| **Employee Name** (Print) |  | **Assessment**  **Start Date** |  | **Test/Assay Name** |  |
| --- | --- | --- | --- | --- | --- |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Assessment Type:**  (check one) | **Initial Assessment** | **❑** | **6-Month Assessment** | **❑** | **Annual Assessment** | **❑** |

| **1) Direct Observation of Testing** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Skill / Knowledge Assessed** | **Task Observed** | | | **Yes** | **No** | **N/A** | | **Assessor Initial / Date** | |
| Specimen Processing: DNA Extraction | Performs specimen preparation in accordance with approved procedure *(DNA extraction)* | | |  |  |  | |  | |
| Ensures positive specimen identification is maintained | | |  |  |  | |  | |
| Identifies acceptable specimen types and storage requirements | | |  |  |  | |  | |
| Specimen Processing: DNA Quality Control | Performs quality control of DNA in accordance with approved procedure *(Nanodrop, Qubit, Bioanalyzer, or Fragment Analyzer)* | | |  |  |  | |  | |
| Ensures positive specimen identification is maintained | | |  |  |  | |  | |
| Specimen Processing: DNA Shearing and Library Preparation | Performs DNA Shearing in accordance with approved procedure *(Covaris)* | | |  |  |  | |  | |
| Performs Sheared DNA Quality Control testing in accordance with approved procedure *(Bioanalyzer, TapeStation, Fragment Analyzer)* | | |  |  |  | |  | |
| Performs Library Preparation in accordance with approved procedure *(TruSeq)* | | |  |  |  | |  | |
| Performs Library Preparation Quality Control Testing in accordance with approved procedure *(Bioanalyzer, TapeStation, Fragment Analyzer)* | | |  |  |  | |  | |
| Performs Library Preparation Quantitation in accordance with approved procedure *(Qubit, qPCR)* | | |  |  |  | |  | |
| Loading the MiSeq Cartridge | Performs Loading of the MiSeq Cartridge in accordance with approved procedure | | |  |  |  | |  | |
| **Comments** |  | | | | | | | | |
| **Criterion 1) Outcome:** | **Pass** | **Fail** | **N/A** | **Assessor Initial / Date** | | | | |  |
| **2) Monitor Recording and Reporting Results** | | | | | | | | | |
| **Skill / Knowledge Assessed** | **Task Observed** | | | **Yes** | **No** | **N/A** | | **Assessor Initial / Date** | |
| Record NGS process data | Complies with applicable documentation requirements *(e.g. completes NGS Run Data Capture Tool)* | | |  |  |  | |  | |
| **Comments** |  | | | | | | | | |
| **Criterion 2) Outcome:** | **Pass** | **Fail** | **N/A** | **Assessor Initial / Date** | | |  | | |

| **3) Review Intermediate Test Results / Worksheets, QC Records, PT Results, PM Records** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Skill /**  **Knowledge Assessed** | **Task Observed** | | | **Yes** | **No** | **N/A** | | **Assessor Initial / Date** |
| Updates equipment records (calibration, maintenance, etc.) | Updates the preventive maintenance equipment log after each sequencing run | | |  |  |  | |  |
| Reviews NGS process quality control checkpoint data | Records quality control data in the NGS Data Capture Tool and shows ability to make correct decisions on whether to proceed with the NGS process according to the approved procedure | | |  |  |  | |  |
| **Comments** |  | | | | | | | |
| **Criterion 3) Outcome:** | **Pass** | **Fail** | **N/A** | **Assessor Initial / Date** | | |  | |
| **4) Direct Observation of Instrument Maintenance and Function Checks** | | | | | | | | |
| **Skill /**  **Knowledge Assessed** | **Task Observed** | | | **Yes** | **No** | **N/A** | | **Assessor Initial / Date** |
| Performs the Post-Run Wash | Performs Post-Run Wash in accordance with approved procedure | | |  |  |  | |  |
| Perform Maintenance Wash | Performs Maintenance Wash in accordance with approved procedure | | |  |  |  | |  |
| **Comments** |  | | | | | | | |
| **Criterion 4) Outcome:** | **Pass** | **Fail** | **N/A** | **Assessor Initial / Date** | | |  | |

| **5) Assess Test Performance** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Skill /**  **Knowledge Assessed** | **Task Observed** | | | **Yes** | **No** | **N/A** | | **Assessor Initial / Date** |
| Review of quality control checkpoint data and sequence data demonstrate acceptable performance | The results of testing one of the below are as expected:  (select one; attach record)  Previously tested specimens  Internal blind specimens  Proficiency test specimens result | | |  |  |  | |  |
| **Comments** |  | | | | | | | |
| **Criterion 5) Outcome:** | **Pass** | **Fail** | **N/A** | **Assessor Initial / Date** | | |  | |

| **6) Assess Problem Solving Skills** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Skill /**  **Knowledge Assessed** | **Task Observed** | | | **Yes** | **No** | **N/A** | | **Assessor Initial / Date** |
| Troubleshooting | Able to describe potential sources of error and preventive actions | | |  |  |  | |  |
| **Comments** |  | | | | | | | |
| **Criterion 6) Outcome:** | **Pass** | **Fail** | **N/A** | **Assessor Initial / Date** | | |  | |

| **Employee Acknowledgement** | | | |
| --- | --- | --- | --- |
| I certify that I completed the assessment outlined above. | | | |
|  | **Name**  (Print) | **Signature** | **Date** |
| **Employee** |  |  |  |

| **Assessment Result**  (To be completed by the Technical Supervisor) | | | | |
| --- | --- | --- | --- | --- |
| **Criteria for Success:**  **100% Compliance to Procedures** | | Successful | Remediation Required | |
| **Remediation:** (If required) | | | | |
|  | | | | |
|  | **Name**  (Print) | **Signature** | | **Date** |
| **Technical Supervisor** |  |  | |  |

| **Reviews** | | | |
| --- | --- | --- | --- |
|  | **Name**  (Print) | **Signature** | **Date** |
| **Team Lead** |  |  |  |
| **Quality Manager** |  |  |  |

| **Assessor Reference** | | | |
| --- | --- | --- | --- |
| I certify that I conducted the assessment outlined above and the employee completed activities as identified. | | | |
|  | **Name**  (Print) | **Signature** | **Initials / Date** |
| **Assessor** |  |  |  |
| **Assessor** |  |  |  |