

STATEMENTS OF COMPETENCE FOR MOLECULAR GENETIC TECHNOLOGISTS

A competent molecular genetics technologist working independently without constant supervision, can interpret and implement established procedures to prepare appropriate specimens for molecular analysis, perform that analysis, and prepare and describe the results. Competence includes, but is not limited to, skill and knowledge in the following specific areas. Due to the variability of testing applications in specific laboratories, a technologist may not be required to become competent at certain tasks as delineated by the Director of the laboratory.

- 1. Collection, handling, preparation, and processing of various specimens**
 - 1.1 Identify appropriate specimens for study, and methods for collection, preservation and transport.
 - 1.1.1 Select appropriate containers, anticoagulants, and preservatives.
 - 1.1.2 Identify factors important for the transport of specimens such as overnight delivery, containers, and recommended temperatures.
 - 1.1.3 Transport/ship specimens off-site using packaging which meets OSHA safety guidelines.
 - 1.1.4 Store specimens considering time, temperature, etc.
 - 1.2 Assess acceptability of specimen for study.
 - 1.2.1 Check for appropriate labeling of specimen and requisition.
 - 1.2.2 Evaluate suitability of specimen for requested study, both for type and amount obtained.
 - 1.2.3 Judge quality of specimen, noting presence of blood clots or hemolysis in blood samples, presence of blood in amniotic fluid, etc.
 - 1.2.4 Know methods for possible recovery of poor samples.
 - 1.2.5 Notify appropriate individuals of any unsatisfactory samples and document such notification.
 - 1.3 Enter details of specimen into appropriate log books and computer systems.
 - 1.3.1 Assign laboratory accession number to specimen and related records.
 - 1.3.2 Record patient's name and all required and pertinent information.
 - 1.3.3 Record accurate and complete information concerning specimen including amount, anticoagulant, appearance, collection date and time, etc.
 - 1.3.4 Record test requested, noting special test requests, particularly those requiring transport of samples to other laboratories.
 - 1.4 Follow protocols to ensure proper identification of patient materials through the complete process, from accession to final report.
 - 1.5 Assist in maintaining necessary records and laboratory data base, in log books or computers, as appropriate.
- 2. Appropriate techniques for nucleic acid isolation from submitted specimens.**
 - 2.1 Understand and use sterile techniques.
 - 2.1.1 Use measures (such as Universal Precautions) that protect employees from real or potential exposure to infectious agents (e.g., protective clothing, gloves and masks, containers for sample delivery and waste disposal, biological safety cabinets).
 - 2.1.2 Use and document methods to detect, identify, control, and eliminate microbial or chemical contamination.
 - 2.1.3 Practice measures that prevent cross-contamination between samples.
 - 2.2 Choose appropriate method for DNA/RNA isolation.
 - 2.2.1 Isolate DNA/RNA expediently, with consideration to specimen type and test requested.
 - 2.3 Employ proper dilution technique for isolated DNA/RNA.
 - 2.3.1 Choose appropriate type of solution (e.g., TE, water, etc.) for reconstitution of DNA/RNA.
 - 2.3.2 Choose appropriate amount of reconstitution solution for test being performed.
 - 2.4 Determine concentration of DNA/RNA.
 - 2.4.1 Use spectrophotometer to determine optical density and DNA/protein ratio of reconstituted DNA/RNA.
 - 2.4.2 Use fluorimeter and appropriate dye to estimate DNA concentration.
 - 2.4.3 Use gel electrophoresis to estimate concentration and determine quality of DNA/RNA.
 - 2.5 Identify, evaluate, and document probable causes of poor or no DNA/RNA isolation, such as inadequate specimen or reagent failure, and document corrective actions taken.
 - 2.6 Employ proper techniques for storage of DNA/RNA samples.
- 3. Principles and techniques for nucleic acid digestion.**
 - 3.1 Know and understand principles and techniques associated with restriction enzyme digestion.
 - 3.2 Perform restriction enzyme digest.
 - 3.2.1 Determine enzyme(s) and buffer(s) to be used in analysis.
 - 3.2.2 Set up digest using proper concentrations of reagents and DNA.
 - 3.2.3 Use appropriate conditions (temperature, time, etc.) for complete digestion of DNA.
 - 3.2.4 Evaluate and document digestion.
 - 3.2.5 Troubleshoot incomplete digestion.
 - 3.3 Document digestion results using image processor or photography, producing a clear copy.

4. **Perform electrophoretic and other separation techniques.**
 - 4.1 Select matrix for identifying fragment of interest.
 - 4.1.1 Prepare agarose gel and buffer at correct concentration and pH.
 - 4.1.2 Prepare polyacrylamide gel (denaturing or non-denaturing) and buffer at correct concentration and pH.
 - 4.1.3 Prepare capillary column.
 - 4.2 Perform separation technique.
 - 4.2.1 Prepare and load samples, documenting order.
 - 4.2.2 Use appropriate markers.
 - 4.2.3 Monitor migration.
 - 4.3 Operate electrophoresis apparatus at proper voltage, wattage, or current and for appropriate duration.
 - 4.4 Stain gel with appropriate dye, following safety precautions.
 - 4.5 Perform SSCP analysis.
 - 4.6 Perform DSCP (heteroduplex) analysis.
 - 4.7 Perform sequencing analysis.
 - 4.8 Know procedure for polyacrylamide gel drying.
 - 4.9 Document results with autoradiography, luminography or photography.
5. **Transfer nucleic acid to solid matrix.**
 - 5.1 Use appropriate techniques for transferring or immobilization of nucleic acid (Southern blot, dot/slot, reverse dot blot, capillary).
 - 5.1.1 Utilize appropriate membrane for transfer.
 - 5.1.2 Follow protocols for DNA transfer. Prepare and pH solutions appropriately. Know and understand importance of transfer duration.
 - 5.2 Bind DNA to membrane.
 - 5.2.1 Use appropriate method for binding DNA (e.g., baking blot, UV irradiation, etc).
6. **Hybridization techniques.**
 - 6.1 Choose appropriate probe(s) for disease/area of concern.
 - 6.2 Prepare nucleic acid probes.
 - 6.2.1 Use transformation and/or bacteriology techniques to propagate and maintain probe stock.
 - 6.2.1.1 Know and understand techniques for preparing probes, including Flavell preps, midi-preps, mini-preps, etc.
 - 6.2.2 Use cloning procedures to prepare probe.
 - 6.2.3 Isolate probe from cloning vector.
 - 6.3 Label probe using appropriate method (e.g., Nick translation, random prime, chemiluminescence, end labeling, amplification, etc.).
 - 6.3.1 Follow laboratory safety procedures when dealing with radioactive isotopes.
 - 6.3.2 Maintain records of isotope usage and disposal as directed by the Nuclear Regulatory Commission.
 - 6.3.3 Purify labeled nucleic acid probe.
 - 6.3.4 Determine labeling efficiency
 - 6.4 Prepare membrane for prehybridization/hybridization.
 - 6.4.1 Select and prepare solutions for prehybridization/ hybridization/rinsing.
 - 6.4.1.1 Understand importance of components of solutions.
 - 6.4.2 Prepare probe and marker with radioactive or chemiluminescent nucleotides.
 - 6.4.3 Know and understand proper techniques, hybridization temperatures and duration, and rinsing temperatures and duration.
 - 6.5 Prepare membrane for exposure to autoradiographic film.
 - 6.5.1 Expose film at correct temperature for adequate amount of time. Expose for multiple times to achieve optimal signals if necessary.
 - 6.5.2 Develop film using X-ray processor.
7. **Principles and techniques for polymerase chain reaction (PCR).**
 - 7.1 Know and understand principles and techniques associated with PCR analysis.
 - 7.1.1 Monitor and document all phases of PCR.
 - 7.1.2 Be able to determine components and amounts for particular reaction.
 - 7.1.2.1 Calculate amounts for master mix.
 - 7.1.2.2 Calculate primer dilutions.
 - 7.1.3 Optimize conditions for amplification.
 - 7.1.4 Troubleshoot reaction conditions/components for failed or non-specific reactions.
 - 7.1.5 Utilize appropriate controls.
 - 7.2 Be able to choose appropriate primers for disease/area of concern.
 - 7.2.1 Assist in development of new primers.
 - 7.2.2 Synthesize and purify primers if in-house primers are utilized.
 - 7.2.2.1 Perform quality control on in-house primers before use.

- 7.3 Perform restriction digest if required (see section 3).
- 7.4 Perform electrophoretic and other separation techniques (see section 4).
- 7.5 Use various applications of PCR technique.
 - 7.5.1 Perform RT, LCR, TMA, etc. analysis.
- 7.6 Document results on proper forms and in chart.
- 8. Summarize results and report to appropriate authority.**
 - 8.1 Interpret results knowledgeably.
 - 8.1.1 Determine that controls are within range .
 - 8.1.2 Assign allele size to bands on autoradiogram.
 - 8.1.3 Assign basepair size to PCR products.
 - 8.1.4 Determine affected/carrier status.
 - 8.2 Record results in chart.
 - 8.2.1 Recognize and avoid hazards implicit in oral reporting of results.
 - 8.2.2 Draft a neat, accurate report summarizing the findings in understandable text and incorporating the patient identification and all relevant clinical and laboratory data; forward to the appropriate individual for review and signature.
 - 8.2.3 Document conversations or correspondence with individuals requesting information concerning testing and/or results.
 - 8.3 Assess the need and report to the appropriate authority (e.g., supervisor, referring physician, or genetic counselor) additional studies necessary to complete the diagnosis (e.g., repeat the procedure, perform additional testing, request family studies, cytogenetic, or biochemical studies).
 - 8.4 Correlate results with other laboratory results and/or clinical information.
- 9. General laboratory skills, quality control, and quality assurance.**
 - 9.1 Prepare reagents at the proper concentration and pH, with proper labeling, using required grades of water and chemicals.
 - 9.2 Select, operate, clean, and maintain all laboratory equipment and instruments, as appropriate.
 - 9.2.1 Monitor the need for service or repair on any equipment, and report this to appropriate authority.
 - 9.2.2 Document usage of gas tanks, and replace as necessary.
 - 9.2.3 Record equipment temperatures with reference thermometers, and adjust controls if necessary.
 - 9.2.4 Record centrifuge speed, using a tachometer, and adjust if necessary.
 - 9.3 Understand principles of sterilization and decontamination procedures (e.g., use of disinfectants, steam, dry heat, gas, ultraviolet irradiation, and membrane filtration).
 - 9.4 Maintain adequate stocks of laboratory supplies and chemicals.
 - 9.4.1 Understand limits on stock imposed by "shelf life" and expiration dates.
 - 9.5 Employ appropriate cleaning procedures for general laboratory safety.
 - 9.6 Practice established procedures for general laboratory safety.
 - 9.6.1 Use Universal Precautions as established by Centers for Disease Control (CDC) and individual state or local governments.
 - 9.6.2 Understand and use procedures for laboratory emergencies (e.g., fire, accident/injury, natural disaster, chemical spill, or power failure).
 - 9.6.3 Use correct procedures for storage, handling, and disposal of different kinds of materials and waste: biological and chemical; volatile or stable; radioactive: sharps and glass.
 - 9.7 Maintain a system to ensure laboratory quality control in all areas, to comply with all regulatory requirements.
 - 9.7.1 Maintain a system to ensure accuracy of molecular results, including appropriate documentation, throughout all steps of laboratory procedures.
 - 9.7.2 Maintain a system to ensure confidentiality and security of patient records.
 - 9.7.3 Maintain a system to appropriately label, store, and monitor shelf life, sterility, and quality of all media, reagents, and chemicals.
 - 9.7.4 Maintain an easily accessible collection of current Material Safety Data Sheets for all chemicals used in the laboratory Procedures-
 - 9.7.5 Maintain a system of records for equipment and instruments (serial numbers, date of purchase, maintenance checks, gauge readings, dates and type of service or repair).
 - 9.7.6 Practice the techniques, procedures, and policies used in the laboratory, as documented in the laboratory manual.
 - 9.7.7 Assist in reviewing and revising the laboratory manual.
 - 9.7.8 Participate in laboratory proficiency testing, as appropriate.
 - 9.8 Exhibit appropriate ethical and professional standards at all times.
 - 9.8.1 Demonstrate an attitude of responsibility and respect toward the patient.
 - 9.8.2 Demonstrate a respectful and cooperative attitude toward professional colleagues.
 - 9.8.3 Demonstrate an honest, forthright manner in carrying out professional tasks.
 - 9.9 Apply principles and procedures for laboratory management, supervision and problem solving, as appropriate.

10. General principles of biology and genetics.

- 10.1 Understand principles of general biology and genetics.
 - 10.1.1 Understand DNA structure (base sequence, pairing, replication, packaging into chromosomes).
 - 10.1.2 Explain transcription, splicing, translation, and variation of gene expression between tissues.
 - 10.1.3 Explain genomic organization (LI repeats, Alu sequences, minisatellites, etc.) and gene structure (regulatory regions, exons, introns, stop codons, polyadenylation signal)
 - 10.1.4 Describe recombinant DNA technology, vector properties, vector capacities, and cloning schemes.
 - 10.1.5 Describe polymorphism and polymorphic markers.
- 10.2 Understand principles of molecular diagnostics.
 - 10.2.1 Explain mode of inheritance at level of organism (dominant, co-dominant, recessive, autosomal, sex-linked, multifactorial, polygenic, inheritance of imprinted genes).
 - 10.2.2 Explain action of gene at cellular level (dominant, dominant-negative, recessive).
 - 10.2.3 Describe molecular mutations and how to test for specific ones (e.g., FMR1 trinucleotide repeat expansion analyzed for repeat size, methylation, and/or presence of protein).
 - 10.2.3.1 Explain gene expression at cellular level (dominant, dominant-negative, or negative.)
 - 10.2.3.2 Keep abreast with new technology.
 - 10.2.4 Discuss basic principles of genetic counseling including pedigree analysis.
 - 10.2.4.1 Have knowledge of Bayesian risk analysis.
 - 10.2.5 Describe risk factors for mutations (advanced maternal age and nondisjunction, advanced paternal age and new autosomal dominant mutations, mutagens and carcinogens).
 - 10.2.6 Correlate molecular genetic results with cytogenetic results for prenatal diagnosis, family studies, and cancer diagnostics or cancer risk assessment.