1.7 Training Checklists and Competency Evaluations

Training Checklists for Waived or Nonwaived Testing (Moderately Complex):

Professional staff will have received basic training in laboratory procedures by “on-the-job-training” (OJT), graduating from medical school (MD), graduating from a nursing program (RN), or through the Advanced Nurse Practitioner (ANP) course, or by certification in laboratory sciences (MT or MLT). All new staff will receive training from appropriate personnel (Region Laboratory Consultant, general supervisor for the laboratory or nursing mentor) for all laboratory procedures and specimen collection requirements.

All Staff Will Receive Updated Training When:

- New or different kits, procedures and/or equipment are introduced.
- PT failure occurs and/or the laboratory is notified of unsuccessful PT.
- Staff is/are performing at a level of unsatisfactory for annual competency evaluation and/or annual EPDP.
- Documentation for CLIA is required for all new staff training or updated staff training.
- Documentation is accomplished by using the standardized Training Checklists and standardized Competency Evaluations found in this manual.
- Training Checklists are also used when proficiency test failure indicates retraining of staff is needed.

Epidemiologic Outbreaks: Region Laboratory Consultant’s Responsibility

In an epidemiological outbreak, training checklists and/or competency evaluation forms MUST be FAXED and/or hard copies mailed to the Region Laboratory Consultant for all mobilized professional staff that will be performing laboratory tests in the outbreak zone. It is strongly recommended that the affected Region Laboratory Directors (Medical Director) and/or Region Laboratory Consultants be notified BEFORE mobilization is going to occur. It is the responsibility of the affected Region Laboratory Consultant to request Training Checklists/Competency Evaluations from the home Region Laboratory Consultant, and maintain files on all temporary staff assigned to the county or Region (only staff who perform laboratory testing) during an epidemiological event. If a temporary staff CANNOT produce annual competency and/or training checklists for an analyte, then this staff person CANNOT perform laboratory testing. Ultimately it is the Laboratory Director (Medical Director) who is responsible for the laboratory testing staff in his/her region. All files on temporary mobilized staff MUST be kept for a minimum of two (2) years or until the next CLIA site inspection, whichever is longer. This is to maintain compliance for CLIA site inspections.
Competency Evaluations for Waived or Nonwaived Testing (Moderately Complex):

1. All staff performing laboratory procedures (waived and/or nonwaived) MUST be evaluated at least two times per year:
   - The first year of employment, or
   - After the introduction of a new method, equipment, or
   - If failure of proficiency testing occurs (less than 80%), or
   - If any component of the checklist or competency evaluation is unsatisfactory, or
   - For any test method in which a PT is performed NOT using a commercial vendor test procedure, method verification/validation; for example, CAP, API, etc., or
   - For all personnel performing Darkfield Microscopy for the detection of syphilis.

2. Thereafter, the staff can be evaluated annually if:
   - The staff successfully perform all proficiency testing and/or method verification (comparison testing) with a minimum of 80% accuracy, or
   - All components of the checklist or previous competency evaluations have been successful.

3. Competency Evaluation (CE) needs to encompass all of the following:
   - Direct observation of test performance.
   - Monitoring the recording and reporting of test results.
   - Review of worksheets, QC records, and preventive maintenance (PM) records.
   - Direct observation of performance of instrument maintenance and function checks.
   - Assessment of problem solving skills.
• Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing (PT) samples.

Proficiency Testing for Nonwaived Testing (Moderately Complex):

Proficiency testing (PT) is used to monitor the performance and quality of laboratory testing. PT is a program in which samples are sent to the laboratory for analysis. The sample is tested in the same manner as a patient’s specimen. Results are returned to the commercial program sponsor (CAP, AAB, WSHL, etc.) for tabulation and grading. The Region Laboratory Director, Region Laboratory Consultant (general supervisor), and individuals performing the PT tests MUST review the results. If one or more challenges are missed, corrective action MUST be taken and documented (blue and/or black ink ONLY). PT is required for all nonwaived tests and is strongly recommended for all waived testing. For more information, see Section 4.4 in this manual.

CLIA requires all staff performing moderately complex testing (nonwaived) to participate in PT for each analyte (test) they perform at least once a year. For example, if Nurse A performs Gram stains, wet preps and 10% KOH in the clinic, Nurse A MUST take a PT for each of those tests at least one time every year. CLIA currently does NOT require PT for waived testing. However, it is strongly recommended that PT for waived testing be conducted for the QA of laboratory testing.

Method Verification or Comparison Testing:

If a commercial proficiency testing (PT) program is NOT available, method verification/comparison testing can be done. This needs be done twice annually. Verification/comparison testing can be done by:

• 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 or photographs to be viewed.

• Work with another laboratory and test the same specimen. Compare results.

• Have two people in the clinic read the same result. Compare results.

• NOTE 1: this method CANNOT be used for Darkfield Microscopy testing; the competency for Darkfield is done through bi-annual Darkfield Competency Workshops. Contact the QA Director at the Bureau of Laboratories for detailed information concerning training opportunities.
• **NOTE 2**: employee competency and method verification/comparison testing can be done at the same time. Documentation (blue and/or black ink ONLY) of these activities is required by CLIA. See forms for method verification/comparison and competency evaluation in this manual.

- Documentation of twice annual method verification/comparison testing **MUST** be recorded on the appropriate DHEC form.

**Training Checklists and Competency Evaluations:**

Training checklists are listed first as Waived or Nonwaived in alphabetical order (see Table of Contents in this manual for listed order); then the Competency Evaluation Forms. Copies of these forms can be found on the electronic file sent to all Region Laboratory Consultants and/or their designee. Do NOT substitute any other forms!

1. **Blood Collection Training Checklists**
   - DHEC 2491 Training Checklist for Capillary Puncture: Finger Stick Method for Patients Greater Than 1 Year and Adults
   - DHEC 2489 Training Checklist for Capillary Puncture: Heel Stick for Patients Less Than 1 Year of Age
   - DHEC 2492 Training Checklist for Capillary Puncture: Heel Stick for Filter Paper Method
   - DHEC 2490 Training Checklist for Venipuncture Blood Collection

2. **Waived Testing Training Checklists**
   - DHEC 2441 Waived: HemoSense™ INRatio Training Checklist
   - DHEC 2443 Waived: Rapid HIV Test Training Checklist...
   - DHEC 2440 Waived: Qualitative Urine Pregnancy Training Checklist...
   - DHEC 2442 Waived: Vaginal pH Training Checklist...
   - DHEC 2447 Waived: Urinalysis (Dipstick) Training Checklist...
   - DHEC 2459 Waived: Hemoglobin Training Checklist...
   - DHEC 2460 Waived: Vaginal Amine (Whiff) Training Checklist...

3. **Nonwaived Testing Training Checklists**
   - DHEC 2494 Nonwaived: Brightfield Microscopy Training Checklist...
   - DHEC 2497 Nonwaived: Darkfield Microscopy Training Checklist...
   - DHEC 2498 Nonwaived: Gram Stain Training Checklist...
   - DHEC 2499 Nonwaived: 10% KOH Training Checklist...
   - DHEC 2449 Nonwaived: RPR (Qualitative) Training Checklist...
   - DHEC 2493 Nonwaived: RPR Semi-Quantitative Training Checklist...
   - DHEC 2496 Nonwaived: Wet Prep Training Checklist...
4. Personnel Competency Documentation: Personnel Assessment Form
   • DHEC 2445 Personnel Competency & Proficiency Test Documentation for Waived Testing
   • DHEC 2480 Personnel Competency Documentation for Nonwaived Testing Procedures

**NOTE:** Copies of these forms can be found on the electronic file provided by the Office of Quality Assurance, Bureau of Laboratories, SCDHEC.