

BioFire® COVID-19 Test v1.1 Electronic Report Module

Overview

The BioFire® FilmArray® Link Software and BioFire COVID-19 Test v1.1 Electronic Report Module (hereafter referred to as the COVID-19 v1.1 ERM throughout this document) facilitate the transfer of BioFire COVID-19 Test results from a BioFire FilmArray System to a laboratory information system (LIS).

The software functions as follows:

- The BioFire FilmArray Link Software retrieves BioFire COVID-19 Test result data.
- The data is sent to the COVID-19 ERM, where the data is formatted into an XML file (an electronic report).
- The BioFire FilmArray Link Software then sends the electronic report to the LIS.

NOTE: *The COVID-19 v1.1 ERM is compatible with all versions of the BioFire FilmArray Link Software.*

Purpose of the Document

The purpose of this document is to provide instructions for installing the COVID-19 v1.1 ERM on a BioFire FilmArray 2.0 System or a BioFire FilmArray Torch System.

This document also describes how BioFire COVID-19 Test results are reported. The reporting information can be used to map the BioFire COVID-19 Test results from the electronic reports to an LIS.

Installing the Electronic Report Module

The BioFire FilmArray Link Software must be installed on the BioFire FilmArray 2.0 or Torch System before installing the COVID-19 v1.1 ERM. This electronic reporting module will only process BioFire® COVID-19 Test results.

TECHNICAL :: NOTE

Before installing:

1. Download the ERM software from the BioFire Defense website:
 - Visit the BioFire Defense FilmArray Support website at <https://www.biofiredefense.com/product-support/filmarray-support/> and then find the ERM software in the BioFire COVID-19 Test (EUA) drop down menu.
 - Complete the form that is displayed, and then save the installation file to the root directory on a removable drive.
2. Refer to the appropriate instructions below to install the software on a BioFire FilmArray 2.0 or Torch System.

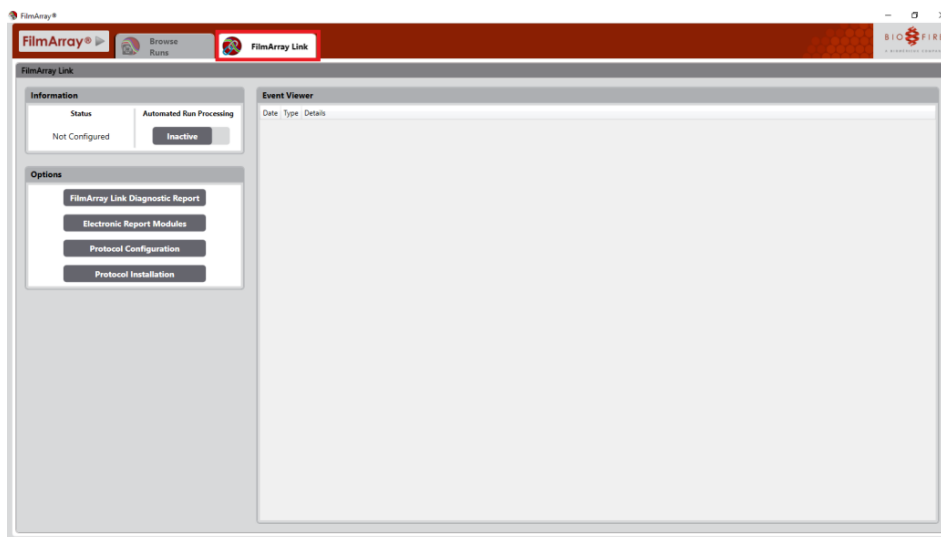
BioFire FilmArray 2.0 System

To install the COVID-19 v1.1 ERM on a FilmArray 2.0 System computer:

1. Insert the removable media containing the installation file into the computer.
2. Launch the software from the shortcut on the desktop.

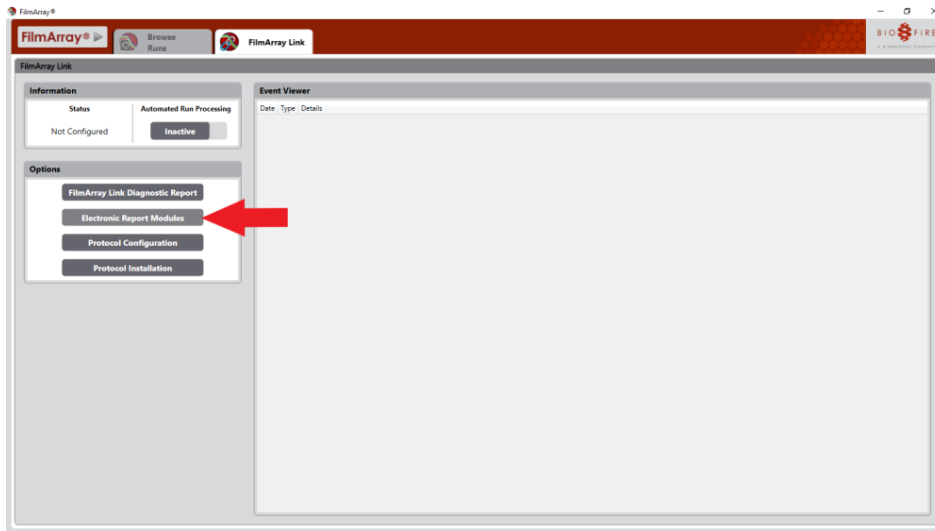


3. Click the **FilmArray Link** tab.

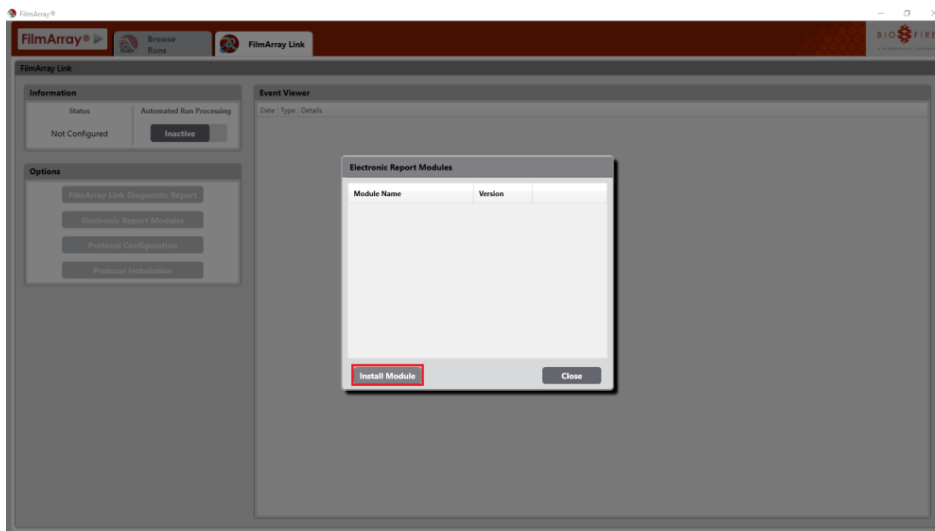


TECHNICAL NOTE

- Click the **Electronic Report Modules** button under Options on the tab.



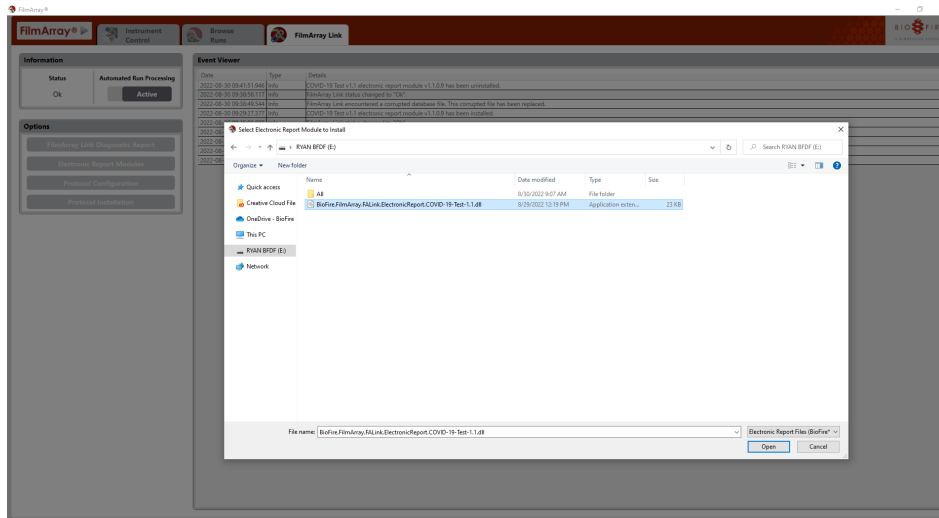
- Click the **Install Module** button in the Electronic Report Modules window.



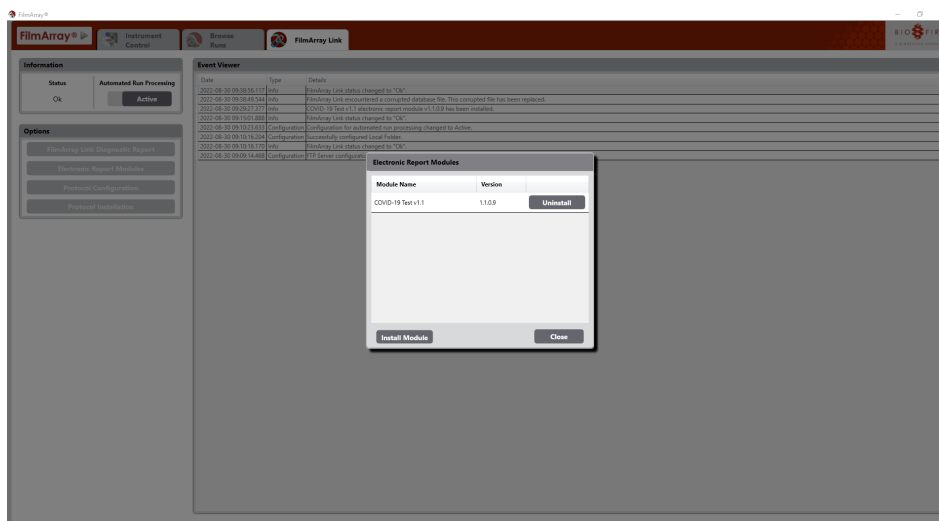
TECHNICAL NOTE

- Navigate to the removable media drive and double-click the installation file:
BioFire.FilmArray.FALink.ElectronicReport.COVID-19-Test-1.1.dll.

TECHNICAL NOTE



- When the software has been successfully installed, the module name (COVID-19 Test v1.1) and version (1.1.0.9) are displayed in the Electronic Report Module Management window.

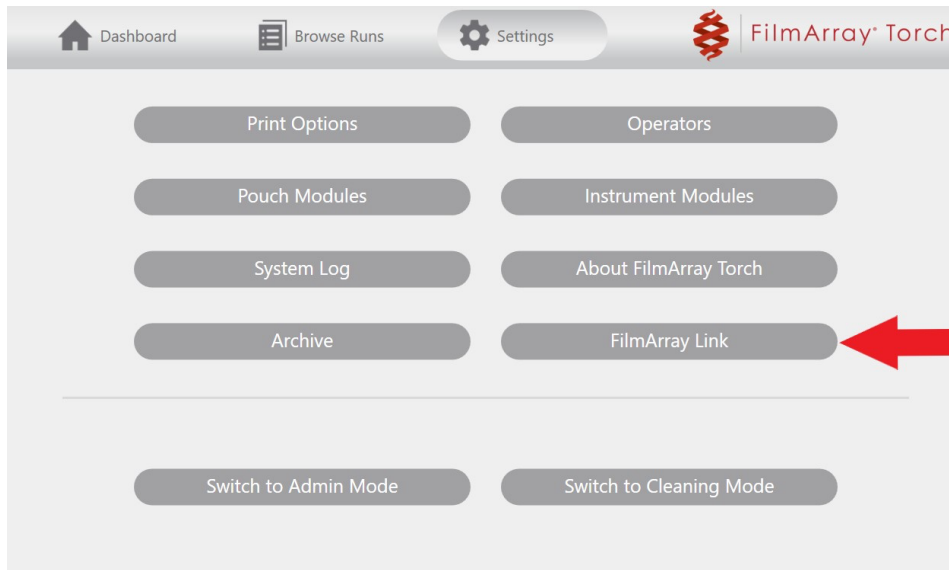


- Disconnect the removable media from the computer.

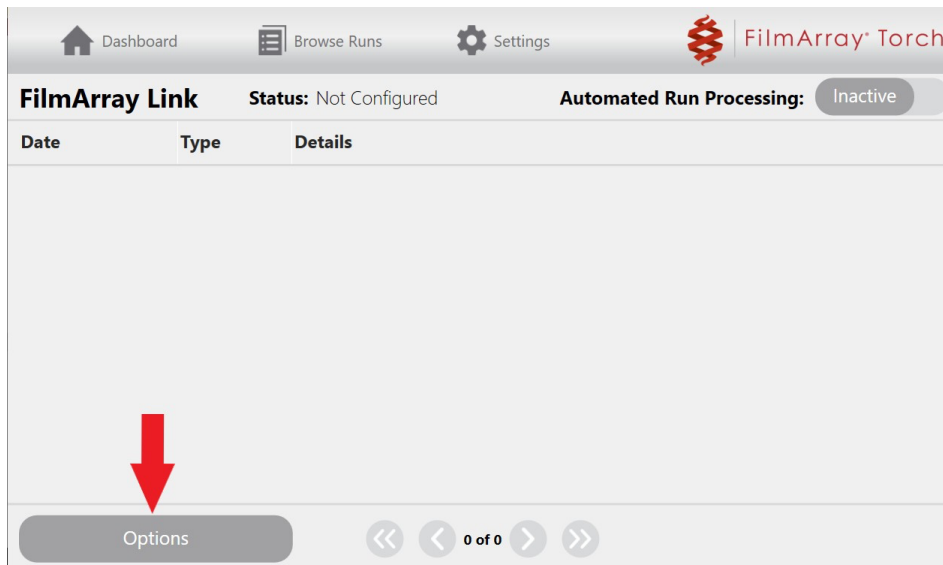
BioFire® FilmArray Torch System

To install the COVID-19 v1.1 ERM on a FilmArray Torch System base:

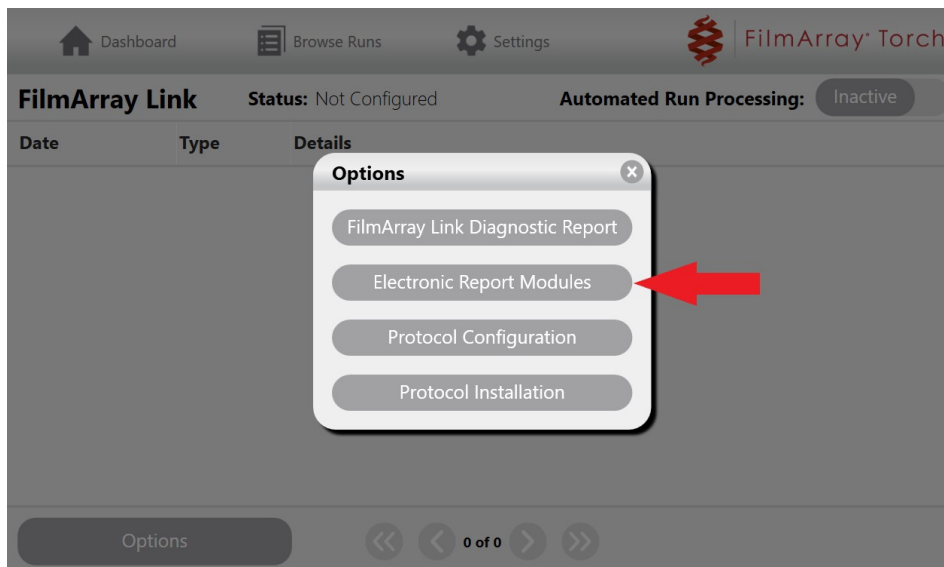
1. Connect the removable media containing the installation file into the system base.
2. Select the **FilmArray Link** option on the Settings screen.



3. Select **Options** on the FilmArray Link screen and then select the **Electronic Report Modules** option.

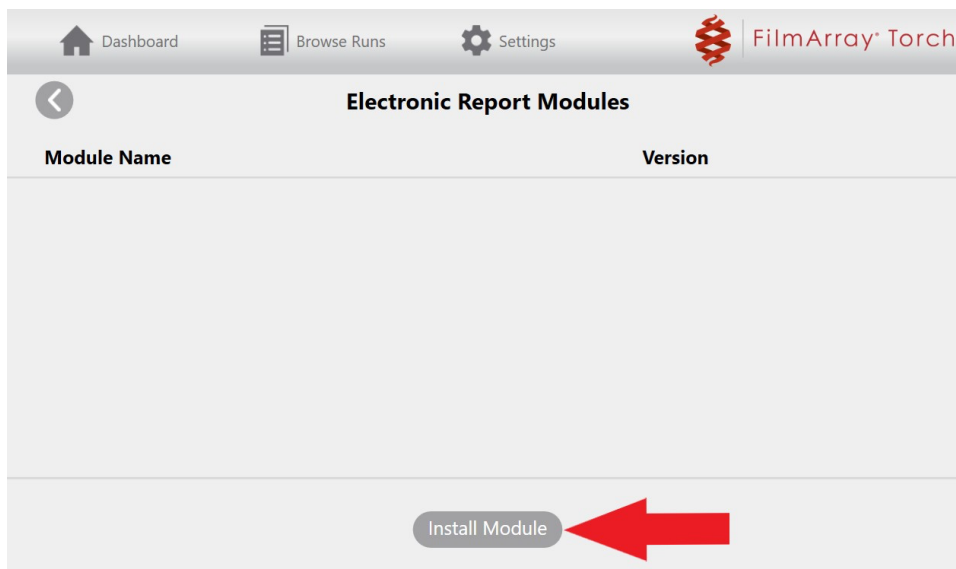


TECHNICAL NOTE



TECHNICAL NOTE

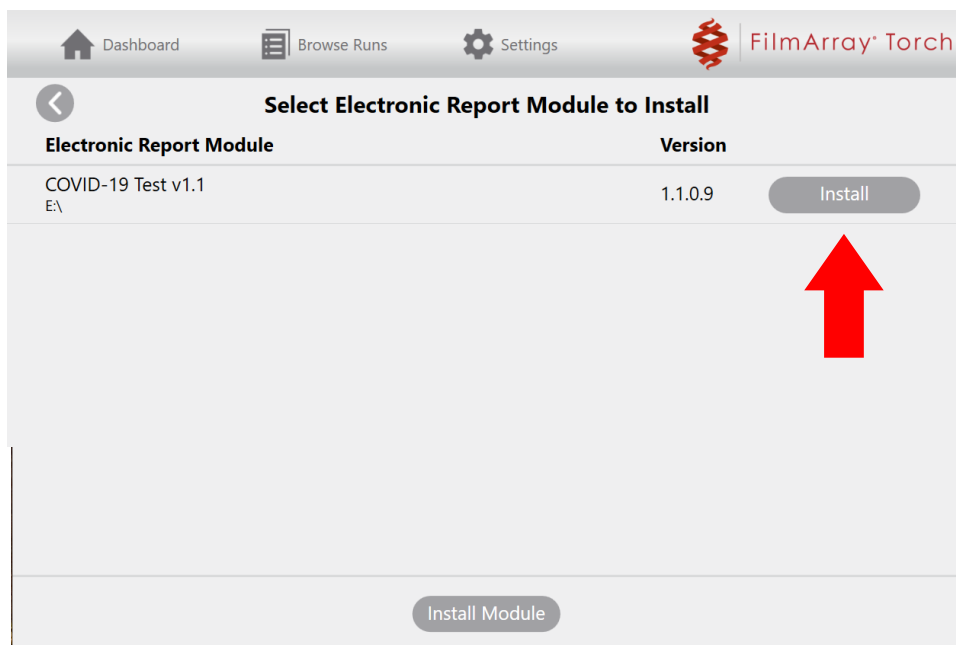
4. Select the **Install Module** option on the Electronic Report Modules screen.



5. Select the **Install** option associated with the COVID-19 v1.1 ERM (version 1.1.0.9).

NOTE: The software will only display installation files available in the root directory of the connected removable drive.

A list of installed modules will be displayed once the installation is complete.



6. Disconnect the removable media from the system base.

NOTE: *It is recommended to uninstall outdated and old software modules (i.e., COVID-19 v1.0). This will remove any chance of errors by selecting the wrong module.*

BioFire® COVID-19 Test Results in the Electronic Report

The COVID-19 v1.1 ERM formats BioFire COVID-19 Test results into electronic reports. Each electronic report contains information from a single BioFire COVID-19 Test. The electronic report includes the name of the target, as well as the corresponding target code and test result.

Table 1 shows the reported target name, target code, and all possible results for the COVID-19 target. Note that the reported target will only have one of the possible results associated with it for the BioFire COVID-19 Test v1.1. The target shown in Table 1 is always reported in the electronic reports, regardless of the result.

TECHNICAL NOTE

Table 1. BioFire COVID-19 Test Result Reporting

Target Observations				
Code	Display Name	Coding System	Possible Result Number(s)	Possible Result Code(s)
PCR_COV2	SARS-CoV-2	BMX	1	DETECT
			2	NOT_DETECT

Technical Support Contact Information

BioFire Defense is dedicated to providing the best customer support available. For any questions or concerns, please contact the BioFire Technical Support team for assistance.

General Information

Email: support@biofiredefense.com

Phone: 1-801-262-3592

Fax: 1-801-447-6907



TECHNICAL NOTE