TITLE: PREVI™ Color Gram and Cytocentrifuge Rotor Maintenance

PRINCIPLE / PURPOSE: The automated gram stainer is intended for use to stain specimens as a step in the practice of diagnosing disease. The equipment must be properly maintained and in good working order.

SCOPE: This procedure is intended for the maintenance of the PREVI™ Color Gram (Automated Gram Stain) utilized for microbiology staining.

COMPLEXITY LEVEL: High

SAFETY: Always wear protective clothing and eye protection when using the Nozzle Cleaning solution. Dispose of used cleaning solution appropriately.

SPECIMEN: Not Applicable during the maintenance process.

EQUIPMENT AND MATERIALS:

Maintenance Kit: Priming tool, silicon grease, nozzle wire, nozzle cleaning strainer, nozzles, nozzle tool, nozzle wrench, nozzle brush, and nozzle cleaning tubes, volume test tubes, and nozzle maintenance tray.

-250 mL graduated cylinder (found in chemistry)

-Nozzle cleaning solution (flammable cabinet)

CALIBRATION: N/A

QUALITY CONTROL: N/A for maintenance process.

PROCEDURE:

Color Gram DAILY:

**CLEAN alcohol purge stage**

**NOTE**: The Clean Alcohol Purge stage requires the use of 10ml of alcohol divided equally among nozzles A, B, and C. This used to clean the carousel after staining. The same function is performed when **Standby/Ready** is pressed.

1. Place the empty carousel in the instrument and close the lid.
2. Press CLEAN button.
3. Open the lid and remove the carousel when the Clean Cycle has finished.
4. Spray and wipe the interior of the bowl and nozzles with ethanol 70% solution.

**NOTE**: The Clean Alcohol Purge stage automatically occurs after each staining cycle.

NOTE: At the end of the day, the shift will press the shutdown button and another CLEAN alcohol purge will begin to run. This step assists in the prevention of clogging of the nozzles and tubing.

Monitoring Reagent Levels

The PREVI™ Color Gram instrument automatically monitors reagent levels A, B, and C. A blinking light will indicate when reagent bottles should be replaced. It is still necessary to monitor reagent levels visually to ensure reagent bottles do not run dry. Reagents D and E are not sensor monitored and must be visually monitored.

Replacing a Reagent Bottle

1. Remove the empty reagent bottle from the drip tray but do not disconnect the dip tube.

For reagents A, B, and C go to step 2. For reagents D and E skip to step 7.

1. Go to System Set up.
2. Select Reagents.
3. Select Change next to the appropriate reagent.
4. Scan the barcodes on the reagent bottle.
5. Select Save.
6. Open the new bottle.
7. Place the new bottle in the drip tray.
8. Unscrew the cap and remove the dip tube from the empty bottle.
9. Insert the dip tube into the new reagent bottle and loosely screw on the ring cap. Do not screw cap on too tightly (slightly loose).

Emptying the Waste Container

1. Unscrew the cap frim the full waste container.
2. Discard the waste into 5 gallon flammable waste container.
3. Reinstall the cap to the empty waste container.

Pattern Test

The Pattern Test is used to ensure the nozzles are clear of debris and spraying properly.

1. Select Maintenance.
2. Select Pattern Test to start the pattern test.
3. Hold a sheet of white paper towel in front of nozzle A near the drive hub.
4. Select the A prime button.
5. Check the quality of the pattern. If the pattern is not correct, refer to the Nozzle Cleaning section.

Correct Pattern Test Result



Incorrect Pattern Test Result



Color Gram Weekly:

Performing the Volume Test

The Volume Test requires the maintenance kit.

IMPORTANT: The Volume Test must be performed weekly.

1. Select Maintenance.
2. Select Volume Test.
3. Hold a Volume Test tube (small tube) in place so that nozzle A is covered.
4. Select the appropriate prime button briefly.

Reagent will spray into the tube for 20 seconds.

1. Remove and close the tube.
2. Record the reagent letter on the tube.
3. Measure and record the volume of reagent in the tube.
4. Place the tube in the appropriate position in the maintenance box.
5. Repeat Step 3 through Step 8 for each nozzle.
6. Check each tube according to Table 9: Volume Test Tolerance.

Table 9: Volume Test Tolerance

|  |  |  |
| --- | --- | --- |
| Tube | Minimum | Maximum |
| A | 10 mL | 12 mL |
| B, C | 9 mL | 11 mL |
| DF, DR, E | 9 mL | 11 mL |

— If the volume is within the tolerance range, go to Step 11.

— If the volume is outside the tolerance range:

1. Attempt to clear the nozzle orifice with the brush found in the maintenance kit.
2. If necessary, remove the nozzle and perform the Cleaning Nozzles procedure.
3. If there is still a problem, replace the nozzle.

Note: If the problem persists after you have replaced the nozzle, contact your bioMérieux representative.

1. Prepare the maintenance kit for future use:
2. Empty the contents of the tubes into the bowl.
3. Rinse the tubes with distilled water.
4. Put the tubes back into their original place in the maintenance box or tube tray.
5. Select Back twice to return to the main screen.

Color Gram Monthly:

1 – Nozzle DF (distilled water, front)

2 – Nozzle A (Safranin)

3 – Nozzle B (Iodine)

4 – Nozzle C (Crystal Violet)

5 – Nozzle E (Alcohol)

6 – Nozzle DR (distilled water, rear)

7 – Drive Hub



Nozzle Cleaning Solution

The nozzle cleaning solution is used for the PREVI® Color Gram instrument maintenance operations. Nozzle cleaning solution is concentrated, and is available as 2.5L concentrated nozzle cleaning solution contained in a 5L bottle or as 250 mL concentrated nozzle cleaning solution contained in a 500 mL bottle.

Preparing Nozzle Cleaning Solution

Before cleaning the nozzles, you must dilute the nozzle cleaning solution.

WARNING

1. Add 2.5L of approved alcohol to the 5L bottle or add 250 mL of approved alcohol to the 500 mL bottle.
2. Record the expiration date on the bottle(s).

Disassembling Nozzles

Nozzle disassembly requires the Maintenance Kit and diluted nozzle cleaning solution.

IMPORTANT: If the compression screw cannot be easily loosened, use light penetrating oil and a 5/8-in. wrench to loosen the nozzle.

1. Remove the nozzle using the nozzle tool from the Maintenance Kit.

Figure 30: Removing the Nozzle



1. Disassemble the nozzle.



1. Place the nozzle parts in the 50 mL conical tube.
2. Note the reagent letter on the tube.
3. Repeat Step 1 through Step 4 for each nozzle.

Cleaning Nozzles

1. Perform the Disassembling Nozzles procedure.
2. Fill the tube with 25 mL of diluted nozzle cleaning solution and cap the tube.
3. Gently invert the tube at least ten times to ensure all parts come in contact with the nozzle cleaning solution.
4. Soak the parts as long as possible.
5. Place the tube in its labeled position.
6. Repeat these steps for each nozzle.

Reassembling Nozzles

1. Hold your thumb or the strainer over the end of the tube to keep the nozzle parts in the tube. Pour out the liquid used to clean the nozzle parts into the strainer.
2. Inspect the nozzle parts. Remove any material in the swirl cone grooves by sliding a piece of paper along each grove (for 4 total groves).
3. Push the nozzle orifice cleaning wire through the back of the disassembled nozzle.
4. Place the nozzle parts back into the tube and rinse them with distilled water.
5. Rinse the parts again with 70% ethanol.
6. Apply a small amount of silicone lubricant to the compression screw.
7. Reassemble the nozzle by placing the compression screw on the nozzle disassembly tool, then inserting the swirl cone into the compression screw.

Note: Hold all the parts in a vertical position until reassembly is complete.

Figure 32: Reassembling Nozzles



1. Reinstall the nozzle housing over the swirl cone and compression screw.
2. Reinstall the nozzle insert by snapping it in place on the back of the nozzle.
3. Return the assembled nozzle to its original position in the instrument.



1. Repeat Step 1 through Step 10 for each nozzle.
2. Perform the Performing a Hub Pattern Test procedure.
3. Perform the Performing the Volume Test procedure.

Manually Priming Reagent Lines

1. Remove the carousel from the bowl.
2. Remove the nozzle connected to the line to be manually primed.
3. Insert the nozzle adapter of the priming tool (included in the maintenance kit) into the nozzle holder.
4. Turn the nozzle adapter clockwise to install the adapter into the nozzle holder.



1. Withdraw the priming tool plunger halfway to create a vacuum. Hold the plunger in position.
2. Select Maintenance.
3. Select and hold the prime button for that nozzle to start the reagent pump.
4. Run the reagent into the tube until the fluid is free of bubbles, then release the prime button.

WARNING

Do not pull the plunger completely out of the priming tool. Pulling the plunger out

of the tool may result in splashing or spraying of reagents. Do not push the

plunger in while it is connected to the nozzle holder.

1. Turn the nozzle adapter counterclockwise to remove it from the nozzle holder.
2. Discard the collected fluid into the stainer bowl.
3. Reinstall the nozzle.
4. Perform the Performing a Hub Pattern Test procedure.
5. Perform the Performing the Volume Test procedure.

Removing Reagent Bottles

1. Unscrew the cap and remove the dip tube from the bottle.
2. Place the end of the dip tube in a bottle of approved alcohol.
3. Reinstall the original cap on the reagent bottle.
4. Remove the reagent bottle from the tray.

Cleaning Dip Tubes

1. Perform the Removing Reagent Bottles procedure.
2. Ensure the ends of the dip tubes are in containers of approved alcohol.
3. Remove the nozzles.
4. Place an empty carousel in the instrument and shut the lid.
5. Press Maintenance.
6. Press 60 Sec Prime.
7. Press ABCDE.

The instrument will pump alcohol through each reagent line for 60 seconds and will remove all the stain and water left in the pumps.

Disinfecting the Reagent D Bottle

1. Fill the reagent D (distilled water) bottle with a fresh 10% bleach solution.
2. Allow the bleach to stand in the bottle for 10 minutes.
3. Rinse the bottle thoroughly with tap water.
4. Rinse the bottle thoroughly with deionized water.

Priming Lines Simultaneously

Note: If you are performing this procedure as part of the installation, remove all the nozzles.

1. Insert an empty carousel and close the lid.
2. Select Maintenance.
3. Select 60 Sec Prime.
4. Choose one of the following:

— Select ABCDE to prime all lines simultaneously.

— Select the appropriate prime button for 1 minute.

The pumps will run for 1 minute and prime the lines.

Note: If you removed the nozzles prior to performing this procedure, reinstall the nozzles.

B Line Flushing

1. Remove the nozzle B.
2. Perform a B-line flush by pressing .
3. Press.
4. Load 500 ml of distilled water in the B line position and press .
5. Remove the remaining distilled water. Load 200 ml of the diluted nozzle cleaning solution in the B line position and press .
6. Allow to sit for at least 1 hour, up to 12 hours if possible.
7. After soaking, load 500 ml of distilled water in B line position to rinse and press .
8. Load 200 ml of iodine and press .
9. Reinstall nozzle B.
10. Press .

Color Gram Yearly:

Preventative Maintenance every two years by a bioMérieux Field Service Engineer.

Cytocentrifuge Weekly:

1. Inspect the rotor gasket for cracks and other damage.
2. Disinfect the rotor. Refer to the Disinfecting the Cytocentrifuge Rotor section for details.)
3. Check the lid latch mechanism. If it is difficult to manipulate, refer the Lubricating the Lid Latch section.

Disinfecting the Cytocentrifuge Rotor

1. Spray 70% ethanol on the rotor.
2. After 20 minutes, rinse the rotor with distilled water. Allow to dry.

Lubricating the Lid Latch

1. Turn the lid upside down.
2. Place a small amount of lubricant directly into the lid locking pin hole.
3. Work the locking pin back and forth several times.
4. Wipe off any excess oil or greases at the mouth of the locking hole.

Cytocentrifuge Yearly:

1. Contact bioMérieux representative to replace the gaskets on the PREVI™ Color Cytocentrifuge Rotor.

SUPPLEMENTAL MATERIALS / ADDENDUM:

Maintenance Log

CALCULATIONS: N/A

INTERPRETING AND REPORTING RESULTS: N/A

PROCEDURAL NOTES: None

RELATED PROCEDURES:

PREVI™ Color Gram (Automated Gram Stain)

LIMITATIONS OF PROCEDURE: N/A

REFERENCES:

1. PREVI™ Color Gram Instructions for use manual.

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HISTORY PAGE

SOP Number: MICRO-633-CH

SOP Title: PREVI™ Color Gram and Cytocentrifuge Maintenance

Written By: Jacee Farmer

Manual in which Hard Copy of this SOP is located: Microbiology Manual

Distribution: SharePoint

Supersedes Procedure:

SOP CHANGE CONTROL

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