of KOH on the other end of slide. DO NOT MIX saline and KOH. Two slides may be prepared if desirable. (If using a tube of saline, do not place drop of saline on the slide.)
- b. Mix specimen thoroughly with each drop of the solutions on slide. Dip specimen in saline first, then in KOH, or use two different spatulas or swabs. You may notice a fishy or amine odor when the KOH is added. If so, record Amine Test Positive.
- c. Hold the cover slip at a 45° angle at the edge of the liquid and gently drop on slide. The specimen will spread out beneath the cover slip.

Test tube method (optional)

- a. Place the specimen in tube of saline. Gently mix specimen.
- b. Prepare the slide using the stick or spatula and placing one small drop of well-mixed specimen from the saline suspension onto each end of the glass slide, about one-inch apart. Cover slip the specimen on the left side of the slide. Hold the cover slip at a 45° angle at the edge of the liquid and gently drop on slide. The specimen will spread out beneath the cover slip.
- c. Add one small drop of 10% KOH to clear the specimen on the right side of the slide. Cover slip. You may notice a fishy or amine odor when the KOH is added. If so, record Amine Test Positive.

4. Read microscopically

- a. Turn microscope on and set Koehler illumination. (See Appendix, Use of the Microscope)
- b. Place the slide on the microscope stage and use low power to find and focus on the specimen.
- c. Examine specimen on low power, then turn to high power, and examine 10 high power fields on the saline side, noting the presence of *Trichomonas*, clue cells, yeast, white blood cells (WBC), bacteria, and normal epithelial cells. Record results as the average of each element seen per high power field.
- d. Move the stage so the KOH specimen is under the high power objective. Examine 10 high power fields for yeast cells and/or pseudohyphae. (Other elements are usually destroyed by the KOH.) Record your results.

A systematic method of examining the specimen is to examine 3 sites on each edge of the cover slip and 2 sites in the center. Thoroughly review the entire slide. Even if one organism is identified, continue to scan the slide in a systematic manner. Vaginal secretions may have multiple organisms.

1. Amine Test (KOH Test, “Whiff” Test)– You may notice a fishy odor when KOH is added. This is often noted when "clue cells" are present in the specimen. This fishy odor is recorded as **Amine Test positive**.

Vaginal Wet Mount

<u>Condition</u>	<u>Organism(s)</u>	<u>Amine Test</u>	<u>* pH</u>	<u>Signs/Symptoms</u>	<u>Microscopic Findings</u>			<u>Report</u>
					<u>Saline</u>	<u>KOH</u> (Potassium hydroxide)	<u>WBC</u> (White blood cells)	
Normal	Lactobacilli predominate	Neg	< 4.5		Squamous epithelial cells. Lactobacilli.	No findings.	Absent to rare	
Bacterial vaginosis (BV)	A change in bacterial flora is seen in this condition. (Decrease in lactobacilli and increase in coccobacilli). Gardnerella vaginalis and Mobiluncus species are associated with bacterial vaginosis.	Pos	>4.7	Homogeneous grayish-white discharge that is profuse. Malodorous fishy (amine) odor. May be totally asymptomatic. Previously known as nonspecific vaginitis, Gardnerella vaginitis, and Haemophilus vaginitis.	>1 Clue cell/high power field † (hpf). Normal lactobacilli are markedly decreased. Clue cells are significant when found. Presence of BV has been associated with an increased risk of preterm labor. It is often associated with chorioamnionitis, postpartum endometritis and PID.	No findings.	<1/Epithelial cell.	Report clue cells. Quantitate by giving average of clue cells per hpf. Report presence of motile Mobiluncus like organisms.
Candida vaginitis (Yeast Infection)	Candida albicans (Occasionally other Candida species)	Neg	4.0-4.5	Discharge is white, curd-like, cheesy, often adherent to vaginal mucosa. Odor is absent. Often associated with profound itching.	Yeast cells. Hyphae.	Yeast cells. Hyphae.	Few.	Report budding yeast and hyphae. Quantitate by giving average of yeast cells per hpf.
Trichomonal vaginitis	<i>Trichomonas vaginalis</i>	Neg	≥6	Discharge is yellowish to greenish, frothy, copious, with foul odor (acid). Itching. May be totally asymptomatic.	Motile trichomonads. Note: may be difficult to distinguish from WBC if specimen is allowed to cool and motility is lost.	No findings.	>1/Epithelial cell. An increase in number of WBC is often evident in the wet mount.	<i>Trichomonas</i> found. (Significant when found.)

* NLTNSE Reference † hpf – High power field

III. SPECIMEN COLLECTION PROCEDURES

SPECIMEN/SAMPLE INTEGRITY

See *Laboratory Services Directory* <http://health.state.tn.us/lab/Directory/Section1.pdf> to order laboratory supplies.

A test result is no better than the quality of the specimen received in the laboratory. Blood and other body fluids removed from the body start to change immediately. When proper methods of collection, transportation, processing and storage are provided, the sample received in the laboratory is of good diagnostic value.

For each specimen collected, follow the recommendations of the laboratory to receive the specimen. Follow specific procedures for completing request forms, collecting specimen, and transporting specimen.

- 1. Media received for specimen collection should be handled as specified by the manufacturer.**
 - a. Note the package insert or other information included with the media for storage and handling requirements. For example, note that solid plates of media should be stored with the bottom half of the plate (the half holding the media) facing down, to prevent condensation on the surface of the media.
 - b. Note the temperature at which media should be stored and whether or not it should come to room temperature before use.
 - c. Media should be visually inspected for contaminants, cracking (which means it has been frozen), or other clues that the media is not fit for use.
 - d. The date of the receipt, expiration dates and the condition of the media should be entered in a log when the media is received.
- 2. All temperature-controlled spaces and equipment, including incubators, refrigerators, and freezers are monitored on a scheduled basis to assure proper performance.**
- 3. Specimen collection instructions include:**
 - a. The preparation of the patient
 - b. The type of specimen to be collected
 - c. The timing for collection (i.e. first morning voided urine)
 - d. The need for preservatives
 - e. Instructions for special handling (i.e. frozen or dry ice, < 2 hrs to exam)
 - f. The requirements for labeling and packaging
 - g. The need for clinical data (i.e. previous diagnosis or condition).

Basic Specimen/Sample Considerations

1. Patient Preparation: For each test, procedural steps are followed on how the patient is to be prepared prior to specimen collection. Explain the test and its purpose to the patient. Obtain patient consent, written consent when required.

2. Handling Requirements: Special handling may be required between the times of specimen collection and delivery to the laboratory. Chemicals can be altered, microorganisms die, and the specimen altered if improperly handled during transportation. Transportation considerations include:

Time: The sample should be sent to the laboratory in as short a time as possible. If it cannot be processed within a reasonable time period (varies from sample to sample), steps must be taken to prevent undesirable changes.

Temperature: Refrigeration is often the most appropriate storage when a delay occurs between collection of specimen and its testing/shipment. Follow procedure for each specimen.

Exposure to light: Exposure to light results in the degradation of certain plasma analytes, especially bilirubin. Samples from newborns should be especially protected when monitoring bilirubin levels. Wrap samples in aluminum foil or provide light-tight containers.

Excessive vibration and rough handling: Vigorous handling of the specimen may result in hemolysis of red cells, spillage of the specimen, or the breakage of collection tube or specimen container. Treat every sample as potentially infectious. Leakage resulting from spillage and breakage of the specimen container increases the possibility of accidental infection. The collection container or tube should remain in an upright position and should be protected against any rough handling.

3. Labeling Procedures: Label the specimen correctly with 2 identifiers. The person collecting the specimen is responsible for accurately identifying the specimen at the time of collection. Identify the specimen immediately while the form, specimen tube and patient are in the same location. The patient's name and date of collection is written on the specimen tube. Available computer generated labels may be used. If a tear-off strip (ID number) is used, tape this to the specimen.
4. Completing Request Forms: follow the instructions for completing each request form. Some of these instructions include specific content related to specimen collection and transportation.
5. Packaging and Mailing Requirements: Proper packaging protects the specimen while in transit and the personnel who handle the package:

Follow the shipping and handling instruction in the most current Tennessee Department of Health Division of Laboratory Services Directory of Laboratory Services Manual @ <http://health.state.tn.us/lab/Directory/>.

The Etiological Agent/Biological Materials label should be affixed to all shipments of etiological agents (cultures, viral suspensions, bacterial toxins, etc.) in accordance with current Federal Regulations.

6. Specimen Collection Kits and Mailing Containers

Specimen collection kits are available in local health departments. They are intended exclusively for use in submitting specimens to the designated laboratories and should be ordered by local health departments as needed. Do not over order (stockpile) supplies. Calculate your needs for a month and order supplies accordingly once each month.

7. Criteria For Unacceptable Specimens: A specimen may be rejected for any one of these reasons:

Inadequate or Improperly Labeled Specimens

Sample tubes or collection containers with no label or the wrong name should not be accepted.

Inadequate Sample Volume For Amount Of Additive Used

If less than the required volume of blood is collected, there will be an excessive amount of additive that may affect the accuracy of the test result. For example, too much liquid anticoagulant relative to the blood volume results in a dilution error for prothrombin time in any sample collected in a citrated tube.

Improper Collection Tube Or Container

Certain tests require specific anticoagulants or preservatives to maintain the integrity of the specimen. The wrong additive can have a detrimental effect on the specimen, resulting in an inaccurate result.

Improper Transportation

Specimens received in the laboratory that have been improperly transported should be rejected. Examples are (1) specimens that should be chilled during transport but are received at room temperature and (2) GC specimens that should be sent in a CO₂ atmosphere but are not.

Hemolysis

Cell counts and certain chemical analyses will be adversely affected by the lysis of red cells. Hemolysis may result from a difficult venipuncture or from too vigorous handling. A new sample should be requested or obtained when hemolysis is evident.

Inappropriate Time Frame

Sample received after appropriate time frame for testing to be done.

VENOUS BLOOD COLLECTION
FOLLOW CDC RECOMMENDED UNIVERSAL
PRECAUTIONS FOR DRAWING BLOOD.

This procedure is used for collection of venous blood specimens.

Equipment and Supplies

PPE
Specimen tubes
Appropriate laboratory request forms
Alcohol swab
Blood collection set
Tourniquet
Dry small gauze pad or cotton or rayon ball
Bandaid

Procedure

1. Position the Patient:
 - a. Have the patient lying down or sitting at a small table where arm may be extended in a comfortable position.

2. Choosing Venipuncture Site:
 - a. Inspect extended arm for visible veins, scar tissue, hematoma, etc.
 - b. Apply tourniquet midway between elbow and shoulder. (Blood is most often obtained from the antecubital vein of the forearm.)
 - c. Palpate vein.

3. Performing the Venipuncture:
 - a. Cleanse the site with alcohol swab. Allow the skin to dry.
 - b. Fix the skin and hold the vein taut by placing the thumb about an inch below the site of needle entry and pulling the skin toward the hand.
 - c. Insert needle bevel up, in line with the vein.

4. Collection of Blood:

For blood collection with safety collection set procedure go to <http://www.vanishpoint.com/Simple4.aspx?PageId=193>

 - a. Fill appropriate tubes needed for specimen(s)
 - b. Release tourniquet before activating safety mechanism.
 - c. Remove needle from arm.
 - d. Apply pressure with dry gauze or rayon or cotton ball and a bandaid.

- e. For blood tubes containing additives, gently rotate back and forth 8-10 times.
 - f. Dispose of soiled equipment into appropriate biohazard container; wash hands.
5. Complete the appropriate request form for the designated laboratory.
 6. Prepare blood for mailing/transport.
 7. If delays occur, place blood specimen in the refrigerator.

Serum Separation

Tests requiring serum should be drawn in gel or serum separator tubes unless otherwise indicated.

1. Draw blood into evacuated tube without anticoagulants or preservatives.
2. Invert tube GENTLY 5 times to mix activator with blood.
3. Allow blood to clot for about 30 minutes (but no longer than 1 hour).
4. Centrifuge for 15 minutes.
5. Transfer serum to a transfer tube.
6. Label tube appropriately.

Possible Causes of Hemolysis:

- Skin too wet with antiseptic.
- Moisture in the syringe or collection tube.
- Prolonged use of tourniquet.
- Use of a small needle to withdraw a large volume of blood.
- Vigorous shaking of the blood specimen.
- Vigorous expulsion of blood from the syringe into the collection tube.

Management Guidelines

Manage findings according to health department policy.

SPECIMEN COLLECTION FOR STATE LAB PROCEDURES

AIDS SEROLOGY

HUMAN IMMUNODEFICIENCY VIRUS (HIV) TESTING

<http://health.state.tn.us/lab/Directory/Section2.pdf>

CHLAMYDIA & GC SCREEN: by DNA PROBE

<http://health.state.tn.us/lab/Directory/Section2.pdf>

GONORRHEA (GC) CULTURE

<http://health.state.tn.us/lab/Directory/Section2.pdf>

HANDLING OF NEISSERIA GONORRHOEAE CULTURES

<http://health.state.tn.us/lab/Directory/Section2.pdf>

HEPATITIS B SURFACE ANTIGEN (HBsAG) TESTING

<http://health.state.tn.us/lab/Directory/Section5.pdf>

MUMPS TITER

<http://health.state.tn.us/lab/Directory/Section5.pdf>

RUBELLA TITER

<http://health.state.tn.us/lab/Directory/Section5.pdf>

RUBEOLA TITER

<http://health.state.tn.us/lab/Directory/Section5.pdf>

SYPHILIS SEROLOGY

<http://health.state.tn.us/lab/Directory/Section5.pdf>

STOOL SPECIMENS FOR OVA AND PARASITES

<http://health.state.tn.us/lab/Directory/Section3.pdf>

STOOL SPECIMENS AND RECTAL SWABS FOR BACTERIAL CULTURES

<http://health.state.tn.us/lab/Directory/Section2.pdf>

THROAT CULTURE FOR GROUP A *STREPTOCOCCUS*

<http://health.state.tn.us/lab/Directory/Section5.pdf>

IV. APPENDICES

Tennessee Department of Health Laboratory Services
<http://health.state.tn.us/lab/directory.htm>

Contact Information
<http://health.state.tn.us/lab/Directory/Section1.pdf>

Requisition for Lab Supplies
<http://health.state.tn.us/lab/Directory/Section1.pdf>

LABORATORY DEFINITIONS

Critical Values

Critical values ('panic values') are test results that fall outside the low or high critical limit for the particular test in question. Immediate notification of the appropriate medical personnel must be made when critical values are obtained. It is appropriate to repeat the test immediately to verify the results before finally reporting the result. In health department settings, the reporting of critical results usually follows the clinical supervision lines of authority. All actions are documented.

Expiration Date

The expiration date is the last day a reagent kit, control, etc. can be used. The manufacturer prints the expiration date for the unopened product on the product. If the expiration date changes when the product is opened, a new expiration date is recorded on the product. If an expiration date is given as month/year, the product expires on the last day of that month.

False Negative Result

A negative result for a patient who is truly positive for the condition or constituent in question.

False Positive Result

A positive result for a patient who is truly negative for the condition or constituent in question.

Lot Number

The lot number (control number) is the number given to a batch of a product by the manufacturer. This number (to be recorded on the appropriate log when the product is used for testing) is important if the product fails to perform adequately. The lot number changes with every batch and is different from the product order number.

NIST Thermometer

The NIST thermometer is a National Institute of Standards and Technology thermometer. Readings of thermometers in laboratory instruments and clinical machines must be compared to readings with a NIST thermometer upon their initial use and then annually.

Normal Values

Normal values (expected or reference values) are a range of values established for each test (analyte) and include the values expected when performing a test on a healthy person.

Measurements

Conventional Measurements

Length

Meter (m) = 39.37 in
Centimeter (cm) = 1/100 m (2.5 cm = 1 in)
Millimeter (mm) = 1/1000 m

Weight

Kilogram (kg) = 2.2 lb
Gram (g) 453 g = 1 lb
Milligram (mg) 1/1000 kg
Microgram (mcg or ug) = 1/1000 mg
Nanogram (ng) = 1/1000 mcg
Picogram (pg) = 1/1000 ng
Femtogram (fg) = 1/1000 pg

Volume

Liter (L) = 1000 ml (cc) = 1.05 qt
Deciliter (dl) = 100 ml = 1/10 L
Milliliter (ml) = 1 ml = 1/1000 L = 1 cc

Quality Control (QC)

The set of laboratory procedures designed to ensure that the test method is working properly and that the results are appropriate to diagnostic needs. QC includes testing control samples, analyzing the results, and taking appropriate corrective action when indicated.

Specificity

A measure of those who are correctly identified as not having a disease through use of a screening test.

Sensitivity

A measure of those who are correctly identified as having a disease through use of a screening test.

Temperature Scales

Fahrenheit Scale (F.)

A temperature scale with the freezing point of water at 32°F. and the boiling point at 212°F.

Given a temperature on the Celsius scale, multiply by 9/5 and add 32 to convert it to Fahrenheit. $F^{\circ} = (C^{\circ} \times 9/5) + 32$.

Celsius Scale (C.)

A temperature scale with the boiling point of water at 100°C. and the melting point of ice at 0°C. Celsius degrees are equivalent to centigrade degrees.

Given a temperature on the Fahrenheit scale, subtract 32 and multiply by 5/9 to convert it to Celsius. $C^{\circ} = (F^{\circ} - 32) \times 5/9$.

Most laboratories report temperatures using the Celsius scale.

Common Temperature Scale Conversions

<u>Celsius</u>	<u>Fahrenheit</u>	<u>Comment</u>
121°C.	249.8°F.	Autoclave temperature for sterilization
100°C.	212.0°F.	Boiling point of water
37°C.	98.6°F.	Human body temperature (Normal)
0°C.	32.0°F.	Freezing point of water

PRODUCT/INSTRUMENT INFORMATION SHEET

Name of Test Used at This Site _____

Product or Reagents _____

Manufacturer _____

Storage Requirements _____

Shelf Life after Opened _____

Phone Number for Technical Services _____

Controls _____

Manufacturer _____

Levels _____

Storage Requirements _____

Shelf Life after Opened _____

Phone Number for Technical Services _____

Instrument (if applicable) _____

Manufacturer _____

Mode _____

Phone Number for Technical Services _____

Supervisor _____ Date Approved _____

Instructions for completing the Product/Instrument Information Sheet: Use to rapidly identify product information when a procedure is used that is not in the manual. Complete this sheet, and add it and the product insert to the manual.

**Tennessee Department of Health
Community Health Services
Specimen/Quality Control Log
Instructions**

Purpose:

To keep a log for specimens tested and quality controls performed.

Explanation and Definition:

An individual log for each type of test performed including quality control is kept at the work site. If more than one machine or reagent bottle is used for the same test, then a separate log is kept for each. A convenient way to accomplish this task is to place a long on a clipboard with each machine or reagent bottle.

General Information:

Each item on the log has been numbered; the instructions are written to correspond to those numbers. When either a new test product is used or a new quality control material is used, a new log is started. Double line or X out remaining lines when all 20 lines on the log are not used. This will indicate completion of the log.

Instructions:

1. **Clinic Site** – Record the name of clinic site.
2. **Test** – Record the name of laboratory test.
3. **HemoCue Calibration** – When the log is used for the HemoCue machine, record the control cuvette number and the value provided **for that specific machine. Control cuvettes are not interchangeable.**
4. **Test Used** – Record the specific name of the product used, the manufacturer, the lot number, the date opened and the expiration date from the product package or the date of expiration based upon shelf life following opening of the product.
5. **Quality Control Materials** – Record the name of the product; the manufacturer; lot number; date opened; expiration date from the product package or the date of expiration based upon shelf life following opening of the product; and given values for each control. For example, the HemoCue will have a high and a low control; therefore both of the blocks are to be completed. Given values are provided for urine pH, sugar and protein.
6. **Date Tested** – Record the date of the test. (Date Tested, Date Collected and Date Reported are the same.)
7. **Patient ID # or QC** – Record the patient's unique identification number or when performing the quality control test record the name of the quality control material that matches the material identified in #5 above.
8. **Results (Patient or QC)** – Record the results, positive, negative or numerical value, from the patient specimen or the results of the quality control test.
9. **QC A/NA** – Record A for acceptable if the quality control test results are within the expected given values as in #5 above. Record NA (Not Acceptable) if the quality control test was outside the given values.
10. **Comments** – Record other patient and/or quality control information as appropriate.
11. **Initials** – Record the initials of the individual performing the test and the quality controls. A generic signatures/initials list must be available to identify the initials on this log with a signature.

12. **Corrective Action** – If the quality control test results are not within the identified given values indicated, then corrective action is performed. Record the date, the problem, the action taken and the kind of follow-up performed to assure resolution of the problem.

Used By:

Health Department staff performing laboratory tests.

Retention Time:

Retain logs for two (2) years.

Addendum:

Patient test results may be recorded on the patient's medical record. However, if there are any problems with patient results, they should be recorded on the Specimen/Quality Control Log, and corrective action should be documented.

**Tennessee Department of Health
Community Health Services
Fecal Occult Blood Specimen/Quality Control Log
Instructions**

Purpose:

To keep a log for specimens tested and quality controls performed.

Explanation and Definition:

A log is kept for fecal occult blood specimens. If a new batch of slides is used with a different lot number or if a new bottle of developer is used with a different lot number, then a new log must be started.

General Information:

Each item on the log has been numbered; the instructions are written to correspond to those numbers. Double line or X out remaining lines when all 20 lines on the log are not used. This will indicate completion of the log. Use a separate line to record each test. If a series of three (3) tests is performed, use a separate line for each test.

Instructions:

1. **Clinic Site** – Record the name of clinic site.
2. **Slide Used** – Record the specific name of the product used, the manufacturer, the lot number and the expiration date.
3. **Developer** – Record the specific name of the product used, the manufacturer (the slide used and the developer must name the same manufacturer), date opened and the expiration date.
4. **Date** – Record the date the screening test was given to patient. (The three dates: date given, date collected and date performed might all be the same date if all accomplished on the same day.)
5. **Patient ID #** - Record the patient's unique identification number.
6. **Collection Date** – Record the date the specimen was collected either by patient or staff.
7. **Date Test Performed** – Record the date staff performed the screening test.
8. **Test Results** – Record either Positive or Negative.
9. **Controls** – Record the results of the quality control tests (Performance Monitor). The expected results of the QC are the positive is positive and the negative is negative.
10. **QC** – Record A for acceptable quality control results as stated above. Record NA for not acceptable if quality control results are not as stated above.
11. **Comments** – Record other patient and/or quality control information as appropriate.
12. **Initials** – Record the initials of the individual performing the test and the quality controls. A generic signatures/initials list must be available to identify the initials on this log with a signature.
13. **Corrective Action** – If the quality control test results are not as expected, indicate the laboratory's corrective action performed. Record the date, the problem, the action taken and the kind of follow-up performed to assure resolution of the problem.

Used By:

Health Department staff performing fecal occult blood tests.

Retention Time:

Retain logs for two (2) years.

**Tennessee Department of Health
Community Health Services
Generic Laboratory Log for Specimens Mailed or Forwarded
Instructions**

Purpose:

To maintain a running log of all specimens mailed or forwarded to any laboratory.

Explanation and Definition:

It is intended that this log be used in either of two ways for all specimens mailed or forwarded to any laboratory:

- 1) An integrated log is kept that lists all laboratories on the same page, or
- 2) A separate log is kept for each individual laboratory or laboratory test.

General Information:

Each item on the log has been numbered; the instructions are written to correspond to these numbers.

Instructions:

1. **Clinic Site** – Record the name of the county/clinic site.
2. **Date Collected** – Record the date the specimen is collected from the patient.
3. **Medical Record # and/or Patient Name** – Record the patient’s unique identification number or name. May also record tear strip number if appropriate.
4. **Name of Lab Test** – Record the name of Lab test requested.
5. **Laboratory Code** – Record the appropriate laboratory code (A, B, C, D, E, F or G) according to where the specimen was sent. Complete this column at the time of specimen collection.
6. **Date Specimen Mailed or Forwarded to Lab** – Record the date the specimen actually leaves the Health Department.
7. **Date Results Received and Results** – Record the date the test results are received in the Health Department. Using the “Legend for Results”, record the appropriate abbreviation for the results of the laboratory test. Complete laboratory results are recorded in the medical record.

Used By:

Health Department staff who collect and mail/forward laboratory specimens.

Retention Time:

Retain logs for two (2) years.

EQUIPMENT TEMPERATURE RECORD

Desired Temperature Range _____

Instrument _____ Room _____

Read daily. Record temperature in spaces below. (Numerical)

Date	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.	
1													1
2													2
3													3
4													4
5													5
6													6
7													7
8													8
9													9
10													10
11													11
12													12
13													13
14													14
15													15
16													16
17													17
18													18
19													19
20													20
21													21
22													22
23													23
24													24
25													25
26													26
27													27
28													28
29													29
30													30
31												-	31

* Out of Service, Supervisor Aware

**Tennessee Department of Health
Community Health Services
Equipment Temperature Record
Instructions**

Purpose:

To assure the integrity of laboratory specimens that require refrigeration or incubation prior to forwarding to the reference laboratory.

Instructions:

1. The temperature of the incubator/refrigerator is to be read daily.
2. The reading is to be recorded on the Equipment Temperature Record.
3. Persons recording the temperature reading will so indicate by placing their initials beside the reading.
4. Freezer temperature (ice maintained in solid state) is indicated by placing “√” in column. Use “X” if thawed.
5. If the temperature is not within the desired temperature range, the supervisor is to be notified at once.
6. The supervisor will be responsible for making arrangements for repairs and/or whatever corrective action is indicated.
7. The incubator shall not be used until problem is corrected and space for daily temperature recording will be marked with an asterisk (*).
8. Retain records for a minimum of two (2) years in the clinic site.

**Tennessee Department of Health
Community Health Services
Thermometer Calibration**

1. NCCLS guidelines are followed to calibrate thermometers at 0°C and 34°C. Calibrations should be checked yearly.
2. If the thermometer does not read the same as the NIST thermometer, a correction is noted on the label. This correction needs to be made every time a reading is taken. It is possible that there will be a correction at one temperature and not at another temperature.
3. To use, place thermometer in suitable liquid (water is acceptable unless thermometer is to be placed in freezer). The bulb should be suspended in the liquid. It should not touch the bottom of the container.
4. Read the temperature the first thing in the morning. Make correction, if necessary, before recording reading (see example below).

EXAMPLE OF TEMPERATURE CORRECTION

0°C – 0.5°C correction

34°C – No correction

Use correction if reading refrigerator temperature. If thermometer reading is 4°C, subtract 0.5°C and record reading as 3.5°C.

If reading incubator temperature, correction is not required.

5. It is recommended (but not required) that thermometers be stored vertically. This helps prevent the separation of the mercury column. If column does become separated, it can be joined. A procedure is available at the State Lab.

REFERENCES

Personal Communication with Paul Teichert, Brooklyn Thermometer Company, July 19, 1994 (516-694-7610) Faye Abdulla.

Personal Communication with B. W. Mangum, Ph.D., National Institute of Standards and Technology, Gaithersburg, Maryland, July 28, 1994. (301-975-4808) Faye Abdulla.

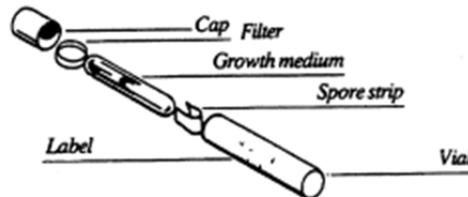
**Tennessee Department of Health
Community Health Services
Autoclave Quality Control
Using the Attest Biological Indicator**

The Attest biological indicator for steam sterilization uses *Bacillus stearothermophilus*, the standard spore used to challenge the sterilization process. This system allows rapid, reliable monitoring of the sterilization process.

Equipment and Supplies

Attest Biological Indicators for Steam Sterilization, 1662 (store at room temperature)
Attest Incubator, 56°±2°C (This is a dry heat block).
Thermometer

Diagram of Attest Biological Indicator for Steam Sterilization



When the growth medium ampule is crushed, the spore strip is exposed to growth medium. If the indicator is not sterile, spores will grow and the medium will change color.

Testing Procedure

1. Monitor the autoclave at least once a week each week that the autoclave is used.
2. Sterilization of the Indicator (exposure to steam)
 - a. Identify the indicator by writing the sterilizer and load numbers and the processing date on the Attest vial label.
 - b. Place an indicator in a suitable test pack that is representative of the load (e.g., a tray for loads that include metal instruments).
 - c. Process the load as usual.
 - d. Allow the test pack to cool for at least 10 minutes. CAUTION: Failure to cool may cause the glass ampoule to burst, which may result in injury from flying debris.
 - e. Retrieve the Attest indicator from the test pack. Check the chemical indicator on the label. It changes from rose to brown during the autoclave process.
3. Incubation of the Attest indicator
 - a. Incubate within two hours of removing from the autoclave. (If the indicator cannot be incubated within 2 hours, it can be refrigerated up to 24 hours or frozen up to 4 days.)
 - b. Incubate an unautoclaved Attest indicator of the same lot each time an indicator is tested.
 - c. Crush the indicator in the incubator. Place the bottom of the indicator into the incubator's metal heating block. Push the indicator straight back, see figures 1 and 2. This activates the indicator by exposing the spores to the growth media. Push the crushed indicator down to firmly seat in the metal heating block, figure 3.

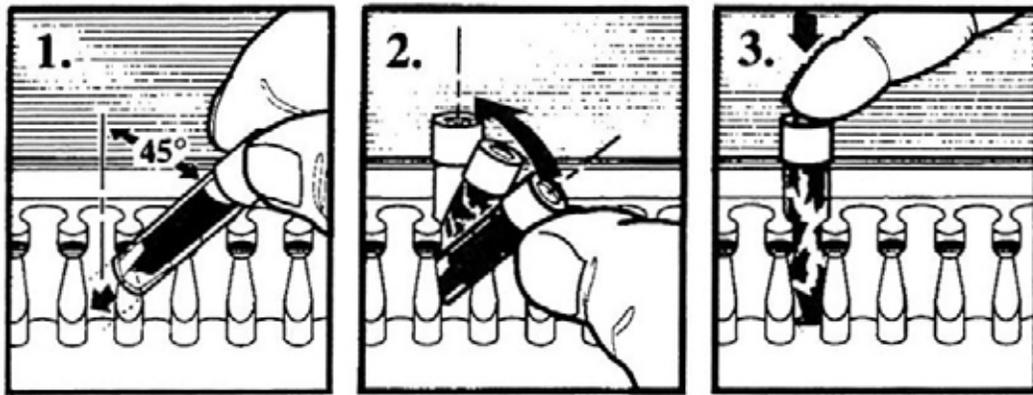


Figure 1

Figure 2

Figure 3

- d. Incubate at $56^{\circ}\pm 2^{\circ}\text{C}$ for 48 hours. Check the temperature and examine the indicator at 24 and 48 hours.
 - e. If the autoclaved indicator shows any color change from purple to yellow, the test is positive. Immediately take corrective action as described below.
4. Record results on the Attest Biological Monitoring System Log.

Interpretation of Results

Negative (purple). This indicates no growth of the spores.

Positive (yellow). This indicates growth of the spores.

The autoclaved indicator should be **NEGATIVE**. The control indicator should be **POSITIVE**.

Corrective Action

Take corrective action steps **AS SOON AS EVIDENCE OF GROWTH IS NOTED** in the autoclaved indicator.

1. Retrieve the load autoclaved with the spore strip that is positive. **These items are not sterile.**
2. Determine the autoclave problem and correct.
3. Retest the autoclave with several Attest indicators placed throughout the test load.
4. Repeat the sterilization process of the load retrieved in Step 1.

Attest

Biological Monitoring System For Steam Sterilization

Date	Sterilizer Number	Load Number	Date & Time In Incubator/ Initials	Date & Time Out Incubator/ Initials	Results (Circle one)	Control (Circle one)
(Or affix sterilization load label)					+ -	+ -
					+ -	+ -
					+ -	+ -
					+ -	+ -
					+ -	+ -
					+ -	+ -
					+ -	+ -
					+ -	+ -
					+ -	+ -

**Tennessee Department of Health
Community Health Services
Bacteriological Culture Media Quality Control Log
Instructions**

Purpose:

To keep a log for quality control of bacteriological culture media for specimen collection.

Explanation and Definition:

An individual log for each type of bacteriological culture media is kept at the work site.

General Information:

Each item on the log has been numbered; the instructions are written to correspond to those numbers.

Instructions:

1. **Clinic Site** – Record the name of the county/clinic site.
2. **Media** – Record the name of the media.
3. **Manufacturer** – Record the name of the manufacturer.
4. **Date Received/Inspected** – Record the date received and inspected. Record only one date if received and inspected the same day. If received one day and inspected later, record both dates.
5. **Lot #** – Record the lot number of the media. This is supplied by the manufacturer. If lot number is not given, record date made.
6. **Expiration Date** – Record the expiration date given by the manufacturer.
7. **Visual Inspection; A/NA (Reason if NA)** – Visually examine media for contamination; cracked or broken containers; unequal filling; cracked, hemolyzed, or frozen media; and media with an excessive number of bubbles. Record results. If there are no problems, accept media (NA). If the media is not acceptable, report to Laboratory Services.
8. **Initials** – Record the initials of the individual inspecting the media. A generic signatures/initials list must be available to identify the initials on this log with a signature.

Used By:

Health Department staff who maintain bacteriological culture media.

Retention Time:

Retain logs for two (2) years.

V. PRODUCT INSERTS
(ADDED BY REGION)