ASCP BOARD OF CERTIFICATION

# SPECIALIST AND INTERNATIONAL SPECIALIST IN MOLECULAR BIOLOGY, SMB(ASCP) AND SMB(ASCP$^{i}$)

## EXAMINATION CONTENT GUIDELINE

### EXAMINATION MODEL

The SMB(ASCP) and SMB(ASCP$^{i}$) certification examinations are composed of 100 questions given in a 2 hour 30 minute time frame. All exam questions are multiple-choice with one best answer.

Exam 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. Additionally, regulatory questions are based on U.S. sources (e.g., AABB, FDA, CLIA, etc.).

### EXAMINATION CONTENT AREAS

The SMB exam questions encompass the following content areas within Molecular Biology: Molecular Science, Molecular Techniques, Laboratory Operations, and Applications of Molecular Testing. Each of these content areas comprises a specific percentage of the overall 100-question exam. The content areas and percentages are described below:

| CONTENT AREA | DESCRIPTION | EXAM 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 specific overview of the SMB exam, please refer to the **CONTENT OUTLINE** starting on page 2.

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## EXAMINATION CONTENT OUTLINE

### I. MOLECULAR SCIENCE (5 – 10%)

#### 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%)

#### 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%)

#### 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%)

### 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)

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**Examples provided (as indicated by e.g.) are not limited to those listed.**

**All Board of Certification examinations use conventional and SI units for results and reference ranges.**

***END OF CONTENT GUIDELINE***