How to Improve the Laboratory Experience – CLS and MLT Working Together

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The critical role laboratories play in the delivery of healthcare

- Laboratory test results are used by physicians and other healthcare practitioners to direct patient care.
  - Aid in the diagnosis and treatment of disease
  - Aid in the assessment of general health
  - Over 80% of medical decisions are based on laboratory test results
Clinical laboratory career ladder

- **Phlebotomist**
  - HS diploma or GED, minimum of 40 hours clinical experience to include at least 50 venipunctures, 10 skin punctures and pass an exam.
  - Can assist and/or set up testing with supervision.

- **Medical Laboratory Technician**
  - Associate’s degree, 6 months of clinical experience and pass an exam.
  - Can supervise laboratory assistants and phlebotomists.
  - Perform waived and moderate complexity testing with supervision.

- **Clinical Laboratory Scientist**
  - Bachelor’s degree, 12 months of clinical experience and pass an exam.
  - Can supervise laboratory assistants, phlebotomists, MLTs and CLS, manage laboratories, and direct waived laboratories.
  - Perform waived, moderate and high complexity testing.
Clinical laboratory career ladder, continued

- **Clinical Laboratory Bioanalyst**
  - Master’s degree, 5 years of clinical experience and pass an exam.
  - Can supervise laboratory assistants, phlebotomists, MLTs and CLS, manage laboratories and direct waived, moderate, and high complexity laboratories.
  - Perform waived, moderate and high complexity testing.

- **Clinical Laboratory Director**
  - MD or PhD with board certification.
  - Can direct waived, moderate and high complexity laboratories.
  - Perform waived, moderate and high complexity testing.
What is laboratory test complexity?

The US Food and Drug Administration (FDA) classifies tests as:

- Waived (simple) – example: urine pregnancy test
- Moderate (medium difficulty) – example: automated hematology and chemistry tests
- High (most difficult) – example: isolation and identification of human pathogens from culture media or bone marrow flow cytometry

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
Waived: Urine pregnancy test
Moderate: Automated hematology tests
High: Isolation and identification of human pathogens
What’s the problem?

There is a critical shortage of Clinical Laboratory Professionals in California who can perform testing activity

- Clinical Laboratory Scientists
- Medical Laboratory Technicians
- Most clinical laboratories have CLS or MLT vacancies lasting years – especially with experienced leadership positions
- Retirements out pace new graduate hires
Why is there a problem?

- Reduced number of training programs
  - Programs are expensive to run
  - Limited number of clinical training sites
  - Programs graduate only 250 students per year
  - State needs approximately 1200 new CLPs per year
- The aging workforce
  - Acceleration of retirements
    - Nationally, 40% between 46 and 66 yrs old
    - In CA the mean age of clinical laboratory scientists is approximately 55 yrs old
- Increased demand
  - Aging patient population/Chronic care management
  - More tests ordered per patient
  - New methods and life saving procedures
What actions are needed to address the staffing shortage?

- Produce more CLSs and MLTs
- Integrate more MLTs into the laboratory workforce to perform the “routine” testing
- Statewide laboratory workforce initiative
- Recruitment and marketing of the profession
- Manufacturer participation
Medical Laboratory Technicians (MLT) can help.

- Who are they?
- What is their training?
- What they are NOT
- What can they do?
- How can they help?
MLTs – Who are they?

- Mid-level laboratory professional who has obtained an associates degree level education from a NAACLS or CA approved MLT training program which
  - Includes a six month externship at a clinical laboratory.
  - All must pass an approved national exam.
- Training: MLT training programs currently offered at De Anza, Folsom, College of the Canyons Community Colleges, etc.
- Training can be completed in approximately 2 years, including prerequisite classes.
MLTs – What is their training?

Prerequisites to admission to MLT programs include college level:

- Biology (anatomy and physiology)
- Chemistry (general and organic)
- Microbiology
- CA certified phlebotomist
Consists of 7 lecture/laboratory classes. Student’s pass each class to be eligible for clinical externship.

- Clinical Hematology
- Clinical Urinalysis
- Clinical Coagulation
- Clinical Chemistry I and II
- Clinical Microbiology
- Clinical Immunology/Immunohematology
MLT: Clinical Externships

There are 4 Clinical Rotations:

<table>
<thead>
<tr>
<th>Rotation</th>
<th>Hours</th>
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<tbody>
<tr>
<td>Clinical Chemistry</td>
<td>216</td>
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<tr>
<td>Clinical Hematology/Coag/UA</td>
<td>216</td>
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<tr>
<td>Clinical Microbiology</td>
<td>216</td>
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<tr>
<td>Clinical Immunology/Immunohematology</td>
<td>180</td>
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</tbody>
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MLTs – What they are not

- MLTs are not CLSs!
- MLTs are not being trained to take CLS jobs
- MLTs are more than Lab Assistants
- MLTs are being trained to be an asset to the laboratory
- MLTs release their own test results
- MLTs are not trained in 6 months
  - They complete 7 clinical courses in addition to the 6 month externship
  - These courses are transferable to the CSU as part of a BS in Microbiology or Biology or to obtain a CLS training license
Integrating MLTs into the Workforce

- MLT employees can be an asset in the laboratory
- MLTs can perform the routine tasks now required of CLSs
- CLSs will now be free to work in areas of emerging technologies
MLTs – What can they do?

- In the State of CA, MLTs are able to perform waived and moderately complex testing with the exception microscopy and immunohematology
- [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm)
- Perform phlebotomy, supervise LPT & CPT 1s
- Report test results after training and competency has been documented
MLT Regulations Include:

- (Supervisory CLS): MLT ratio of 1:4 be maintained in the clinical laboratory
- Onsite supervision when moderately complex testing is being done by an MLT
- MLTs are required to complete 12 units of continuing education/year and pay biannual fees to the state
MLTs: The missing piece of the puzzle

- MLTs can fill the gap between a laboratory assistant and a CLS
  - Reagent and control preparation
  - Make dilutions
  - Perform calibration, QC and load patient samples, identify abnormal results and prepare specimens per protocol
  - Report test results after training and competency has been documented
MLTs are permitted to:

- Perform daily, weekly, monthly, and as needed maintenance and troubleshooting.
- Perform method validation on moderately complex tests.
- Perform microbiology setups.
- IT support or supervision.
- Coordinate POCT activity.
- Perform phlebotomy.
- Supervise phlebotomy and/or lab assistants.
- Perform waived and moderately complex tests.
- Perform complex specimen processing procedures.
Hematology Department

- Automated analyzer
  - Perform maintenance
  - Calibrate instrument
  - Run QC samples
  - Review data
  - Verify normal results; repeat analysis or confirmation testing per protocol
- Prepare and stain peripheral blood smear for CLS review
Hematology Department continued

- Sedimentation Rates
- Sickle cell testing
- Spun hematocrits
- Special staining techniques
  - Reticulocyte stain
  - Malaria smears
  - Kleihauer-Betke
- Assist in bone marrow slide preparation
Chemistry Department

- Automated analyzers
  - Perform maintenance and troubleshooting
  - Perform and accept calibrations
  - Prepare and run QC materials
  - Review patient results, verify normal results, repeat or dilute specimens as required
  - Make dilutions and prepare reagents
Perform and report rapid serology testing rated waived or moderate complexity
- H. pylori antibody
- Monospot test
Perform and report occult blood testing
Osmolarity testing
Urinalysis

- Operate urinalysis analyzer, reporting normal results, perform confirmation testing (e.g. Icotest ®) and referring questionable results for CLS review
- Prepare urine sediment for CLS review
- Preservation of specimens
Coagulation

- Operate automated instrumentation, verifying normal results and preparing abnormal specimens per protocol
- Perform maintenance, troubleshoot, and calibrate instrumentation
- Prepare and run QC material
- Complete complex specimen processing (e.g. pooling, aliquoting, and freezing specimens)
Microbiology Department

- Culture set-ups
- Perform rapid testing
  - Rapid Strep
  - RSV
- Prepare gram stains
- Answer technical questions
Work Scenario #1

- Four chemistry autoanalyzers
- Four MLT operators
- One CLS chemistry supervisor on-site
- MLT #1, 2, & 3 running chemistry panels and individual analytes (e.g. glucose, TSH, PSA, HA1C, etc.) on autoanalyzers and reporting normal values and diluting/rerunning above assay range results
- MLT #4 calibrates new lots of Ca and Mg reagents and accepts calibration per protocol
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- MLT #4 calibrates new lots of Ca and Mg reagents and accepts calibration per protocol
- MLT activities are within their scope of practice
Work Scenario #2

- One MLT hematology autoanalyzer operator reviews data with a WBC interference flag
- One CLS hematology supervisor on lunch break
- MLT prepares and stains peripheral blood smear
- MLT reviews blood smear to confirm WBC and verifies CBC with automated differential results
Work Scenario #2

- One MLT hematology autoanalyzer operator reviews data with a WBC interference flag
- One CLS hematology supervisor on lunch break
- MLT prepares and stains peripheral blood smear
- MLT reviews blood smear to confirm WBC and verifies CBC with automated differential results

- MLTs reviewing blood smear is out of their scope of practice in California
- Reviewing a blood smear is a test requiring microscopy
MLT Career Opportunities

- May be employed by laboratories (e.g. hospital, reference, physician office, independent labs, etc.) that perform moderate and/or waived testing (i.e. approximately 90% of core lab testing activity)

- May be employed to supervise LPTs, CPT 1s, and specimen collection/processing activity/sites

- Can perform routine tasks previously done by CLSs that can not be done by lab assistants

- CLSs will now be free to work in areas of overall supervision, administration, education, and emerging technologies
Possible MLT salary range

- MLTs can perform about 90% of the testing activity and receive about 75% of local CLS wages
In Conclusion

- Licensure of mid-level testing personnel as MLTs has positively impacted the laboratory personnel workforce shortage in California, but will not solve all of our staffing issues nor take the place of the CLS.

- We must continue to encourage, recruit, educate, and train future laboratorians.

- Ultimately, this will help clinical laboratories to continue to provide critical diagnostic laboratory testing for all.