Examination Model

The American Society for Clinical Pathology Board of Certification (ASCP BOC) SMB 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. 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.

It is highly recommended that candidates successfully pass the ASCP BOC Scientist in Molecular Biology (MB) certification examination prior to attempting the SMB certification examination.

Role of a Specialist in Molecular Biology (SMB)

- Uses molecular diagnostic methods to detect and characterize acquired and inherited diseases, including malignant, metabolic, and infectious diseases
- Possesses specialized skills in molecular methodologies and operates at an advanced level, providing support in high-complexity testing, test development, and troubleshooting
- Has advanced knowledge of molecular testing methods, clinical applications, and regulatory standards
- Able to assume supervisory responsibilities; specialists serve as leaders, educators, and advisors within their specialty area

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	**5 – 10%**
Molecular Techniques	Nucleic acid isolation, separation and detection, nucleic acid amplification, sequencing, and other molecular techniques	**30 – 35%**
Laboratory Operations	Contamination, specimen processing, reagents, assays (performance, validation, and troubleshooting), results (calculation, interpretation, and reporting), quality control, proficiency testing, instrumentation, guidelines and regulations, continuing education, competency, safety, and laboratory administration	**25 – 30%**
Applications of Molecular Testing	Infectious disease, oncology, genetic disorders, histocompatibility, genetic identity, engraftment, and pharmacogenomics	**35 – 40%**

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

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

5 – 10% 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. Separation and Detection
1. Electrophoresis
   a. Gel (including agarose and acrylamide)
   b. Capillary
2. Blotting and probing procedures (including washing and stringency)
3. Probe hybridization
4. Nucleic acid purification
5. Probe structure (e.g., TaqMan, FRET, simple, beacon, Scorpions)

C. Nucleic Acid Amplification
1. Polymerase chain reaction (PCR)
   a. Oligonucleotide design and preparation
   b. Reaction optimization
2. PCR variations (e.g., real-time, nested, multiplex, arrays, reverse transcriptase, allele-specific)
3. Other: e.g., Hybrid Capture, ligase chain reaction, cleavase, branched DNA (bDNA) technology, sequence-based (NASBA), transcription-mediated technology (TMA), strand displacement amplification (SDA), loop-mediated isothermal amplification (LAMP)

D. Sequencing
1. Sanger sequencing
2. Next-generation sequencing (NGS)
3. Other (e.g., pyrosequencing)
4. Bioinformatics

E. Other Techniques

1. Melt-curve analysis
2. Nucleic acid labeling
3. *In situ* hybridization (ISH)
4. Restriction fragment length polymorphism (RFLP)
5. Epigenetic modification detection
6. Array technology (e.g., bead, microarray)
7. Multiplex ligation-dependent probe amplification (MLPA)
8. Mass spectrophotometry (e.g., MALDI-TOF MS)
9. Multi-locus sequence typing (MLST)

III. Laboratory Operations

25 – 30% 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

1. Specimen processing, preparation, transport, and storage
   a. 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

1. Test system categories: analyte-specific reagent (ASR), research use only (RUO), *in vitro* diagnostic (IVD), and laboratory-developed test (LDT)
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

F. Laboratory Administration

1. Financial Management
   a. Budgets
   b. Capital equipment acquisition
   c. Cost analysis, reimbursement
   d. Purchasing, inventory
2. Operations Management
   a. Laboratory information system (LIS) development, implementation, and maintenance
   b. Facilities management (e.g., laboratory design)
   c. Intra/Interdepartmental relations (e.g., communications with clinical staff)
3. Personnel management
   a. Motivation
   b. Staffing, productivity
   c. Counseling/disciplinary action
4. Quality Management
   a. Perform advanced statistical analysis
   b. Assay/method/instrument selection and design
   c. Assay/method/instrument evaluation, validation, and verification
   d. Quantitative calculations (e.g., standard curves)

IV. Applications of Molecular Testing

35 – 40% 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, MTHFR)
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. Mitochondrial disorders

D. Other

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

END OF CONTENT GUIDELINE