



Wet-lab Foundational Course

Basic Laboratory Requirements and Operational Setup

NGS Academy for the Africa CDC









of modules

Module last updated:

December 2024

Basic Laboratory Requirements
and Operational Setup for NGS
Implementation

Number of sessions	1
Total learning time	4 hours
Target audience	Wet laboratory personnel (i.e., scientists, laboratory technicians, etc.) and managerial personnel (i.e., HODs, laboratory managers, policy makers, etc.)
Format	Lectures, videos
Level of the module	Introductory



Contributors

Olusolu Akanbi, Elizabeth Akande, Onikepe Folarin, Carla Garcia, Siddiqah George, Shahiid Kiyaga, Carolina Matos, Andargachew Mulu, and Eugene Yeboah.



Recommended prerequisite module(s)

- Module G06. Introduction to Genomic Sequencing and NGS
- Module W01. Introduction to Biosafety and Biosecurity



Module description

Building on the foundational knowledge of laboratory biosafety and biosecurity, and NGS principles gained in modules W01 and G06, this module delves into the practical technical aspects of implementing NGS in a laboratory, and/or introducing a new NGS workflow. Participants will learn about essential considerations for laboratory setup, workflow optimization, sample management, quality control, and data management. This will assist participants in identifying the most suitable bench protocol for an NGS experiment, and in transferring skills across protocols, with applications in pathogen genomic surveillance. In this module participants are introduced to the following topics and/or concepts:

- A brief review of the basic concepts underpinning NGS
- A brief reexamination of various NGS technologies and their applications
- A high-level review of a typical NGS workflow
- Advantages of NGS over other molecular methods
- The role of proofreading polymerases in sequencing
- Primary equipment and material requirements for an NGS laboratory
- Laboratory setup and maintenance for NGS applications
- · A costing tool facilitating budgeting and resource mobilisation associated with genomic surveillance
- NGS laboratory infrastructure and design for workflow optimization
- Establishing a sample management system
 - Laboratory handbook content
 - o Systems for sample collection, handling, transport, storage, and disposal
 - Rationale for defining sample acceptance and rejection criteria
 - o criticality of sample quality for the accuracy of diagnostic test results
 - Maintaining sample integrity and regulation compliance when transporting samples
- Formulating a quality control management system for NGS
 - Selecting relevant sample preparation techniques
 - o Electing suitable library preparation methods
- Formulating evaluation plans for various NGS method
- Quality control procedures for different steps of an NGS workflow
- The required steps of an NGS validation protocol
- NGS data management: communicating with your IT department and bioinformaticians



Module learning outcomes

On completion of this module, the participants will have a basic knowledge of, or will be able to:

- Briefly discuss the fundamental principles of next-generation sequencing, including the concepts of sequencing by synthesis, massively parallel processing, and the significance of sequencing accuracy
- Conduct a high-level comparison of different NGS technologies such as Illumina, Ion Torrent, and PacBio
- Briefly discuss the application of different NGS technologies in genomics, transcriptomics, and epigenomics
- Describe the essential equipment and reagents necessary for successful NGS, including library preparation kits, sequencing platforms, and bioinformatics tools.
- Outline the main steps of a typical NGS workflow, from sample preparation and library construction to sequencing and data analysis.
- Discuss the key design principles of a molecular laboratory
- List the main requirements for setting up an NGS laboratory
- Explain how to safely integrate an NGS workflow in a molecular laboratory

- Explain the role of a costing tool in facilitating budgeting and resource mobilisation during genomic surveillance
- List the key laboratory aspects to be considered before selecting or scaling up an NGS protocol
- Apply and adapt NGS principles and protocols to existing laboratory conditions
- List the key aspects to be considered before selecting a library preparation method
- Develop an evaluation plan applicable to various NGS methods
- Discuss different quality control checkpoints in an NGS protocol
- List the mandatory content of an experimental data sheet for quality control purposes
- Develop NGS validation protocols which captures the accuracy, sensitivity, specificity, and detection limit
 of the NGS method
- Explain the purpose of obtaining high-quality nucleic acids for sequencing
- Describe common nucleic acid extraction methods
- Develop troubleshooting strategies for NGS experiments
- Create basic NGS workflows for new pathogens of interest
- Explain the principles of data acquisition and transfer in the context of sequencing
- Discuss the importance of organising and ensuring accessibility of sequencing data to enhance its analysis and interpretation



Module assessments

Module practical: Not applicable

Module quiz: Assessment questions available on the ASLM platform



Module resources

- Frontiers | DNA polymerases drive DNA sequencing-by-synthesis technologies: both past and present
- US CDC Laboratory Training
- Illumina | Sequencing: How to Plan Your First Sequencing Project
- Illumina | Advantages of NGS over other molecular methods
- Frontiers | Application of next-generation sequencing to identify different pathogens
- NIH| NLM Next Generation Sequencing of Infectious Pathogens
- APHL | Next Generation Sequencing Implementation Guide
- WHO practical guidance on technical aspects of genomic sequencing and analysis of SARS-CoV-2
- Protocols.io | NGS Lab Setup Collection
- NIH | NLM Design Requirements Manual
- The Role of Organizational Design in the Future of Work
- WHO | The use of next-generation sequencing for the surveillance of drug-resistant tuberculosis: An implementation manual
- PHG Foundation | Implementing pathogen genomics: A case study
- NIH | NLM Implementing laboratory automation for next-generation sequencing: benefits and challenges for library preparation
- WHO | Genomics costing tool

- ScienceDirect | Challenges in the Setup of Large-scale Next-Generation Sequencing Analysis Workflows
- MRI Global | Sample Management
- WHO | Laboratory quality management system: handbook
- ASM | Practical Guidance to Implementing Quality Management Systems in Public Health Laboratories Performing Next-Generation Sequencing: Personnel, Equipment, and Process Management (Phase 1)
- ScienceDirect | Standardization and quality management in next-generation sequencing
- NIH | NLM CCMG practice guideline: laboratory guidelines for next-generation seguencing
- ScienceDirect: ACMG clinical laboratory standards for next-generation sequencing
- APHL | Laboratory Test Verification and Validation Toolkit
- US FDA | Guidelines for the Validation of Analytical Methods Using Nucleic Acid Sequenced-Based Technologies
- US CDC | The Next Generation Sequencing Quality Initiative
- Frontiers | Methods to improve the accuracy of next-generation sequencing
- New York Department of Health | Validation of Next Generation Sequencing (NGS) Methods for Identification and/or Characterization of Infectious Agents
- NBIS Workshop 2023 | Introduction to Bioinformatics using NGS data
 - Quality Control of NGS Data
 - o Research Data Management
- ScienceDirect: Standards and Guidelines for Validating Next-Generation Sequencing Bioinformatics
 Pipelines: A Joint Recommendation of the Association for Molecular Pathology and the College of
 American Pathologists
- ScienceDirect | A Clinician's Guide to Bioinformatics for Next-Generation Sequencing
- Frontiers | Integrated Systems for NGS Data Management and Analysis: Open Issues and Available Solutions
- NIH | NLM Privacy and ethical challenges in next-generation sequencing



References

- OpenAI. (2024). Gemini response on learning objectives for basic laboratory requirements and operational setup for NGS implementation module. Retrieved July 29, 2024, from https://gemini.google.com/
- OpenAI. (2024). ChatGPT 4o mini response on learning objectives for basic laboratory requirements and operational setup for NGS implementation module. Retrieved July 29, 2024, from https://chatgpt.com/
- OpenAI. (2024). Claude 3.5 Sonnet response on learning objectives for basic laboratory requirements and operational setup for NGS implementation module. Retrieved July 29, 2024, from https://claude.ai/
- OpenAI. (2024). Copilot response on learning objectives for basic laboratory requirements and operational setup for NGS implementation module. Retrieved July 29, 2024, from https://copilot.microsoft.com/



We would like to thank the following individuals, in alphabetical order of last name, for their valuable time and effort spent in designing (i.e., drafting, reviewing, and refining) this module: **Elizabeth Akande, Essia Belarbi, Aaron Dean, Onikepe Folarin, Carla Garcia, Siddiqah George, Carolina Matos, and Eugene Yeboah**.

Furthermore, we would like to thank the following institutions, societies, journals and individuals from whom we sourced open-access resources used in this module: American Society for Microbiology, Association of Public Health Laboratories, Canadian College of Medical Geneticists, CDC NGS Quality Workgroup, Frontiers in Bioengineering and Biotechnology, Frontiers in Genetics, Frontiers in Microbiology, Foundation for Innovative New Diagnostics, Illumina, Journal Storage, Midwest Research Institute Global, National Bioinformatics Infrastructure Sweden, National Institutes of Health | National Library of Medicine, National Institute for Occupational Safety and Health, New York Department of Health, Protocols.io, Public Health England, ScienceDirect, The Next Generation Sequencing Quality Initiative, United States Centers for Disease Control and Prevention, United States Food and Drug Administration | Foods Program Regulatory Science Steering Committee, World Health Organization, Working Group of the American College of Medical Genetics and Genomics Laboratory Quality Assurance Committee; Ron Agatep, Alex Adjei, Bruno Amati, Gregory Armstrong, Cath Arnold, Manal Aziz, Sherri Bale, Megan Baldwin, Pinar Bayrak-Toydemir, Jonathan Berg, Valerio Bianchi, Pranami Bora, Kerry Brown, Stefano Campaner, Alexi Carter, Arnaud Ceol, Cheng-Yao Chen, Chu Cheng, Christopher Coldren, Ottavio Croci, Stefano de Pretis, Joshua Deignan, Harriet Feilotter, Zhongjie Fe, Philipp Franke, Michael Friez, Marcus Frohme, Peter Frommolt, Birgit Funke, Eugenia Galeota, Paula Gibbs, Jörn Glökler, Kathie Grant, Jonathan Green, Marta Gwinn, Madhuri Hegde, Kathy Hochul, Stacey Hume, Rebecca Hutchins, Claire Jenkins, Arivarasan Karunamurthy, Nefize Kip, Kamal Kishore, Eric Klee, Elin Kronander, Pranav Kulkarni, Nicholas Bradley Larson, Annette Leon, Kara Levinson, Stephen Lincoln, Elaine Lyon, Duncan MacCannell, David Magnus, Nicole Martinez-Martin, Marcus Mayrhofer, Elizabeth McCready, James McDonald, Joseph Miller, Marco Morelli, Atis Muehlenbachs, Aljuboori Nafea, Tanya Nelson, Ann Oberg, Alessandro Ogier, Jillian Parboosingh, Mattia Pelizzola, Kristy Phan, Mrudula Pullambhatla, Xiaorong Qian, Heidi Rehm, Somak Roy, Adeeba Saboor, Ahmed Salama, Jillian Socea, Marsha Speevak, Dimitri Stavropoulos, Tracy Stockley, Victoria Stone, Selen Stromgren, Sherryl Taylor, Robyn Temple-Smolkin, Yigang Tong, Karl Voelkerding, Chen Wang, Duanyang Wang, Liguo Wang, Yuer Wang, Pengfeng Xiao, Shan Xu, Maria Zambon.



Recommended modules to follow this module

• Module W03. Introduction to Fundamental Laboratory Skills and Calculations

Last updated: December 2024