**Conducting Personnel competency Assessment**

**for the Illumina Miseq Sequencer**

1. **Purpose**

This procedure outlines the steps for assessing the competency of personnel to run the Illumina MiSeq next generation sequencer from initial sample quality control to the review of sequencing run quality metrics. Competency should be assessed after successful completion of training. Competency assessment is required every six months during the first year the individual tests patient specimens. Thereafter, competency assessment must be performed at least annually. Competency assessment can be done throughout the year by coordinating it with routine practices and procedures to minimize impact on workload.

1. **Scope**

This document applies to all staff that operate the Illumina MiSeq next generation sequencer and supervisors that oversee these operations. CLIA competency assessment consists of six criteria: 1) Direct observation of testing; 2) Monitor recording and reporting results; 3) Review intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4) Direct observation of instrument maintenance and function checks; 5) Assess test performance; and 6) Assess problem solving skills.

*Note that this document is written to meet CLIA requirements; if your laboratory is not subject to the requirements of CLIA, please consult your Quality Manager to tailor the content of this document to meet your laboratory’s specific needs.*

1. **Related Documents**

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| **Title** | **Document Control Number** |
| MiSeq Competency Assessment Form |  |
| *List your laboratory’s SOPs as appropriate* |  |

1. **Responsibility**

| **Position** | **Responsibility** |
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| All laboratory staff | * Complete all necessary competency assessment requirements |
| Team Lead | * Determine the competency assessment needs for the laboratory team * Designate the assessor |
| Assessor | * Assess staff as directed by the Team Lead * Document competency assessment activities |
| Technical Supervisor | * Document final assessment results and remediation activities, if required |
| Branch Chief | * Ensure applicable laboratory staff are accountable for completing all competency assessment requirements described in this procedure * Review and approve this procedure |
| Quality Manager | * Review competency assessment documentation |

1. **Definitions**

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| **Term** | **Definition** |
| Competency | The ability of laboratory personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. |
| Competency assessment | Ensures that laboratory personnel are fulfilling their duties as required by federal regulation. |

1. **Equipment/Materials**
   1. Illumina MiSeq Sequencer
   2. Library preparation and sequencing reagents
2. **Safety Precautions**
   1. All BSL-2 practices, safety equipment, and facility design must comply with the requirements listed in the most current version of Biosafety in Microbiology and Biomedical Laboratories.
   2. Appropriate PPE must be worn at all times when working in the laboratory, including laboratory coat, gloves, and safety glasses (if splashes are anticipated).
3. **Procedure**
   1. Perform direct observation of routine testing, including sample preparation (if applicable), specimen handling, specimen processing, and test performance.
      1. Observe the performance of the skill/knowledge areas listed in the MiSeq Competency Assessment Form section 1) Direct Observation of Testing.
      2. Indicate Yes, No, or N/A for each Task Observed, initial and date; include Comments as needed for tasks marked No or N/A.
      3. Record the outcome (Pass or Fail), initial and date.
   2. Monitor recording and reporting test results; assess during direct observation of testing.
      1. Observe the performance of all skill/knowledge areas listed in the MiSeq Competency Assessment Form section 2) Monitor Recording and Reporting Results.
      2. Indicate Yes, No, or N/A for each Task Observed, initial and date; include Comments as needed for tasks marked No or N/A.
      3. Record the outcome (Pass or Fail), initial and date.
   3. Review intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
      1. Observe the performance of all skill/knowledge areas listed in the MiSeq Competency Assessment Form section 3) Review Intermediate Test Results / Worksheets, QC Records, PT Results, PM Records.
      2. Indicate Yes, No, or N/A for each Task Observed, initial and date; include Comments as needed for tasks marked No or N/A.
      3. Record the outcome (Pass or Fail), initial and date.
   4. Perform direct observation of instrument maintenance and function checks.
      1. Observe the performance of all skill/knowledge areas listed in the MiSeq Competency Assessment Form section 4) Direct Observation of Instrument.
      2. Indicate Yes, No, or N/A for each Task Observed, initial and date; include Comments as needed for tasks marked No or N/A.
      3. Record the outcome (Pass or Fail), initial and date.
   5. Assess test performance by comparing results with previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
      1. Observe the performance of all skill/knowledge areas listed in the MiSeq Competency Assessment Form section 5) Assess Test Performance.
      2. Indicate Yes, No, or N/A for each Task Observed, initial and date; include Comments as needed for tasks marked No or N/A.
      3. Record the outcome (Pass or Fail), initial and date.
   6. Assess problem solving skills.
      1. Observe the performance of all skill/knowledge areas listed in the MiSeq Competency Assessment Form section 6) Assess Problem Solving Skills.
      2. Indicate Yes, No, or N/A for each Task Observed, initial and date; include Comments as needed for tasks marked No or N/A.
      3. Record the outcome (Pass or Fail), initial and date.
   7. Document completion of competency assessment.
      1. Document employee acknowledgement through signature and date.
      2. Indicate assessment result and if required, document remediation actions taken (to be completed by the Technical Supervisor).
      3. Obtain final review and signatures by the Technical Supervisor, Team Lead, and Quality Manger.
      4. List all assessors who participated in the assessment with signature, initials, and date. *(Add lines to the form as needed.)*
4. **Revision History**

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| **Rev #** | **DCR #** | **Changes Made to Document** | **Date** |
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1. **Approval**

Approval Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_