

# Technologist in Molecular Biology - MB(ASCP) and MB(ASCP<sup>i</sup>) Examination Content Guideline

## **Examination Model**

The American Society for Clinical Pathology Board of Certification (ASCP BOC) MB certification examination is composed of 100 questions given in a 2-hour 30-minute time frame. All examination questions are multiple-choice with one best answer. The examination is administered using the format of computer adaptive testing (CAT). More information is available on the ASCP BOC website.

The examination questions may be both theoretical and/or procedural. Theoretical questions measure skills necessary to apply knowledge, calculate results, and correlate patient results to disease states. Procedural questions measure skills necessary to perform laboratory techniques and follow quality assurance protocols.

## **Examination Content Areas**

The examination questions encompass the following content areas within molecular biology. Each of these content areas comprises a specific percentage of the overall 100-question examination.

Content Area	Description	Examination Percentage
Molecular Science	Nucleic acid chemistry, basic molecular theory, biochemical reagents, and human/microbial genetics	20 - 25%
Molecular Techniques	Nucleic acid isolation, manipulation of RNA/DNA, separation and detection, nucleic acid amplification, sequencing, and other molecular techniques	30 - 35%
Laboratory Operations	Contamination, specimen processing/preparation/storage, reagents (selection, preparation, storage, disposal, and documentation), assays (performance, validation, and troubleshooting), results (calculation, interpretation, and reporting), quality control, proficiency testing, equipment and instrumentation, guidelines and regulations, continuing education, competency, and safety	15 - 20%
Applications of Molecular Testing	Infectious disease, oncology, genetic disorders, genetic identity, engraftment, and pharmacogenomics	30 - 35%

For a more detailed overview of the examination, refer to the content outline starting on page 2.



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### **Examination Content Guideline**

### **EXAMINATION CONTENT OUTLINE**

- Regulatory questions on the examination are based on U.S. sources (e.g., AABB, FDA, CLIA, etc.).
- The examples provided in this content outline (as indicated by e.g.,) are not limited to those listed.
- The laboratory results and reference ranges on the examination will be provided in both conventional and SI units.

#### I. MOLECULAR SCIENCE

#### 20 - 25% of total examination

### A. Nucleic Acid Chemistry

- 1. Sugars
- 2. Bases
- 3. Chemical structure
- 4. Associated proteins
- 5. Mutations

#### **B.** Basic Molecular Theory

- 1. Replication
- 2. Transcription
- 3. Exons, introns, and splicing
- 4. Translation
- 5. Chromosome structure
- 6. Extrachromosomal structure (e.g., phage, plasmid, mitochondrial)
- 7. Protein structure

#### C. Biochemical Reagents

- 1. Polymerase enzymes
  - a. DNA
  - b. RNA
- 2. Endo and exonuclease enzymes
- 3. Reverse transcriptase
- 4. DNA ligase
- 5. Assay development and design

#### D. Genetics

- 1. Human
- 2. Microbial

#### II. MOLECULAR TECHNIQUES

# 30 - 35% of total examination

#### A. Nucleic Acid Isolation

- 1. Automated methods
- 2. Manual methods

#### **B.** Manipulation of RNA/DNA

- 1. Nucleic acid labeling
- 2. Restriction fragment length

polymorphism (RFLP)

3. Bisulfite conversion

#### C. Separation and Detection

- 1. Electrophoresis
  - a. Gel (including agarose and acrylamide)
  - b. Capillary
- 2. Probe stringency
- 3. Probe hybridization
- 4. Nucleic acid purification
- 5. Probe structure (e.g., TaqMan, FRET, simple, beacon, Scorpions)

#### D. Nucleic Acid Amplification

- 1. Polymerase chain reaction (PCR)
  - a. Oligonucleotide design and preparation
  - b. Reaction optimization
- PCR variations (e.g., real-time, nested/hemi-nested, multiplex, arrays, reverse transcriptase, allele-specific, digital)
- Other (e.g., Hybrid Capture, sequencebased [NASBA], transcription-mediated technology [TMA], loop-mediated isothermal amplification [LAMP])

#### E. Sequencing

- 1. Sanger sequencing
- 2. Next-generation sequencing (NGS)
- 3. Other (e.g., pyrosequencing, RNA sequencing)
- 4. Bioinformatics (e.g., file processing, pipeline, quality score, read depth)

#### F. Other Techniques

- 1. Melt-curve analysis
- 2. Epigenetic modification detection
- 3. Array technology (e.g., bead, microarray)
- 4. Mass spectrometry (e.g., MALDI-TOF MS)



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**Examination Content Guideline** 

#### III. LABORATORY OPERATIONS

#### 15 – 20% of total examination

# A. Contamination (e.g., biological, amplified, and non-amplified nucleic acid)

- 1. Prevention
- 2. Monitoring and detection
- 3. Elimination

#### **B.** Quality Assurance

- Specimen processing, preparation, transport, and storage
  - Evaluate quality and quantity of specimen
  - b. Evaluate quality and quantity of nucleic acid
- 2. Reagent selection, preparation (including calculations), storage, disposal, and documentation
- 3. Assay performance and validation
- 4. Assay troubleshooting
- 5. Result calculation, interpretation, and reporting
- 6. Quality control and proficiency testing
  - a. Assay controls
  - b. Proficiency testing
- 7. Equipment and instrumentation: principles, calibration, maintenance, troubleshooting, and validation

#### C. Guidelines and Regulations

- Test system categories: analyte-specific reagent (ASR), research use only (RUO), in vitro diagnostic (IVD), and laboratorydeveloped procedure (LDP)
- 2. Regulations and Standards: CLIA, TJC, CAP, CMS, CLSI, and FDA

#### D. Personnel

- 1. Continuing education
- 2. Competency

#### E. Safety

- 1. Handling/disposal of hazardous materials
  - a. Biological
  - b. Chemical

# IV. APPLICATIONS OF MOLECULAR TESTING

#### 30 - 35% of total examination

#### A. Infectious Disease

- 1. Qualitative analysis (e.g., MRSA, *Clostridioides difficile*, respiratory pathogens, STI)
- 2. Quantitative analysis (e.g., viral load)
- 3. Genotypic characterization (e.g., molecular epidemiology, viral typing, resistance testing)

#### **B.** Oncology

- 1. Leukemias/lymphomas (e.g., CML, ALL, translocations, clonal rearrangements)
- 2. Solid tumors
- 3. Hereditary cancer syndromes (e.g., breast, colon, ovarian)

#### C. Genetics

- 1. Hemoglobinopathies (e.g., thalassemias, sickle cell anemias)
- 2. Coagulopathies (e.g., factor V Leiden, prothrombin)
- 3. Trinucleotide repeat disorders (e.g., fragile X, Huntington, muscular dystrophy)
- 4. Single gene disorders (e.g., cystic fibrosis, Gaucher, hereditary hemochromatosis)
- 5. Epigenetic disorders (e.g., Prader-Willi, Angelman)
- 6. Disease-associated HLA

#### D. Other

- 1. Genetic identity (e.g., parentage, specimen identification)
- 2. Engraftment
- 3. Pharmacogenomics (e.g., trastuzumab, warfarin, clopidogrel, carbamazepine)

#### **END OF CONTENT GUIDELINE**