1. **Purpose**

This procedure provides instructions for the maintenance of the Ion OneTouch 2 (OT2) 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 OneTouch 2 used within the *(Your Lab / Branch, etc.)* for template preparation prior to DNA sequencing on the Ion PGM Sequencer.

1. **Related Documents**

|  |  |
| --- | --- |
| **Title** | **Document Control #** |
| Ion OneTouch 2 PreventiveMaintenance 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** |
| Ion OneTouch 2 Cleaning Adaptor (single use) | Provided in Ion PGM Template OT2 Supplies 400 Kit (Part no. 44798799) and Ion PGM Template OT2 Supplies 200 Kit (Part no. 4480981) | Post-Run Clean |
| Ion Proton OT2 Oil  (450 mL) | Provided in the Ion PGM™ Template OT2 Solutions 400 Kit (Part no. 4479880) and Ion PGM Template OT2 Solutions 200 Kit (Part no. 4481105) | Post-Run Clean |
| Kimwipes (or equivalent) | N/A | Post-Run Clean |
| 50 mL conical tube | N/A | Post-Run Clean |

1. **Safety Precautions**
   1. Take sharps precaution when using the disposable injector needle
   2. When using the OnteTouch 2 Instrument heat block take precaution for the hot surface when removing Amplification Plate
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. **Annual Preventative Maintenance:** Refer to service contract
      3. **Monthly Preventative Maintenance:** None
      4. **Weekly Preventative Maintenance:** None
      5. **Post-Run Clean:** Note: Perform the Post-Run Clean after the completion of each sequence run.
         1. Ensure the latest firmware is installed on the OneTouch 2 instrument.
         2. Ensure there is at least 20 mL of Ion OneTouch Oil in the left Reagent Tube. Add oil if necessary.
         3. Remove and discard the used Reaction Filter Assembly.
         4. Keep the Ion OneTouch 2 Amplification Plate in the heat block.
         5. Firmly insert the 3 ports of the single-use Cleaning Adaptor into the 3 holes on top of the instrument.
         6. Remove the disposable injector from the Injector Hub.
         7. Remove the disposable tubing from the pinch valve.
         8. Place the used injector into an empty 50 mL conical tube in a tube rack by the instrument.
         9. On the instrument home screen, touch “**Clean**” and follow all prompts.
         10. When all tasks are complete, touch “**Next**.”
         11. When cleaning is complete, dispose of the waste in the 50 mL conical tube.
         12. Remove and dispose of the used Amplification Plate, disposable injector, and tubing.
         13. Touch “**Open Lid**” to open the centrifuge lid, wipe the residue from the lid with a Kimwipe and close the lid.
         14. Touch “**Next**” to return to the home screen.
      6. **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 Ion PGM Template OT2 User Guide for the kit you are using (e.g. 200, 400, etc.).)
      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.
         * Equipment under warranty may require that repairs are completed by the manufacturer.
         * Is disinfection / decontamination required?
         * 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**
   1. CLSI, Laboratory Implementation, Verification & Maintenance: Approved Guideline GP31-A.
   2. Ion PGM TemplateOT2 200 Kit User GuidePub #: MAN0007220. Rev. B.0. 2015
   3. Ion PGM Template OT2 400 Kit User Guide Pub#: MAN0007218. Rev. A.0. 2014
   4. Ion PGM Checklist-Ion OneTouch 2 Template Preparation Pub #: MAN0009128 Rev.1.0.

**Revision History**

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

**Approval Signature**

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