



Introduction

The BioFire 2.0 and BioFire Torch Systems are capable of interfacing with a laboratory information system (LIS). Test information can be electronically transferred between a BioFire FilmArray System to an LIS. This checklist outlines 5 basic steps to implement the BioFire LIS interface.

Step 1: Discovery

Responsible party: Laboratory LIS Personnel

- Complete the online BioFire FilmArray LIS Connection Request Form on BioFire's website:

<https://www.biofiredefense.com/biofire-filmarray-lis-connection-request-form/>

Once the form has been submitted, a BioFire representative will assist you throughout this process.

- Identify and contact the project stakeholders. Stakeholders can include, but are not limited to:
 - Lab Personnel
 - Local Networking and IT Security Personnel
 - Internal LIS Support Personnel
 - LIS Vendor Representative
- Determine the type of interface to be implemented (i.e., HL7 or XML) and contact the LIS Vendor Representative to obtain an appropriate driver. If a driver is not available, BioFire can provide additional assistance to LIS vendors for the development of a driver.

NOTE: If a driver cannot be provided or developed, a middle-ware solution can be utilized. The responsible party will need to contact a middle-ware vendor or devise an alternative solution.

Step 2: Security

Responsible parties: Local Networking and IT Security Personnel, Internal LIS Support Personnel

- Determine if your institution requires a cybersecurity questionnaire to be completed prior to connecting the BioFire System to the network.
- Perform a security review of the BioFire System if required. Refer to the MDS2 (Manufacturer Disclosure Statement for Medical Device Security, <https://www.biofiredx.com/support/documents/#toggle-id-4>) form for more information regarding security of the BioFire System.

NOTE: A BioFire representative will be available to answer security related questions throughout the review process.

- Identify the protocol that will be used to facilitate the communication. The protocol used largely depends on the specifications of the LIS driver. Contact your LIS vendor for the recommended protocol.

The XML interfacing option supports the following protocols:

- Local Folder Protocol (SMB)
- Network Shared Folder Protocol (SMB)
- LIS Shared Folder Protocol (SMB)
- File Transfer Protocol (FTP)
- Hypertext Transfer Protocol (HTTP)
- Hypertext Transfer Protocol Secure (HTTPS)

The HL7 interfacing option supports the Minimum Lower Layer Protocol (MLLP). If utilizing the HL7 interfacing option, determine if unidirectional or bidirectional communication over MLLP will be used.

- Connect the BioFire System to the local network.

Step 3: Software

Responsible parties: Lab Personnel, Internal LIS Support Personnel, LIS Vendor Representative

- Install and configure the BioFire FilmArray Link Software. A BioFire representative will provide the documentation for the installation and configuration instructions of the BioFire Link Software and Electronic Report Modules. These documents will also contain the result codes required for mapping the results in the LIS.
- Install and configure the LIS Driver. Contact your LIS Vendor Representative to have the LIS driver installed.

Step 4: Validation

Responsible parties: Lab Personnel, Internal LIS Support Personnel, LIS Vendor Representative

- Verify the test results from the BioFire System are received by and processed in the LIS/ middle-ware. If using the HL7 interfacing option in bidirectional communication mode, verify that messages transferred between the BioFire System and LIS are sent and received as expected.
- Validate the interface using test procedures that meet the appropriate standards for CLIA and other applicable laboratory accrediting agencies.

Step 5: Go Live!

- Once the validation is complete, patient results can be sent to the production environment of the LIS.

Technical Support Contact Information

BioFire Defense is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the BioFire Technical Support team for assistance.

BioFire Defense Technical Support

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