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MEDICAL LABORATORY IMMUNOLOGY PRACTICE ANALYSIS REPORT

For Development of

DMLI(ASCP)

Content Guideline and Examination

for DMLI Exam Publication April 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 Diplomate in Medical Laboratory Immunology (DMLI) 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 January 2020 ASCP BOC examination committee meeting, the Medical Laboratory Immunology 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).

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 three major sections:

- Immunology
- Molecular Diagnostics
- Laboratory Operations

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 Medical Laboratory Immunology 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 survey was sent by the American Society for Microbiology (ASM) to all active American Board of Medical Laboratory Immunology (ABMLI) Diplomates. The survey was open for a 3-week period between July 27, 2020 – August 18, 2020.

SURVEY ANALYSIS

Respondents were asked an initial survey question to indicate whether they are currently employed in a laboratory performing clinical diagnostic immunology testing. Those who indicated that they are currently retired, unemployed, or employed as clinical laboratory educators were removed from the survey. Additionally, respondents with a master's degree or lower were removed from the survey, as well as those working in a country other than the U.S., U.S. territories, or Canada.

The remaining survey respondents were asked to answer the rest of the demographic questions and rate all tasks in the survey. The tasks were divided amongst three major sections (immunology, molecular diagnostics, and laboratory operations).

COMMITTEE REVIEW AND DISCUSSION

During the October 2020 examination committee meeting, the Medical Laboratory Immunology Examination Committee reviewed the practice analysis results. They agreed that the demographic results accurately reflected the DMLI 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 Lists for DMLI **(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 committee created the new DMLI exam content guideline based on the Final Task Lists for DMLI **(Appendix B)**. They determined where to set the exam content area percentages on the content guideline. The committee wrote questions and reviewed and revised all questions as needed. They classified all questions according to the content 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

DIPLOMATE IN MEDICAL LABORATORY IMMUNOLOGY (DMLI)

DEMOGRAPHIC ANALYSIS

Total survey respondents: 54
Total usable respondents: 44

Usable individual respondents met the following criteria:

- Currently employed in a laboratory performing clinical diagnostic immunology testing, in a laboratory-related industry, in a translational research role, or in a regulatory role.
- Have obtained a doctorate degree (MD, DO, PhD).
- Currently employed in the U.S., U.S. Territories, or Canada.

Summary of demographic results:

- Doctoral Certifications:
  - 100% are ABMLI certified.
  - 14% are ABHI certified.
  - 6% are ABB certified.
  - 4% are ABMM certified.
  - 2% are ABAI certified.
- Education:
  - 100% of respondents have a doctorate.
    - 33% have an MD.
    - 90% have a PhD.
- Years of experience:
  - Mean: 20 years of experience
  - Minimum: 5 years of experience
  - Maximum: 40 years of experience
- Geographic Distribution: there are respondents from across the U.S. The states with the highest response rate include:
  - 9% from Illinois, New York, Ohio, Pennsylvania, and Utah.
  - 7% from California and North Carolina.
  - 5% from Colorado, Georgia, Maryland, Texas, Virginia, and Wisconsin.
- Facility:
  - 45% work in hospitals.
  - 43% work in academic medical centers.
  - 34% work in independent (reference/commercial) laboratories.
  - 5% work in consulting.
- Age:
  - Mean: 55 years of age
  - Minimum: 37 years of age
  - Maximum: 70 years of age
- Gender:
  - 30% are female.
  - 70% are male.

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Appendix B

DIPLOMATE IN MEDICAL LABORATORY IMMUNOLOGY (DMLI)

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

IMMUNOLOGY
IMMUNOLOGY TECHNIQUES
Agglutination techniques (e.g., latex, particle, hemagglutination, flocculation)
Precipitation techniques (e.g., radial, Ouchterlony)
Nephelometry
Turbidometry
Enzyme immunoassay
Complement fixation
Chemiluminescence
Western blot
Immunoblotting
Immunofluorescence
Multiplex liquid- or bead-based techniques
Flow cytometry
Monoclonal antibody production
Immunohistochemical studies (e.g., TdT, CD markers)
HLA typing by serologic and molecular methods
Immunofixation
Serum protein electrophoresis
Light chain analysis
Molecular genetic testing (e.g., FISH, PCR)
Rapid tests (e.g., lateral flow assays)
Functional assays (e.g., radioactive based, non-radioactive based, flow cytometry)
IMMUNOLOGY TESTING
Inflammation Testing
Systemic inflammation (e.g., CRP, ESR, cytokines)
GI inflammation (e.g., calprotectin, lactoferrin)
Immunodeficiency Testing
Assessment of cellular responses (e.g., neutrophil oxidative burst, lymphocyte antigen and mitogen proliferation, cytokine production)
Immunophenotyping (e.g., lymphocyte subsets, leukocyte adhesion panel)
Humoral (e.g., complement, immunoglobulins)
Hematologic Testing
Paroxysmal nocturnal hemoglobinuria testing
Fetal hemoglobin
Platelet analysis by flow cytometry
Stem cell enumeration (e.g., CD34)
Infectious Disease Testing
Bacterial serology (e.g., syphilis, Lyme, strep)
Viral serology (e.g., hepatitis, herpesviruses, HIV)

Mycotic serology (e.g., *Histoplasma*, *Aspergillus*, *Candida*)
Parasitic serology (e.g., *Plasmodium*, *Toxoplasma*)
Cytokine testing for tuberculosis (e.g., QuantiFERON)
Systemic and Organ Autoimmunity Testing
Systemic (e.g., ANA, ENA, anti-DNA, RF, anti-CCP, aPL)
Kidney (e.g., ANCA, GBM)
Neurologic (e.g., NMDAR, acetylcholine binding receptor)
GI (e.g., celiac antibodies, IBD)
Endocrine (e.g., diabetes, thyroid)
Vasculitides (e.g., ANCA)
Hematologic (e.g., anti-neutrophil antibodies, platelet antibodies)
Skin (e.g., pemphigus)
Reproductive (e.g., anti-ovarian antibodies)
Musculoskeletal (e.g., myositis, anti-striated muscle)
Pulmonary (e.g., anti-GM-CSF, GBM, ANCA)
Cardiovascular (e.g., anti-myosin)
Cryoglobulins
Allergy Testing
Total IgE
Allergen-specific IgE
Allergen-specific IgG
Allergen component
Cellular allergen-specific response (e.g., basophil function test)
Histocompatibility/Immunogenetic and Transplant Immunology Testing
HLA typing (e.g., phenotyping, genotyping)
HLA antibody screening (e.g., cytotoxicity, solid-phase, crossmatch)
Post-transplant monitoring (e.g., chimerism)
Immuknow
Disease association (e.g., celiac, spondyloarthritis [ankylosing spondylitis])
Cancer Testing
Tumor markers (e.g., AFP, CEA, PSA)
Paraneoplastic antibodies (e.g., anti-Hu, anti-Ri, anti-Yo)
Cancer immune monitoring (e.g., PDL1, CAR T cells)
Leukemia/Lymphoma panel (immunophenotyping)
Minimal residual disease (by flow cytometry or molecular methods)
MOLECULAR DIAGNOSTICS
MOLECULAR TECHNIQUES
Nucleic acid amplification (e.g., PCR, PCR variations, TMA)
Separation techniques (e.g., electrophoresis)
Hybridization methods (e.g., Southern blot, array technology, FISH, colony blot)
Nucleic acid sequencing (e.g., Sanger sequencing, pyrosequencing, next-generation sequencing)
Microbial identification by sequencing (e.g., 16S ribosomal RNA)

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MOLECULAR TESTING
Infectious Disease Testing
Bacterial molecular testing (e.g., Lyme, *Chlamydia*, GC*, Bordetella pertussis*, *C. difficile*)
Viral molecular testing (e.g., hepatitis, herpesviruses, HIV, HPV, influenza)
Mycotic molecular testing (e.g., *Cryptococcus*)
Parasitic molecular testing (e.g., *Toxoplasma*)
Hematology/Oncology Testing
Leukemias/lymphomas (e.g., clonality, translocations)
Solid tumors (HER2/neu, BRAF)
Immune Deficiency Testing
Newborn screening (e.g., TRECs)
PID genetic testing (e.g., whole genome sequencing)
LABORATORY OPERATIONS (MANAGEMENT/SUPERVISION)
Oversight of specimen collection, preparation, and processing (e.g., specimen evaluation for acceptability)
Manual result entry (e.g., add interpretive comments, reference, or resource information to the report)
Correlation of test results with other data (e.g., clinical history, other lab results) and take corrective action as necessary
Communication with healthcare providers regarding test results (e.g., report interpretation, amended results)
Evaluation/verification/validation of new instrumentation, methodologies, or assays
Oversight of safety activities (e.g., PPE, fume hoods, fire, safety data sheets, biosafety cabinets)
Oversight of hazard disposal, decontamination, and storage
Regulatory compliance and lab accreditation (e.g., CAP, CLIA, HIPAA, OSHA)
Maintenance of patient records and laboratory database
Departmental policy/procedure writing, review, and revision
Billing and coding
Supervision/direction of department staff in daily operations (e.g., reagent preparation, test performance)
Personnel management activities (e.g., hiring, discipline, job descriptions, evaluations, scheduling)
Budgeting and purchasing decisions
Laboratory information system (LIS) implementation and validation
Quality assurance program oversight (e.g., peer group QC evaluation, cross-functional teams, outcome measures, IQCP, proficiency testing)
Evaluation of quality assessment/improvement activities (e.g., preanalytical, analytical, and postanalytical)
Development and implementation of training, competency, and educational programs (e.g., in-laboratory trainer, program faculty)