

## **American Society for Clinical Pathology Board of Certification (ASCP BOC)**

### **Practice Analysis Report: Scientist in Molecular Biology - MB Specialist in Molecular Biology - SMB**

For Development of:

Content Guideline and July 1, 2023 Examination Publication for  
MB(ASCP) & MB(ASCP<sup>i</sup>) Credentials

and

Content Guideline and June 1, 2026 Examination Publication for  
SMB(ASCP) & SMB(ASCP<sup>i</sup>) Credentials

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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 credentialing 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 examination is fair, valid, job-related, and most importantly, legally defensible (Chinn and Hertz 2010)<sup>1</sup>. The American Society for Clinical Pathology Board of Certification (ASCP 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 practice safely and effectively in the field. 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 examinations. This ensures that the examinations are reflective of current practices, and it helps guarantee that individuals who become credentialed are current and up-to-date on the state of practice and perform safely and effectively as credentialed laboratory professionals.

## Practice Analysis Process

The ASCP BOC conducted a practice analysis survey to inform the Scientist in Molecular Biology – MB and Specialist in Molecular Biology – SMB examination categories. The process for conducting a practice analysis consists of the following steps:

1. Survey Development
2. Demographics
3. Task Inventory – Skill Questions
4. Rating Criteria
5. Survey Construction
6. Pilot Testing and Revision
7. Survey Distribution
8. Survey Analysis
9. Subject Matter Expert (SME) Review and Discussion
10. Examination Revision and Publication

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

## Survey Development

During the July 2021 ASCP BOC Molecular Biology Examination Committee Meeting, the examination committee volunteers, serving as subject matter experts (SMEs), provided the input and discussion to develop a practice analysis survey. The SMEs 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.

## Demographics

The demographic questions asked respondents about their experience, education, job title, type of facility, gender, age, etc. The purpose of these questions was to aid the SMEs in deciding whether the sample of respondents obtained was representative of the profession in general. The demographic data also provided analytic categories that allowed refinement of the survey population to utilize only those responses from individuals at the targeted professional level.

## Task Inventory – Skill Questions

The SMEs 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 indicated that they did not perform a task, they were asked to select 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 SMEs tested a pilot version of the survey. They reviewed and revised different aspects of the survey (e.g., information correctness, grammar/spelling, survey branching). The pilot testing comments and edits informed the final version of the survey.

## Survey Distribution

The SMEs determined that the survey should be sent to all current MB(ASCP) and SMB(ASCP) credential holders in the ASCP BOC Personify database. The survey was open for a 3-week period between November 3 – 24, 2021. The ASCP BOC team also directly emailed the survey to the SMEs and encouraged these volunteers to disseminate the survey to their colleagues. Additionally, the survey link was shared with The Association of Genetic Technologists (AGT), and posted on ASCP BOC 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. Responses from individuals currently working as a supervisor or manager were considered to be inappropriate for the entry-level MB examination category and were therefore excluded from the analysis. These responses were used in the analysis for the SMB examination category. 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.

## SME Review and Discussion

During the July 2022 Molecular Biology Examination Committee Meeting, the SMEs reviewed the practice analysis results. They agreed that the demographic results accurately reflected the MB and SMB populations (**Appendices A & C**).

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 examinations. The SMEs reviewed all tasks performed by less than 40% of the respondents. If the SMEs determined that a task was critical to patient care and/or was up-and-coming in practice, then it was retained on the task lists and considered valid for the examinations. If a task was considered outdated or too esoteric, then it was removed from the task lists and not included on the examinations. The task decisions were compiled into the Final Task Lists for MB and SMB (**Appendices B & D**) which were used to inform the examination content guidelines and the content for the examinations.

## Examination Revision and Publication

The SMEs revised the MB and SMB Examination Content Guidelines based on the Final Task Lists for MB and SMB (**Appendices B & D**). They reviewed the content area percentages and determined no changes were needed. The SMEs also reviewed the examination databases according to the updated content guidelines and deleted or revised questions accordingly. They wrote new questions to fulfill the content guidelines, and reclassified questions according to the updated guidelines. After this work was completed, the SMEs performed standard setting to determine the pass point of each examination, and the new MB examination was published on July 1, 2023, and the new SMB examination was published on June 1, 2026.



# MB Demographic Analysis

There were 178 total usable survey respondents. Usable respondents met the following criterion:

- Currently employed as a medical laboratory professional working in a molecular diagnostics laboratory as a laboratory/molecular scientist or research and development scientist

ASCP BOC Credentials
<b>Respondents may have multiple credentials. The most common credentials included:</b>
<ul style="list-style-type: none"> <li>• 94% Scientist in Molecular Biology - MB(ASCP) or MB(ASCP<sup>i</sup>)</li> <li>• 14% Medical Laboratory Scientist - MLS(ASCP) or MLS(ASCP<sup>i</sup>)</li> <li>• 4% Medical Laboratory Technician - MLT(ASCP) or MLT(ASCP<sup>i</sup>)</li> <li>• 2% Scientist in Cytogenetics - CG(ASCP) or CG(ASCP<sup>i</sup>)</li> <li>• 2% Cytologist - CT(ASCP) or CT(ASCP<sup>i</sup>)</li> </ul>

Experience
<b>Years of experience:</b>
<ul style="list-style-type: none"> <li>• Mean: 8</li> <li>• Minimum: 1</li> <li>• Maximum: 30</li> </ul>

Age
<b>Years of age:</b>
<ul style="list-style-type: none"> <li>• Mean: 38</li> <li>• Minimum: 23</li> <li>• Maximum: 65</li> </ul>

Geographic Distribution
<b>There were respondents from across the U.S. The highest percentage were from:</b>
<ul style="list-style-type: none"> <li>• 13% Texas</li> <li>• 11% California</li> <li>• 5% Florida</li> <li>• 5% Illinois</li> <li>• 5% Minnesota</li> <li>• 5% Utah</li> </ul>

Facility
<b>Respondents worked in the following types of facilities:</b>
<ul style="list-style-type: none"> <li>• 44% hospitals</li> <li>• 44% independent (reference/commercial) laboratories</li> <li>• 5% public health laboratories</li> <li>• 7% other types of facilities</li> </ul>

Education
<b>Highest level of education completed:</b>
<ul style="list-style-type: none"> <li>• 42% baccalaureate degree</li> <li>• 16% postbaccalaureate program certificate</li> <li>• 31% master's degree</li> <li>• 10% doctorate (MD, PhD, DCLS) or postdoctoral training</li> </ul>

Gender
<ul style="list-style-type: none"> <li>• 64% female</li> <li>• 29% male</li> <li>• 1% nonbinary</li> <li>• 6% chose not to answer</li> </ul>

## MB Final Task List

The following topics were included on the MB examination based on the practice analysis results (see SME Review and Discussion on page 5).

<b>Specimen Collection, Preparation, and Processing</b>
<b>Specimen Collection and Processing</b>
<ul style="list-style-type: none"> <li>• Verify containers, anticoagulants, transport media, and preservatives that are appropriate for specimen type/test</li> <li>• Identify factors important for the transport of specimens</li> <li>• Store specimens</li> <li>• Evaluate acceptability of specimens for requested test(s)</li> <li>• Process specimens for nucleic acid isolation</li> <li>• Take corrective actions for unsatisfactory specimens</li> </ul>
<b>Preparation of RNA/DNA</b>
<ul style="list-style-type: none"> <li>• Select appropriate nucleic acid isolation method</li> <li>• Perform nucleic acid isolation</li> <li>• Perform cell-free nucleic acid isolation</li> <li>• Evaluate quality and quantity of nucleic acid</li> <li>• Store nucleic acid</li> </ul>

<b>Molecular Diagnostic Techniques</b>
<b>Manipulation of RNA/DNA</b>
<ul style="list-style-type: none"> <li>• Label nucleic acid</li> <li>• Perform restriction fragment length polymorphism (RFLP)</li> <li>• Perform bisulfite conversions</li> </ul>
<b>Polymerase Chain Reaction (PCR)</b>
<ul style="list-style-type: none"> <li>• Design oligonucleotides/primers</li> <li>• Prepare oligonucleotides/primers</li> <li>• Determine optimal reaction conditions for the procedure</li> <li>• Conventional PCR</li> <li>• Allele-specific PCR</li> <li>• Reverse transcriptase (RT) PCR</li> <li>• Nested/hemi-nested PCR</li> <li>• Qualitative real time PCR</li> <li>• Quantitative real time PCR</li> <li>• Multiplex PCR</li> <li>• Digital PCR</li> <li>• Melt-curve analysis</li> </ul>

<b>Other Techniques</b>
<ul style="list-style-type: none"> <li>• Transcription-mediated amplification (i.e., TMA, NASBA)</li> <li>• Loop-mediated isothermal amplification (LAMP)</li> <li>• CRISPR</li> <li>• Mass spectrometry (e.g., MALDI-TOF MS)</li> </ul>
<b>Separation Techniques</b>
<ul style="list-style-type: none"> <li>• Determine method and reagents for nucleic acid separation</li> <li>• Gel electrophoresis</li> <li>• Capillary gel electrophoresis</li> </ul>
<b>Hybridization Techniques</b>
<ul style="list-style-type: none"> <li>• Hybrid capture</li> <li>• Bead array</li> <li>• Microarray</li> </ul>
<b>Sequencing Techniques</b>
<ul style="list-style-type: none"> <li>• Determine and select appropriate sequencing method for testing</li> <li>• Sanger sequencing</li> <li>• Pyrosequencing</li> <li>• Next-generation sequencing (NGS)</li> <li>• Bioinformatics (file processing, pipeline, etc.)</li> <li>• Variant interpretation</li> </ul>

<b>Laboratory Operations</b>
<b>Test Resulting</b>
<ul style="list-style-type: none"> <li>• Evaluate test results</li> <li>• Document test results</li> <li>• Correlate test results with other lab results and/or clinical information</li> <li>• Recognize/troubleshoot failures and variances</li> <li>• Report results to laboratory authority</li> <li>• Report results to appropriate public health organization as required</li> <li>• Maintain archive of results</li> <li>• Verify receipt of patient consent forms, when required</li> <li>• Maintain records and laboratory database</li> </ul>



# Scientist in Molecular Biology - MB Specialist in Molecular Biology - SMB Practice Analysis Report Appendix B

<b>Reagents</b>
<ul style="list-style-type: none"> <li>Select, prepare, label, and store reagents</li> <li>Evaluate reagent quality</li> <li>Perform calculations and unit conversions to prepare reagents</li> <li>Maintain reagent log</li> </ul>
<b>Equipment</b>
<ul style="list-style-type: none"> <li>Operate, calibrate, and/or maintain equipment</li> <li>Identify, troubleshoot, and document malfunctions and corrective actions</li> <li>Record daily temperatures and equipment functions</li> </ul>
<b>Contamination</b>
<ul style="list-style-type: none"> <li>Prevent biological and nucleic acid contamination</li> <li>Detect biological and nucleic acid contamination</li> <li>Remove biological and nucleic acid contamination</li> </ul>
<b>Cleaning and Stocking</b>
<ul style="list-style-type: none"> <li>Maintain inventory and adequate stocks of laboratory supplies and chemicals</li> <li>Employ cleaning procedures</li> </ul>
<b>Safety</b>
<ul style="list-style-type: none"> <li>Follow established procedures for general laboratory safety</li> <li>Handle/dispose of hazardous materials – biological</li> <li>Document correct handling and disposal of biological hazardous materials</li> <li>Handle/dispose of hazardous materials – chemical</li> <li>Document correct handling and disposal of chemical hazardous materials</li> </ul>
<b>Quality Assurance</b>
<ul style="list-style-type: none"> <li>Perform quality control and document quality indicators</li> <li>Review and evaluate quality indicators</li> <li>Perform calibration and verify calibrators</li> <li>Review results</li> <li>Verify accuracy of results</li> <li>Perform proficiency testing (PT)</li> <li>Train staff and students</li> <li>Assess peer competency</li> </ul>
<b>Validation/Verification</b>
<ul style="list-style-type: none"> <li>Verify FDA-approved assays</li> <li>Validate new equipment</li> <li>Design new laboratory-developed procedures (LDPs)</li> <li>Optimize new LDPs</li> <li>Validate LDPs</li> </ul>

<ul style="list-style-type: none"> <li>Design and implement assay automation (e.g., program liquid handlers)</li> </ul>
<b>Statistics</b>
<ul style="list-style-type: none"> <li>Perform statistical analyses (i.e., positive predictive values)</li> <li>Method evaluation, validation, and/or verification</li> <li>Create standard curves</li> <li>Calculate clinical limits / sensitivity and specificity</li> <li>Analyze Levey-Jennings plots</li> </ul>

<b>Molecular Biology Specimen Analysis</b>
<b>Infectious Disease</b>
<ul style="list-style-type: none"> <li>HIV</li> <li>HPV</li> <li>Respiratory pathogens (e.g., Bordetella spp.)</li> <li>Gastrointestinal pathogens (e.g., Norovirus)</li> <li>Transplant pathogens (e.g., CMV, BK)</li> <li>Bacterial resistance markers (e.g., MRSA, VRE, KPC, NDM)</li> <li>Hepatitis pathogens (e.g., HBV, HCV)</li> <li>Genitourinary pathogens (e.g., GC, CT)</li> <li>Fungal pathogens (e.g., Aspergillus spp.)</li> <li>Gastrointestinal parasites (e.g., Giardia spp.)</li> <li>Bloodborne parasites (e.g., Plasmodium spp.)</li> <li>CNS pathogens (e.g., meningitis)</li> </ul>
<b>Hematology/Oncology</b>
<ul style="list-style-type: none"> <li>Leukemias/lymphomas (e.g., CML, ALL, translocations, clonal rearrangements)</li> <li>Solid tumor testing</li> <li>Hereditary cancer syndromes (e.g., breast, colon, ovarian)</li> <li>Personalized cancer treatment</li> </ul>
<b>Genetics</b>
<ul style="list-style-type: none"> <li>Pharmacogenomics (e.g., trastuzumab, warfarin, clopidogrel, carbamazepine)</li> <li>Hemoglobinopathies (e.g., thalassemias, sickle cell anemias)</li> <li>Coagulopathies (e.g., factor V Leiden, prothrombin, MTHFR)</li> <li>Trinucleotide repeat disorders (e.g., fragile X, Huntington, muscular dystrophy)</li> <li>Single gene disorders (e.g., cystic fibrosis, Gaucher, hereditary hemochromatosis)</li> <li>Epigenetic disorders (e.g., Prader-Willi, Angelman)</li> <li>Disease-associated HLA</li> </ul>



ASCP BOARD OF  
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**Scientist in Molecular Biology - MB**  
**Specialist in Molecular Biology - SMB**  
Practice Analysis Report  
**Appendix B**

**Identity Testing**

- Engraftment
- Sample identity and/or specimen contamination
- Paternity



## SMB Demographic Analysis

There were 74 total usable survey respondents. Usable 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:
  - SMB certified
  - Technical supervisor/QA
  - Manager/administrator
  - Director
  - Educator

ASCP BOC Credentials
<b>Respondents may have multiple credentials. The most common credentials included:</b>
<ul style="list-style-type: none"> <li>• 92% Scientist in Molecular Biology - MB(ASCP) or MB(ASCP<sup>i</sup>)</li> <li>• 16% Medical Laboratory Scientist - MLS(ASCP) or MLS(ASCP<sup>i</sup>)</li> <li>• 11% Specialist in Molecular Biology - SMB(ASCP) or SMB(ASCP<sup>i</sup>)</li> <li>• 4% Medical Laboratory Technician - MLT(ASCP) or MLT(ASCP<sup>i</sup>)</li> <li>• 4% Cytologist - CT(ASCP) or CT(ASCP<sup>i</sup>)</li> </ul>

Geographic Distribution
<b>There were respondents from across the U.S. The highest percentage were from:</b>
<ul style="list-style-type: none"> <li>• 11% Texas</li> <li>• 10% California</li> <li>• 7% Minnesota</li> <li>• 5% Michigan, New Jersey, Pennsylvania</li> </ul>

Education
<b>Highest level of education completed:</b>
<ul style="list-style-type: none"> <li>• 30% baccalaureate degree</li> <li>• 4% postbaccalaureate program certificate</li> <li>• 47% master's degree</li> <li>• 4% doctorate (MD, PhD, DCLS) or postdoctoral training</li> <li>• 15% postdoctoral training</li> </ul>

Experience
<b>Years of experience:</b>
<ul style="list-style-type: none"> <li>• Mean: 14</li> <li>• Minimum: 2</li> <li>• Maximum: 38</li> </ul>

Age
<b>Years of age:</b>
<ul style="list-style-type: none"> <li>• Mean: 44</li> <li>• Minimum: 25</li> <li>• Maximum: 65</li> </ul>

Facility
<b>Respondents worked in the following types of facilities:</b>
<ul style="list-style-type: none"> <li>• 42% hospitals</li> <li>• 43% independent (reference/commercial) laboratories</li> <li>• 10% public health laboratories</li> <li>• 5% other types of facilities</li> </ul>

Gender
<ul style="list-style-type: none"> <li>• 73% female</li> <li>• 19% male</li> <li>• 8% chose not to answer</li> </ul>

## SMB Final Task List

The following topics were included on the SMB examination based on the practice analysis results (see SME Review and Discussion on page 5).

<b>Specimen Collection, Preparation, and Processing</b>
<b>Specimen Collection and Processing</b>
<ul style="list-style-type: none"> <li>• Verify containers, anticoagulants, transport media, and preservatives that are appropriate for specimen type/test</li> <li>• Identify factors important for the transport of specimens</li> <li>• Store specimens</li> <li>• Evaluate acceptability of specimens for requested test(s)</li> <li>• Process specimens for nucleic acid isolation</li> <li>• Take corrective actions for unsatisfactory specimens</li> </ul>
<b>Preparation of RNA/DNA</b>
<ul style="list-style-type: none"> <li>• Select appropriate nucleic isolation method</li> <li>• Perform nucleic acid isolation</li> <li>• Perform cell-free nucleic acid isolation</li> <li>• Evaluate quality and quantity of nucleic acid</li> <li>• Store nucleic acid</li> </ul>

<b>Molecular Diagnostic Techniques</b>
<b>Manipulation of RNA/DNA</b>
<ul style="list-style-type: none"> <li>• Label nucleic acid</li> <li>• Perform restriction fragment length polymorphism (RFLP)</li> <li>• Perform bisulfite conversions</li> </ul>
<b>Polymerase Chain Reaction (PCR)</b>
<ul style="list-style-type: none"> <li>• Design oligonucleotides/primers</li> <li>• Prepare oligonucleotides/primers</li> <li>• Determine optimal reaction conditions for the procedure</li> <li>• Conventional PCR</li> <li>• Allele-specific PCR</li> <li>• Reverse transcriptase (RT) PCR</li> <li>• Nested/hemi-nested PCR</li> <li>• Qualitative real time PCR</li> <li>• Quantitative real time PCR</li> <li>• Multiplex PCR</li> <li>• Digital PCR</li> <li>• Melt-curve analysis</li> </ul>

<b>Other Techniques</b>
<ul style="list-style-type: none"> <li>• Transcription-mediated amplification (i.e., TMA, NASBA)</li> <li>• Loop-mediated isothermal amplification (LAMP)</li> <li>• CRISPR</li> <li>• Mass spectrometry (e.g., MALDI-TOF MS)</li> </ul>
<b>Separation Techniques</b>
<ul style="list-style-type: none"> <li>• Determine method and reagents for nucleic acid separation</li> <li>• Gel electrophoresis</li> <li>• Capillary gel electrophoresis</li> </ul>
<b>Hybridization Techniques</b>
<ul style="list-style-type: none"> <li>• Determine and select appropriate hybridization method for testing</li> <li>• Hybrid capture</li> <li>• Bead array</li> <li>• Microarray</li> <li>• <i>in situ</i> hybridization</li> </ul>
<b>Sequencing Techniques</b>
<ul style="list-style-type: none"> <li>• Determine and select appropriate sequencing method for testing</li> <li>• Sanger sequencing</li> <li>• Pyrosequencing</li> <li>• Next-generation sequencing (NGS)</li> <li>• Bioinformatics (file processing, pipeline, etc.)</li> <li>• Variant interpretation</li> </ul>

<b>Laboratory Operations</b>
<b>Test Resulting</b>
<ul style="list-style-type: none"> <li>• Evaluate test results</li> <li>• Document test results</li> <li>• Correlate test results with other lab results and/or clinical information</li> <li>• Recognize/troubleshoot failures and variances</li> <li>• Report results to laboratory authority</li> <li>• Report results to appropriate public health organization as required</li> </ul>



# Scientist in Molecular Biology - MB Specialist in Molecular Biology - SMB

## Practice Analysis Report

### Appendix D

<ul style="list-style-type: none"> <li>Maintain archive of results</li> <li>Verify receipt of patient consent forms, when required</li> <li>Maintain records and laboratory database</li> </ul>
<b>Reagents</b>
<ul style="list-style-type: none"> <li>Select, prepare, label, and store reagents</li> <li>Evaluate reagent quality</li> <li>Perform calculations and unit conversions to prepare reagents</li> <li>Maintain reagent log</li> </ul>
<b>Equipment</b>
<ul style="list-style-type: none"> <li>Operate, calibrate, and/or maintain equipment</li> <li>Identify, troubleshoot, and document malfunctions and corrective actions</li> <li>Record daily temperatures and equipment functions</li> </ul>
<b>Contamination</b>
<ul style="list-style-type: none"> <li>Prevent biological and nucleic acid contamination</li> <li>Detect biological and nucleic acid contamination</li> <li>Remove biological and nucleic acid contamination</li> </ul>
<b>Cleaning and Stocking</b>
<ul style="list-style-type: none"> <li>Maintain inventory and adequate stocks of laboratory supplies and chemicals</li> <li>Employ cleaning procedures</li> </ul>
<b>Safety</b>
<ul style="list-style-type: none"> <li>Follow established procedures for general laboratory safety</li> <li>Handle/dispose of hazardous materials – biological</li> <li>Document correct handling and disposal of biological hazardous materials</li> <li>Handle/dispose of hazardous materials – chemical</li> <li>Document correct handling and disposal of chemical hazardous materials</li> </ul>
<b>Quality Assurance</b>
<ul style="list-style-type: none"> <li>Perform quality control and document quality indicators</li> <li>Review and evaluate quality indicators</li> <li>Perform calibration and verify calibrators</li> <li>Review results</li> <li>Verify accuracy of results</li> <li>Perform proficiency testing (PT)</li> <li>Train staff and students</li> <li>Assess peer competency</li> </ul>
<b>Validation/Verification</b>
<ul style="list-style-type: none"> <li>Verify FDA-approved assays</li> </ul>

<ul style="list-style-type: none"> <li>Validate new equipment</li> <li>Design new laboratory-developed procedures (LDPs)</li> <li>Optimize new LDPs</li> <li>Validate LDPs</li> <li>Design and implement assay automation (e.g., program liquid handlers)</li> </ul>
<b>Statistics</b>
<ul style="list-style-type: none"> <li>Perform statistical analyses (i.e., positive predictive values)</li> <li>Method evaluation, validation, and/or verification</li> <li>Create standard curves</li> <li>Calculate clinical limits / sensitivity and specificity</li> <li>Analyze Levey-Jennings plots</li> </ul>

<b>Molecular Biology Specimen Analysis</b>
<b>Infectious Disease</b>
<ul style="list-style-type: none"> <li>HIV</li> <li>HPV</li> <li>Respiratory pathogens (e.g., Bordetella spp.)</li> <li>Gastrointestinal pathogens (e.g., Norovirus)</li> <li>Transplant pathogens (e.g., CMV, BK)</li> <li>Bacterial resistance markers (e.g., MRSA, VRE, KPC, NDM)</li> <li>Hepatitis pathogens (e.g., HBV, HCV)</li> <li>Genitourinary pathogens (e.g., GC, CT)</li> <li>Fungal pathogens (e.g., Aspergillus spp.)</li> <li>Gastrointestinal parasites (e.g., Giardia spp.)</li> <li>Bloodborne parasites (e.g., Plasmodium spp.)</li> <li>CNS pathogens (e.g., meningitis)</li> </ul>
<b>Hematology/Oncology</b>
<ul style="list-style-type: none"> <li>Leukemias/lymphomas (e.g., CML, ALL, translocations, clonal rearrangements)</li> <li>Solid tumor testing</li> <li>Hereditary cancer syndromes (e.g., breast, colon, ovarian)</li> <li>Personalized cancer treatment</li> </ul>
<b>Genetics</b>
<ul style="list-style-type: none"> <li>Pharmacogenomics (e.g., trastuzumab, warfarin, clopidogrel, carbamazepine)</li> <li>Hemoglobinopathies (e.g., thalassemias, sickle cell anemias)</li> <li>Coagulopathies (e.g., factor V Leiden, prothrombin, MTHFR)</li> <li>Trinucleotide repeat disorders (e.g., fragile X, Huntington, muscular dystrophy)</li> </ul>



- 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

- Coordinate the development and implementation of new assays (LDP)
- Manage assay nonconformance and correction
- Manage supply chain and/or workflow
- Manage laboratory environment (e.g., placement of new equipment, new workstations)
- Verification/release of final results

**Laboratory Management/Supervision**

- Review, report, and evaluate proficiency testing (PT) results
- Investigate/report/summarize PT exceptions
- Write/develop departmental procedures
- Review/update departmental procedures (e.g., annually)
- Develop and implement departmental policies
- Review/update departmental policies (e.g., annually)
- Hire department staff
- Supervise/direct department staff in daily operations
- Conduct personnel evaluations and administer disciplinary actions
- Schedule staff
- Order supplies and inventory maintenance
- Develop and manage budget
- Manage equipment acquisition and depreciation
- Facilitate laboratory information system (LIS) development, implementation, and maintenance
- Manage quality assurance program (e.g., QC evaluation, documentation, outcome measures)
- Manage safety program (e.g., PPE, fume hoods, fire, electrical, SDS)
- Manage hazmat program (e.g., disposal, decontamination, and storage)
- Manage regulatory compliance with agencies (e.g., CLIA, OSHA, EPA, state and local)
- Manage training and/or education of staff and students
- Assess/evaluate competency of personnel
- Provide assistance/information to patients
- Provide assistance/information to physicians, nursing and other healthcare providers
- Ensure/manage HIPAA compliance
- Coordinate the implementation of new assays (FDA approved/EUA)