

**Frederick National Laboratory
for Cancer Research**

sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure

SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 1 of 25

Supersedes

3.0

Effective Date: 17Sep21

Written by:

Printed Name:	Title:	Signature/Date:

Approved by:

Printed Name:	Title:	Signature/Date:

QA Approved by:

Printed Name:	Title:	Signature/Date:

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 2 of 25

Supersedes

3.0

Effective Date: 17Sep21

1. PURPOSE

- 1.1 The purpose of this procedure is to describe the use and maintenance of BioTek Microplate Washers.

2. SCOPE

- 2.1 This procedure applies to all BioTek Microplate Washers.

3. REFERENCES

- 3.1 BioTek 405 TS Microplate Washer User Manual
3.2 BioTek ELx405 Microplate Washer User Manual
3.3 BioTek EL406 Microplate Washer User Manual
3.4 10007: Non-Routine Equipment Maintenance
3.5 10009: General Record Review
3.6 26003: Use and Maintenance of a Molecular Device Plate Reader
3.7 26012: Use and Maintenance of an Analytical and Precision Balance
3.8 26016: Operation, Use and Maintenance of the Water Purification Systems
3.9 15000: Waste Disposal at the Advanced Technology Research Facility
3.10 15006: Reagent Preparation for the HPV Serology Laboratory

4. RESPONSIBILITIES

- 4.1 The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.
4.2 The Quality Control Analyst or designee is responsible for reviewing and following this procedure. Quality Control Analyst or designee is responsible for maintaining the Quarterly Microplate Washer Carryover Check.
4.3 The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 3 of 25

Supersedes

3.0

Effective Date: 17Sep21

4.4 The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.

4.5 Trained personnel perform equipment maintenance record review per "10009: General Record Review."

5. DEFINITIONS

5.1 As Needed Maintenance – maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.

5.2 ELISA - Enzyme-linked Immunosorbent Assay

5.3 Non-routine Maintenance – maintenance that is performed in response to equipment malfunction or failure.

5.4 OD - Optical Density

5.5 Routine Maintenance – maintenance that is performed at planned intervals to identify and prevent problems before they result in equipment failure.

5.6 TOC – Total Oxidizable Carbon

5.7 Type II Water – Pure/Analytical Grade, used for standard applications (Resistivity >1 MΩ-cm and TOC ≤ 50 ppb)

6. REAGENTS, MATERIALS, AND EQUIPMENT

6.1 Reagents

6.1.1 Bleach, Concentrated (FNLCR Warehouse, Cat # 68100251 or equivalent)

6.1.2 Dulbecco's Phosphate-Buffer Saline (DPBS) (1X) (Gibco, Cat # 14190-136 or equivalent)

6.1.3 Tartrazine Solution (Refer to "15006: Reagent Preparation for the HPV Serology Laboratory," Section 16)

6.1.4 Tergazyme (VWR, Cat # 21837-118 or equivalent)

6.1.5 Wash Buffer (Refer to 15006)

6.1.6 Water, Type II

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 4 of 25

Supersedes

3.0

Effective Date: 17Sep21

6.2 Equipment

6.2.1 Analytical Balance with QuickLock glass panels assembled (or equivalent)

6.2.2 Microplate Reader

6.2.3 Plate Washer (Model 405 TS or equivalent)

6.2.4 Pipettes

6.2.5 Spoon, Small (VWR, Cat # 13197-386 or equivalent)

6.3 Consumables

6.3.1 Measuring Scoop, 10 mL (VWR, Cat # 83008-684 or equivalent)

6.3.2 96-well Plate, MaxiSorp (Nunc, Cat# 439454 or equivalent)

6.3.3 Pipette Tips

6.3.4 50 mL Reagent Reservoir (FNLCR Warehouse, Cat # 66401270 or equivalent)

6.3.5 50 mL Tubes, Conical (Warehouse, Cat # 66401493 or equivalent)

6.3.6 Weigh Boats, Small (Thomas, Cat# 9885D37 or equivalent)

6.3.7 Wipe, Low-Lint, Wypalls (FNLCR Warehouse, Cat # 79300335 or equivalent)

7. HEALTH AND SAFETY CONSIDERATIONS

7.1 Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.

7.2 Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.

7.3 Refer to "15000: Waste Disposal at the Advanced Technology Research Facility," "EHS-WM-1: Disposal and Minimization of Chemical Waste," and "EHS-WM-2: Biological Waste Handling and Disposal" for waste disposal processes.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 5 of 25

Supersedes

3.0

Effective Date: 17Sep21

- 7.4 While Tartrazine is not toxic, care should be taken to not inhale or ingest it. If inhaled, Tartrazine may produce **an allergic or asthmatic reaction**. May also irritate skin. If breathing is difficult, immediately go to an area with fresh air and alert supervisor. If Tartrazine comes in contact with skin, wash area immediately with soap and water, and watch for any skin irritation. Personnel can wear a mask while working with Tartrazine to help prevent inhalation.
- 7.5 Avoid spilling liquids on the Plate Washer. Potential shock hazard or instrument damage could result from the internal components being exposed to liquid. If a spill occurs while a program is running, abort the program and turn the instrument off. Immediately wipe up all spills. See As Needed Maintenance Step 10.3 for handling spills. Do not use the plate washer if the internal components have been exposed to fluids.
- 7.6 Always turn off the Plate Washer and unplug it before cleaning the outer surface.
- 7.7 Some areas of the Plate Washer or its components can present pinch hazards while in operation. Keep hands and fingers clear of these areas while operating the instrument.

8. PROCEDURE PRINCIPLES

- 8.1 Place low-lint absorbent wipe on counter or in Biosafety Cabinet. When procedure states to "tap plate gently on an absorbent wipe," remove washed plate from Plate Washer, transfer plate above wipe, turn plate upside down and horizontal, and tap entire horizontal surface of plate on absorbent wipe in one smooth even motion to dislodge any residual wash buffer from plate.
- 8.2 Reagent bottles for this procedure are dedicated and labeled: "Type II Water," "Wash Buffer," or "Tergazyme." Reagent bottles are rinsed with Type II Water before being refilled.
- 8.3 All connections to reagent bottles and waste bottles must be secured for the vacuum from the pump to begin.
- 8.4 Refer to the process-specific procedure for the Wash Protocol needed (step 9.2.3) for the assay being performed.
- 8.5 Once the plate washer has been primed and in use, if reagent bottle is disconnected then re-connected to instrument, a Buffer Prime (step 9.2.2) is required to remove any residual air within tubing to re-establish vacuum.
- 8.6 Disconnect tubing from waste collection bottles when decontaminating waste for disposal. Fumes from disinfectant may cause corrosion within vacuum pump system and cause failures.
- 8.7 Do not autoclave washer manifold.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 6 of 25

Supersedes

3.0



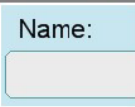









Effective Date: 17Sep21

9. OPERATION

9.1 Icons

9.1.1 See Image 1 for Plate Washer icons.

Image 1: Plate Washer Icons

	Numbers: Touch any field that requires a numeric value to open a field-sensitive number pad. Use the number pad to specify volume, times, and other values. To enter negative numbers use the down (decrement) arrow.
	Pick Lists: touch a field with a down arrow to open a pick list to select an option.
	Text: Touch any text field or comments box to open a keyboard. Use the keyboard to name protocols, input runtime prompts, enter comments, etc.
	Scrolling: Press the down or up arrows to scroll a list with more items than fit on the screen.
	Quick access to prime the washer, wash a plate, and when equipped: AutoClean to sonicate the manifold and Verify™ Technology to check for clogged aspirate and dispense tubes.
	To create and modify protocols.
	To run maintenance and quality control protocols.
	To change instrument settings, obtain protocols from a memory stick, etc.
	Home: Press the home button to return to the Home screen at any time.
	Previous: Press the previous button to go to the previous screen.
	Help: To learn more about a screen, press its Help button.
	Green buttons make the 405 TS perform.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 7 of 25

Supersedes

3.0

Effective Date: 17Sep21

9.2 Daily Use

9.2.1 Startup

9.2.1.1 Turn Plate Washer ON.

9.2.1.2 Ensure Plate Washer is connected to a bottle filled with Type II Water. Press **Maintenance**.

9.2.1.3 Press **W-DAY_RINSE** then press **START**.

9.2.1.4 Once program is completed, return to main menu by tapping "Home" button on the upper left corner of the screen.

9.2.2 Buffer Prime

Note: Prime the washer manifold with buffer only once, prior to start of experiment or after refilling wash buffer bottle during use.

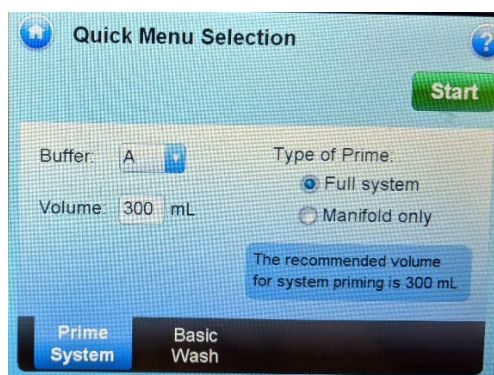
9.2.2.1 Connect Plate Washer to reagent bottle filled with washing buffer.

9.2.2.2 On Home screen press **Quick**, then select **Prime System**.

9.2.2.3 Verify volume is at least 300 mL and Buffer is connected to the correct tubing (Example: Tube A). Select "Full system" under Type of Prime, then press **START**. See Image 2.

9.2.2.4 Once program is completed, return to main menu by tapping "Home" button on the upper left corner of the screen.

Image 2: Quick Menu Selection Screen



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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 8 of 25

Supersedes

3.0

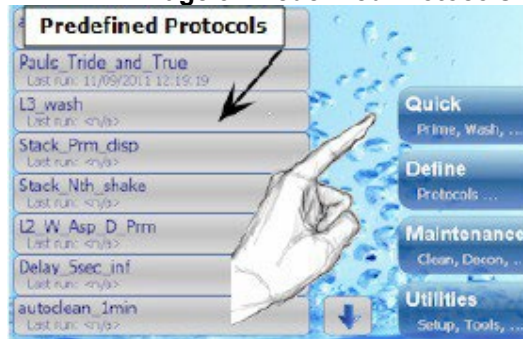
Effective Date: 17Sep21

9.2.2.5 Run Assay Wash Protocol

9.2.2.6 Pre-programmed Protocol

9.2.2.6.1 Using the touch screen, choose a predefined protocol from home screen. See Image 3.

Image 3: Predefined Protocols



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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 9 of 25

Supersedes

3.0

Effective Date: 17Sep21

9.2.2.6.2 Press **START** to run program.

9.2.2.7 Create or Edit a Protocol

9.2.2.7.1 Select **Define** on Home/Maintenance screen.

9.2.2.7.2 Press **Create** or highlight protocol and press **Edit**.

9.2.2.7.3 Naming

9.2.2.7.3.1 New protocols: Touch Name field to open a keyboard. Enter a unique name for protocol.

9.2.2.7.3.2 Editing protocols: Press Info button and touch Name field to change protocol name. This will create a new copy of the protocol being edited. Delete original protocol if no longer needed.

9.2.2.7.4 Plate Type

9.2.2.7.4.1 New protocols: If needed, touch Plate Type field to select a different plate type.

9.2.2.7.4.2 Editing protocols: Press Info button and touch Plate Type field to change plate type.

9.2.2.7.5 Press **Save** to save protocol. All saved protocols are shown on Home screen for easy retrieval.

9.2.2.7.6 Add or Edit Steps

9.2.2.7.6.1 New protocols: To add a step to protocol, touch **Add** button and select a step and define its parameters.

9.2.2.7.6.2 Editing protocols: Highlight a step and press **Edit** to modify its parameters.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 10 of 25

Supersedes

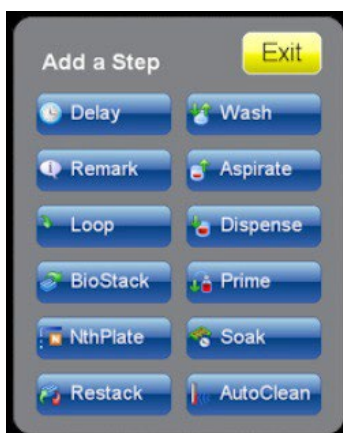
3.0

Effective Date: 17Sep21

9.2.2.7.6.3

Adding steps: Highlight <end of steps> or a step to be preceded by the new step, and press **Add** and the action button to insert a step. See Image 4.

Image 4: Add a Step Screen



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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 11 of 25

Supersedes

3.0

Effective Date: 17Sep21

9.2.2.7.6.4 Continue adding or editing steps, as needed.

9.2.2.7.6.5 Press **Save** to save protocol. All saved protocols are shown on Home screen for easy retrieval.

Note: Optionally, do a test run to verify the protocol performs as expected. **Test Run** executes protocol. Fill reagent bottles with Type II Water or disconnect reagent bottles to preserve reagent.

9.2.3 Shutdown

Note: Monthly Maintenance can be performed in place of Shutdown. See Step 10.1.

9.2.3.1 Connect Plate Washer to reagent bottle with Type II Water. Press **Maintenance**.

9.2.3.2 Press **W-DAY_RINSE** then press **START**.

9.2.3.3 Repeat step 9.2.4.2.

9.2.3.4 Return to Maintenance Menu and Press **W-RINSE_AND_SOAK** and press **START**. Once manifold is in water chamber, turn Plate Washer OFF.

9.2.4 Proceed to step 11 for waste disposal.

10. MAINTENANCE

10.1 Monthly MaintenanceClean Plate Carrier system

Note: If liquid has overflowed or spilled onto plate carrier, transport rail, or glide strips, some buildup may occur and prevent the microplate from seating correctly on the carrier. This can interfere with plate transport.

10.1.1.1 Turn Plate Washer off.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 12 of 25

Supersedes

3.0

Effective Date: 17Sep21

- 10.1.1.2 Lift carrier up and remove from transport rail.
- 10.1.1.3 Clean Plate Carrier System components (carrier, rails, and glide strips, priming trough), by spraying removable items with cavicide. Wait three minutes prior to wiping each item with a low-lint towel. Non-removable items such as the carrier rails, spray cavicide on a low-lint towel and wipe the area.
- 10.1.1.4 After disinfecting with cavicide, wipe components with low-lint wipe moistened with either Type II Water or 70% ethanol or isopropanol.
- 10.1.1.5 Use low-lint absorbent wipe to dry components.
- 10.1.1.6 Reinstall carrier.
- 10.1.1.7 If necessary, release spring-loaded microplate clamp in the back-left corner of the carrier to level the carrier on the base.
- 10.1.2 Clean Exterior Surfaces and Mist Shield
 - 10.1.2.1 Spray cavicide on a low-lint towel and wipe exterior surfaces and mist shield.
- 10.1.3 Clean Plate Washer
 - 10.1.3.1 Tergazyme Preparation: Dilute 1:100 for typical use into reagent bottle marked "Tergazyme."

Note: For example, 10 mL of Tergazyme for every 1 L of Type II Water. A 10 mL scoop may be used to measure Tergazyme if powder.
 - 10.1.3.2 Fill another reagent bottle with Type II Water.
 - 10.1.3.3 Connect Plate Washer to reagent bottle with Tergazyme solution from step 10.1.3.1.
 - 10.1.3.4 On Home screen press **Quick**, select **Prime System**.
 - 10.1.3.5 Verify volume is 300 mL and reagent bottle is connected to correct tube (Example: Tube A). Select "Full system" under Type of Prime, then press **START**. See Image 2.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 13 of 25

Supersedes

3.0

Effective Date: 17Sep21

- 10.1.3.6 Once program has completed, return to main menu by tapping "Home" button on upper left corner of screen. See Image 2.
- 10.1.3.7 Press **Maintenance**.
- 10.1.3.8 Press **W-DAY_RINSE**, then press **START**.
- 10.1.3.9 Once program has completed, return to main menu by tapping "Home" button on the upper left corner of the screen.
- 10.1.3.10 Press **W-RINSE_AND_SOAK** and press **START**.
- 10.1.3.11 Once program has completed, return to main menu by tapping "Home" button on the upper left corner of the screen.
- 10.1.3.12 Transfer tube from Tergazyme reagent bottle to Type II Water reagent bottle.
- 10.1.3.13 Press **Maintenance**.
- 10.1.3.14 Press **W-DAY_RINSE**, then press **START**.
- 10.1.3.15 Repeat 10.1.3.14 twice (In total **W-DAY_RINSE** procedure will be performed three times with the Type II Water).
- 10.1.3.16 Clean all Plate Washer reagent bottles and their components, to include aspirate and dispense tubing, used over the course of the month with remaining Tergazyme solution.
- 10.1.3.17 Remove all residual Tergazyme with tap water, then rinse with Type II Water and air-dry overnight.
- 10.1.3.18 Document maintenance on "26002-02: Plate Washer Maintenance Form."
- 10.1.3.19 Proceed to Step 11 for waste disposal.

10.2 Quarterly Maintenance

10.2.1 Remove and Clean the Washer Manifold

- 10.2.2 Run Plate Washer system "dry" by connecting an empty supply bottle and running **W-RINSE_&_SOAK** prime protocol, until tubing is empty.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 14 of 25

Supersedes

3.0

Effective Date: 17Sep21

10.2.3 Turn off Plate Washer, disconnect power cable and remove mist shield.

10.2.4 Carefully remove manifold and end plates.

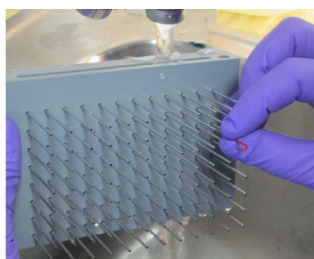
10.2.5 Soak manifold in Tergazyme solution described in 10.1.3.1 for 20-40 minutes.

10.2.6 Using a soft-bristled brush, thoroughly clean the outside surfaces.

10.2.7 Clean inside each tube with the appropriate stylus.

10.2.8 Flush hot tap water through the cross channels to wash away debris. See Image 5.

Image 5: Manifold rinsed through cross channels while cleaning with stylus.



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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 15 of 25

Supersedes

3.0

Effective Date: 17Sep21

Note: Avoid pressing the stylus against the sides of the tubes during cleaning. This can cause the tubes to bend, adversely affecting dispense precision.

10.2.8.1 Rinse manifold with Type II Water.

Note: Check to see if water comes out of all dispense and aspirate tubes. If not, soak the manifold in Tergazyme solution overnight and repeat steps 10.2.1.1.

10.2.8.2 Reassemble manifold, end plates, mist shield.

10.2.8.3 Reconnect power cable and turn on Plate Washer.

10.2.8.4 Prime system with Type II Water by running **W-DAY_RINSE Prime** protocol. Inspect for leaks.

Note: If fluid leaks out of the back of Plate Washer, firmly seat tubing.

Note: If fluid leaks from the manifold, disassemble and reassemble.

10.2.8.5 Verify aspirate/dispense performance with Microplate Washer Carryover Check

10.2.9 Microplate Washer Carryover Check

Note: Record information on “26002-01: Microplate Washer Carryover Check”

10.2.9.1 Fill a reagent bottle with any available wash buffer that is used in assays with that Plate Washer, then connect reagent bottle to Plate Washer.

10.2.9.2 For example: 1X Wash Buffer, PBS_0.05T, or other found in 15006.

10.2.9.3 Add 200 µL of Tartrazine Solution to each well of a 96-well MaxiSorp plate.

10.2.9.4 Open “Plate Washer carryover.spr” from Plate Reader, per “26003: Use and Maintenance of a Molecular Devices Plate Reader”, program templates.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 16 of 25

Supersedes

3.0

Effective Date: 17Sep21

10.2.9.5 Save the file as a data file (*.sda). Use the following naming scheme – “PlateWasherCarryover_EquipmentID# DDMMYY.sda”. Example: PlateWasherCarryover_HSL133_05MAY21.sda. Save the file under HSL > Equipment Verification > Plate Washer> HSL number (for example, HSL133).

10.2.9.6 Verify wavelength is set to 450 nm using 650 nm as a blank.

10.2.9.7 Verify minimum and maximum OD values range, 2.20 – 3.00.

10.2.9.8 Insert plate into Plate Reader oriented normally with well A1 at topmost left corner.

10.2.9.9 Read plate as “Pre 1” and save result.

10.2.9.10 Remove plate and turn it 180°, with well A1 at bottommost right corner. Read plate again as “Pre 2”. Save results.

10.2.9.11 Remove Plate from Plate Reader and wash on Plate Washer being tested using “HPV ELISA WASH with PRIME” protocol. See Attachment 1 for protocol parameters. Tap plate gently on absorbent wipe in Biosafety Cabinet.

10.2.9.12 Add 200 µL of 1X DPBS to each well.

10.2.9.13 Insert plate into Plate Reader again with A1 oriented to the top left corner.

10.2.9.14 Read as “Post 1” and save results.

10.2.9.15 Remove plate from Plate Reader and turn it 180° with well A1 at the bottommost right corner. Read as “Post 2”. Save results.

10.2.9.16 Print results and attach to 26002-01 per HSL_QS_017.

10.2.9.17 Quarterly Maintenance Quality Control Acceptance Criteria

10.2.9.17.1 “Pre 1” and “Pre 2” OD value must be between 2.20 and 3.00.

10.2.9.17.2 Carryover percent (%) must be ≤1.0%. Carryover percent should be calculated using the following equation:

$$\frac{\text{MMMM M.OO O pppppppp}}{\text{NNNNNN 0000 pppppp}} \times 100$$

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 17 of 25

Supersedes

3.0

Effective Date: 17Sep21

- 10.2.9.18 If “Pre 1” and “Pre 2” OD values are not in acceptable range, repeat steps 10.2.2.2 – 10.2.2.9 with 1:2 serial dilutions of Tartrazine solution, then repeat carryover test, Steps 10.2.2.2 – 10.2.2.15 with the Tartrazine dilution that falls within the 2.2 – 3.0 OD range.
- 10.2.9.19 If OD value is in acceptable range but carryover value acceptance criteria is not met, perform carryover test again to verify test was performed correctly.
- 10.2.9.20 If carryover value acceptance criteria does not pass after second test, perform the following:
 - 10.2.9.20.1 Clean Plate Washer Manifold per section 10.2.1.
 - 10.2.9.20.2 Repeat the carryover check once shutdown maintenance is complete.
- 10.2.9.21 If the carryover value acceptance criteria does not pass a third time, label Plate Washer “out of service” and notify Scientific Manager.
- 10.2.9.22 When Plate Washer passes criteria, record performance of quarterly maintenance on 26002-02.

10.3 As Needed Maintenance

- 10.3.1 If fluid collects in the overflow bottle, thoroughly rinse the level-switch assembly and bottle with Type II Water. See User Manual for details.
- 10.3.2 If hex nuts securing the quick-disconnects to the bottle cap become loose or corroded: tighten, clean, or replace, as needed.
- 10.3.3 See User Manual to change fuse, as needed.
- 10.3.4 Clean Plate Carrier System

Note: If liquid has overflowed or spilled onto plate carrier, transport rail, or glide strips, some buildup may occur and prevent the microplate from seating correctly on the carrier. This can interfere with plate transport.

- 10.3.4.1 Turn Plate Washer off.
- 10.3.4.2 Lift carrier up and remove from transport rail.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 18 of 25

Supersedes

3.0

Effective Date: 17Sep21

- 10.3.4.3 Clean Plate Carrier System components (carrier, rails, and glide strips, priming trough), by spraying removable items with cavicide. Wait three minutes prior to wiping each item with a low-lint towel. Non-removable items such as the carrier rails, spray cavicide on a low-lint towel and wipe the area.
- 10.3.4.4 After disinfecting with cavicide, may wipe components with low-lint wipe moistened with either Type II Water or 70% ethanol or isopropanol.
- 10.3.4.5 Use low-lint absorbent wipe to dry components.
- 10.3.4.6 Reinstall the carrier.
- 10.3.4.7 If necessary, release spring-loaded microplate clamp in the back-left corner of the carrier to level the carrier on the base.
- 10.3.5 Document As Needed Maintenance in its respective section on form 26002-02: Plate Washer Maintenance Form.

10.4 Non-Routine Maintenance

- 10.4.1 In the case that the Plate Washer is not operating correctly, transition processes being performed to another unit (when applicable), post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: Non-Routine Equipment Maintenance."
- 10.4.2 Document the nature of any failures or malfunctions, how and when it was discovered, and the personnel involved on "10007-01: Non-Routine Equipment Maintenance Form."
- 10.4.3 Initiate a service request and complete the non-routine maintenance process following 10007.

11. WASTE DISPOSAL

Note: Perform waste disposal daily, or as needed, during Plate Washer use and maintenance.

- 11.1 Disconnect tubing from waste collection bottles.
- 11.2 Decontaminate liquid waste with a final concentration of 10% bleach for 30 minutes or autoclave waste according to "15000: Waste Disposal at the Advanced Technology Research Facility."

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 19 of 25

Supersedes

3.0

Effective Date: 17Sep21

11.2.1 Rinse waste collection bottle with tap water until clean followed by Type II Water.

12. ATTACHMENTS

12.1 Attachment 1: HPV ELISA WASH with PRIME Protocol

12.2 Attachment 2: 26002-01: Microplate Washer Carryover Check

12.3 Attachment 3: 26002-02: Plate Washer Maintenance Form

13. REVISION HISTORY

Version	Change	Reason
1.0	Create new SOP for the use and maintenance of a BioTek plate washer in the HSL at ATRF	New SOP.
2.0	Update results section in forms.	Review Form .02 Results section Softmax template does not match Data capture.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 20 of 25

Supersedes

3.0

Effective Date: 17Sep21

Version		
3.0	<ol style="list-style-type: none"> Updated to new template; forms now separate. Minor formatting and grammatical revisions throughout procedure. Removed HSL_GL_002, HSL_GL_003, HSL_GL_007, HSL_GL_008, HSL_GL_009, HSL_GL_010, HSL_EQ_005.01, and Softmax software, and Added HSL_QS_017 to References section. Added Tartrazine solution, DPBS, Wash Buffer, and created subsections in Equipment and Materials section. Added additional safety information from plate washer user manual. Deleted ATRF, HPV, HSL, and SOP and added ELISA, OD and Type I water to Definitions section. Added Procedural Principles section with information about designated reagent bottles and reference to process procedure for wash protocol. Screenshots added to Operation and Maintenance section. Added Long Shutdown maintenance, and use of pre-programmed wash protocol to Operation and Maintenance Section. Revised Monthly and Quarterly Maintenance sections. Revised forms HSL_EQ_004.01 and HSL_EQ_004.02. New form HSL_EQ_004.03. 	<ol style="list-style-type: none"> Consistency between procedures. Clarification. Removed references not in body of procedure, added reference in body of procedure. Materials used in process; clarification. Clarification. Deleted definitions either not in procedure or used earlier in procedure; added definitions used in procedure. Clarification. Clarification, ease of use. To reflect current practice. Clarification. Ease of use. Ease of use and tracking of maintenance.

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 21 of 25

Supersedes

3.0

Effective Date: 17Sep21

Version	Change	Reason
4.0	<ol style="list-style-type: none">1. Add responsibilities of Quality Control Analyst.2. Corrected "Considerations" in section 7.3. Added Non-Routing and As Needed Maintenance4. Updated Reference Section5. Minor grammar and wording changes6. Updated Quarterly Maintenance (Tartrazine)7. Updated Routine Maintenance	<ol style="list-style-type: none">1. Added clarification of responsibilities.2. Misspelled.3. Reflect GDP guidelines4. Reflect current naming scheme5. Clarification, ease of use6. Clarification, ease of use7. To closer align to User Manual guidance

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 22 of 25

Supersedes

3.0

Effective Date: 17Sep21

Attachment 1: HPV ELISA WASH with PRIME Protocol

Page: 1 Printed: 5/23/2019 5:20:16 PM

File Name: HPV ELISA Wash with Prime.LHC
File Location: D:\Protocols
Last Saved: 4/26/2019 11:04:48 AM

LHC Version: 2.19.1

Instrument: EL408
Port: USB EL408 sn:18061715
Settings: 96-tube Dual Washer manifold
Buffer Switching
Cell Washing

Plate Type: 96 Well Plate
Protocol Name: HPV ELISA
Protocol Version: <no data>
Archive Revision: 43
Comments: <no data>
Step Details: W-Wash

Pre-dispense before washing: No
Bottom Wash: Yes
Buffer: A
Volume: 300 µL/well
Flow Rate: 7
Z Offset: 121 steps (15.37 mm above carrier)
X Offset: 0 steps (center of well)
Y Offset: 0 steps (center of well)
Pre-dispense: not available
Number of Wash Cycles: 3
Aspirate per cycle
Travel Rate: 3 7.3 & 1.0 mm/sec
Delay: 0 msec
Z Offset: 13 steps (1.65 mm above carrier)
X Offset: 0 steps (center of well)
Y Offset: 38 steps (2.81 mm front of center)
Secondary Aspirate: No
Dispense per cycle
Buffer: A
Volume: 350 µL/well
Flow Rate: 7
Z Offset: 100 steps (12.70 mm above carrier)
X Offset: 0 steps (center of well)
Y Offset: 0 steps (center of well)
Pre-dispense: not available
Delay start of Vacuum until Volume dispensed: 0 µL/well
Shake/Soak after dispense: No
Pre-dispense between cycles: No
Final Aspirate: No
Shake/Soak
Move carrier home: No
Shake: No
Soak: Yes
Duration: 00 min, 05 sec
W-Aspirate
Travel Rate: 3 7.3 & 1.0 mm/sec
Delay: 0 msec
Z Offset: 10 steps (1.27 mm above carrier)
X Offset: -20 steps (0.91 mm left of center)

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SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 23 of 25

Supersedes

3.0

Effective Date: 17Sep21

Attachment 2: 26002-01: Microplate Washer Carryover Check Form

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>		Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Form	
Form Title: BioTek Plate Washer Carry-Over Testing Form			
Document ID: 26002-01		Version:	DRAFT
Associated SOP: 26002		Effective Date:	17Sep21
Supersedes:	3.0	Page 1 of 1	

Equipment		
Description	Equipment ID	Calibration Due Date
BioTek Plate Washer	<input type="checkbox"/> HSL_ <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
Plate Reader	<input type="checkbox"/> HSL_ <input type="checkbox"/> Other:	
Pipette: µl	<input type="checkbox"/> PIP_	

Reagents		
Description	Lot Number	Expiration Date
Tartrazine Solution		
Wash Buffer		

Results First Run			
File Name:			
Reading	O.D. Values (2.20 - 3.00)	Carryover (%) (≤ 1.0%)	
Pre-1	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
Pre-2	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

☐ N/A Results Second Run

File Name:		
Reading	O.D. Values (2.20 - 3.00)	Carryover (%) (≤ 1.0%)
Pre-1	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Pre-2	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Comments:
☐ N/A
☐ Pre-1 and Pre-2 OD Values fail, retest.
☐ Pre-1 and Pre-2 OD Values fail second time: retest with new Tartrazine lot, 15006.01, using new 26002.02 form.
☐ Carryover only fail, retest.
☐ Carryover only second fail: perform Shutdown Maintenance on Plate Washer and Monthly Calibration on Plate Reader. Retest using new lot of Tartrazine Solution.
☐ Third Carryover fail: notify Scientific Manager, equipment placed Out of Service.

Performed by/date:	
Reviewed by/date:	

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Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure

SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 24 of 25

Supersedes

3.0

Effective Date: 17Sep21

Attachment 3: 26002-02: Plate Washer Maintenance Form

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Form Title: Plate Washer Maintenance Form			
Document ID: 26002-02		Version:	DRAFT
Associated SOP: 26002		Effective Date:	17Sep21
Supersedes Version:	3.0	Page 1 of 2	

Equipment ID:		Maintenance Year (YYYY)	
----------------------	--	--------------------------------	--

Monthly Maintenance						
Month	January	February	March	April	May	June
Tergazyme Lot #:						
Tergazyme Expiration Date:	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
Cavicide Lot #:						
Expiration Date:						
Performed By/Date:						
Reviewed By/Date:						
Month	July	August	September	October	November	December
Tergazyme Lot #:						
Tergazyme Expiration Date:	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
Cavicide Lot #:						
Expiration Date:						
Performed By/Date:						
Reviewed By/Date:						

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Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure

SOP Title: Use and Maintenance of a BioTek Plate Washer

Document ID: 26002

Version

4.0

Page 25 of 25

Supersedes

3.0

Effective Date: 17Sep21

**Frederick National Laboratory
for Cancer Research**
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Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure Form

Form Title: Plate Washer Maintenance Form

Document ID: 26002-02

Version:

DRAFT

Associated SOP: 26002

Effective Date:

17Sep21

Supersedes Version:

3.0

Page 2 of 2

Quarterly Maintenance

Quarter:	Q1	Q2	Q3	Q4
Cavicide Lot #:				
Expiration Date:				
Recorded By/Date:				
Reviewed By/Date:				

As Needed Maintenance: | | N/A

Date	Activity Performed	Recorded by/date	Reviewed by/date
<input type="checkbox"/> N/A			
<input type="checkbox"/> N/A			

Reviewed by: _____

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