

## UNC-Chapel Hill Masters in Clinical Laboratory Science- Molecular Diagnostic Science (MCLS-MDS) Program

### Checklist for Meeting Minimum Requirements for Entry-Level Competency

- A. The student must perform testing in all of the following laboratory areas of the institution:
- Molecular Genetics/Inherited Disease
  - Molecular Oncology
  - Molecular Microbiology/Infectious Disease
- B. The student must achieve competency by performing a variety of tests using different test methodologies (see section C. below) in each of the three laboratory areas. Examples of appropriate molecular test menu assays for competency include, but are not limited to:
- Genetics/Inherited Disease
    - Fragile X Syndrome
    - Cystic Fibrosis
    - Hemochromatosis
    - Factor II and/or Factor V
    - Prader-Willi / Angelman Syndrome
    - *NKX2.5* mutation analysis
    - Connexin 26 and connexin 30 for hearing loss
    - Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)
    - Galactosemia (*GALT*)
    - Primary Ciliary Dyskinesia/Kartagener Syndrome (*DNAI1* and *DNAH5*)
    - Clopidogrel or warfarin resistance testing
  - Oncology
    - B-cell/T-cell gene rearrangement
    - *JAK2*, *EGFR*, *KRAS*, *NRAS*, *KIT*, *MLH1*, *BRAF*,.... mutation detection
    - *BRCA1* and *BRCA2* mutations
    - *BCR-ABL1* translocation
    - *FLT3* and *NPM1* defects
    - DNA fingerprinting for bone marrow transplant
    - Microsatellite instability
  - Microbiology/Infectious Disease
    - Microorganism Detection
    - Viral Loads
    - Viral Genotyping
    - Antimicrobial Resistance Testing

C. The student must be deemed competent in all of the following phases of testing:

1. Pre-Analytical Phase

- Receive and evaluate specimens for acceptability and proper test orders.
- Prepare samples for molecular analysis, storage, or send-out.
- Perform a majority of the methods of nucleic acid extraction, isolation, and purification used by the laboratory to include manual and automated methods.
- Evaluate nucleic acids for concentration and purity.

2. Analytical Phase

- Student must be trained on and deemed competent to perform testing using a variety of the following methods if used by the institution:
  - Polymerase Chain Reaction
    - Endpoint PCR
    - Real-time PCR
    - Reverse transcription PCR
    - Other variations of PCR
  - Non-PCR Amplification
    - Transcription Mediated Amplification (TMA)
    - Strand Displacement Amplification (SDA)
    - Nucleic Acid Sequence Based Amplification (NASBA)
  - Electrophoresis
    - Capillary
    - Gel
  - Melt Curve Analysis
  - Microarrays
  - Matrix Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF)
  - Sequencing
    - Sanger
    - Pyrosequencing
    - Next-Generation
  - Nucleic Acid Hybridization Techniques
    - Invader™
    - Hybrid Capture
    - Southern Blot
    - Sequence Specific Primer (SSP)
    - Sequence Specific Oligonucleotide Probe (SSOP)
    - Fluorescent In situ Hybridization (FISH)- desirable, but not required
  - Other molecular-based methods or test platforms used by the institution
- Student should be deemed competent in organizing workflow, instrument operation and maintenance, and trouble-shooting.

3. Post-Analytical Phase

- Analyze and verify patient results.
- Evaluate assay controls for acceptability.
- Report results using the laboratory information system if permitted to do so by the institution.

**The student's proposed plan to meet the rotation objectives and competency should be accompanied by the following:**

- Test menus from each molecular laboratory section within the institution to include the test methodology or molecular platform used for each test.
- A proposed schedule for training for all academic semesters included in the rotation.
- A signed letter from the Laboratory Director stating that he/she and the student's immediate Supervisor(s) agree with and approve the rotation plan.
- The Laboratory Director's contact information so that the Division of CLS can initiate an affiliation agreement.

**Rotation Objectives:**

1. Explain the principle of the method, instrument used, and clinical indication for the method/assay.
2. Identify the specimens, reagents, standards, and controls used.
3. State the reference range, if applicable, and identify results which are normal and abnormal.
4. Perform the test using the procedures available in the laboratory.
5. Perform analyses efficiently and in an organized manner.
6. Interpret results with respect to clinical conditions.
7. Recognize spurious results due to factors such as:
  - a. poor specimen collection.
  - b. improper specimen identification/labeling.
  - c. improper anticoagulants.
  - d. interfering substances.
  - e. non-lysis of RBCs or WBCs.
  - f. instrument malfunctions.
  - g. operator/technical error.
8. Suggest additional tests needed for confirmation.
9. Operate instruments needed for test performance, including daily maintenance and basic trouble-shooting.
10. Perform quality control procedures and justify their use in terms of accreditation requirements.
11. Verify and report patient results as appropriate.
12. Calculate the following statistics: mean, standard deviation, and coefficient of variation.
13. Determine and/or evaluate assay validation data to include:
  - a. accuracy
  - b. precision

- c. analytical sensitivity
  - d. analytical specificity
  - e. reportable range
  - f. reference range
  - g. positive and negative predictive values
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14. Exhibit good work practices, i.e., paying attention to detail, writing legibly, making only minimal errors, recognizing and correcting errors.
  15. Follow all safety regulations.
  16. Communicate appropriately, e.g., seeking guidance from staff.
  17. Work in an ethical and trustworthy manner.
  18. Be prepared for each day's work by thorough preparation, review of information presented in on-line courses, and review of laboratory test procedures.
  19. Use appropriate interpersonal skills.
  20. Demonstrate positive personal traits.