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The NGS Quality Workgroup developed these documents and tools as examples for use by next-generation sequencing laboratories. These documents and tools are not controlled files; format and content must be modified as needed to meet the document control, quality management system or regulatory requirements within your laboratory. It is the responsibility of the laboratory to take any necessary actions to ensure the information within these documents remains applicable.

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MiSeq Equipment Pre-Installation Checklist

Equipment Name: Illumina MiSeq

Before purchasing equipment, verify that the following requirements are, or can be, met:

Requirement	Requirement Met?	Comments
Electrical ☐ **100-110 V AC** with 10-amp grounded dedicated line OR ☐ **220-240 V AC** with 6-amp grounded line	Yes ☐ No ☐	
Wattage ☐ **400 Watts**	Yes ☐ No ☐	
Required Power Protection ☐ **Uninterrupted Power Supply** (APC Back-UPS Pro #BR1500G, recommended, other similar UPS acceptable)	Yes ☐ No ☐	
Water Access to one of the following types of laboratory grade water: ☐ Illumina PW1 ☐ 18 Megohm water ☐ Milli-Q water ☐ Super-Q water ☐ Molecular biology-grade water	Yes ☐ No ☐	
Waste ☐ Create profile within CDC on-line Hazardous Waste Turn-In System	Yes ☐ No ☐	

Requirement	Requirement Met?	Comments
Ventilation ☐ Sufficient for MiSeq thermal output of 1,364 Btu/h **Note:** The thermal output of 1,364 Btu/h is for the MiSeq only; ventilation should be sufficient for the total thermal output of the room.	Yes ☐ No ☐	
Operating Temperature Range ☐ **19˚-25˚C** **Note:** Verify with facilities that the temperature range is maintained 24 hours a day, 7 days a week; monitor prior to instrument arrival.	Yes ☐ No ☐	
Operating Humidity Range ☐ **30–75%**	Yes ☐ No ☐	
Elevation ☐ **Below 2,000 meters (6,500 feet)**	Yes ☐ No ☐	
Air Quality ☐ **Pollution Degree II** environment or better	Yes ☐ No ☐	
Vibration Specifications • Dedicated, sturdy, and immobilized lab bench without castors • No shaker, vortexer, centrifuge, heavy fans, etc. on same bench • Away from frequently-used doors • No keyboard tray below the bench • Do not touch the instrument or open the reagent compartment or flow cell compartment during sequencing. • Do not place objects on top of the instrument. **Note:** Equipment is sensitive to vibrations.	Yes ☐ No ☐	

Requirement	Requirement Met?	Comments
Network Connections Yes ☐ No ☐ **Note**: Use a 1 gigabit connection between the instrument and your data management system. This connection can be made directly or through a network switch. Upon connection to a network, configure Windows Update so that theMiSeq does not automatically update. Illumina recommends waiting one month after a Windows release before allowing an update.	Yes ☐ No ☐	If No, explain:
External Data Storage Yes ☐ No ☐ **Note:** To request SciComp storage: • Go to http://info.biotech.cdc.gov/ • Click on "Support" • Click on "Sequencer Storage Request" • Complete form and submit	Yes ☐ No ☐	If Yes, specify (e.g. SciComp): If No, explain:
Door/Elevator/Access Point Clearance <u>Crated Dimensions and Weight</u> • Height: **30.25 in** • Width (side to side): **28.5 in** • Depth (front to back): **33 in** • Weight: **200 lbs**	Yes ☐ No ☐	
Lab Bench Requirements • Width: **48 in** • Height: **36 in** • Depth: **30 in** • Instrument Weight: **126 lbs** • Casters: **No**	Yes ☐ No ☐	

Requirement	Requirement Met?	Comments
Operating Clearance **Instrument Dimensions** • Height: **20.6 in** • Width (side to side): **27 in** • Depth (front to back): **22.2 in** • Weight: **126 lbs.** **Clearance Requirements** • Back Clearance: **4 in** • Side Clearance: **24 in (each side)** • Top Clearance: **24 in** • Usage Access: **power switch on right side of instrument**	Yes ☐ No ☐	
Dedicated Physically Separate Areas (If using MiSeq for sequencing PCR amplicons) ☐ Dedicate physically separate pre-PCR laboratory space where pre-PCR processes are performed (DNA extraction, quantification, and normalization) ☐ Dedicate physically separate post-PCR laboratory space where PCR products are made and processed ☐ Dedicate separate full sets of equipment and supplies (pipettes, incubator, heat block, vortexer, centrifuge, etc.) to pre-PCR and post-PCR lab processes. Do not share equipment and supplies between processes ☐ Dedicate separate storage areas (freezers and refrigerators) for pre-PCR and post-PCR consumables **Note:** Do not use the same sink to wash pre-PCR and post-PCR materials. Do not share water purification systems for pre-PCR and post-PCR processes. Store all supplies used in pre-PCR protocols in the pre-PCR area, and transfer to the post-PCR area as needed.	Yes ☐ No ☐ N/A ☐	

Requirement	Requirement Met?	Comments
Documentation ☐ Training Documents ☐ Equipment Maintenance Documents ☐ Other: _____	Yes ☐ No ☐	
Ancillary equipment required Access to or acquisition of the following: ☐ Automated Liquid Handler (optional) ☐ Thermocycler ☐ Instrument for sizing, quantitation, and quality check of DNA (e.g.Bioanalyzer, TapeStation, Qubit) ☐ Instrument for shearing DNA (e.g. Covaris) (optional depending on library prep method) ☐ Benchtop centrifuge, plate centrifuge ☐ Other: _____	Yes ☐ No ☐	
Other Requirement(s) _____ _____ ☐ N/A	Yes ☐ No ☐	

***References:** MiSeq System Guide Doc # 15027617 v01 Spetember 2015

Completed By (signature): _____

Date: _____

Approved By (signature): _____

Date: _____

Equipment Name: Life Technologies Ion Personal Genome Machine (PGM) System

Before purchasing equipment, verify that the following requirements are, or can be, met:

Requirement:	Requirement Met?	Comments
Electrical; instrument requirements **Ion PGM Sequencer:** ☐ Voltage: 110/120 VAC (220/240 VAC) ☐ Current: 9 A (max) ☐ Frequency: 50/60 Hz **Ion Torrent Server:** ☐ Voltage: 110/120 VAC (220/240 VAC) ☐ Current: 11 A (max) ☐ Frequency: 50/60 Hz **Ion OneTouch 2:** ☐ Voltage: 110/120 VAC (220/240 VAC) ☐ Current: 5.5 A (max) ☐ Frequency: 50/60 Hz **Ion OneTouch ES:** ☐ Voltage: 110/120 VAC (220/240 VAC) ☐ Current: 375 mA (160 mA) (max) ☐ Frequency: 50/60 Hz **Ion Chef System:** ☐ Voltage: 100-240 VAC ☐ Current: 14 A (max) ☐ Frequency: 50/60 Hz	Yes ☐ No ☐	

Requirement:	Requirement Met?	Comments
Electrical; additional requirements ☐ Receptacle: 2-prong with ground pin ☐ Main AC line voltage tolerances must be up to +/- 10% of nominal voltage ☐ If supplied power cords are not suitable for installation, ensure all power cords used are: • Max 10 ft. length • Grounding type • Capable with the power supply receptacles used to connect to main power • UL compliant	Yes ☐ No ☐	
Wattage ☐ Ion PGM Sequencer: **200-300 Watts** ☐ Ion Torrent Server: **1100 Watts** ☐ Ion Chef System: **1350 Watts**	Yes ☐ No ☐	
Power Protection ☐ Adequate to provide protection (e.g. UPS)	Yes ☐ No ☐	
Water ☐ Access to 18 Megohm laboratory grade water	Yes ☐ No ☐	

Requirement:	Requirement Met?	Comments
Gas Nitrogen gas cylinder located within 10 ft. of the instrument and chained to a wall/bench: Yes ☐ No ☐ **ONE of the following required:** ☐ A pressurized house line ☐ Size 1-A nitrogen gas cylinder that holds approximately 7.2m^3 of gas when full **ALL of the following required:** ☐ 2-gauge regulator with a Compressed Gas Association (CGA) 580-cylinder adaptor on the inlet side and a Swagelok (or equivalent) end-fitting that accepts 0.25in (6.35mm) outer diameter tubing ☐ The secondary gauge must allow regulation between 25-45psi via CGA 580-cylinder adaptor with a needle type shut-off valve on the exit side ☐ The needle valves should have a Swagelok (or equivalent) end-fittings ready for connection to a 0.25in (6.35mm) outer diameter tubing ☐ Pre-purified nitrogen of 99.998% (grade 4.8) or greater purity	Yes ☐ No ☐	
Waste ☐ Plastic consumables • Refer to local regulations for diposal ☐ Chemical waste • Refer to SDS for checmical waste disposal instructions	Yes ☐ No ☐	
Ventilation ☐ Ion OneTouch2 Instrument:**20in(50 cm)** ☐ Ion PGM Sequencer: **4in(10 cm)** ☐ Minimum airflow: **6-10 air changes/hour**	Yes ☐ No ☐	

Requirement:	Requirement Met?	Comments
Operating Temperature Range ☐ **15-30˚C** ☐ **Ion Chef Sytem: 20-25˚C**, less than 2˚C fluctuation over a two-hour period **Note:** Verify with facilities that the temperature range is maintained 24 hours a day, 7 days a week; monitor prior to instrument arrival.	Yes ☐ No ☐	
Operating Humidity Range ☐ **10%-90%**, relative humidity ☐ **Ion Chef System: 40%-60%**, non-condensing	Yes ☐ No ☐	
Elevation ☐ Between sea level and 2,000 meters (6,500 feet) above sea level	Yes ☐ No ☐	
Vibration Specifications ☐ Dedicated and sturdy lab bench ☐ No equipment that causes vibrations such as freezers, shaker, vortexer, centrifuge, heavy fans, shearing instruments, etc. on same bench or in contact with bench **Note:** Equipment is sensitive to vibrations.	Yes ☐ No ☐	

Requirement:	Requirement Met?	Comments
Network Connections ☐ Ion Torrent Server is directly connected to the Ion PGM Sequencer via standard Category 6 Ethernet cable ☐ Room must have at least one active network jack ☐ A dynamic or static IP address must be reserved for the Ion Torrent Server ☐ The Ion Torrent Server must have outbound internet access and be behind an appropriately configured firewall in order to receive full technical support • Software updates are retrieved by access through HTTP/port-80 • Timely support is retrieved by access through HTTPS/port-443 and SSH/port-22 ☐ If applicable, the Ion Chef System must be connected to the Torrent Server either using a category 6 Ethernet cable or indirectly via LAN network that has been configured to permit HTTP-443, SSH-22, and FTP-20/21 traffic.	Yes ☐ No ☐	If No, explain:
External Data Storage Yes ☐ No ☐ Note: to request SciComp storage: • Go to http://info.biotech.cdc.gov/ • Click on “Support” • Click on “Sequencer Storage Request” • Complete form and submit	Yes ☐ No ☐	If Yes, specify (e.g. SciComp): If No, explain:

Requirement:	Requirement Met?	Comments
Door/Elevator/Access Point Clearance Maximum Crated Dimensions and Weight • Height: **28.3 in** • Depth (front to back): **34.0 in** • Width (side to side): **34.0 in** • Weight: **295** Dimensions of Crated System Components *(Height x Depth x Width, Weight)* • **Ion PGM Sequencer:** 26.5 x 26.0 x 29.5 in, 95 lbs. • **Ion Torrent Server:** 28.3 x 27.8 x 13.5 in, 66 lbs. • **Ion OneTouch 2:** 18.0 x 18.0 x 21.0 in, 44 lbs. • **Ion OneTouch ES Instrument:** 14.5 x 14.5 x 17.5 in, 13 lbs. • **Ion Chef System:** 28.0 x 34.0 x 34.0 in, 295 lbs.	Yes ☐ No ☐	
Operating Clearance; instrument dimensions Dimensions of System Components *(Height x Depth x Width, Weight)* • **Ion PGM Sequencer:** 21x20x24 in, 65 lbs • **Ion Torrent Server:** 22.3x21.2x8.5 in, 55 lbs • **Ion OneTouch 2:** 12x16x14 in, 37.5 lbs • **Ion OneTouch ES:** 9.5x16x11 in, 12 lbs • **Ion Chef System:** 22.1(33 open)x27.6x28.1 in, 150 lbs	Yes ☐ No ☐	

Requirement:	Requirement Met?	Comments
Operating Clearance; individual clearance requirements **<u>Ion PGM Sequencer:</u>** • Back Clearance: **4 in** • Side Clearance: **4 in** (left) **8 in** (right) • Top Clearance: **12 in** • Front Clearance: **12 in** from front edge of bench to sequencer bezel, **8 in** from bench to conical tubes, **36 in** of aisle space **<u>Ion Torrent Server:</u>** • Back Clearance: **24 in** • Side Clearance: **2 in** (each side) • Top Clearance: **2 in** • Front Clearance: **12 in** **<u>Ion OneTouch 2:</u>** • Back Clearance: **4 in** • Side Clearance: **4 in** (each side) • Top Clearance: **12 in** • Front Clearance: **12 in** **<u>Ion OneTouch ES:</u>** • Back Clearance: **12 in** • Side Clearance: **12 in** (each side) • Top Clearance: **12 in** • Front Clearance: **12 in** **<u>Ion Chef System:</u>** • Back: **4 in** • Side: **4 in** (each side) • Top: **14 in** • Front: **6.7 in**	Yes ☐ No ☐	

Requirement:	Requirement Met?	Comments
Location Conducive to Lab Workflow ☐ All Ion System components are located in the post-PCR room or area; sequencer and server (and Chef, if applicable) are ideally on a separate bench from all other equipment, including the OneTouch2 system	Yes ☐ No ☐	
Documentation ☐ Training Documents ☐ Equipment Maintenance Documents ☐ Other: _____	Yes ☐ No ☐	
Ancillary equipment required Access to, or acquisition of, the following: ☐ Automated Liquid Handler (optional) ☐ Thermocycler ☐ Instrument for sizing, quantitation, and quality check of DNA (e.g. Bioanalyzer, Qubit) ☐ Instrument for shearing DNA (e.g. Covaris) (optional depending on library prep method) ☐ Benchtop centrifuge, plate centrifuge ☐ Other: _____	Yes ☐ No ☐	
Other Requirement(s): _____ _____ ☐ N/A	Yes ☐ No ☐	

***References:** Ion PGM System Site Preparation Guide Publication # MAN0007516 Rev. A0 2017, Ion Chef System Site Preparation Guide MAN0007956)

Completed By (signature): _____

Date: _____

Approved By (signature): _____

Date: _____

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Vendor-Performed IQ-OQ Coversheet

Equipment Name:		
Manufacturer:		
Equipment Model:		
Serial Number:		
Unique ID:		
CDC Barcode Number:		
IQ Date / OQ Date:		
Initial Warranty / Maintenance Dates of Service:		
Order Confirmation Number (vendor-specific):		
Performed By: (tech/vendor name)		
Team Lead Review: (or designee)	**Sign:**	
	Print:	**Date:**
Quality Assurance Requirement:	**Equipment added to ID Database?** ☐ Yes ☐ No, explain:	
Quality Assurance Review:	**Sign:**	
	Print:	**Date:**

Note: Attach documentation provided by the vendor to this coversheet.

1.0 Purpose

This procedure provides instructions for the maintenance of the Illumina MiSeq to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *"insert laboratory name here"*.

2.0 Scope

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

3.0 Related Documents

Title	Document Control Number
MiSeq Preventive Maintenance Wash Flowchart	
MiSeq In-Use Equipment Maintenance Log	
MiSeq Standby Equipment Maintenance Log	
Equipment Out of Service Form	
Master Equipment Inventory Log	
Master Maintenance / Calibration Schedule	

4.0 Responsibilities

Position	Responsibility
All laboratory staff	• Ensures equipment is properly maintained according to established criteria • Follows documented equipment procedures
Branch Chief / Team Lead	• Ensures documented procedures for the proper maintenance of designated equipment are established • Ensures documented procedures are followed
Quality Manager	• Ensures documented equipment procedures are available to the end user • Maintains a master list of equipment used by the laboratory

5.0 Definitions

Term	Definition
Preventive maintenance	Systematic inspection, detection, correction, and prevention of incipient failures for the purpose of preventing actual or major failures.

6.0 Equipment / Materials

Supply	Catalog Number	Procedure
Tween 20	Sigma-Aldrich Cat. # P7949 or equivalent	• Post-Run Wash • Maintenance Wash • Standby Wash
Laboratory Grade Water	N/A	• Post-Run Wash • Maintenance Wash • Standby Wash
6% Sodium hypochlorite	N/A	• Post-Run Wash with Template Line Wash
MiSeq Tube	Illumina Part # MS-102-9999	• Post-Run Wash with Template Line Wash

7.0 Safety Precautions

a. The MiSeq waste bottle contains formamide, an aliphatic amide that is a probable reproductive toxin. Personal injury can occur through inhalation, ingestion, skin contact, and eye contact.

8.0 Procedure

8.1 Maintenance

a. 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.

b. Reference the *MiSeq Preventive Maintenance Wash Flowchart* for additional guidance on maintenance wash requirements.

8.2 Weekly Maintenance

a. Cleaning

i. Cleaning should be performed weekly.

ii. Using a Kimwipe®, wipe the outer casing to remove dust. Do not touch the instrument if it is running.

iii. Record in *laboratory cleaning / maintenance log*.

b. Power Cycle the Instrument

i. To power cycle in Windows mode:

- Close MiSeq Control Software and ensure no other programs are running and shut-down the computer from the Windows Start button.
- Once the computer has shut down, turn off the power switch on the back of the MiSeq instrument, and leave it off for a minimum of 60 seconds.
- Turn on the power switch and let the computer start normally.
- Record in *laboratory cleaning / maintenance log*.

ii. To power cycle in Kiosk mode:

- Go to **Manage Instrument** and select **Shutdown**

- Once the computer has shut down, turn off the power switch on the back of the MiSeq instrument and leave it off for a minimum of 60 seconds.
- Turn on the power switch and let the computer start normally.
- Record in *laboratory cleaning / maintenance log*.

8.3 Post-Run Wash

a. A post-run wash must be completed after each sequencing run. The post-run wash takes approximately 20 minutes to complete.

b. Leave the used flow cell on the instrument.

c. Prepare fresh wash solution with Tween 20 and laboratory-grade water.

i. Add 10 ml 100% Tween 20 to 90 ml laboratory grade water. These volumes result in 10% Tween 20.

ii. Add 50 ml 10% Tween 20 to 950 ml laboratory grade water. These volumes result in a 0.5% Tween 20 wash solution.

iii. Invert five times to mix.

d. Prepare the wash components with fresh wash solution, as follows:

i. Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.

ii. Add 350 ml wash solution to the 500 ml wash bottle.

e. When the sequencing run is complete, select **Start Wash**. The software automatically raises the sippers in the reagent chiller.

f. Open the reagent compartment door and reagent chiller door, wait for sippers to raise and slide the used reagent cartridge from the chiller.

g. Slide the wash tray into the reagent chiller until it stops, then close the reagent chiller door.

h. Raise the sipper handle in front of the PR2 bottle and waste bottle until it locks into place.

i. Remove the PR2 bottle and replace it with the wash bottle.

i. **Discard the PR2 bottle in a laboratory hazardous waste container.** Do not reuse any remaining PR2.

j. Remove the waste bottle and discard the contents appropriately. **(Caution: waste contains formamide; discard using the CDC Hazardous waste turn-in system.)** Return the waste bottle to the reagent compartment.

k. Slowly lower the sipper handle, making sure that the sippers lower into the wash bottle and waste bottle, proceed to close the reagent compartment door.

l. Select **Next**. The post-run wash begins.

m. When the wash is complete, leave the used flow cell, wash tray, and wash bottle containing the remaining wash solution on the instrument.

n. Record the following on the *MiSeq In-Use Equipment Maintenance Log*:

i. Sequence run start date

ii. Post-run wash date

iii. Indication that post-run wash did not include template line wash (N)

iv. Initials of operator performing maintenance

8.4 Post-Run Wash with Template Line Wash

a. MCS v2.5 or higher is required to perform this post-run wash with template line wash procedure. A post-run wash with template line wash is completed after each sequencing run. The post-run wash with template line wash takes approximately 30 minutes to complete.

b. Leave the used flow cell on the instrument.

c. Prepare fresh wash solution with Tween 20 and laboratory-grade water.

- **i.** Add 10 ml 100% Tween 20 to 90 ml laboratory grade water. These volumes result in 10% Tween 20.
- **ii.** Add 50 ml 10% Tween 20 to 950 ml laboratory grade water. These volumes result in a 0.5% Tween 20 wash solution.
- **iii.** Invert five times to mix.

d. Prepare fresh sodium hypochlorite wash solution with laboratory grade water, as follows:

- **i.** Add 36 µl of 5% sodium hypochlorite to 864 µl laboratory grade water. These volumes result in a 1:25 sodium hypochlorite dilution.
- **ii.** Add 50 µl of the 1:25 sodium hypochlorite dilution to 950 µl of laboratory grade water in an Illumina supplied MiSeq tube.

e. Prepare the wash components with fresh wash solution, as follows:

- **i.** Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.
- **ii.** Add 350 ml wash solution to the 500 ml wash bottle.

f. Insert the MiSeq tube containing 0.01% sodium hypochlorite wash solution into position 17 of the wash tray until the neck of the tube is flush with the tray.

g. When the sequencing run is complete, select **Start Wash**. The software automatically raises the sippers in the reagent chiller.

h. Select **Perform optional template line wash** on the Post-Run Wash screen.

i. Open the reagent compartment door and reagent chiller door, wait for sippers to raise, and slide the used reagent cartridge from the chiller.

- **i.** Slide the wash tray into the reagent chiller until it stops, and then close the reagent chiller door.

j. Raise the sipper handle in front of the PR2 bottle and waste bottle until it locks into place.

k. Remove the PR2 bottle and replace it with the wash bottle.

- **i.** **Discard the PR2 bottle in a laboratory hazardous waste container.** Do not reuse any remaining PR2

l. Remove the waste bottle and discard the contents appropriately. **(Caution: waste contains formamide; discard using the CDC Hazardous waste turn-in system.)** Return the waste bottle to the reagent compartment.

m. Slowly lower the sipper handle, making sure that the sippers lower into the wash bottle and waste bottle and proceed to close the reagent compartment door.

n. Select **Next**. The post-run wash with template line wash begins.

o. When the wash is complete, leave the used flow cell, wash tray, and wash bottle containing the remaining wash solution on the instrument.

p. Record the following on the *MiSeq In-Use Equipment Maintenance Log*:

- **i.** Sequence run start date
- **ii.** Post-run wash date
- **iii.** Indication that the post-run wash did include template line wash (Y)
- **iv.** Initials of operator performing maintenance

8.5 Maintenance Wash

a. A maintenance wash must be completed every 30 days. Additionally, a maintenance wash must be completed if the instrument has been in standby mode. The maintenance wash takes approximately 90 minutes to complete.

b. Leave the used flow cell on the instrument.

c. From the Home screen, select **Perform Wash**.

d. From the Perform Wash screen, select **Maintenance Wash**. The software automatically raises the sippers in the reagent chiller.

e. Perform First Wash

i. Prepare fresh wash solution with Tween 20 and laboratory grade water as follows:
- Add 10 ml 100% Tween 20 to 90 ml laboratory grade water. These volumes result in 10% Tween 20.
- Add 50 ml 10% Tween 20 to 950 ml laboratory grade water. These volumes result in a 0.5% Tween 20 wash solution.
- Invert five times to mix.

ii. Prepare the wash components with fresh wash solution as follows:
- Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.
- Add 350 ml wash solution to the 500 ml wash bottle.

iii. Open the reagent compartment door and reagent chiller door, wait for sippers to raise, and slide the used reagent cartridge from the chiller.

iv. Slide the wash tray into the reagent chiller until it stops, and then close the reagent chiller door.
- Raise the sipper handle in front of the PR2 bottle and waste bottle until it locks into place.

v. Remove the PR2 bottle and replace it with the wash bottle.
- **Discard the PR2 bottle in a laboratory hazardous waste container.** Do not reuse any remaining PR2

vi. Remove the waste bottle and discard the contents appropriately. **(Caution: waste contains formamide; discard using the CDC Hazardous waste turn-in system.)** Return the waste bottle to the reagent compartment.

vii. Slowly lower the sipper handle, making sure that the sippers lower into the wash bottle and waste bottle. Close the reagent compartment door and Select **Next**. The first wash begins.

f. Perform Second Wash

i. Always use fresh wash solution in the wash tray for each wash step.

ii. When the first wash is complete, remove the wash tray and discard the remaining wash solution.

iii. Refill the wash components with fresh wash solution, as follows:
- Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.

iv. Slide the wash tray into the reagent chiller until it stops, and then close the reagent chiller door.

v. Close the reagent compartment door.

vi. Select **Next**. The second wash begins.

g. Perform Final Wash

i. Always use fresh wash solution in the wash tray for each wash step.

ii. When the second wash is complete, remove the wash tray and discard the remaining wash solution.

iii. Refill the wash components with fresh wash solution, as follows:

- Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.

iv. Slide the wash tray into the reagent chiller until it stops, and then close the reagent chiller door.

v. Close the reagent compartment door.

vi. Select **Next**. The final wash begins.

vii. When the wash is complete, leave the used flow cell, wash tray, and wash bottle containing the remaining wash solution on the instrument.

viii. Record the following on the *MiSeq In-Use Equipment Maintenance Log:*

- Maintenance wash date
- Initials of the operator performing maintenance

8.6 Standby Wash

a. A standby wash must be completed if there are no plans to use the instrument within the next seven days. Additionally, a standby wash must be completed every 30 days until the instrument is brought back into use through a maintenance wash. The standby wash takes approximately 2 hours to complete.

b. Leave the used flow cell on the instrument.

c. From the Home screen, select **Perform Wash**.

d. From the Wash Options screen, select **Standby Wash**. The software automatically raises the sippers in the reagent chiller.

e. Perform First Wash

i. Prepare fresh wash solution with Tween 20 and laboratory-grade water.

- Add 10 ml 100% Tween 20 to 90 ml laboratory grade water. These volumes result in 10% Tween 20.
- Add 50 ml 10% Tween 20 to 950 ml laboratory grade water. These volumes result in a 0.5% Tween 20 wash solution.
- Invert five times to mix.

ii. Prepare the wash components with fresh wash solution, as follows:

- Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.
- Add 350 ml wash solution to the 500 ml wash bottle.

iii. Open the reagent compartment door and reagent chiller door, wait for sippers to raise, and slide the used reagent cartridge from the chiller.

iv. Slide the wash tray into the reagent chiller until it stops, and then close the reagent chiller door.

- Raise the sipper handle in front of the PR2 bottle and waste bottle until it locks into place, and replace the PR2 bottle with the wash bottle.

v. **Discard the PR2 bottle in a laboratory hazardous waste container.** Do not reuse any remaining PR2

vi. Remove the waste bottle and discard the contents appropriately. **(Caution: waste contains formamide; discard using the CDC Hazardous waste turn-in system.)** Return the waste bottle to the reagent compartment.
vii. Slowly lower the sipper handle, making sure that the sippers lower into the wash bottle and waste bottle.
viii. Close the reagent compartment door.
ix. Select **Next**. The first wash begins.

f. Perform Second Wash

i. **Always use fresh wash solution in the wash tray for each wash step.**
ii. When the first wash is complete, remove the wash tray and discard the remaining wash solution.
iii. Refill the wash components with fresh wash solution, as follows:
- Add wash solution to each reservoir of the wash tray, fill each reservoir to 90% capacity or 6 ml of wash solution into each reservoir.

iv. Slide the wash tray into the reagent chiller until it stops, and then close the reagent chiller door.
v. Close the reagent compartment door.
vi. Select **Next**. The second wash begins.
vii. When the wash is complete, leave the used flow cell, wash tray, and wash bottle containing the remaining wash solution on the instrument.
viii. Record the following on the *MiSeq Standby Equipment Maintenance Log:*
- Standby wash date
- Initials of operator performing maintenance

8.7 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.

i. Place an "Out of Service (OOS)" form on the equipment.
ii. 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.
iii. "Troubleshoot" source of the problem (sample, reagent, operator, equipment, etc.). (Refer to Illumina MiSeq System User Guide.)
iv. Call Manufacturer's Technical Assistance, if needed. Record the technical support case number.
v. 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.

vi. Items sent to a manufacturer for repair and ultimately replaced must be reported to the responsible property office.
vii. Record in *laboratory OOS / maintenance log* and attach service report, if applicable.
viii. Place equipment back into service after verification / qualification completed.
ix. Maintain a history of maintenance / repair / service.

9.0 References

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

9.2 Illumina MiSeq System Guide Document #15027617 v04 July 2018

10.0 Revision History

Rev #	DCR #	Change Summary	Date

11.0 Approval

Reviewed By: _____ Date: _____

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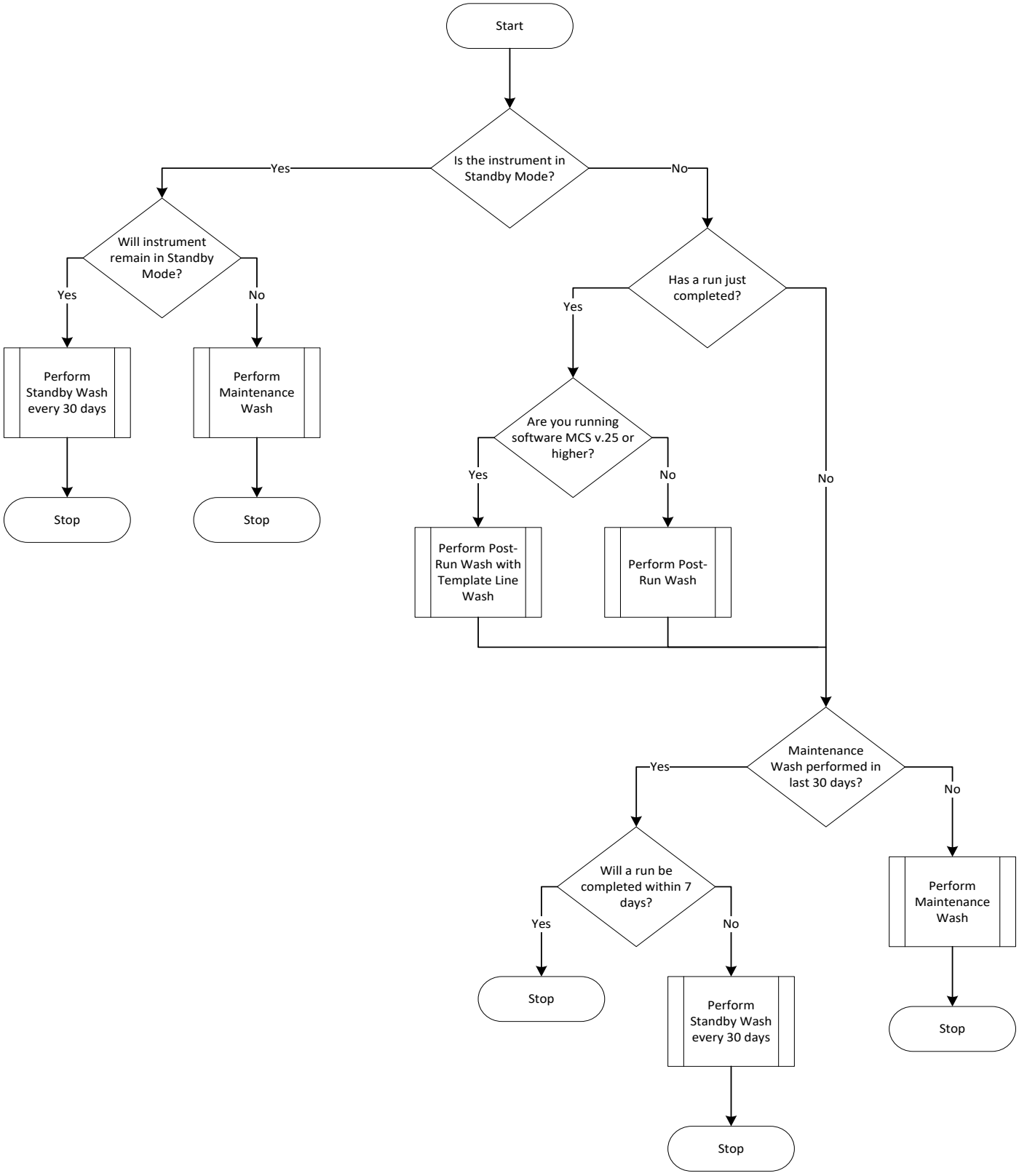
MiSeq Preventive Maintenance Wash Flowchart

Document #:	Revision #:	Effective Date:	Page 1 of 1



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MiSeq In-Use Equipment Maintenance Log

Lab:	Building #:	Room #:
Equipment: MiSeq	Equipment ID:	
Manufacturer: Illumina	Model # :	
Serial # :	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

Perform Post-Run Wash after each sequencing run				
Sequence Run Start Date	**Post-Run Wash Date**	**Post-Run Wash with Template Line Wash (Y/N)**	**Initials**	**Comments**
Perform Maintenance Wash monthly				
Maintenance Wash Date	**Initials**	If logging additional runs within a 30-day period, enter N/A for Maintenance Wash and Log End Date		
			Log ____ of ____	Comments:

Approval Signature:_____ Date:_____

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MiSeq Standby Equipment Maintenance Log

Document #:	Revision #:	Effective Date:	Page 1 of 1

Lab:	Building #:	Room #:
Equipment: MiSeq	Equipment ID:	
Manufacturer: Illumina	Model # :	
Serial # :	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

Perform Standby Wash if instrument will not be used within 7 days, and repeat monthly while idle		
Standby Wash Date	**Initials**	**Comments**

When instrument has been in standby mode, perform Maintenance Wash before first sequencing run	
Maintenance Wash Date	**Initials**

Approval Signature:_____ Date: _____

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MiSeq Equipment Error Log

1.0 Run Information

Laboratory:			
Building #:		**Room #:**	
Equipment:	Illumina MiSeq Sequencer	**Equipment ID:**	
Run ID:		**Error Date:**	
Initiator:		**Date:**	
Submitter:		**Date:**	
Reviewer:		**Date:**	

2.0 Error Report

Error description
(e.g. MiSeq error message, cluster density, % pass filter, description of erroneous data, sequencing step, etc.)

Troubleshooting action(s) taken:	
(e.g. Volume test run, data examined, Illumina technical support involved?)	
Notified staff of error	Yes ☐ No ☐
Notified manufacturer of error	Yes ☐ No ☐
Illumina Case Number:	
Other field reports available and attached:	Yes ☐ No ☐

Post-troubleshooting verification	
Performed post-troubleshooting verification:	Yes ☐ No ☐
Verification test used:	
Verification test results:	
Changes to process or procedure needed?	Yes ☐ No ☐ **Explain:**

3.0 Protocol Summary (or attach library preparation workbook)

3.1 Library Preparation

Preparer Name:	

Date Prepared:			
Kit Name:			
Reagent Names:			
Lot Numbers:			
Expiration Dates:			
Library QC Results:			

3.2 Sequencing Kit Information

Loader Name:			
Loading Concentration (pM):			
Cycles (300, 500, etc.):			
Version (V1, V2, etc.):			
Reagent Names:			
Lot Numbers:			
Expiration Dates:			

4.0 Comments

Comment Description:

Approval Signature:_____ Date:_____

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Ion PGM Sequencer Preventive Maintenance SOP

1.0 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"*.

2.0 Scope

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

3.0 Related Documents

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

4.0 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

5.0 Definitions

Term	Definition
Preventive maintenance	Systematic inspection, detection, correction, and prevention of incipient failures for the purpose of preventing actual or major failures.

6.0 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

7.0 Safety Precautions

7.1 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.

7.2 Appropriate PPE must be worn at all times when working in the laboratory, including laboratory coat, gloves, and safety glasses (if splashes are anticipated).

8.0 Procedure

8.1 Maintenance

a. 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.

b. Reference the Ion PGM Sequencer Preventive Maintenance Wash Flowchart for additional guidance on maintenance wash requirements.

8.2 Annual Preventative Maintenance

a. This is provided by the vendor with the purchase of a service contract.

8.3 Prepare for Cleaning (Weekly or Daily)

a. 18MΩ Water

i. Use only 18 MΩ water.

ii. Always use fresh 18 MΩ water straight from a purification system; do not use 18 MΩ water that was collected or stored in containers.

b. Set-Up

i. Remove any bottles attached to the Ion PGM Sequencer.

ii. Do not remove old sipper tubes before cleaning as they are used during the cleaning procedure.

iii. 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.

iv. Ensure an old chip is in position on the instrument before cleaning.

8.4 Weekly Maintenance

a. 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).

b. Clean with chlorite solution if the instrument has been left with reagents for more than 48 hours (for example, over the weekend).

c. 1 M NaOH Preparation

i. Each week prepare a stock of 1 M NaOH by diluting 10 M NaOH with 18 MΩ water.

d. Chlorite Cleaning

i. Empty any remaining solution from each cleaning bottle (two 250 mL bottles and one 2 L bottle).

ii. Rinse each bottle twice with 100 mL of 18 MΩ water.

iii. 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).

iv. 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.

v. Press "**Clean**" on the touchscreen and select "**Chlorite Cleaning**" checkbox.

vi. Add 250 mL of the filtered chlorite solution into a 250 mL cleaning bottle

vii. 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.

viii. 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.

ix. Place collection trays below the sipper tubes in the dNTP positions and press "**Next**" to begin cleaning.

x. 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.

xi. 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).

xii. Press "**Next**" to return to the Main Menu and proceed to Initialization.

8.5 Daily Maintenance

- **a.** Clean daily with 18 MΩ water when instrument is in use (not necessary on weekends).
- **b.** Clean with 18 MΩ water after less than 1000 flows (e.g. 2 x 200 base read runs).
- **c.** 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.
- **d.** Clean with 18 MΩ water if a chlorite clean was done a week ago and the machine has not been in use.
- **e.** Record pH check results during instrument initialization on the *Ion PGM In-Use Equipment Daily Maintenance Log*.
- **f. 100 mM NaOH Preparation**
  - **i.** Prepare 100 mM NaOH by diluting 1 M stock NaOH with 18 MΩ water.
  - **ii.** 500 µL of 100 mM NaOH is needed per initialization.
- **g. Cleaning with 18 mQ Water**
  - **i.** 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.
  - **ii.** Press "**Clean**" on the touchscreen and select the "**18 MOhm water cleaning**" checkbox.
  - **iii.** Add 250 mL of 18 MΩ water into the 250 mL cleaning bottle.
  - **iv.** 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.
  - **v.** Following the touchscreen instructions, place the empty 2L cleaning bottle in the W2 position and the empty 250 mL bottle in the W3 position.
  - **vi.** Place collection trays below the sipper tubes in the dNTP positions.
  - **vii.** Press "**Next**" to begin cleaning.
  - **viii.** 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).
  - **ix.** Press "**Next**" to return to the Main Menu and proceed to initialization.

8.6 Instrument Power Off

- **a.** If the instrument will not be used for more than 3 days:
  - **i.** From **Main Menu**, select "**Tools > Shut Down**."
  - **ii.** If you have not already cleaned the instrument, Select "**18MΩ Water Cleaning**" and press "**Next**" to start the cleaning process.
  - **iii.** When cleaning is complete, press "**Shut Down**."
  - **iv.** After you exit the main touchscreen, press "**Halt**" button, then "**OK**" when prompted. The instrument will power down.

8.7 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.

- **a.** Place an "Out of Service (OOS)" form on the equipment.
- **b.** 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.

c. "Troubleshoot" source of the problem (sample, reagent, operator, equipment, etc.). (Refer to Ion PGM Sequencing 200 Kit User Guide MAN0007273.)

d. Call Manufacturer's Technical Assistance, if needed. Record the technical support case number.

e. Determine what repair / maintenance is to be performed when you call for service.

- **i.** Equipment under warranty may require that repairs are completed by the manufacturer.
- **ii.** Is disinfection / decontamination required?
- **iii.** How is disinfection / decontamination performed? Define appropriate disinfectant, time required, recommended precautions, areas to be decontaminated, etc.

f. Items sent to a manufacturer for repair and ultimately replaced must be reported to the responsible property office.

g. Record in *laboratory OOS / maintenance log* and attach service report, if applicable.

h. Place equipment back into service after verification / qualification completed.

i. Maintain a history of maintenance / repair / service.

9.0 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.

10.0 Revision History

Rev #	DCR #	Change Summary	Date

11.0 Approval Signature

Reviewed By: _____ Date: _____

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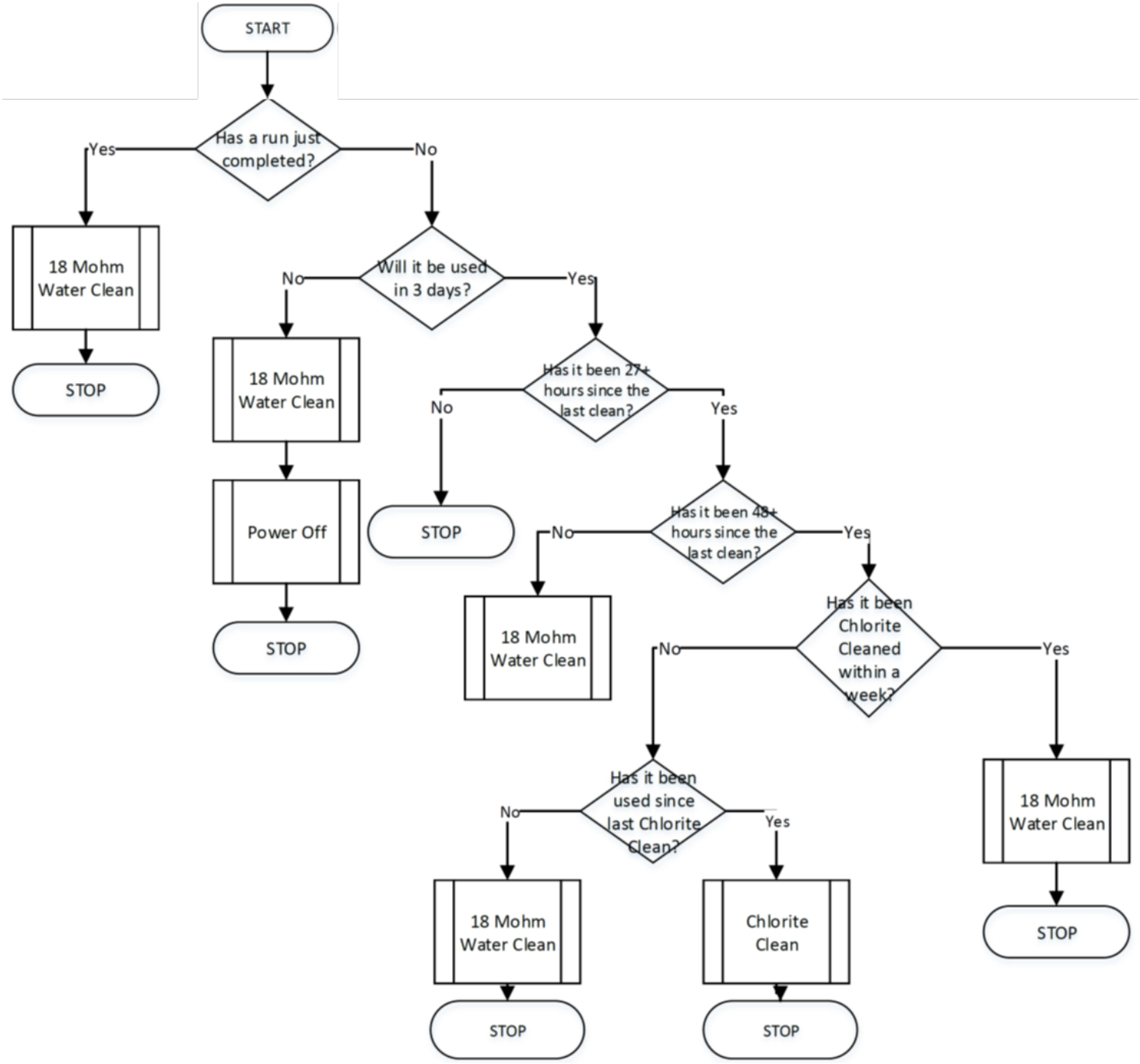
Ion PGM Preventive Maintenance Wash Flowchart

Document #:	Revision #:	Effective Date:	Page 1 of 1



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Ion PGM In-Use Equipment Daily Log

Document #:	Revision #:	Effective Date:	Page 1 of 2

Lab:	Building #:	Room #:
Equipment: Ion PGM Sequencer	Equipment ID:	
Manufacturer: Life Technologies/Ion Torrent	Model # :	
Serial # :	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

Perform 18 MOhm water clean daily when instrument is in use			
18 MOhm Water Wash Date	Sequence Run Start Date	pH Reading	Initials
		R0:	
		R1:	
		R2:	
		R3:	
		W2:	
		W1:	
		PASS ☐ FAIL ☐	
		R0:	
		R1:	
		R2:	
		R3:	
		W2:	
		W1:	
		PASS ☐ FAIL ☐	
		R0:	
		R1:	
		R2:	
		R3:	
		W2:	
		W1:	
		PASS ☐ FAIL ☐	
		R0:	
		R1:	
		R2:	
		R3:	
		W2:	

		W1:	
		PASS ☐ FAIL ☐	
		R0:	
		R1:	
		R2:	
		R3:	
		W2:	
		W1:	
		PASS ☐ FAIL ☐	
Comments:			

Approval Signature:_____ Date:_____

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Ion PGM In-Use Equipment Weekly Maintenance Log

Document #:	Revision #:	Effective Date:	Page 1 of 1

Lab:	Building #:	Room #:
Equipment: Ion PGM Sequencer		Equipment ID:
Manufacturer: Life Technologies/Ion Torrent		Model # :
Serial # :		ESO/CDC Barcode #:
Log Start Date:		Log End Date:

Perform chlorite wash weekly or if instrument has been sitting with reagents for 48+ hours			
Wash Date	**Fresh Chlorite Solution? (2-3 hours)**	**Initials**	**Comments**
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		

Approval Signature:_____ Date:_____

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Ion PGM Power-Off Equipment Maintenance Log

Lab:	Building #:	Room #:
Equipment: Ion PGM Sequencer	Equipment ID:	
Manufacturer: Life Technologies/Ion Torrent	Model # :	
Serial # :	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

If instrument will not be used for >3 days, select "Tools > Shut Down," complete 18 MOhm Water Clean, and then press "Shut Down"		
18 mΩ Wash and Power-Off Date	**Initials**	**Comments**

Approval Signature:_____ Date: _____

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Ion PGM Equipment Error Log

1.0 Run Information

Laboratory:			
Building #:		**Room #:**	
Equipment:	Ion PGM Sequencer	**Equipment ID:**	
Run ID:		**Error Date:**	
Initiator:		**Date:**	
Submitter:		**Date:**	
Reviewer:		**Date:**	

2.0 Error Report

Error description
(e.g. error message, pH out of range, cannot detect chip, poor sample loading, description of erroneous data, sequencing step, etc.)

Troubleshooting action(s) taken:	
(e.g. replaced chip, adjusted pH of reagents, data examined, Thermo Fisher technical support involved?)	
Notified staff of error	Yes ☐ No ☐
Notified manufacturer of error	Yes ☐ No ☐
Thermo Fisher Case Number:	
Other field reports available and attached:	Yes ☐ No ☐

Post-troubleshooting verification	
Performed post-troubleshooting verification:	Yes ☐ No ☐
Verification test used:	
Verification test results:	
Changes to process or procedure needed?	Yes ☐ No ☐ **Explain:**

3.0 Protocol Summary (or attach library preparation workbook)

3.1 Library Preparation

Preparer Name:			
Date Prepared:			
Kit Name:			
Reagent Names:			
Lot Numbers:			
Expiration Dates:			
Library QC Results:			

3.2 Sequencing Kit Information

Loader Name:			
Loading Concentration (pM):			
Flows (e.g. 80, 128, 180, etc.)			
Chip Type and version:			
Reagent Names:			
Lot Numbers:			
Expiration Dates:			

4.0 Comments

Comment Description

5.0 Revision History

Rev #	DCR #	Changes Made to Document	Date

6.0 Approval

Approval Signature:_____ Date:_____

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Ion Chef Preventive Maintenance SOP

1.0 Purpose

This procedure provides instructions for the maintenance of the Ion Chef to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *"insert laboratory name here"*.

2.0 Scope

This document applies to the instrument used for library and template preparation and chip loading prior to DNA/RNA sequencing on the Ion Personal Genome Machine (PGM) Sequencer used within the *(Your Lab / Branch, etc.)*

3.0 Related Documents

Title	Document Control Number
Ion Chef Preventive Maintenance Log	
Equipment Out of Service Form	LQMP.EQ.C.002.F08
Master Equipment Inventory Log	LQMP.EQ.C.002.F02
Master Maintenance / Calibration Schedule	LQMP.EQ.C.002.F04

4.0 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

5.0 Definitions

Term	Definition
Preventive maintenance	Systematic inspection, detection, correction, and prevention of incipient failures for the purpose of preventing actual or major failures.

6.0 Equiment / Materials

Supply	Catalog Number	Procedure
Powder-free, nitrile gloves	N/A	Daily Post-Run Clean
Isopropyl alcohol (70%)	N/A	Daily Post-Run Clean
Kimwipes (or equivalent)	N/A	Daily Post-Run Clean

7.0 Safety Precautions

Component	Precautions
UV Light (254nm)	Wear appropriate protective clothing, eye wear, and gloves while working near the instrument during cleaning cycle. Do not look directly at the UV light while it is illuminated.

8.0 Procedure

8.1 Maintenance

a. 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.

8.2 Annual Preventative Maintenance

a. Refer to service contract.

8.3 Monthly Preventative Maintenance

a. None

8.4 Weekly Preventative Maintenance

a. None

8.5 Post-Run Clean

Note: perform the Post-Run Clean after each run.

a. Open the instrument door using the touchscreen and wait for the latch to open.

b. Lift the instrument door until the latch mechanism engages.

c. Remove and discard used consumables from the instrument, such as PCR plate and used pipette tips.

i. Handle the disposable reservoir with care as liquid waste may have collected at the bottom.

ii. Do not reuse the waste pipette tip rack.

d. Move the empty Tip Cartridge to the waste tip position.
   i. Always move the empty Tip Cartridge from the new tip position to the waste tip position.
   ii. Do not discard the empty Tip Cartridge.
e. Remove and discard the Ion PGM IC Reagents Cartridge.
   i. Ensure transfer of QC samples before removal/discard of the IC Reagents Cartridge.
f. Remove and discard the Ion PGM IC Solutions Cartridge.
g. Close the lid of the Chip-loading Cartridge.
h. Remove and discard the Enrichment Cartridge.
i. Remove and discard consumables from the Recovery Centrifuges, including Recovery Station Lids and Tubes.
j. Inspect the Recovery Cartridges; if there is excess liquid, follow steps **8.5.10.a** through **8.5.10.h** to clean components. If there is no excess liquid, proceed to step **8.5.11**.
   i. Wear powder-free, nitrile gloves when cleaning.
   ii. Remove the buckets from the Recovery Centrifuge.
   iii. Clean the inside and outside of each bucket with a Kimwipe and place buckets on a clean, dry surface while you proceed.
   iv. Use Kimwipes to clean the inside rim of the centrifuge.
   v. Remove all fluid from the bottom of the centrifuge bowl.
   vi. Wet Kimwipes with 70% isopropanol to clean the inside rim, bottom of the centrifuge bowl, inside and outside of the centrifuge buckets.
   vii. Dry all components and surfaces with a clean, dry Kimwipe.
   viii. Re-install the buckets and close the centrifuge lid.
k. Close the instrument door by first lifting slightly to disengage the locking mechanism, then pushing down on the door until locks engage.
l. Touch “Next” on the screen that appears on the Ion Chef touchscreen after a run completes.
   i. If you are cleaning the instrument at any other time, touch “Settings” then “Clean Ion Chef.”
m. Confirm all consumables are removed from the instrument, except the empty Tip Cartridge in the waste tip position.
n. Touch “Next” and with the door closed, touch “Start.”
   i. The instrument performs a load check before starting the cleaning routine. During this time, the Ion Chef stops ventilation and illuminates the UV light within the instrument.
   ii. UV light is emitted at 254nm. Follow guidance stated above under “Safety Precautions.”

8.6 **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.

a. Place an "Out of Service (OOS)" form on the equipment.

b. 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.

c. "Troubleshoot" source of the problem (sample, reagent, operator, equipment, etc.). (Refer Ion PGM IC User Guide for the kit you are using (e.g. 200, 400, etc.).)

d. Call Manufacturer's Technical Assistance, if needed. Record the technical support case number.

e. Determine what repair / maintenance is to be performed when you call for service.

   i. Equipment under warranty may require that repairs are completed by the manufacturer.

   ii. Is disinfection / decontamination required?

   iii. How is disinfection / decontamination performed? Define appropriate disinfectant, time required, recommended precautions, areas to be decontaminated, etc.

f. Items sent to a manufacturer for repair and ultimately replaced must be reported to the responsible property office.

g. Record in laboratory OOS / maintenance log and attach service report, if applicable.

h. Place equipment back into service after verification / qualification completed.

i. Maintain a history of maintenance / repair / service.

9.0 References

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

9.2 Ion PGM IC 200 Kit User Guide Pub #: MAN0007661. Rev. C.0. 2015.

10.0 Revision History

Rev #	DCR #	Change Summary	Date

11.0 Approval

This document has been approved by the CDC CLIA Laboratory Director as the standard practice for CLIA-regulated CDC Infectious Diseases Laboratories under certificates 11D0668319 and 11D2030855.

Approved:

_____

The NGS Quality Workgroup developed these documents and tools for use by next-generation sequencing laboratories. These documents and tools were developed based upon best available information, reviewed, edited, and approved by the participants in the group listed above. Prior to implementing these processes in your lab, review the date the document was finalized (included in the file name) and take any necessary actions to ensure the information remains applicable. These documents and tools are not controlled files; you are encouraged to modify the format (e.g. header/footer, sections) as needed to meet the document control requirements of the quality management system within your laboratory.

Ion Chef Preventive Maintenance Log

Document #:	Revision #:	Effective Date:	Page 1 of 2

Lab:	Building #:	Room #:
Equipment: Ion Chef	Equipment ID:	
Manufacturer: Life Technologies/Ion Torrent	Model # :	
Serial # :	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

Sequence Run Finish Date	Post-Run Clean Date	Name	Comments

The NGS Quality Workgroup developed these documents and tools for use by next-generation sequencing laboratories. These documents and tools were developed based upon best available information, reviewed, edited, and approved by the participants in the group listed above. Prior to implementing these processes in your lab, review the date the document was finalized (included in the file name) and take any necessary actions to ensure the information remains applicable. These documents and tools are not controlled files; you are encouraged to modify the format (e.g. header/footer, sections) as needed to meet the document control requirements of the quality management system within your laboratory.

Ion Chef Preventive Maintenance Log

Approval Signature:_____ Date:_____

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Ion OneTouch 2 Preventive Maintenance SOP

1.0 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"*.

2.0 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.

3.0 Related Documents

Title	Document Control #
Ion OneTouch 2 Preventive Maintenance Log	
Equipment Out of Service Form	
Master Equipment Inventory Log	
Master Maintenance / Calibration Schedule	

4.0 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

5.0 Definitions

Term	Definition
Preventive maintenance	Systematic inspection, detection, correction, and prevention of incipient failures for the purpose of preventing actual or major failures.

6.0 Equipment / Materials

Supply	Catalog Number	Procedure
Ion OneTouch 2 Cleaning Adaptor (single use)	Provided in Ion PGM Template OT2 Supplies 400 Kit (Part no.	Post-Run Clean

	44798799) and Ion PGM Template OT2 Supplies 200 Kit (Part no. 4480981)	
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

7.0 Safety Precautions

7.1 Take sharps precaution when using the disposable injector needle

7.2 When using the OnteTouch 2 Instrument heat block take precaution for the hot surface when removing Amplification Plate

8.0 Procedure

8.1 Maintenance

a. 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.

b. Annual Preventative Maintenance: Refer to service contract

c. Monthly Preventative Maintenance: None

d. Weekly Preventative Maintenance: None

e. Post-Run Clean: Note: Perform the Post-Run Clean after the completion of each sequence run.

i. Ensure the latest firmware is installed on the OneTouch 2 instrument.

ii. Ensure there is at least 20 mL of Ion OneTouch Oil in the left Reagent Tube. Add oil if necessary.

iii. Remove and discard the used Reaction Filter Assembly.

iv. Keep the Ion OneTouch 2 Amplification Plate in the heat block.

v. Firmly insert the 3 ports of the single-use Cleaning Adaptor into the 3 holes on top of the instrument.

vi. Remove the disposable injector from the Injector Hub.

vii. Remove the disposable tubing from the pinch valve.

viii. Place the used injector into an empty 50 mL conical tube in a tube rack by the instrument.

ix. On the instrument home screen, touch "**Clean**" and follow all prompts.

x. When all tasks are complete, touch "**Next**."

xi. When cleaning is complete, dispose of the waste in the 50 mL conical tube.

xii. Remove and dispose of the used Amplification Plate, disposable injector, and tubing.

xiii. Touch "**Open Lid**" to open the centrifuge lid, wipe the residue from the lid with a Kimwipe and close the lid.

xiv. Touch "**Next**" to return to the home screen.

f. 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

i. Place an "Out of Service (OOS)" form on the equipment.

ii. 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.

iii. "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.).)

iv. Call Manufacturer's Technical Assistance, if needed. Record the technical support case number.

v. 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.

vi. Items sent to a manufacturer for repair and ultimately replaced must be reported to the responsible property office.

vii. Record in *laboratory OOS / maintenance log* and attach service report, if applicable.

viii. Place equipment back into service after verification / qualification completed.

ix. Maintain a history of maintenance / repair / service.

9.0 References

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

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

9.3 Ion PGM Template OT2 400 Kit User Guide Pub#: MAN0007218. Rev. A.0. 2014

9.4 Ion PGM Checklist-Ion OneTouch 2 Template Preparation Pub #: MAN0009128 Rev.1.0.

Revision History

Rev #	DCR #	Change Summary	Date

Approval Signature

Reviewed By: _____ Date: _____

The NGS Quality Workgroup developed these documents and tools for use by next-generation sequencing laboratories. These documents and tools were developed based upon best available information, reviewed, edited, and approved by the participants in the group listed above. Prior to implementing these processes in your lab, review the date the document was finalized (included in the file name) and take any necessary actions to ensure the information remains applicable. These documents and tools are not controlled files; you are encouraged to modify the format (e.g. header/footer, sections) as needed to meet the document control requirements of the quality management system within your laboratory.

ION OneTouch 2 Preventive Maintenance Log

Lab:	Building #:	Room #:
Equipment: Ion OneTouch 2	Equipment ID:	
Manufacturer: Life Technologies/Ion Torrent	Model # :	
Serial #:	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

Perform the Post-Run Clean after each sequencing run				
Sequence Run Finish Date	**Post-Run Clean Date**	**≥ 20 mL Ion OT oil in left Reagent Tube?**	**If No, oil added to left Reagent Tube?**	**Initials**
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
		☐ Yes ☐ No	☐ Yes ☐ No	
Comments				

Approval Signature:_____ Date:_____

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Ion OneTouch ES Preventive Maintenance SOP

1.0 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"*.

2.0 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.

3.0 Related Documents

Title	Document Control Number
Ion OneTouch ES Preventive Maintenance Log	
Equipment Out of Service Form	
Master Equipment Inventory Log	
Master Maintenance / Calibration Schedule	

4.0 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

5.0 Definitions

Term	Definition
Preventive maintenance	Systematic inspection, detection, correction, and prevention of incipient failures for the purpose of preventing actual or major failures.

6.0 Equipment / Materials

Supply	Catalog Number	Procedure
Xiameter PMX-200 Silicone Fluid	Neely Industries: PMX200-12500PT	Annual Maintenance

7.0 Safety Precautions

a. 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.

8.0 Procedure

8.1 Maintenance

a. 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.

b. Annual Maintenance: *Syringe Lubrication*: Note: refer to Appendix B of Ion PGM Template OT2 200 Kit User Guide for instructions with photos.

i. Disassemble the syringe (located on the back of the instrument).

ii. Disconnect tubing.

iii. Remove the 2 screws.

iv. Remove the retainer.

v. Pull the syringe body toward you to remove from the instrument.

vi. Remove the plunger from the syringe body.

vii. Apply a thin layer of Xiameter PMX-200 Silicon Fluid to the inside of the syringe body with a gloved finger.

viii. 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.

c. Monthly Maintenance: *Residual Volume Test*

i. Set up the Ion OneTouch ES.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. Remove and discard the used 8-well strip.

vii. 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).

d. Weekly Maintenance: None.

e. **Daily Maintenance:** None.

f. 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.

i. Place an "Out of Service (OOS)" form on the equipment.

ii. 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.

iii. "Troubleshoot" source of the problem (sample, reagent, operator, equipment, etc.). (Refer to Ion PGM Template OT2 User Guides)

iv. Call Manufacturer's Technical Assistance, if needed. Record the technical support case number.

v. 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.

vi. Items sent to a manufacturer for repair and ultimately replaced must be reported to the responsible property office.

vii. Record in *laboratory OOS / maintenance log* and attach service report, if applicable.

viii. Place equipment back into service after verification / qualification completed.

ix. Maintain a history of maintenance / repair / service.

9.0 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

10.0 Revision History

Rev #	DCR #	Change Summary	Date

11.0 Approval

Approval Signature: _____ Date: _____

The NGS Quality Workgroup developed these documents and tools for use by next-generation sequencing laboratories. These documents and tools were developed based upon best available information, reviewed, edited, and approved by the participants in the group listed above. Prior to implementing these processes in your lab, review the date the document was finalized (included in the file name) and take any necessary actions to ensure the information remains applicable. These documents and tools are not controlled files; you are encouraged to modify the format (e.g. header/footer, sections) as needed to meet the document control requirements of the quality management system within your laboratory.

Ion OneTouch ES Preventive Maintenance Log

Document #:	Revision #:	Effective Date:	Page 1 of 1

Lab:	**Building #:**	**Room #:**
Equipment: Ion OneTouch ES	**Equipment ID:**	
Manufacturer: Life Technologies/Ion Torrent	**Model # :**	**Log Start Date:**
Serial #:	**ESO/CDC Barcode #:**	**Log End Date:**

Perform Residual Volume Test Monthly					
Residual Volume Test Date Performed	**Residual volume ≤5µL?** (If Yes, reagents prepared and 8-well strip filled)	**Residual volume >5µL?** (If Yes, restore defaults and perform calibration)	**Aspiration irregular?** (If Yes, restore defaults and perform calibration)	**8-well strip lifts?** (If Yes, verify tip placement, restore defaults and perform calibration)	**Initials**
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	

Perform Syringe Lubrication Annually		
Syringe Lubrication Date Performed	**Initials**	**Comments**

Approval Signature:____ Date:____________

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MiSeq Software Update Evaluation SOP

1.0 Purpose

This procedure provides instructions for evaluating Illumina MiSeq instrument software updates to determine necessary actions to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *"insert laboratory name here"*.

2.0 Scope

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

3.0 Related Documents

Title	Document Control Number
MiSeq Software Update Form	
Illumina MiSeq Software Release Notes	*include applicable version*

4.0 Responsibilities

Position	Responsibility
All laboratory staff	• Ensure software is updated according to established laboratory guidelines • Follow documented software update process
Branch Chief / Team Lead	• Ensure documented procedures for the evaluation of software updates are established • Ensure documented procedures are followed • Review and approve the MiSeq Software Update Form
Quality Manager	• Ensure documented software update procedures are available to the end user • Review and approve the MiSeq Software Update Form

5.0 Procedure

5.1 Any updates to the equipment software require evaluation and approval prior to installation.

5.2 Obtain the MiSeq Software Update Form and the Illumina MiSeq Software Release Notes

5.3 ***Complete the MiSeq Software Update Form***

a. Record the current and new software versions.Note: There are multiple components to the MiSeq software, record the current and new version numbers for each.

b. Document the Illumina sequencing workflow(s) currently used in the laboratory.

c. Review each bullet point in the software release notes and evaluate the following:

i. Determine if the update affects the sequencing workflow used in the laboratory.

ii. Determine if the update potentially affects the sequencing data output results.

d. Evaluate the action required to ensure the equipment functions as expected following the software updates:

Updates affect the sequencing workflow?	Updates potentially affect the sequencing data?	Required Action
No	No	None
Yes	No	None
Yes	Yes	Verification

e. Install the software updates as directed in the release notes.

f. If verification is required, proceed to step **5.3.7**; otherwise proceed to step **5.3.8**.

g. Complete a verification run as described below prior to releasing the equipment back into service.

i. Using a standard, well-characterized sample previously ran in the laboratory, perform a sequencing run.

ii. If the sequencing data obtained with the new software versions are comparable to the data obtained with the prior software versions, no further action is needed.

iii. If the sequencing data obtained with the new software versions are not comparable to the data obtained with the prior software versions, conduct a revalidation of the assay.

h. Attach additional information as needed (e.g. Release Notes documentation, Verification / Validation data) to the MiSeq Software Update Form.

i. Sign, date, and obtain applicable reviews and approvals.

6.0 Revision History

Rev #	DCR #	Change Summary	Date

7.0 Approval

Reviewed By: _____ Date: _____

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MiSeq Software Update Form

Lab:	Building #:	Room #:
Equipment: MiSeq	**Equipment ID:**	
Manufacturer: Illumina	**Model #:**	
Serial #:	**ESO/CDC Barcode #:**	
Log Start Date:	**Log End Date:**	

Current Software Versions:	
New Software Versions:	
Illumina Sequencing Workflow(s) currently used in the laboratory:	

Release Notes Reviewed?	Do the updates affect the sequencing workflow used in the laboratory?	Do the updates potentially affect the sequencing data output results?
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Required Action:	☐ Verification ☐ None **Explanation:**	

Software Updates Installed Successfully?	☐ Yes ☐ No	Install Date:
Results of Verification (and Validation, if applicable)		

Operator Signature / Date	
Quality Manager Signature / Date	
Approval Signature / Date	

The NGS Quality Workgroup developed these documents and tools for use by next-generation sequencing laboratories. These documents and tools were developed based upon best available information, reviewed, edited, and approved by the participants in the group listed above. Prior to implementing these processes in your lab, review the date the document was finalized (included in the file name) and take any necessary actions to ensure the information remains applicable. These documents and tools are not controlled files; you are encouraged to modify the format (e.g. header/footer, sections) as needed to meet the document control requirements of the quality management system within your laboratory.

Ion PGM Sequencer Update Evaluation SOP

1.0 Purpose

This procedure provides instructions for evaluation of Ion PGM Sequencer instrument software updates to determine necessary actions to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *"insert laboratory name here"*.

2.0 Scope

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

3.0 Related Documents

Title	Document Control Number
Ion PGM Sequencer Software Update Form	

4.0 Responsibilities

Position	Responsibility
All laboratory staff	• Ensure software is properly updated according to established laboratory guidelines • Follow documented software update process
Branch Chief / Team Lead	• Ensure documented procedures for the proper documentation of software updates are established • Ensure documented procedures are followed • Review and approves the Ion PGM System Software Update Form
Quality Manager	• Ensure documented software update procedures are available to the end user • Review and approve the Ion PGM Sequencer Software Update Form

5.0 Procedure

5.1 Any updates to the equipment software require evaluation and approval prior to installation.

5.2 Obtain the Ion PGM Sequencer Software Update Form and the Ion software release notes.

5.3 ***Complete the Ion PGM Sequencer Software Update Form***

a. Record the current and new software versions. Note: Indicate the TorrentSuite versions and attach a list of software versions for Ion PGM Sequencer components, as applicable.

b. Identify the Ion-related instruments in use.

c. Document the Ion PGM sequencing workflow(s) currently used in the laboratory.

d. Indicate if any additional plug-ins or kits are downloaded.

e. Review each bullet point in the software release notes and evaluate the following:

i. Determine if the update affects the sequencing workflow used in the laboratory.

ii. Determine if the update potentially affects the sequencing data output results.

f. Evaluate the action required to ensure the equipment functions as expected following the software updates:

Updates affect the sequencing workflow?	Updates potentially affect the sequencing data?	Required Action
No	No	None
Yes	No	None
Yes	Yes	Verification
No	Yes	Verification

g. Install the software updates as directed in the release notes.
  i. Ensure that the version of the current software components meets the update requirements. If the current version is older than what is required in the release notes for normal update, contact technical support to ensure a successful update.
  ii. Use the same user account for both the Torrent Browser and instrument software updates.

h. If verification is required, proceed to step g); otherwise proceed to step h).

i. Complete a verification run as described below prior to releasing the equipment back into service.
  i. Using a standard, well-characterized sample previously ran in the laboratory, perform a sequencing run.
  ii. If the sequencing data obtained with the new software versions are comparable to the data obtained with the prior software versions, no further action is needed.
  iii. If the sequencing data obtained with the new software versions are not comparable to the data obtained with the prior software versions, conduct a revalidation of the assay.

j. Attach additional information as needed (e.g. Release Notes documentation, Verification / Validation data) to the Ion PGM Sequencer Software Update Form.

k. Sign, date, and obtain applicable reviews and approvals.

l. After updating the Torrent server, ensure all Ion-related instruments such as the Ion PGM Sequencer, Ion Chef, Ion OneTouch 2, and Ion OneTouch ES instruments are also updated, as applicable.

6.0 Revision History

Rev #	DCR #	Change Summary	Date

7.0 Approval

Reviewed By: _____ Date: _____

The NGS Quality Workgroup developed these documents and tools for use by next-generation sequencing laboratories. These documents and tools were developed based upon best available information, reviewed, edited, and approved by the participants in the group listed above. Prior to implementing these processes in your lab, review the date the document was finalized (included in the file name) and take any necessary actions to ensure the information remains applicable. These documents and tools are not controlled files; you are encouraged to modify the format (e.g. header/footer, sections) as needed to meet the document control requirements of the quality management system within your laboratory.

Ion PGM Sequencer Update Form

Lab:	Building #:	Room #:
Equipment:	Equipment ID:	
Manufacturer:	Model #:	
Serial #:	ESO/CDC Barcode #:	
Log Start Date:	Log End Date:	

Current Software Version(s):	
New Software Version(s):	
After server software is updated, ensure instrument software is also updated	☐ Ion PGM Sequencer ☐ Ion Chef ☐ Ion OneTouch 2 Instrument ☐ Ion OneTouch ES Instrument
Ion PGM Workflow(s) currently used in the laboratory:	
Additional Plug-ins or Kits Downloaded? (if Yes, specify)	☐ Yes ☐ No

Release Notes Reviewed?	Do the updates affect the sequencing workflow used in the laboratory?	Do the updates potentially affect the sequencing data output results?
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Required Action:	☐ Verification ☐ None Explanation:	

Software Updates Installed Successfully?	☐ Yes ☐ No	Install Date:
Results of Verification (and Validation, if applicable)		

Operator Signature / Date	
Quality Manager Signature / Date	