| **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** |  |  |  |