| **Employee Name** (Print) |  | **Assessment****Start Date** |  |
| --- | --- | --- | --- |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 and Qubit, Bioanalyzer, or Fragment Analyzer)* | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Ensures positive specimen identification is maintained | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Specimen Processing: DNA Shearing and Library Preparation | Performs DNA Shearing and Library Preparation in accordance with approved procedures *(example: Covaris or enzymatic)* | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Performs Sheared DNA Quality Control testing in accordance with approved procedure *(Bioanalyzer, TapeStation, Fragment Analyzer)* | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Performs Library Preparation Quality Control Testing in accordance with approved procedure *(gel electrophoresis, Bioanalyzer)* | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Performs Library Preparation Quantitation in accordance with approved procedure *(bioanalyzer, qPCR, Qubit)*  | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Automated System: Loading the Ion Chef | Prepares reagents and loads libraries into the Ion Chef in accordance with approved procedure (check N/A if the Ion Chef is not used) | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Template Preparation | Performs Template Preparation and enrichment in accordance with approved procedure (check N/A if the Ion Chef was used) | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Loading the Ion chip | Performs loading of the Ion chip in accordance with approved procedure (check N/A if the Ion Chef was used) | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **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, records in lab notebook)* | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **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 or other record 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 on all required instruments in accordance with approved procedure | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Perform Maintenance Wash | Performs other maintenance washes on all required instruments 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** |  |  |  |