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MB PRACTICE ANALYSIS REPORT

For Development of

MB(ASCP) & MB(ASCP^{i})

Content Guideline and Examination

For MB Exam Publication July 1, 2023

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INTRODUCTION

The purpose of conducting a practice analysis (a.k.a. job analysis or job task analysis) is to provide the foundation of a certification examination by defining practice in a profession. The practice analysis provides evidence of content validation. It is required by psychometric standards and is considered best practice for high-stakes examination development. It also ensures the certification examination is fair, valid, job-related, and most importantly, legally defensible (Chinn and Hertz 2010)[1]. The ASCP Board of Certification (BOC) conducts a practice analysis approximately every five years in accordance with ASCP BOC Policy and requirements of the accrediting body, ANAB (ANSI [American National Standards Institute] National Accreditation Board), under ISO/IEC 17024.

A practice analysis is a formal process for determining or verifying the responsibilities of individuals in the job/profession, the knowledge individuals must possess, and the skills and abilities necessary to perform the job at a minimally competent level. It provides a complete and modern understanding of the duties and functions of practicing laboratory professionals. The practice analysis process is carried out in the form of a survey that lists all the tasks thought to be completed by practicing laboratory professionals. The results of the practice analysis inform the specifications and content of the ASCP BOC certification examinations. This ensures that the examinations are reflective of current practices, and it helps guarantee that individuals who become certified are current and up-to-date on the state of practice and are competent to perform as certified laboratory professionals.

PRACTICE ANALYSIS PROCESS

The ASCP BOC conducted a practice analysis survey to inform the Technologist in Molecular Biology (MB) certification examination category.

The process for conducting a practice analysis consists of the following steps:

1. Survey Development
2. Demographics
3. Task Inventory – Knowledge and Skill Questions
4. Rating Criteria
5. Survey Construction
6. Pilot Testing and Revision
7. Survey Distribution
8. Survey Analysis
9. Committee Review and Discussion
10. Examination Content Guideline, Standard Setting, and Exam Publication

SURVEY DEVELOPMENT

During the July 2021 ASCP BOC examination committee meeting, the Molecular Biology Examination Committee provided the input and discussion to develop a practice analysis survey. The committee members (subject matter experts) collectively discussed all pertinent aspects of their profession to design a concise survey to extract useful feedback from field professionals while maximizing response rate. The survey had two main components: demographics and task inventory with appropriate rating scales for each.

[1] Chinn, R.N., and N.R. Hertz. 2010. *Job Analysis: A Guide for Credentialing Organizations.* Lexington: Council on Licensure, Enforcement and Regulation (CLEAR).

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DEMOGRAPHICS

The demographic questions asked respondents about their experience, education, job titles, type of facility, gender, age, etc. The purpose of these questions was to aid the committee in deciding whether the sample of respondents obtained was representative of the profession in general.

TASK INVENTORY – KNOWLEDGE AND SKILL QUESTIONS

The committee developed a series of job-related task questions that formed the body of the survey. The survey had five major sections:

- Specimen Collection, Preparation, and Processing
- Molecular Diagnostic Techniques
- Laboratory Operations
- Molecular Biology Specimen Analysis
- Laboratory Management/Supervision

RATING CRITERIA

The rating scale used for the job-related task questions asked respondents to indicate whether or not they currently performed specific tasks as part of their jobs. If the respondents noted that they did not perform a task, they were asked to indicate whether they were expected to have knowledge of the concept or protocol to perform their jobs.

SURVEY CONSTRUCTION

The practice analysis survey was created and delivered through Key Survey. Using an electronic tool allowed survey review and testing via the internet, email tracking of respondents using email addresses, and the ability to send email reminders for completion of the survey.

PILOT TESTING AND REVISION

The Molecular Biology Examination Committee tested a pilot version of the survey. They reviewed and revised different aspects of the survey (e.g., information correctness, grammar/spelling, survey branching, etc.). The pilot testing comments and edits informed the final version of the survey.

SURVEY DISTRIBUTION

The Molecular Biology Examination Committee determined that the survey should be sent to all current MB certificants in the ASCP BOC Personify database. The survey was open for a 3-week period between November 3, 2021 – November 24, 2021. ASCP BOC staff also directly emailed the survey to the committee and encouraged the committee membership to disseminate the survey to their colleagues. Additionally, the survey link was shared with The Association of Genetic Technologists (AGT), and posted on ASCP social media sites (i.e., Facebook, Instagram, and LinkedIn).

SURVEY ANALYSIS

The respondents were asked to answer all questions and rate all tasks in the survey. The tasks were divided amongst five major sections (Specimen Collection, Preparation, and Processing; Molecular Diagnostic Techniques; Laboratory Operations; Molecular Biology Specimen Analysis; and Laboratory Management/Supervision).

Responses from individuals currently working as a supervisor or manager were considered to be inappropriate for the entry-level MB certification category and were therefore excluded from the technologist-level analysis.

Any individuals not currently practicing (e.g., retired, unemployed, or simply not working in a molecular diagnostics laboratory) were removed from the practice analysis survey.

COMMITTEE REVIEW AND DISCUSSION

During the July 2022 examination committee meeting, the Molecular Biology Examination Committee reviewed the practice analysis results. They agreed that the demographic results accurately reflected the MB population **(Appendix A).**

In general, tasks performed by at least 40% of the respondents were retained on the task lists and considered valid to be included on the examination. The committee reviewed all tasks performed by less than 40% of the respondents. If the committee determined that these tasks were critical to patient care and/or were up-and-coming in practice, then the task was retained on the task list and considered valid for the examination. If the task was considered outdated or too esoteric, then it was removed from the task list and not included on the exam. The committee decisions were compiled into the Final Task List for MB **(Appendix B)** which was used to inform the exam content guideline and the content for the certification exam.

EXAMINATION CONTENT GUIDELINE, STANDARD SETTING, AND EXAM PUBLICATION

The Molecular Biology Examination Committee revised the MB exam content guideline based on the Final Task List for MB **(Appendix B)**. They reviewed the content area percentages and determined no changes were needed. The committee reviewed the exam database according to the updated content guideline and deleted or revised questions accordingly. They wrote new questions to fulfill the content guideline, and reclassified questions according to the updated guideline. After this work was completed, the committee performed standard setting to determine the pass point of the exam, and the new exam was published.

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Appendix A

TECHNOLOGIST IN MOLECULAR BIOLOGY (MB)

DEMOGRAPHIC ANALYSIS

Total usable survey respondents: 178

Usable individual respondents met the following criteria:

- Currently employed as a medical laboratory professional working in a molecular diagnostics laboratory
- Includes respondents who fit any of the following criteria:
  o Laboratory/molecular technologist
  o Research and development technologist/scientist

Summary of demographic results:

- Certifications:
  - 94% are MB certified.
  - 14% are MLS certified.
  - 4% are MLT certified.
  - 2% are CG certified.
  - 2% are CT certified.
- Highest level of education completed:
  - 42% have a baccalaureate degree.
  - 31% have a master's degree.
  - 16% have a postbaccalaureate program certificate.
  - 7% have a doctorate (MD, PhD, DCLS).
- Years of experience:
  - Mean: 8 years
  - Minimum: 1 year
  - Maximum: 30 years
- Geographic Distribution: there are respondents from across the U.S. The states with the highest response rate include:
  - 13% from Texas.
  - 11% from California.
  - 5% each from Florida, Illinois, Minnesota, and Utah.
- Facility:
  - 44% work in hospitals.
  - 44% work in in independent (reference/commercial) laboratories.
  - 5% work in public health laboratories.
- Age:
  - Mean: 38 years of age
  - Minimum: 23 years of age
  - Maximum: 65 years of age
- Gender:
  - 64% are female.
  - 30% are male.

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Appendix B

TECHNOLOGIST IN MOLECULAR BIOLOGY (MB)

FINAL TASK LIST (TOPICS KEPT ON EXAM BASED ON PRACTICE ANALYSIS RESULTS)

SPECIMEN COLLECTION, PREPARATION, AND PROCESSING
Specimen Collection and Processing
Verify containers, anticoagulants, transport media, and preservatives that are appropriate for specimen type/test
Identify factors important for the transport of specimens
Store specimens
Evaluate acceptability of specimens for requested test(s)
Process specimens for nucleic acid isolation
Take corrective actions for unsatisfactory specimens
Preparation of RNA/DNA
Select appropriate nucleic isolation method
Perform nucleic acid isolation
Perform cell-free nucleic acid isolation
Evaluate quality and quantity of nucleic acid
Store nucleic acid
MOLECULAR DIAGNOSTIC TECHNIQUES
Manipulation of RNA/DNA
Label nucleic acid
Perform restriction fragment length polymorphism (RFLP)
Perform bisulfite conversions
Polymerase Chain Reaction (PCR)
Design oligonucleotides/primers
Prepare oligonucleotides/primers
Determine optimal reaction conditions for the procedure
Conventional PCR
Allele-specific PCR
Reverse transcriptase (RT) PCR
Nested/hemi-nested PCR
Qualitative real time PCR
Quantitative real time PCR
Multiplex PCR
Digital PCR
Melt-curve analysis
Other Techniques
Transcription-mediated amplification (i.e., TMA, NASBA)

Loop-mediated isothermal amplification (LAMP)
CRISPR
Mass spectrometry (e.g., MALDI-TOF MS)
Separation Techniques
Determine method and reagents for nucleic acid separation
Gel electrophoresis
Capillary gel electrophoresis
Hybridization Techniques
Hybrid capture
Bead array
Microarray
Sequencing Techniques
Determine and select appropriate sequencing method for testing
Sanger sequencing
Pyrosequencing
Next-generation sequencing (NGS)
Bioinformatics (file processing, pipeline, etc.)
Variant interpretation
LABORATORY OPERATIONS
Test Resulting
Evaluate test results
Document test results
Correlate test results with other lab results and/or clinical information
Recognize/troubleshoot failures and variances
Report results to laboratory authority
Report results to appropriate public health organization as required
Maintain archive of results
Verify receipt of patient consent forms, when required
Maintain records and laboratory database
Reagents
Select, prepare, label, and store reagents
Evaluate reagent quality
Perform calculations and unit conversions to prepare reagents
Maintain reagent log
Equipment
Operate, calibrate, and/or maintain equipment
Identify, troubleshoot, and document malfunctions and corrective actions
Record daily temperatures and equipment functions
Contamination
Prevent biological and nucleic acid contamination

Detect biological and nucleic acid contamination
Remove biological and nucleic acid contamination
Cleaning and Stocking
Maintain inventory and adequate stocks of laboratory supplies and chemicals
Employ cleaning procedures
Safety
Follow established procedures for general laboratory safety
Handle/dispose of hazardous materials – biological
Document correct handling and disposal of biological hazardous materials
Handle/dispose of hazardous materials – chemical
Document correct handling and disposal of chemical hazardous materials
Quality Assurance
Perform quality control and document quality indicators
Review and evaluate quality indicators
Perform calibration and verify calibrators
Review results
Verify accuracy of results
Perform proficiency testing (PT)
Train staff and students
Assess peer competency
Validation/Verification
Verify FDA-approved assays
Validate new equipment
Design new laboratory-developed procedures (LDPs)
Optimize new LDPs
Validate LDPs
Design and implement assay automation (e.g., program liquid handlers)
Statistics
Perform statistical analyses (i.e., positive predictive values)
Method evaluation, validation, and/or verification
Create standard curves
Calculate clinical limits / sensitivity and specificity
Analyze Levey-Jennings plots
MOLECULAR BIOLOGY SPECIMEN ANALYSIS
Infectious Disease
HIV
HPV
Respiratory pathogens (e.g., *Bordetella* spp.)
Gastrointestinal pathogens (e.g., Norovirus)
Transplant pathogens (e.g., CMV, BK)

Bacterial resistance markers (e.g., MRSA, VRE, KPC, NDM)
Hepatitis pathogens (e.g., HBV, HCV)
Genitourinary pathogens (e.g., GC, CT)
Fungal pathogens (e.g., *Aspergillus* spp.)
Gastrointestinal parasites (e.g., *Giardia* spp.)
Bloodborne parasites (e.g., *Plasmodium* spp.)
CNS pathogens (e.g., meningitis)
Hematology/Oncology
Leukemias/lymphomas (e.g., CML, ALL, translocations, clonal rearrangements)
Solid tumor testing
Hereditary cancer syndromes (e.g., breast, colon, ovarian)
Personalized cancer treatment
Genetics
Pharmacogenomics (e.g., trastuzumab, warfarin, clopidogrel, carbamazepine)
Hemoglobinopathies (e.g., thalassemias, sickle cell anemias)
Coagulopathies (e.g., factor V Leiden, prothrombin, MTHFR)
Trinucleotide repeat disorders (e.g., fragile X, Huntington, muscular dystrophy)
Single gene disorders (e.g., cystic fibrosis, Gaucher, hereditary hemochromatosis)
Epigenetic disorders (e.g., Prader-Willi, Angelman)
Disease-associated HLA
Identity Testing
Engraftment
Sample identity and/or specimen contamination
Paternity