American Medical Technologists
Molecular Diagnostics Technologist (MDT) Certification Competencies and Examination Specifications

Summary Table

	Work Area	Number of Questions	Percentage of Exam
I.	General Laboratory	36	18%
II.	General Molecular Diagnostics Theory	40	20%
III.	Molecular Laboratory Procedures	20	10%
IV.	Diagnostic Methods	104	52%
Total		200	100%

Question Weightings, Work Areas, Task Areas, and Competencies

Number of Items

[36] I. General Laboratory (18% of exam)

A. Safety
   1. Employ safe laboratory practices
   2. Evaluate and triage biohazard spills
   3. Understand OSHA requirements
   4. Employ the use of personal protective equipment
   5. Evaluate chemical hazards

B. Reagents and Supplies
   1. Examine reagent and sample stability

C. Quality Assurance and Quality Control
   1. Understand QA and QC
   2. Distinguish between QA and QC
   3. Explain the importance of both QA and QC

D. Know and understand HIPAA compliance

E. Safety Data Sheets (SDS)
   1. Describe how to access SDS
   2. Interpret SDS

F. Monitor and maintain laboratory equipment and instrumentation

G. Policies and Procedures
   1. Understand regulatory requirements as they relate to policy development and protocol

H. Basic dilutions

[40] II. General Molecular Diagnostics Theory (20% of exam)

A. DNA/RNA
   1. Define DNA, RNA, and chromosome
   2. Describe the structure of DNA (double helix, anti-parallel, etc.)
   3. Describe differences between DNA and RNA
   4. Describe central dogma (i.e., replication, transcription, translation, and reverse transcription)
   5. Define eukaryote and prokaryote

B. Proteins and protein expression
   1. Describe protein structure
   2. Describe how a protein is translated (e.g., triplet codon, wobble, etc.)

C. Endonucleases and exonucleases
   1. Explain the use of endonucleases and exonucleases in the molecular laboratory

CI. Basic genetics
   1. Understand and know the differences between human, bacterial, viral, and fungal genetics
   2. Knowledge of chromosomal abnormalities (e.g., Down Syndrome, Edwards syndrome, Patau syndrome)
   3. Understand single-gene genetic disorders (e.g., cystic fibrosis, thrombophilia)
   4. Understand germline vs. somatic mutations

CII. Infectious diseases (parasitic, viral, bacterial, fungal)
   1. Understand basic virology (e.g., know which viruses are RNA vs. DNA)
   2. Know which infectious agents are associated with organ transplant patients
   3. Understand the importance and applicability of viral genotyping
   4. Understand the genes associated with antimicrobial resistance in the common bacterial infections (e.g. TB, MRSA, etc.)

CIII. Oncology

1. Understand basic concepts of oncology as they pertain to molecular testing
2. Recognize recurrent hallmark molecular signatures for well-established diagnoses (e.g., BCR/ABL)
3. Describe basic oncology kinase pathways (i.e., how the response to drug is mediated by mutations)

CIV. Pharmacogenomics

[20] III. Molecular Laboratory Procedures (10% of exam)

A. Evaluate sources of contamination (prevention, monitoring, and elimination)/carryover, RNase-free environments

B. Distinguish between molecular and biological contaminants

C. Describe workflow and understand its importance, (unidirectional) test setup, and physical separation

D. Evaluate QC metrics as they relate to molecular testing (quantitative vs. qualitative)

E. Evaluate specimen acceptability (e.g., ID, handling, storage, rejection criteria, aliquots) and preservation

F. Describe a laboratory-developed test and the additional steps required to validate and report

G. Demonstrate proper pipette technique and understand appropriate volume use for each pipette

H. Apply proficiency testing as it pertains to molecular testing

I. Understand regulatory requirements as applicable to molecular testing

J. Explain DNA and RNA extraction procedures
    1. Prepare complimentary DNA from RNA
    2. Determine nucleic acid quantity and quality

[104] IV. Diagnostic Methods (52% of exam)

A. Evaluate the utility and limitations of molecular diagnostic assays

B. Describe primer design (including the avoidance of cross homology and template structure)

C. Evaluate primer performance characteristics

D. Explain how to properly reconstitute reagents (master mix based on run size), controls, calibrators, probes, primers

E. Understand the number and type of controls necessary for each test, with acceptability criteria

F. Know cutoffs for determination of positive and negative tests

G. Evaluate calibrations for quantitative tests (HBV, HIV)

H. Monitor statistics of positive and negative rates
    1. Contamination rates
    2. Test performance
    3. Inhibition

I. Describe standard curve and how to establish linearity, including how to graph and interpret data

J. Understand the fundamental role of microRNA

K. Understand the importance of housekeeping genes

L. Understand how to query and cite mutation references using literature resources

M. Polymerase chain reaction
    1. Define PCR
    2. Describe the principles of PCR
    3. Describe TaqMan probe chemistry
    4. Describe melting curve analysis
    5. Determine PCR test result cutoffs
    6. Understand PCR contamination sources
    7. Define assay ranges for quantitative tests
    8. Explain allele-specific PCR
    9. Explain differences between target and signal amplification
    10. Explain different types of PCRs (including bDNA, nested PCR, RT)
    11. Demonstrate basic skills of performing qualitative PCR
    12. Demonstrate basic skills of performing multiplex PCR
    13. Calculate T_m of DNA
    14. Calculate concentrations and perform dilutions
    15. Interpret C_T graph and values
    16. Interpret differences in C_T values

N. Assays
    1. Describe necessary components of assay validation (sensitivity, specificity, accuracy, precision)

2. Explain the steps in performing the validation study for non-FDA-approved or modified-approved FDA molecular assays (precision, accuracy, reportable range, reference range, analytic sensitivity and specificity) for all specimen types and tests

O. Sequencing
    1. Recognize optimized signal reading patterns
    2. Establish acceptability criteria of primary sequence data
    3. Determination of sense and anti-sense strands
    4. Interpretation of sequence variations
    5. Know limitations and benefits of sequencing
    6. Explain principles of next-generation sequencing (NGS) and whole exome/genome sequencing, including principles related to wet bench procedures and bioinformatics

P. Microarrays
    1. Explain principles of microarrays (genomic and expression, targeted vs. whole genome, oligonucleotide and SNP designs and detection abilities)
    2. Evaluate microarray amplification and detection
    3. Know the limitations and benefits of microarray testing
    4. Employ basic software applications to analyze microarrays and NGS data

Q. Additional Techniques
    1. Demonstrate the basic skills and knowledge to perform FISH
        a. Understand scoring
        b. Determine appropriate target and control probes
        c. Evaluate background fluorescence
        d. Interpret various probe designs and understand when each design is most appropriate
        e. Understand assay limitations and benefits
        f. Understand inherent challenges with various specimen types (fresh sample vs. paraffin-embedded tissue)
    2. Demonstrate basic skills and understanding of theory related to gas chromatography–mass spectrometry (GC-MS)
    3. Demonstrate basic skills and understanding of theory related to other amplification techniques
    4. Electrophoresis
        a. Discuss electrophoresis
        b. Explain how to load gels (calculation and sample quantity)
        c. Provide interpretations
        d. Explain the need for molecular weight markers (MWM)
        e. Explain gel electrophoresis
        f. Demonstrate basic skills related to gel electrophoresis
        g. Interpret gel
        h. Explain capillary electrophoresis

R. Demonstrate basic skills with DNA/RNA extraction

1. Nucleic acid extraction
a. Isolate and purify extraction
b. Employ manual and automated methods
c. Process various specimen types (blood, tissue, body fluids, swabs, etc.)
d. Measure quantity and quality of nucleic acids for testing