1. **Purpose**

This document provides instructions for the preventive maintenance of the Ion Personal Genome Machine (PGM) Sequencer to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *“insert laboratory name here”*.

1. **Scope**

This document applies to Ion PGM Sequencer used within the *(Your Lab / Branch, etc.)* for DNA or RNA sequencing.

1. **Related Documents**

|  |  |
| --- | --- |
| **Title** | **Document Control #** |
| Ion PGM Preventive Maintenance Wash Flowchart |  |
| Ion PGM In-Use EquipmentWeekly Maintenance Log |  |
| Ion PGM In-Use EquipmentDaily Maintenance Log |  |
| Ion PGM Equipment Power Off Maintenance Log |  |
| Equipment Out of Service Form |  |
| Master Equipment Inventory Log |  |
| Master Maintenance / Calibration Schedule |  |

1. **Responsibility**

| **Position** | **Responsibility** |
| --- | --- |
| All Laboratory Staff | * Ensure equipment is properly maintained according to established criteria * Follow documented equipment procedures |
| Branch Chief / Team Lead | * Ensure documented procedures for the proper maintenance of designated equipment are established * Ensure documented procedures are followed |
| Quality Manager | * Ensure documented equipment procedures are available to the end user * Maintain a master list of equipment used by the laboratory |

1. **Definitions**

|  |  |
| --- | --- |
| **Term** | **Definition** |
| Preventive maintenance | [Systematic](http://www.businessdictionary.com/definition/systematic.html) [inspection](http://www.businessdictionary.com/definition/inspection.html), detection, [correction](http://www.businessdictionary.com/definition/correction.html), and [prevention](http://www.businessdictionary.com/definition/prevention.html) of incipient [failures](http://www.businessdictionary.com/definition/failure.html) for the purpose of preventing actual or major failures. |

1. **Equipment / Materials**

|  |  |  |
| --- | --- | --- |
| **Supply** | **Catalog Number** | **Procedure** |
| 18 MΩ water from a purification system such as Elga PURELAB Flex Water Purification system (or equivalent) | N/A | * Weekly clean * Daily clean |
| Cleaning bottles (provided) | N/A | * Weekly clean * Daily clean |
| Collection trays (provided) | N/A | * Weekly clean * Daily clean |
| Used chip | N/A | * Weekly clean * Daily clean |
| Used sipper tube (from previous run or provided) | N/A | * Weekly clean * Daily clean |
| Ion PGM Cleaning Tablet (provided in kit, store at 4ºC) | N/A | * Weekly chlorite clean |
| 1 M NaOH | N/A | * Weekly chlorite clean |
| 1 L glass bottle | N/A | * Weekly chlorite clean |
| 0.22 µm or 0.45 µm vacuum filtration system and filter | N/A | * Weekly chlorite clean |

1. **Safety Precautions**
   1. All practices, safety equipment, and facility design must comply with the requirements for the laboratory’s BSL rating. Refer to your laboratory’s biosafety manual and the most current version of Biosafety in Microbiology and Biomedical Laboratories for more information.
   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).
2. **Procedure**
   1. **Maintenance**
      1. Any update to the equipment, inclusive of software updates, requires evaluation and approval prior to installation. Performance of Installation, Operational, and possibly Performance Qualification may be required.
      2. Reference the Ion PGM Sequencer Preventive Maintenance Wash Flowchart for addtional guidance on maintenance wash requirements.
   2. **Annual Preventative Maintenance**
      1. This is provided by the vendor with the purchase of a service contract.
   3. **Prepare for Cleaning (Weekly or Daily)**
      1. **18MΩ Water**
         1. Use only 18 MΩ water.
         2. Always use fresh 18 MΩ water straight from a purification system; do not use 18 MΩ water that was collected or stored in containers.
      2. **Set-Up**
         1. Remove any bottles attached to the Ion PGM Sequencer.
         2. Do not remove old sipper tubes before cleaning as they are used during the cleaning procedure.
         3. Separate cleaning bottles are provided with the system. After the provided Wash Bottles have been used for the specified number of runs, mark the bottles as “Cleaning Use Only” to be used as extra cleaning bottles.
         4. Ensure an old chip is in position on the instrument before cleaning.
   4. **Weekly Maintenance**
      1. Clean with chlorite solution once a week, unless the instrument has not been used since last chlorite clean (in which case clean with 18 MΩ water; see “**Cleaning with 18 MΩ water**” below).
      2. Clean with chlorite solution if the instrument has been left with reagents for more than 48 hours (for example, over the weekend).
      3. **1 M NaOH Preparation**
         1. Each week prepare a stock of 1 M NaOH by diluting 10 M NaOH with 18 MΩ water.
      4. **Chlorite Cleaning**
         1. Empty any remaining solution from each cleaning bottle (two 250 mL bottles and one 2 L bottle).
         2. Rinse each bottle twice with 100 mL of 18 MΩ water.
         3. Fill a glass bottle with 1 L 18 MΩ water and add an Ion PGM Cleaning Tablet (chlorite tablet), allowing it to dissolve completely (~10min).
         4. When the tablet is dissolved, add 1 mL of 1 M NaOH, mix gently by inverting, and filter the solution using 0.22µm or 0.45µm filter.
            * Use this chlorite solution within 2-3 hours and discard any unused solution.
         5. Press “**Clean**” on the touchscreen and select “**Chlorite Cleaning**” checkbox.
         6. Add 250 mL of the filtered chlorite solution into a 250 mL cleaning bottle
         7. Rinse the outside of the sipper tube in the W1 position on the instrument with a squirt bottle containing 18 MΩ water and attach the bottle to the W1 position.
         8. Follow the touchscreen instructions: place the empty 2 L cleaning bottle in the W2 position and the empty 250 mL cleaning bottle in the W3 position.
         9. Place collection trays below the sipper tubes in the dNTP positions and press “**Next**” to begin cleaning.
         10. When prompted, remove the W1 cleaning bottle (containing chlorite solution), rinse the outside of the sipper tube with a squirt bottle containing 18 MΩ water, then install a clean 250 mL cleaning bottle filled with 250 mL of 18 MΩ water in the W1 position.
         11. When cleaning is complete, remove all bottles and sipper tubes from the W1, W2, and W3 positions (leave the reagent sipper tubes and collection trays in place).
         12. Press “**Next**” to return to the Main Menu and proceed to Initialization.
   5. **Daily Maintenance** 
      1. Clean daily with 18 MΩ water when instrument is in use (not necessary on weekends).
      2. Clean with 18 MΩ water after less than 1000 flows (e.g. 2 x 200 base read runs).
      3. Clean with 18 MΩ water if more than 27 hours, but less than 48 hours, have elapsed between the last cleaning/initialization and the start of a run.
      4. Clean with 18 MΩ water if a chlorite clean was done a week ago and the machine has not been in use.
      5. Record pH check results during instrument initialization on the *Ion PGM In-Use Equipment Daily Maintenance Log*.
      6. **100 mM NaOH Preparation**
         1. Prepare 100 mM NaOH by diluting 1 M stock NaOH with 18 MΩ water.
         2. 500 µL of 100 mM NaOH is needed per initialization.
      7. **Cleaning with 18 mQ Water**
         1. Empty any remaining solution from each cleaning bottle (two 250 mL bottles and one 2 L bottle) and rinse each bottle twice with 100 mL fresh 18 MΩ water.
         2. Press “**Clean**” on the touchscreen and select the “**18 MOhm water cleaning**” checkbox.
         3. Add 250 mL of 18 MΩ water into the 250 mL cleaning bottle.
         4. Rinse the outside of the sipper tube in the W1 position on the instrument with a squirt bottle containing 18 MΩ water, and attach the bottle to the W1 position.
         5. Following the touchscreen instructions, place the empty 2L cleaning bottle in the W2 position and the empty 250 mL bottle in the W3 position.
         6. Place collection trays below the sipper tubes in the dNTP positions.
         7. Press “**Next**” to begin cleaning.
         8. When complete, remove all bottles and sipper tubes from the W1, W2, and W3 positions (leave the reagent sipper tubes and collection trays in place).
         9. Press “**Next**” to return to the Main Menu and proceed to initialization.
   6. **Instrument Power Off**
      1. If the instrument will not be used for more than 3 days:
         1. From **Main Menu**, select “**Tools > Shut Down**.”
         2. If you have not already cleaned the instrument, Select “**18MΩ Water Cleaning**” and press “**Next**” to start the cleaning process.
         3. When cleaning is complete, press “**Shut Down**.”
         4. After you exit the main touchscreen, press “**Halt**” button, then “**OK**” when prompted. The instrument will power down.
   7. **Repair / Service / Unscheduled Maintenance**

*NOTE: if your laboratory has an equipment troubleshooting or Out of Service SOP, delete the text below, include a reference to the SOP, and add the SOP as a related document in Section 3.0.*

* + 1. Place an “Out of Service (OOS)” form on the equipment.
    2. Document the problem on the *laboratory OOS / maintenance log*, stating date / time taken OOS, reason why the equipment was taken OOS, and initials / date of responsible individual.
    3. “Troubleshoot” source of the problem (sample, reagent, operator, equipment, etc.). (Refer to Ion PGM Sequencing 200 Kit User Guide MAN0007273.)
    4. Call Manufacturer’s Technical Assistance, if needed. Record the technical support case number.
    5. Determine what repair / maintenance is to be performed when you call for service.
       1. Equipment under warranty may require that repairs are completed by the manufacturer.
       2. Is disinfection / decontamination required?
       3. How is disinfection / decontamination performed? Define appropriate disinfectant, time required, recommended precautions, areas to be decontaminated, etc.
    6. Items sent to a manufacturer for repair and ultimately replaced must be reported to the responsible property office.
    7. Record in *laboratory OOS / maintenance log* and attach service report, if applicable.
    8. Place equipment back into service after verification / qualification completed.
    9. Maintain a history of maintenance / repair / service.

1. **References**

**9.1**  CLSI, Laboratory Implementation, Verification & Maintenance: Approved Guideline GP31-A.

Ion PGM Sequencing 200 Kit v2 User Guide Pub #: MAN0007273 Rev. 3. 2013.

1. **Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Rev #** | **DCR #** | **Change Summary** | **Date** |
|  |  |  |  |

1. **Approval Signature**

Reviewed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_