

BIOFIRE® Systems Preventative Maintenance

1. Introduction

BIOFIRE® FILMARRAY® and BIOFIRE® SPOTFIRE® Systems are designed to alert users when maintenance is required, and therefore do not require preventative maintenance.

Maintenance alerts are a component of the internal error messaging and process controls built into the BIOFIRE® Systems. These controls have been verified by bioMérieux and preclude a preventative maintenance schedule.

This Technical Note includes information relevant to the BIOFIRE® FILMARRAY® 2.0, BIOFIRE® FILMARRAY® TORCH and BIOFIRE® SPOTFIRE® Systems.

NOTE: Due to the sensitive mechanisms which directly impact the interpretation of results, instruments are not able to be serviced in the field. All repairs must be performed under controlled conditions at a service center to safely verify the instrument

2. BIOFIRE® System Self-Tests

BIOFIRE® Systems self-tests fulfill the requirement for preventative maintenance and calibration verification. The BIOFIRE® Systems monitor each of their subsystems with the following self-tests:

- Temperature controls via the thermal and carrier board self-tests
- Optics and fluorescence controls via the fluorimeter self-test
- Sample manipulation controls via the bead beater, seal bar, pneumatics self-tests

If any of these subsystems are out of specification, the instrument will report an error. In addition, test results will be reported as invalid.

3. Pouch Process Controls

Every BIOFIRE® pouch contains process controls to verify that each of the subsystems are functioning appropriately.

- The controls are evenly distributed to ensure accuracy across the array.
- Customer external quality control pouch runs can be used as a record of temperature accuracy verification.

If any of the subsystems are out of specification, the process controls will fail, and all test results will be reported as invalid.



4. General Maintenance

No general maintenance is needed for BIOFIRE® Systems other than the steps listed below:

- Periodically wipe down all outside surfaces of the instrument with a cloth or paper towel and a freshly prepared 10% bleach solution (one part bleach to nine parts water), followed by a water wipe. Alternately, bleach wipes or another disinfectant wipe effective against nucleic acids can be used, followed by a water wipe.
- It is recommended to perform monthly archives.
- It is recommended to shut down and restart the BIOFIRE® FILMARRAY® 2.0 computer on a weekly basis.
- It is recommended to reset the BIOFIRE® FILMARRAY® TORCH Base and BIOFIRE® SPOTFIRE® Control Station on a weekly basis. This action should be performed with the reset button and not the on/off switch.

NOTE: Please refer to the BIOFIRE® FILMARRAY® 2.0, BIOFIRE® FILMARRAY® TORCH and BIOFIRE® SPOTFIRE® Operator Manuals for further information.

Technical Support Contact Information

bioMérieux is dedicated to providing the best customer support available. If you have questions or concerns about this process, please contact your local bioMérieux representative or your authorized distributor.

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