

Installing the BioFire® COVID-19 Test Pouch Module on BioFire® FilmArray® Systems

Introduction

In order to run the BioFire COVID-19 Test on a BioFire FilmArray system, a specific pouch module must be installed.

Pouch Module Availability

The software needed to install the BioFire COVID-19 Test v1.1 Pouch Module can be obtained by downloading it directly from the BioFire Defense website or via a software disk provided by BioFire Defense.

To download the software from the website please follow the instructions below.


1. Insert a USB drive into the USB port or place a writable CD into the disk drive of a computer connected to the internet.
2. Go to BioFire Defense's COVID-19 web page located at: www.biofiredefense.com/covid-19test/.
3. Select the link for the BioFire COVID-19 Test v1.1 under the software section.



TECHNICAL NOTE

4. Fill out the web form

BioFire® COVID-19 Test v1.1 Software Pouch Module – Download Form



In order to run a FilmArray pouch with the FilmArray instrument, a specific Pouch Module must be installed into the FilmArray system software.

Fill out the form to download the BioFire COVID-19 Test v1.1 Pouch Module for the FilmArray Software.

[Download the Pouch Module Installation Instructions](#)

First Name* <input type="text"/>	Last Name* <input type="text"/>
Institution* <input type="text"/>	Department <input type="text"/>
Address	
Street Address <input type="text"/>	
Address Line 2 <input type="text"/>	
City <input type="text"/>	State / Province / Region <input type="text"/>
ZIP / Postal Code <input type="text"/>	Country <input type="text"/>
Phone <input type="text"/>	Email* <input type="text"/>

TECHNICAL NOTE

5. Download the file by clicking “BioFire COVID-19 Test v1.1 Pouch Module”.
6. Extract the files from the downloaded .zip folder and save to the USB drive or CD.

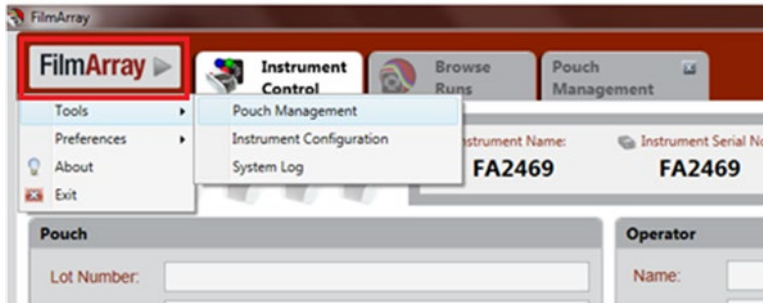
Installing the COVID-19 Test Pouch Module for the BioFire FilmArray 2.0 System

Using the downloaded file from the internet or the software disk, complete the following steps to install the new pouch module on each BioFire 2.0 computer.

1. Insert the USB drive or CD containing the BioFire COVID-19 Test v1.1 Pouch Module into a USB port or disk drive on the BioFire 2.0 computer.
2. Open the FilmArray software from the desktop icon.

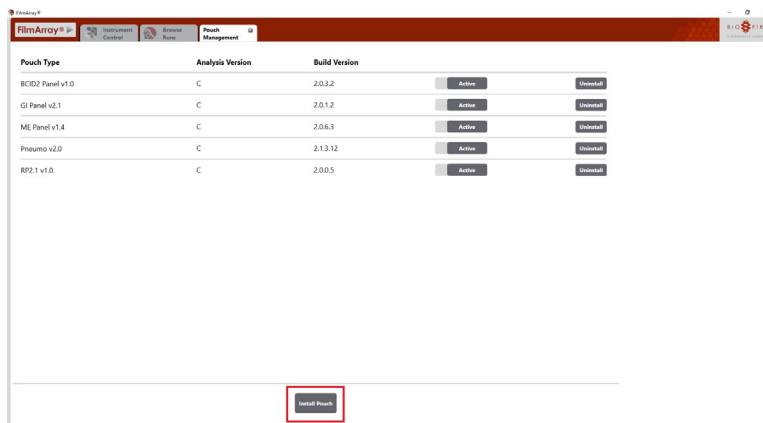


3. Navigate to the 'FilmArray' menu in the top left corner of the software.

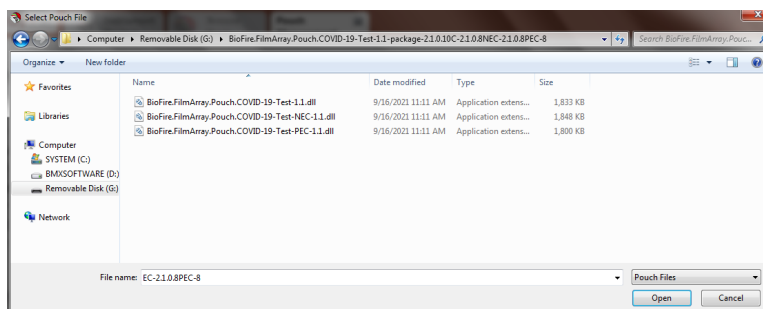


Click 'Tools'. Click 'Pouch Management'.

4. Click 'Install Pouch'.



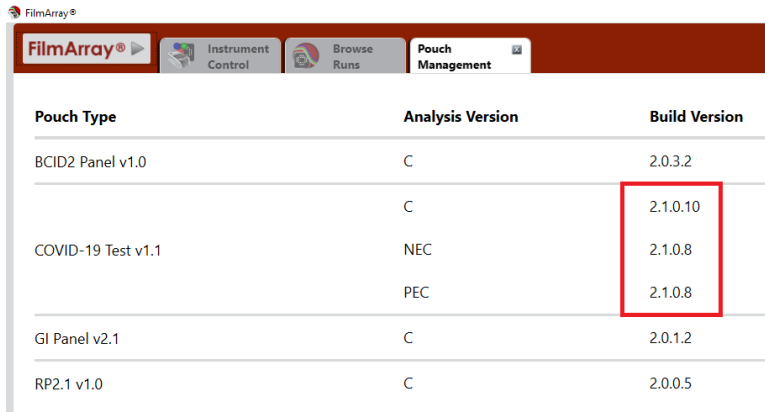
5. Navigate to the USB or disk drive where the pouch modules have been saved.
6. Select the desired pouch module file.
7. Click 'Open'.



NOTE: The BioFire COVID-19 Test v1.1 requires three .dll files which must be installed one at a time.

TECHNICAL NOTE

- Verify the pouch module builds are correct. The BioFire COVID-19 Test v1.1 has three analysis packages with build versions that must match the screenshot below.



Pouch Type	Analysis Version	Build Version
BCID2 Panel v1.0	C	2.0.3.2
COVID-19 Test v1.1	C	2.1.0.10
	NEC	2.1.0.8
	PEC	2.1.0.8
GI Panel v2.1	C	2.0.1.2
RP2.1 v1.0	C	2.0.0.5

NOTE: If the build version doesn't match, the process was not successful. Please contact technical support for assistance.

- Eject the removable drive from the computer.

Installing the BioFire® COVID-19 Test Pouch Module for the BioFire® Torch System

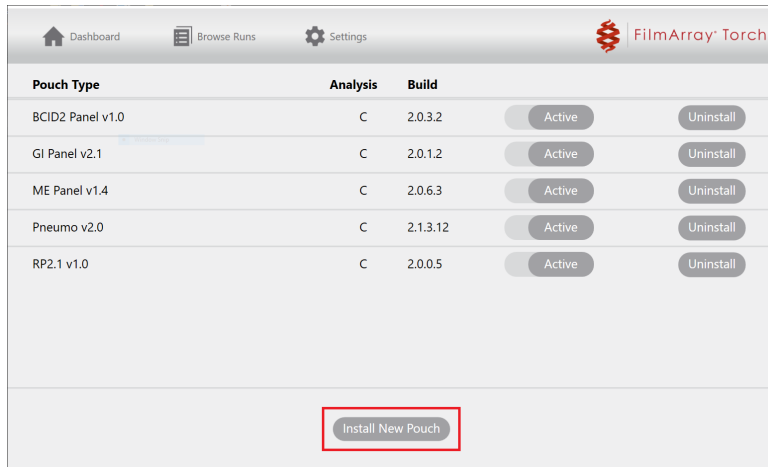
To install the BioFire COVID-19 Test v1.1 Pouch Module on a BioFire Torch System base:

- Insert the removable drive containing the installation file into the BioFire Torch System.
- Select the **'Pouch Modules'** option on the Settings screen.

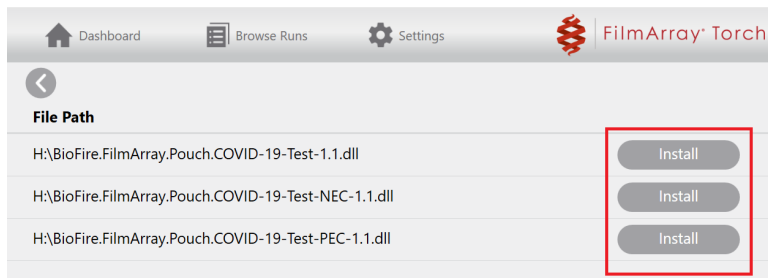


TECHNICAL NOTE

3. Select 'Install New Pouch'.



4. Select the 'Install' option associated with the desired pouch module.



NOTE: The software will display available installation files in the root directory of the connected removable drive; files in subfolders are not displayed. A list of installed modules will be displayed once a file has been installed.

TECHNICAL NOTE

- Verify the pouch module builds are correct. The BioFire COVID-19 Test v1.1 has three analysis packages with build versions that must match the screenshot below.

Pouch Type	Analysis	Build	Active	Uninstall
BCID2 Panel v1.0	C	2.0.3.2	Active	Uninstall
COVID-19 Test v1.1	C	2.1.0.10	Active	
	NEC	2.1.0.8	Active	Uninstall
	PEC	2.1.0.8	Active	
GI Panel v2.1	C	2.0.1.2	Active	Uninstall
RP2.1 v1.0	C	2.0.0.5	Active	Uninstall

Install New Pouch

NOTE: If the build version doesn't match, the process was not successful. Please contact technical support for assistance.

- Remove the removable drive from the system base.

Technical Support Contact Information

BioFire Defense is dedicated to providing the best technical support available. If you have any questions or concerns about this process, 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

Conditions of Authorization

The BioFire COVID-19 Test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

The BioFire COVID-19 Test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of the BioFire COVID-19 Test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.