Certification in Clinical Biochemical Genetics
Logbook Guidelines for
2019 Examination

Purpose:
The purpose of the logbook is to document that the applicant has had direct and meaningful involvement in the processing, analysis, interpretation, and reporting of biochemical genetics laboratory tests and has received ongoing and appropriate laboratory supervision. The logbook cases must provide evidence of at least one year of clinical laboratory bench experience and evidence of well-rounded experience with a wide variety of biochemical genetic techniques involving all major biochemical genetic laboratory testing categories. Conditions submitted in the logbook should represent the broad spectrum of biochemical genetic diagnoses.

Requirements:
Logbooks must be completed in accordance with the instructions provided in this document with cases compiled using the ABMGG Logbook Excel Spreadsheet Tool. While the ABMGG anticipates ongoing review of cases between the trainee and their program director, the applicant should assure that all requirements have been fulfilled before submitting the final logbook for review. The program director will be required to attest to the ABMGG that all specific logbook requirements for this specialty have been fulfilled and are clearly reflected in the logbook. When applying for credentialing to sit for the certification examination in this specialty, the ABMGG reserves the right to request a copy of the logbook for audit and confirm that all requirements have been fulfilled. In this case, an applicant will be notified that they have been selected for audit and will be required to submit the 150 case logbook using the ABMGG Logbook Excel Spreadsheet to the ABMGG within five business days for detailed review.

Case Selection:
1. All specimens must have been processed in settings under an ABMGG or CCMG-accredited training program in clinical biochemical genetics.

2. Supervision for case encounters must be provided by faculty who are ABMGG-certified, ABGC-certified, or CCMG-certified. For cases obtained during rotations in outside laboratories, e.g., state newborn screening laboratories, it is recommended that supervisors be certified by their appropriate certifying board(s). All supervisors must be identified in the training program’s accreditation documents as members of the training faculty.

3. All 150 cases must be obtained during the inclusive dates of the applicant’s clinical biochemical genetics training.
4. Logbook entries must reflect at least one (1) year of clinical laboratory bench experience. No more than half of the cases may be obtained in any four-month period and no more than 25 cases may be obtained in any 30-day period.

5. Each logbook entry must document the applicant’s role(s) in the testing and reporting process, including sample processing, analysis, results interpretation, and/or communication of the test results.

6. Only cases for clinical analysis may be included in the logbook. Experimental or control cases, historical material, proficiency testing, or cases that are part of laboratory quality assurance activities will not be accepted. In laboratories where state regulations do not permit unlicensed individuals to generate a clinical laboratory result, parallel testing of clinical samples between a licensed technologist and trainee may serve to fulfill this requirement.

7. A given patient or family may appear only once in an individual’s logbook, regardless of the number of specimens processed on the patient or family.

8. For applicants seeking certification in more than one laboratory specialty (and therefore submitting more than one logbook), a given patient may only appear in a single logbook, regardless of the number of specimens processed or methodology used.

Description of Logbook Headings/Columns:

- **Entry Number**: The logbook spreadsheet allows a trainee to enter an unlimited number of cases while in training. For the final logbook that may be requested for audit, you must select 150 cases to submit that fulfill all of the defined requirements. The applicant must be able to identify each case by its entry number if questions arise about a logbook entry. Patient names and bona fide hospital or clinic numbers may not be included anywhere in the logbook that is submitted to the ABMGG for audit. Logbooks containing specific information regarding the identity of any patient will not be reviewed.

- **Date**: The date in month/day/year [MM/DD/YYYY] format identifies when the sample was received in the laboratory or, if relevant, the date the patient was seen.

- **Primary Laboratory Testing Category**: For each case, use the numbers 1 through 5 as outlined below to identify the single category that best describes the indication for the clinical biochemical genetic test. Observe limits per category where specified.

  Category 1 **Diagnostic evaluation, postnatal**: Initiated because of clinical symptoms and/or family history; or follow-up testing of abnormal newborn screening results.

  Category 2 **Carrier testing**: Ethnicity-based carrier screening (e.g., Tay-Sachs carrier testing) or biochemical carrier testing based on family history. It is recommended that at least 5 cases be obtained in this category. Up to five cases may represent the interpretation and/or communication of results from molecular-based (DNA) carrier testing of a metabolic disorder.

*Updated: April 2017*
Category 3  **Prenatal diagnosis:** Primary testing of prenatal samples, interpretation, and/or communication of prenatal diagnosis results generated by a referral laboratory, or maternal serum screening, i.e., AFP and other markers. It is recommended that at least 5 cases be obtained in this category. Up to five cases may represent the interpretation and/or communication of results from samples referred to another laboratory for biochemical and/or molecular-based (DNA) testing of a metabolic disorder.

Category 4  **Newborn screening:** Primary testing in a newborn screening laboratory, or interpretation and communication of newborn screening results from a state laboratory to health care providers and families. No more than 35 cases may be obtained from a state screening laboratory. It is recommended that at least 5 cases be obtained in this category.

Category 5  **Management/continuing care:** For follow-up testing of previously diagnosed individuals with a biochemical condition.

- **Laboratory Test/Methodology:** Specify the laboratory test/methodology performed for each case by entering the Methodology number outlined below. Observe limits per method where specified.

1. **Amino acid analysis, quantitative:** e.g., amino acid analyzer, tandem mass spectrometry, or related method.

2. **Organic acid analysis:** e.g., gas chromatography/mass spectrometry.

3. **Acylcarnitines/Acylglycines:** e.g., tandem mass spectrometry or related method.

4. **Screening Tests** (not including newborn screening): e.g., urine screening for mucoplygosaccharides or oligosaccharides; or others. It is recommended that a minimum of 5 cases be obtained in this category.

5. **Enzyme assay:** it is recommended that a minimum of 10 cases be obtained in this category.

6. **Other analyte:** e.g., galactose-l-phosphate, carnitine, succinylacetone, very long-chain fatty acids.

- **Diagnosis:** For each case, enter the diagnosis or condition being evaluated, using the guidelines below. Logbook cases must demonstrate experience with a variety of biochemical methodologies and conditions. It is recommended that no more than 20 cases be for any one diagnosis and strictly required that no more than 35 cases be any one condition, such as phenylketonuria or galactosemia. A maximum of 100 cases may have normal laboratory findings. Note: “normal” implies that no major, clinically significant abnormalities were found. Cases being tested for management of a known diagnosis that have normal results due to treatment or clinical status (e.g., a known VLCAD deficiency patient when asymptomatic, a patient with intermittent MSUD) may be counted as “abnormal.”
For primary metabolic conditions: Enter the diagnosis using the OMIM name or an OMIM alternative title. All cases representing the same condition should be entered using the same diagnosis name. For example: Enter all PKU cases as “PKU,” not “PKU” for some and “phenylketonuria” for others).

For results that are abnormal but not diagnostic for a specific metabolic disorder: Enter the most likely condition underlying the abnormal result, using consistent terminology from case to case. Indicate that the results were abnormal.

Examples:
- Dietary artifact
- Liver immaturity
- Physiologic ketosis
- Peroxisomal disorder, unspecified
- Neural tube defect, increased risk
- Trisomy, increased risk
- Mitochondrial myopathy
- Methylmalonic acidemia/homocystinemia
- SSADH deficiency vs. drug artifact
- Hyperglyceroluria (primary vs. secondary)

For results that are normal following testing for a specific metabolic disorder, initiated because of clinical symptoms, positive family history or abnormal screening result: Enter the disorder being evaluated using the OMIM name or an OMIM alternative title. For newborn screening cases with more than one disorder possible, enter the newborn screening result using standard terminology.

Examples:
- Elevated C3
- Elevated C5
- Elevated C5-OH

For results that are normal following metabolic testing for an unspecified condition: Enter “No abnormality detected” in the Diagnosis field.

- Trainee’s Roles: Check all of the boxes that indicate your role(s) in the testing, interpretation and reporting process. A breadth of experience must be reflected in the logbook. It is recommended that a minimum of three roles be specified for at least 140 cases. Observe specific limits per role where specified.

1. Sample preparation: Preparation of the sample for analysis, including dilution, analyte extraction, and other preparative steps. At least 75 cases must involve this role.

2. Sample analysis: Programming and running of instruments, chromatographic baseline review, peak identification, performance of manual assays. At least 75 cases must involve this role.

3. Interpretation of results: Evaluation of the clinical significance of findings including, where appropriate, gathering additional clinical and/or laboratory data, generating a
differential diagnosis, recommending further testing, and generating a draft or final version of the written report. At least 100 cases must involve this role.

4. Oral communication of results to health care providers who requested the testing or their designated contact: at least 10 cases are required and at least half of these must involve abnormal results. It is recommended that at least 25 cases involve this role.

5. Oral communication of results to patients: at least 10 cases are required for this role; at least half of these cases must involve abnormal results. If institutional liability considerations prohibit trainee's communication with patients, then the trainee's presence during such communication will satisfy the requirement.

- **Supervisor**: Include the full name, degree(s), and type of certification of the supervisor who was present and was directly responsible for your activities regarding that case.