CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC)
NEXT GENERATION SEQUENCING (NGS) WORKGROUP

MEETING SUMMARY REPORT

Workgroup Charge

The CLIAC NGS Workgroup is charged with providing advice to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on education, training, experience, and competencies that should be required by CLIA to qualify personnel performing next generation sequencing bioinformatics data analysis and interpretation.

Workgroup Agreements

The CLIA testing personnel qualifications for laboratories performing high complexity testing should be modified to add a qualification route and additional responsibilities for bioinformaticians.

- A CLIA personnel carve-out should be created to create a path for individuals who perform bioinformatics data analysis to qualify under CLIA, similar to how the current blood gas analysis carve-out is at § 493.1461 and § 493.1489. This carve-out should be developed for all CLIA-required personnel in the clinical laboratory who are involved in bioinformatics.
- The existing CLIA personnel roles (testing personnel, general supervisor, technical supervisor, and director) can be used along with the experience and degree requirements as a framework to build upon. For example, a bachelor's degree plus four years of experience or a PhD plus six months of experience.
- The bioinformatician qualification paths may include specialized requirements for bioinformatics beyond biological sciences, including bioinformatics, genetics, statistics, computer science, software engineering, biochemistry, etc.
- A carve-out would also be needed for general supervisors, technical supervisors, and laboratory directors who oversee bioinformatics activities in laboratories performing high complexity testing using the workgroup's proposal for bioinformatics testing personnel as the baseline.

The workgroup agreed upon the following definitions, qualifications, and responsibilities that can be used to develop a carve-out in the CLIA regulations for bioinformatics testing personnel in laboratories performing high complexity testing.

Definitions

- *Bioinformatician:* Individuals who manage, process, and analyze biological data utilizing specialized software.
- *Bioinformatics:* The interdisciplinary field that develops and applies computational methods to manage, process, and analyze biological data.
- *Bioinformatics Pipeline:* A set of multiple computer programs that may be run in series and/or in parallel to automate the process of analyzing biological data.

Bioinformatician Qualifications

Bioinformaticians in laboratories performing high complexity testing must possess a current license issued by the state in which the laboratory is located if such licensing is required. In addition, bioinformaticians can qualify as testing personnel by meeting one of the requirements listed below.

For a laboratory that performs bioinformatics, bioinformatics testing personnel must meet one of the following CLIA requirements:

- Meet the qualifications for testing personnel performing high complexity testing described at § 493.1489 (b)(1), (2), (3), (4), or (5) and have at least two years of documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing.
- Have earned a bachelor's, master's, or doctoral degree in bioinformatics, computational biology, computer science, mathematical science, or data science and have at least one year of documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing.
- Have education and training equivalency that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes 24 semester hours of science courses that include: (i) six (6) semester hours of chemistry or biology; and (ii) eighteen (18) semester hours of bioinformatics, computational biology, computer science, mathematical science, or data science in any combination and have at least one year of documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing.

Bioinformatician Responsibilities

Bioinformaticians are responsible for managing, processing, and analyzing genomic and/or molecular data utilizing specialized software for the purposes of patient diagnosis or management.

Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. Each individual performing high complexity testing must:

- Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting, and maintaining records of patient test results.
- Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.
- Adhere to the laboratory's quality control policies and document all quality control activities, instrument and procedural calibrations, and maintenance performed.
- Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.
- Be capable of identifying problems that may adversely affect test performance or reporting of test results, and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director.
- Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.
- *Develop and modify, as applicable, workflows, algorithms, and pipelines needed for clinical bioinformatics data analysis.
- *Conduct bioinformatics analysis, troubleshooting, and resolution.
- *Follow regulations and institutional policies related to the integrity, privacy, and security of patient and genomic data in databases and bioinformatics workflow processes throughout the testing process.

**Note: New draft responsibilities are not currently included in the CLIA regulations.*

Meeting #1 Summary – March 15, 2024

1. **What are the current regulatory requirements and guidelines related to the role of bioinformatics in clinical and public health laboratories performing NGS?**

   Workgroup Discussion and Comments

   - To set the stage for discussion, Ms. Penny Keller the workgroup's CMS ex officio, provided a presentation on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Final Rule published in the Federal Register on December 28, 2023.
   - Individuals who run a lockdown pipeline will have different expertise, training, and backgrounds than those who need to develop it, assess it, and know what tools are needed to achieve the best scientific outcomes and data analysis.
   - Staff performing bioinformatics activities under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as testing personnel may not have expertise in all the roles discussed. Conversely, staff with expertise in infrastructure and development to run the pipeline may understand those biological pieces, but they might not have the qualifications that CLIA requires.
   - When determining roles under CLIA, the test system and the activities considered for research and development versus those that are part of the clinical test need to be considered.
   - Bioinformatics pipelines are a critical component of the test system.
   - The Health Insurance Portability and Accountability Act (HIPPA), the Health Information Technology for Economic and Clinical Health (HITECH) Act, the HIPAA Omnibus Rule, and cybersecurity requirements related to data privacy in bioinformatics activities must be considered.
   - The current CLIA regulations for personnel performing high complexity testing limit the ability to qualify bioinformaticians, as many do not have the biological science requirements. A carve-out for high complexity testing personnel performing bioinformatics may be needed.
   - Laboratories may utilize third-party companies and services that build and validate the bioinformatics pipeline and return the results to the laboratory but do not have a CLIA certificate.
   - Workgroup members discussed the practice of bioinformatics. Several members suggested dividing the activities into categories with responsibilities and qualifications associated with the roles and noted that often, the same person performs multiple roles.
     1. Pipeline Development and Maintenance
        - Responsibilities
          - Developing, coding, putting it into management workflows, doing many infrastructure pieces, and developing pipelines.
          - Need to understand the biological aspects of what it means to have a different trimming tool and how that will impact some of those downstream variant calls just because of the stringency of the trimming. They need to know how to evaluate those pieces in the context of clinical diagnostics.
          - Serve as backup for bioinformaticians doing the day-to-day work so they know when updates are needed, identify gaps in pipelines, or identify points that need to be optimized or improved to streamline the process.
        - Qualifications
          - Bioinformatics master's or Bioinformatics PhD

- Bachelor's degree in biological science, computational related field, computer science, engineering
- One year of training/experience preferred but not required for entry-level

2. Bioinformaticians
   - Responsibilities
     - Build new tools, libraries, pipelines, databases, data visualizations, dashboards, report templates, Laboratory Information Management System (LIMS)/Electronic Laboratory Reporting (ELR) and electronic health record (EHR) integration, etc.
     - Handle data and run predefined tools, scripts, and pipelines
     - Download sequencing files
     - Conduct routine quality control (QC) and performance monitoring
     - Monitor effectiveness and potential problems over time
     - Resolving issues, such as restarting pipelines manually when errors occur
     - Updating pipelines with new versions of external software updates
     - Upload to LIMS
     - Perform data aggregation
     - Generate reports
     - Report out or share information with interested parties
   - Qualifications
     - MS or PhD in one of the following areas: Computer Science, Bioinformatics, Computer Engineering, Genetics/Genomics, Computational Biology
     - PhD with one year of supervisory experience or an MS with two years of training and experience,
     - The CLIA Laboratory Director should have an additional year of training or experience in interpreting bioinformatics results
3. Data Aggregation/Data Mining/Data Extraction
   - Responsibilities
     - Bioinformatician who will go back and pull data and perform some data visualization.
     - Monitor effectiveness and identification of potential problems over time

2. Harmonization of definitions – Creating or defining the fields/terms used throughout workgroup discussions. Examples include:

- **Health/Laboratory Informatics**
- **Bioinformatics**
- **Clinical Informatics**
- **Translational Informatics**
- **Informatician**
- **Bioinformatician**

Workgroup Discussion and Comments

- The workgroup used the Centers for Disease Control and Prevention (CDC) Request for Information (RFI)**:** personnel and the retention of next generation sequencing data in clinical and public health laboratories (Docket CDC 2020-0051) summary report as a guide for discussing definitions.
- There is a need to distinguish the bioinformatician from the informatician. The bioinformatician generated data related to the structure and function of biological systems. The informatician is more concerned with data related to patient care.

- Once CLIA-related activities are identified, roles can be defined, and educational requirements can be determined.
- Members discussed if the development of the NGS bioinformatics pipeline itself was a CLIA-related activity that needed to have CLIA-required testing personnel.
  - Commercially purchased bioinformatics pipelines and tools may not require having developers under CLIA.
  - Developers should work with the laboratory to develop and establish key thresholds and QC parameters.
  - Developers who are integral to the laboratory processes as laboratories establish performance specifications and perform validation of the bioinformatics pipelines should be CLIA-required testing personnel.
- The impact of clinical testing and testing results should be considered when determining if staff should be qualified under CLIA.
- The laboratory director and technical supervisors need to be knowledgeable on NGS and bioinformatics processes because they are the ones who are ultimately responsible. In addition to the current qualification requirements under CLIA, they should also have one year of training or experience in interpreting bioinformatics results.
- The workgroup discussed removing informaticians from the list of definitions as their roles are not typically related to CLIA activities.
- It is often the same person performing multiple roles, and discussions should focus on the work performed, skill sets needed, and education needed.
- Members noted that qualifying individuals to serve as technical supervisors in laboratories performing NGS is difficult since the current CLIA regulations focus on biological degrees. There is a need to expand CLIA to include genetics or statistics, along with experience in clinical laboratory bioinformatics.
- The CLIA testing personnel qualifications for laboratories performing high-complexity testing should be modified to add an option to allow bioinformaticians to be qualified. The qualification paths may include specialized requirements for bioinformatics beyond biological sciences, including bioinformatics, genetics, statistics, computer science, software engineering, biochemistry, etc.
- There is a need for a carve-out to create a path for individuals who perform NGS or bioinformatics to qualify under CLIA, similar to how the current blood gas analysis carve-out is at § 493.1461 and § 493.1489. This carve-out should be developed for all CLIA-required personnel in the clinical laboratory.
- Professional organizations such as the Association for Molecular Pathology (AMP) are involved in these discussions and may be a source for additional information.

Meeting #2 Summary – April 26, 2024

1. **Workgroup discussion education, training, experience, and competencies for various bioinformatics levels, including:**
   - **An MS or PhD level individual who provides analytic leadership, tool selection, and database oversight.**
   - **A bioinformatics technician who, for example, ensures data files are appropriately formatted for analysis, runs the analysis, and checks for the adequacy of the run.**
   - **The skill sets required for the Laboratory Director (MD/DO or PhD) who carries overall responsibility for the clinical laboratory.**

Workgroup Discussion and Comments

- The workgroup members proposed a definition of bioinformatician that includes an individual who manages, processes, and analyzes genomic and/or molecular data utilizing specialized software for the purposes of patient diagnosis or management.
- The current CLIA personnel qualifications and responsibilities framework should be utilized to develop a carve-out for bioinformaticians.
- A broad definition/term should be used to avoid excluding groups needed for future laboratory needs. The term clinical laboratory informatician encompasses multiple roles related to NGS and may be more inclusive (e.g., bioinformatics and data science).
- The roles within the CLIA test system (pre-analytical, analytical, and post-analytical) should be considered, along with distinguishing between clinical bioinformatics, research and development, and other bioinformatics roles.
- There is a need to allow delegation of certain tasks related to NGS to other personnel.
- The workgroup members discussed the qualifications required for bioinformaticians, including:
    - Master's or PhD in bioinformatics, biostatistics, computer science, data science, mathematics, computer engineering, genetics/genomics, computational biology, or similar field
    - Bachelor's degree in bioinformatics can qualify as testing personnel
    - Bachelor's degree in biology or biological sciences
    - Certifications from a formal academic program are acceptable without a degree
    - UCSD certification: https://extendedstudies.ucsd.edu/courses-and-programs/applied-bioinformatics
    - UCSD BS in Bioinformatics Course: https://biology.ucsd.edu/education/undergrad/maj-min/majors/fall20-later/bioinformatics.html
- Competencies that may be required for bioinformaticians include:
    - Database skills, coding, mining, storage, deployment, genetics, data science, technical proficiency skills, IT, algorithm, and model development
    - Data management, data security, and privacy, cybersecurity, HIPAA, CLIA, QC
- Cybersecurity and HIPAA training are needed for individuals to have the same baseline understanding and language while interacting with clinical workflows.
- The workgroup members discussed the experiences needed for bioinformaticians to qualify under CLIA, including:
    - Bachelor's degree with one year of training/experience preferred but not required for entry-level
    - Master's degree with two years of training and experience
    - PhD should have at least one year of supervisory experience
    - Clinical experience, CLIA, coding, IT, and genetics is desired
    - Testing personnel should have six months or one year of experience in a laboratory or performing analyses
    - Use the current CLIA lab director requirements and add one year of training or experience in interpreting bioinformatics results as a requirement
    - Laboratory directors and general supervisors have a certain level of knowledge, proficiency, and competency in bioinformatics.
- The workgroup members provided a list of bioinformatician roles and responsibilities that include:
    - Writing code and programming for the informatics pipeline
    - Validation of pipelines, revalidation, and development of reports
    - Checking runs, troubleshooting, modifying run sheets or parameters
    - Understanding CLIA roles and regulations

- Operate QC/testing or clinical QC
- Code development (Does not fall under the CLIA requirements)
- Implementing and executing the code (Falls under CLIA requirements)
- Large data manipulation, data management, analysis, proteomics, methylation
- Streamline and scale production
- Oversee the bioinformatics activities, especially in the wet lab (e.g., clinically vet and review code)
- Bioinformatics and IT roles: IT is responsible for activities in production-level environments. IT partners with bioinformatics to develop and automate long-term codes.

2. **Do the current CLIA regulations apply to the personnel discussed?**

Workgroup Discussion and Comments

- Personnel who implement and execute the code and use it on patients fall under CLIA.
- Personnel who develop the code and initial framework are not within the CLIA requirements.
- Individuals with a biology degree qualify as CLIA testing personnel.
- The existing CLIA personnel roles (testing personnel, general supervisor, technical supervisor, and director) can be used along with the experience and degree requirements as a framework to build upon. For example, a bachelor's degree plus four years of experience or a PhD plus six months of experience.
- Workgroup members were asked to provide any recent job announcements or position descriptions to be used to develop draft qualifications and responsibilities for presentation during the next meeting.

Meeting #3 Summary – August 30, 2024

CDC workgroup staff used the previous workgroup meeting transcripts and the position descriptions provided by workgroup members to develop a summary (see Appendix A). From the summary, draft definitions, qualifications, and responsibilities for testing personnel in a laboratory performing high complexity testing were created and provided for workgroup member discussion and refinement. The first draft provided to the workgroup for discussion during the August 30, 2024, meeting is provided below.

DRAFT - Definitions

- *Bioinformatician:* Individuals who manage, process, and analyze genomic and/or molecular data utilizing specialized software for the purposes of patient diagnosis or management.
- *Bioinformatics:* The interdisciplinary field that develops and applies computational methods to analyze biological data, particularly large-scale datasets generated by genomic and proteomic experiments.
- *Next Generation Sequencing (NGS):* A high-throughput methodology that enables rapid sequencing of large segments of DNA or entire genomes.
- *Computational Pipeline:* A series of computational steps that automate the process of analyzing and interpreting biological data.

DRAFT - Bioinformatician Qualifications

Bioinformaticians in laboratories performing high complexity testing must possess a current license issued by the state in which the laboratory is located if such licensing is required. In addition, bioinformaticians can qualify as testing personnel by meeting one of the requirements listed below.

For a laboratory that performs bioinformatics, testing personnel must meet one of the following CLIA requirements:

- Meet the qualifications for testing personnel performing high complexity testing described at § 493.1489 (b)(1), (2), (3), (4), or (5).
- Have earned a bachelor's degree in bioinformatics, computer sciences, or computational biology, and have at least three months of documented laboratory training performing bioinformatics analysis in a laboratory performing high complexity testing.
- Have education and training equivalency that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes 24 semester hours of science courses that include (i) six (6) semester hours of chemistry or biology; (ii) six (6) semester hours of computer sciences; and (iii) twelve (12) semester hours of bioinformatics, computer sciences, mathematical sciences, or computational biology in any combination and have at least three months of documented laboratory training performing bioinformatics analysis in a laboratory performing high complexity testing.

DRAFT - Bioinformatician Responsibilities

Bioinformaticians are responsible for managing, processing, and analyzing genomic and/or molecular data utilizing specialized software for the purposes of patient diagnosis or management.

Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. Each individual performing high complexity testing must:

- Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting, and maintaining records of patient test results.
- Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.
- Adhere to the laboratory's quality control policies and document all quality control activities, instrument and procedural calibrations, and maintenance performed.
- Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.
- *Develop tools and/or algorithms and/or modify pipelines needed for genomic analysis.
- *Conduct bioinformatics analysis, troubleshooting, and resolution.
- *Maintain security measures for results and patient-specific data electronically shared through networked or other interfaced systems throughout the testing process.
- Be capable of identifying problems that may adversely affect test performance or reporting of test results, and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director.
- Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

*Note: New draft responsibilities are not currently included in the CLIA regulations.

Workgroup Discussion and Comments

- The summarized information provides a draft for testing personnel performing bioinformatic activities. However, a carve-out would also be needed for general supervisors, technical supervisors, and laboratory directors who oversee bioinformatic activities in laboratories performing high complexity testing.

- Workgroup members suggested expanding the degree qualifications to include data science, statistics, mathematics, or related fields. Other members suggested information technology or engineering degrees.
- Three or six months of laboratory training or experience performing clinical bioinformatic analysis in a laboratory performing high complexity testing is needed for each qualification path. Many workgroup members felt three months was insufficient time for proper training and experience. The current CLIA regulations indicate that testing personnel who qualify using the education equivalence path must have laboratory training that includes at least three months of documented laboratory training in each specialty in which the individual performs high complexity testing. Therefore, the three month requirement is aligned with the current CLIA requirements.
- There may be a need to include certification requirements.
- It may be clearer to indicate six semester hours of biology or chemistry and 18 semester hours of the other disciplines.
- One member suggested that expanding the applicant pool for bioinformatics testing personnel under CLIA regulations could involve recognizing other relevant training and educational backgrounds that are not strictly limited to the fields of bioinformatics, computer sciences, or computational biology and provided the following suggestions:
    - Biotechnology or Molecular Biology Degrees: Graduates with degrees in biotechnology or molecular biology often have a strong background in laboratory techniques, genetics, and data analysis, which are crucial for bioinformatics roles. Supplementing this with targeted bioinformatics training or certification could make them eligible.
    - Medical Laboratory Science (MLS) Degrees: Individuals with a background in medical laboratory science may already have experience with high-complexity testing. By acquiring additional training in bioinformatics, they could meet the qualifications for bioinformatics testing personnel.
    - Statistics or Biostatistics Degrees: Statistics or biostatistics graduates possess strong analytical and data interpretation skills. They could be well-suited for these roles with additional coursework or certifications in bioinformatics or computational biology.
    - Genomics or Genetics Degrees: Degrees focused on genomics or genetics often include bioinformatics and data analysis components. Candidates from these fields could meet the requirements with additional training in computational techniques and bioinformatics software.
    - Engineering Degrees with a Focus on Bioengineering or Computational Biology: Bioengineers or those with a background in computational biology within engineering programs often possess relevant skills in both biological sciences and computational methods, making them strong candidates after some focused laboratory training.
    - Health Informatics or Biomedical Informatics Degrees: Individuals with degrees in health informatics or biomedical informatics are trained in managing and analyzing large sets of health-related data. With specialized training in bioinformatics, they could contribute to bioinformatics testing personnel roles.
    - Mathematics or Applied Mathematics Degrees with Bioinformatics Focus: Those with a background in mathematics or applied mathematics who have taken bioinformatics-related courses or have completed projects in computational biology could be trained to meet the specific requirements for high-complexity testing.
    - Post-Baccalaureate Certificates or Professional Certifications: Offering post-baccalaureate certificates or professional certifications in bioinformatics, computational biology, or laboratory analysis could help individuals from related fields gain the required qualifications.

    - Apprenticeship Programs: Establishing apprenticeship or internship programs that offer hands-on bioinformatics analysis in laboratories performing high-complexity testing could provide the required training for individuals from diverse educational backgrounds.
    - On-the-Job Training Programs: Developing structured on-the-job training programs within clinical laboratories that allow individuals with relevant degrees to gain experience in bioinformatics could help meet the CLIA requirements while expanding the candidate pool.
- By broadening the recognized educational backgrounds and providing structured pathways for additional training, the applicant pool for bioinformatics testing personnel can be significantly expanded while still maintaining the necessary competencies for high complexity testing.
- Members commented that the third new responsibility may be too focused on IT and not specific to bioinformatics. Others noted that maintaining security measures should be part of the responsibility to ensure secure access to patient information.
- It was suggested that the first new responsibility be broadened to include workflows and pipelines for bioinformatic data analysis.
- The workgroup discussed and refined the draft definitions, assuming that they would apply to clinical laboratory testing under CLIA.

Meeting #4 Summary – October 18, 2024

The draft definitions, qualifications, and responsibilities for testing personnel in a laboratory performing high complexity testing were updated based on the discussions from the August 30, 2024, meeting. The updated draft is provided below and was discussed and refined during the October 18, 2024, workgroup meeting.

DRAFT 2 - Definitions

- *Bioinformatician:* Individuals who manage, process, and analyze biological data utilizing specialized software.
- *Bioinformatics:* The interdisciplinary field that develops and applies computational methods to manage, process, and analyze biological data.
- *Next Generation Sequencing (NGS):* A high-throughput methodology that enables rapid sequencing of large segments of DNA or entire genomes.
- *Bioinformatic Pipeline:* A set of multiple computer programs that may be run in series and/or in parallel to automate the process of analyzing and interpreting biological data.

DRAFT 2 - Bioinformatician Qualifications

Bioinformaticians in laboratories performing high complexity testing must possess a current license issued by the state in which the laboratory is located if such licensing is required. In addition, bioinformaticians can qualify as testing personnel by meeting one of the requirements listed below.

For a laboratory that performs bioinformatics, testing personnel must meet one of the following CLIA requirements:

- Meet the qualifications for testing personnel performing high complexity testing described at § 493.1489 (b)(1), (2), (3), (4), or (5) and have at least *3 or 6 months* of documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing.
- Have earned a bachelor's, master's, or doctoral degree in bioinformatics, computational biology, computer science, mathematical science, or data science and have at least *3 or 6 months* of

documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing.

- Have education and training equivalency that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes 24 semester hours of science courses that include: (i) six (6) semester hours of chemistry or biology; and (ii) eighteen (18) semester hours of bioinformatics, computational biology, computer science, mathematical science, or data science in any combination and have at least *3 or 6 months* of documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing.

DRAFT 2 - Bioinformatician Responsibilities

Bioinformaticians are responsible for managing, processing, and analyzing genomic and/or molecular data utilizing specialized software for the purposes of patient diagnosis or management.

Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. Each individual performing high complexity testing must:

- Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting, and maintaining records of patient test results.
- Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.
- Adhere to the laboratory's quality control policies and document all quality control activities, instrument and procedural calibrations, and maintenance performed.
- Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.
- *Develop and modify, as applicable, workflows, algorithms, and pipelines needed for clinical bioinformatics data analysis.
- *Conduct bioinformatics analysis, troubleshooting, and resolution.
- **Ensure/Adhere to/Follow* regulatory and organizational integrity, privacy, and security of patient and genomic data in databases and bioinformatics workflow processes throughout the testing process.
- Be capable of identifying problems that may adversely affect test performance or reporting of test results, and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director.
- Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

*Note: New draft responsibilities are not currently included in the CLIA regulations.

Workgroup Discussion and Comments

- Members suggested that there was no need to define NGS since it is not included in the bioinformatics personnel qualifications and responsibilities workgroup agreements.
- A suggestion was made to remove data interpretation from the bioinformatics pipeline definition, as interpretation may be associated with the practice of medicine.
- Members discussed the suggested requirement for documented laboratory training performing clinical bioinformatics analysis in a laboratory performing high complexity testing and emphasized the need for a longer requirement for training due to the complexities of the bioinformatics activities. Members agreed that for individuals with bioinformatics education or education equivalency, at least one year should be required. On the other hand, individuals

meeting the current testing personnel qualifications for high-complexity testing may need additional training, which is suggested to be two years.

- Members finalized the workgroup agreements that will be included in the presentation to CLIAC during the November 6-7, 2024, meeting.

Resources

1. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions final rule (CMS-3326-F).
2. The Centers for Disease Control and Prevention (CDC) Request for Information: Personnel and the Retention of Next Generation Sequencing Data in Clinical and Public Health Laboratories, Docket CDC 2020-0051, summary report. https://www.cdc.gov/cliac/docs/november-2021/8a_CDC-NGS-RFI_Comment-Analysis-Report.pdf
3. The Next Generation Sequencing Quality Initiative
4. The NGS Quality Initiative Bioinformatician Competency Assessment Standard Operating Procedure and Bioinformatician Competency Assessment Summary Form.

Appendix A

CLIAC Next Generation Sequencing Workgroup: Summary of Meeting Transcripts and Position Descriptions

Determining Qualifications of a Bioinformatician or Someone Performing Bioinformatics

Summary of Workgroup Meeting Transcripts and Position Descriptions Provided by Workgroup Members

The educational requirements of candidates are typically similar across all institutions as they provide information about the qualifications and experience required for a bioinformatician position. However, the level of education, years of experience, and training will vary depending on whether the position is entry-level. Across multiple institutions, the similarities include the requirement of a degree (e.g., bachelor's, master's, or doctoral) in subjects such as Bioinformatics, Computational Biology, Computer Science, Computer Engineering, Microbiology, Biology, Molecular Biology, Biomedical Sciences, Genetics, Genomics, Virology, Parasitology, Evolutionary Biology, Biostatistics, Genetic Counseling (Master's level), Mathematical Sciences (and related disciplines), Digital Health, or a related field. Few institutions identified degree requirements outside of these, i.e., associate degree, vocational, certificate(s), or otherwise. Across institutions, differences lie in the specific requirements for years of experience and additional educational qualifications. Some institutions mention a preference for candidates with a master's degree or PhD in a specific area of study, while others specify the number of years of experience required. The average number of years of experience varies across the institutions. Some summaries mention a requirement of 2 or more years of experience without a PhD, while others state that none or one year of experience is required with a PhD. Additionally, some institutions may provide additional information about preferred experience or expertise in certain areas within bioinformatics or computational biology.

Some institutions identified the need to divide bioinformatics-related duties among three levels of personnel performing bioinformatics. The workgroup may consider how these requirements vary as applicable to these three levels summarized:

1. Junior—The Junior Bioinformatician will support the bioinformatics team in performing computational analysis on genomic data using established tools under supervision. This role focuses on learning best practices in data analysis while contributing to ongoing research projects.
    a. Duties could include assisting in running established bioinformatics pipelines for NGS data analysis, performing basic quality control checks on sequencing data, helping maintain databases and manage data storage solutions under guidance, developing proficiency in programming languages used within the team (e.g., Python, C++, Visual Basic, C#, etc.), participating in team meetings and contributing to discussions on project progress.
    b. Qualifications could include a bachelor's degree in bioinformatics, computational biology, or a related field, familiarity with the Linux environment and command-line tools, and a basic understanding of genomics and molecular biology concepts.
2. Mid-level - The Mid-Level Bioinformatician will independently conduct bioinformatics analyses and contribute to developing new computational pipelines. This role requires a solid understanding of genomics and strong analytical skills to support both research initiatives and clinical applications.

    a. Duties include designing, testing, and implementing custom bioinformatics pipelines for complex datasets and providing insights into pipeline optimization based on the latest scientific literature. Collaborating with laboratory personnel to align sequencing protocols with bioinformatics requirements, contributing to manuscript preparation, and presenting findings at scientific meetings.
    b. Qualifications could include a master's degree in bioinformatics or a related field or a bachelor's degree with 2+ years' experience in a relevant area. Proficiency with programming languages such as Python, C++, Visual Basic, C#, etc.; experience with Unix/Linux environments; familiarity with version control systems like GitHub.
3. Senior - The Senior Bioinformatician leads the development of advanced computational strategies for large-scale genomic analyses that drive research innovation and clinical decision-making processes.
    a. Duties include leading the design and implementation of robust computational pipelines across various projects within an organization or institution, overseeing quality assurance/control processes to ensure the accuracy of genomic analyses, and setting standards for best practices within the team or department. Mentoring junior members, providing training on advanced techniques in bioinformatics analysis, and fostering an environment conducive to collaborative research efforts across disciplines. Drives strategic planning efforts by staying ahead of emerging trends within genomics. They advise leadership on how to integrate cutting-edge technologies into organizational workflows.
    b. Qualifications include a PhD in Bioinformatics, Computational Biology, or a related field preferred or a master's degree with significant experience (5+ years) leading complex projects within a bioinformatics context. Demonstrated expertise in developing novel algorithms/tools for genome assembly, annotation, variant calling, etc.; extensive knowledge working with cloud computing environments; strong publication record indicative of impactful contributions to the field.

Essential Duties and Competencies of a Bioinformatician or Someone Performing Bioinformatics

Essential Job Duties Summarized from Workgroup Meeting Transcripts and Position Descriptions Provided by Workgroup Members:

Each entity outlines the specific responsibilities and tasks associated with a bioinformatician or similar position. These responsibilities typically include maintaining quality assurance/control of data, developing tools and/or algorithms for genomic analysis, conducting bioinformatics analysis, developing pipelines, troubleshooting and resolution, educating/training staff (bioinformaticians and non-bioinformaticians), guiding policy development or contributing to strategic planning efforts, and summarizing/communicating results (including result reporting). The differences lie in the specific details and emphasis on certain responsibilities based on the organization's or institution's needs and priorities. Some institutions provide more specific examples or additional responsibilities. For example, some institutions have identified requirements for maintaining up-to-date knowledge on emerging technologies and scientific advancements in the field of genomics and bioinformatics, ensuring compliance with data privacy standards when handling sensitive patient information (e.g., HIPAA compliance), and participating in grant writing activities to secure funding for research projects, prior knowledge of clinical/public health laboratory guidelines and regulations, usage of specific tools, scripts, and/or pipelines, familiarity with Laboratory Information Management System (LIMS)/Electronic

Laboratory Reporting (ELR), and electronic health record (EHR) integration, and specific duties regarding data management, data security, and data mining.

Candidate Skills and Characteristics Summarized from Workgroup Meeting Transcripts and Position Descriptions Provided by Workgroup Members:
Required skills and characteristics highlight the additional knowledge and skills required for the Bioinformatics Scientist position. These typically include a deep understanding of genomics and molecular biology, experience analyzing large sequencing datasets, proficiency in programming languages (such as Python), familiarity with Linux/Unix environments, and strong communication skills. The differences lie in the specific technical requirements mentioned, such as working within a High-Performance Computing infrastructure, cloud-based data storage, and analytics interfaces, or experience with version control tools. Additionally, some institutions may mention preferences for expertise in specific lab settings (such as CAP/CLIA and bioinformatics specific to clinical or public health settings), ability to obtain security clearances or specific certifications, knowledge of and compliance with the HIPAA Final Security Rule, HITECH, GINA and HIPAA Omnibus regulatory requirements and project management knowledge/experience.

Competencies Summarized from Workgroup Meeting Transcripts and Position Descriptions Provided by Workgroup Members:
Competencies for Bioinformatician positions are similar across all institutions as they focus on the specific responsibilities related to data quality assessment and data analysis in the context of bioinformatics. These responsibilities typically include coding bioinformatics analysis computer programs, assessing the quality of sequencing data, implementing quality control measures, evaluating the sensitivity and specificity of bioinformatics analysis results, developing evaluation plans, selecting appropriate data for testing, and utilizing data visualization tools. Institutional differences lie in the specific details and emphasis placed on certain responsibilities based on the organization's or institution's needs and priorities. Some institutions may provide more specific examples or additional responsibilities, and a few have identified additional needs, such as the ability to interrogate big data.

Appendix B

Testing Personnel Qualifications § 493.1489 effective December 28, 2024

Testing personnel in laboratories performing high complexity testing must possess a current license issued by the state in which the laboratory is located if such licensing is required. In addition, testing personnel can qualify by meeting one of the routes listed below.

- Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the state in which the laboratory is located.
- Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical, or medical laboratory science, or medical technology from an accredited institution.
- Meet the qualification requirements for laboratory director at § 493.1443(b)(3) or technical supervisor at §493.1449(c)(4) or (5). Qualification routes under this pathway include:
  - Hold an earned doctoral degree and have at least 16 semester hours of doctoral-level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS).
  - Hold an earned doctoral degree and have an approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
  - Have earned a master's degree in chemical, biological, clinical, or medical laboratory science, or medical technology from an accredited institution.
  - Meet bachelor's degree equivalency and have at least 16 semester hours of additional graduate-level coursework in chemical, biological, clinical, or medical laboratory science, or medical technology.
  - Meet bachelor's degree equivalency and have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
  - Have earned a bachelor's degree in chemical, biological, clinical, or medical laboratory science, or medical technology from an accredited institution.
  - Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes forty-eight (48) semester hours of medical laboratory technology courses.
  - Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes forty-eight (48) semester hours of science courses that include: (i) twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; (ii) twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (iii) twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or technology in any combination.
- Have earned an associate degree in laboratory science or medical laboratory technology from an accredited institution.
- Have education and training equivalency to requirements specified at § 493.1489(b)(2)(i). Routes under this pathway include:
  - At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum includes 24 semester hours of medical laboratory technology courses and have laboratory training that includes completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or the Commission

on Accreditation of Allied Health Education Programs (CAAHEP) (this training may be included in the required 60 semester hours).

- At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum includes 24 semester hours of medical laboratory technology courses and have laboratory training that includes at least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.
- At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes 24 semester hours of science courses that include: (i) six (6) semester hours of chemistry; (ii) six (6) semester hours of biology; and (iii) twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination and have laboratory training that includes completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) (this training may be included in the required 60 semester hours).
- At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes 24 semester hours of science courses that include: (i) six (6) semester hours of chemistry; (ii) six (6) semester hours of biology; and (iii) twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination and have laboratory training that includes at least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

- Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
- Be qualified and serving as testing personnel of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Appendix C

CLIAC Next Generation Sequencing (NGS) Workgroup Charge, Topics, and Discussion Questions

BACKGROUND

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. The CLIA regulations were finalized in 1992 and updated in 2003, with only limited updates since then.

As the types of test methods that use technologies such as Next Generation Sequencing (NGS) increase and with their broader uptake by laboratories, having a quality framework with qualified personnel in place is especially important. There are challenges when attempting to apply the almost 30-year-old CLIA regulations to these emerging technologies due to the novelty and complexity of the technology, new paradigms for data analysis, test result interpretation, and the bioinformatics portion of the test process.

The Centers for Disease Control and Prevention (CDC) obtained public comment through a Request for Information (RFI), Docket CDC 2020-0051, to gather feedback about the current state, challenges, and practices relevant to personnel performing bioinformatics activities in clinical and public health laboratories; storage and retention of NGS data files; and maintenance of sequence analysis software. The comment period closed in September 2020 with 16 responses from a diverse set of respondents that included reference laboratories, public health laboratories, academic clinical laboratories, professional societies, industrial partners, and private citizens. The NGS RFI summary report was presented during the November 2021 Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting during the *NGS in Clinical and Public Health Laboratories* session. In addition to the summary report, a public health laboratory's experience with NGS validation and reporting was presented. The Committee deliberated, voted, and approved the following recommendation on the topic of NGS in Clinical and Public Health Laboratories:

CLIAC recommends that CDC, CMS, and FDA convene a workgroup to define the scope of practice and the requisite CLIA qualifications for personnel performing bioinformatics data analysis and interpretation to produce test results that inform clinical decision-making.

Workgroup topics and needed input:
Provide recommendations and cross-reference existing guidelines regarding education, training, experience, and competencies for various bioinformatics levels, for example:

- An MS or PhD level individual who provides analytic leadership, tool selection, and database oversight.
- A bioinformatics technician that, for example, ensures data files are appropriately formatted for analysis, to run the analysis, and to check for the adequacy of the run.
- The skill sets required for the Laboratory Director (MD/DO or PhD) who carries overall responsibility for the clinical laboratory.

Seek input from institutions of higher learning (universities) to develop, in concert with clinical laboratories, a curriculum and training for each level.

Engage certifying bodies (e.g., The American Board of Pathology and the American Society for Clinical Laboratory Science Board of Certification) in developing certification or other credentialing opportunities for clinical bioinformaticians who will work in CLIA laboratories.

The Next Generation Sequencing Workgroup is being established to provide input to CLIAC for deliberation on how CLIA might specifically be updated, considering the CDC NGS request for an information summary report, the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups, and the November 2021 CLIAC recommendation on personnel performing bioinformatics data analysis and interpretation. The focus of the workgroup is to define the scope of practice and the requisite CLIA qualifications for personnel performing NGS bioinformatics data analysis and interpretation to produce test results that inform clinical decision-making.

CHARGE

The workgroup is charged with providing advice to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on education, training, experience, and competencies that should be required by CLIA to qualify personnel performing next generation sequencing bioinformatics data analysis and interpretation.

WORKGROUP DISCUSSION TOPICS

1. **Harmonization of definitions –** Creating or defining the fields/terms that will be used throughout workgroup discussions. Examples include:
    - Health/Laboratory Informatics
    - Bioinformatics
    - Clinical Informatics
    - Translational Informatics
    - Informatician
    - Bioinformatician

2. **What are the current regulatory requirements and guidelines related to the role of bioinformatics in clinical and public health laboratories performing NGS?**

3. **What is the current practice of bioinformatics in clinical and public health laboratories performing NGS?**

4. **Workgroup discussion education, training, experience, and competencies for various bioinformatics levels, including:**
    - An MS or PhD level individual who provides analytic leadership, tool selection, and database oversight.
    - A bioinformatics technician who, for example, ensures data files are appropriately formatted for analysis, runs the analysis, and checks for the adequacy of the run.
    - The skill sets required for the Laboratory Director (MD/DO or PhD) who carries overall responsibility for the clinical laboratory.

5. **Do the current CLIA regulations apply to the personnel discussed?**

DELIVERABLE

The output of the workgroup will be a summary report or periodic reports to CLIAC based on information gathered during teleconferences and potential face-to-face meetings and discussions. The reports will specifically address the priority topic areas and related questions. The workgroup Chair will present the reports at future CLIAC meetings for their deliberation and potential recommendations to HHS on the education, training, experience, and competencies that should be required by CLIA to qualify personnel performing next generation sequencing bioinformatics data analysis and interpretation. The report may

Appendix D

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC)
NEXT GENERATION SEQUENCING (NGS) WORKGROUP ROSTER

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