1. **Purpose**

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

1. **Related Documents**

|  |  |
| --- | --- |
| **Title** | **Document Control Number** |
| Ion OneTouch ES PreventiveMaintenance Log |  |
| Equipment Out of Service Form |  |
| Master Equipment Inventory Log |  |
| Master Maintenance / Calibration Schedule |  |

1. **Responsibilities**

|  |  |
| --- | --- |
| **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** |
| Xiameter PMX-200 Silicone Fluid | Neely Industries:PMX200-12500PT | Annual Maintenance |

1. **Safety Precautions**
	* 1. Xiameter PMX-200 Silicone Fluid - Wear safety glasses. Wash contaminated clothing before re-use. Wash hands before breaks and at end of workday. Ensure adequate ventilation, especially in confined areas. Flammable, do not ingest or touch without gloves. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
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 Maintenance: *Syringe Lubrication***: Note: refer to Appendix B of Ion PGM Template OT2 200 Kit User Guide for instructions with photos.
			1. Disassemble the syringe (located on the back of the instrument).
			2. Disconnect tubing.
			3. Remove the 2 screws.
			4. Remove the retainer.
			5. Pull the syringe body toward you to remove from the instrument.
			6. Remove the plunger from the syringe body.
			7. Apply a thin layer of Xiameter PMX-200 Silicon Fluid to the inside of the syringe body with a gloved finger.
			8. Reassemble the syringe, as follows:
				* Push the plunger all the way into the syringe body then pull back approximately 0.25 inches.
				* Engage the plunger with its matching end on the instrument and insert the valve into its docking position.
				* Replace the retainer, replace the 2 screws (finger-tighten), and reconnect tubing.
		3. **Monthly Maintenance: *Residual Volume Test***
			1. Set up the Ion OneTouch ES.
			2. Install a new tip on the Tip Arm, as follows:
				* Place a new tip in the Tip Loader.
				* Remove the Tip Arm from the cradle and align the metal fitting of the Tip Arm with the tip.
				* Keeping the fitting on the Tip Arm vertical, firmly press the Tip Arm down onto the new tip until the Tip Arm meets the Tip Loader.
				* Hold the Tip Arm to the Tip Loader for ~1 second to ensure proper installation of the tip.
				* Lift the Tip Arm straight up to pull the installed tip from the Tip Loader tube.
				* Return the Tip Arm to the cradle: Tilt the Tip Arm.
			3. Load an 8-well strip onto the Ion OneTouch ES.
				* Load 80 µL water or the Ion OneTouch Wash Solution into the second well (Well 2) from the square tabbed end of the 8-well strip.
				* Load the 8-well strip into the slot of the Tray so that the square tabbed end is to the left, and the 8-strip well is pushed all the way to the right until it touches the end of the slot.
			4. Run the Residual Volume Test: confirm that the tip is centered between the sides of the wells when moving during the test.
				* Turn the ES instrument “ON.”
				* Wait for the system to initialize, the screen displays “rdy” and the Tip Arm performs a series of movements before returning to home position.
				* Press “Start/Stop.”
				* Wait for the instrument to aspirate the solution from Well 2 and completely remove the tip from Well 2, then manually push the 8-well strip to the left so that Well 4 is positioned directly under the Tip Arm.
				* Wait for the instrument to dispense into Well 4.
				* Press “Start/Stop” to stop the test run and press “Start/Stop” again to return the Tip Arm to the home position.
				* Place a P10 pipette at the front bottom of Well 2, aspirate the entire residual volume from the well, then estimate the residual volume.
			5. Remove the used tip: With the Tip Arm in its cradle and while standing above the Tip Arm, twist the tip counterclockwise and pull downward to remove and discard the tip.
			6. Remove and discard the used 8-well strip.
			7. After performing the residual volume test, take one or more of the following actions:
				* If Residual Volume in Well 2 is ≤5µL: proceed to prepare the reagents, then fill the 8-well strip.
				* If Residual Volume in Well 2 is >5µL: the tip height may be too high during aspiration; restore defaults, and calibrate the ES (see User Guide).
				* Aspiration is irregular: The ES is out of calibration, restore defaults and calibrate the ES (see User guide).
				* The 8-well strip lifts as the tip rises to the top of the well: The tip is angled too far or the tip height is set too low; verify that the tip is completely vertical and positioned directly over the notch in the calibration shelf, restore defaults, and calibrate the ES (see User guide).
		4. **Weekly Maintenance:** None.
		5. **Daily Maintenance:** None.
		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 to Ion PGM Template OT2 User Guides)
			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**

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

Ion PGM Template OT2 200 Kit User Guide Pub #: MAN0007220 Rev. B.0. 2015

**9.2** Xiameter PMX-200 Silicone Liquid MSDS Sheet Rev. 2.2. 2017/03/10

1. **Revision History**

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

1. **Approval**

Approval Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_