Selection of Laboratory Performance Verification and Proficiency Testing Materials for use with the BioFire® COVID-19 Test

Purpose

The purpose of this technical note is to inform users of the types of materials that are compatible with the BioFire® COVID-19 Test when carrying out laboratory verifications or proficiency testing.

Selection of Materials for Laboratory Verifications and Proficiency Testing

The BioFire® COVID-19 Test contains three assays designed to detect the presence of SARS-CoV-2. The regions targeted by the BioFire® COVID-19 Test are located in ORF1ab and ORF8. Because the BioFire® COVID-19 Test is designed to detect multiple regions of the SARS-CoV-2 genome, materials that only contain specific genes, or gene fragments are not compatible and will give inaccurate results.

When selecting verification or proficiency testing material for use with the BioFire® COVID-19 Test ensure that the material includes the entire SARS-CoV-2 genome. The following types of materials are appropriate for use with the BioFire® COVID-19 Test when performing proficiency testing or laboratory verifications:

- Known clinical samples
- Simulated clinical samples containing inactivated virus or genomic RNA
- BioFire® COVID-19 External Control Kit

Please contact BioFire Defense with any questions regarding the compatibility of materials for use with the BioFire® COVID-19 Test.

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 FilmArray Technical Support team for assistance.

General Information
Email: support@biofiredefense.com
Phone: 1-801-262-3592
Fax: 1-801-447-6907
1. The initial release of The College of American Physicians SARS-CoV-2 Proficiency Testing Program (COV2-A 2020) contained only fragments of the SARS-CoV-2 genome and is not compatible with the BioFire® COVID-19 Test. However, shipments as of July 27, 2020 include the whole genome.

2. The BioFire® COVID-19 External Control Kit consists of synthetic RNA fragments designed to be amplified by the BioFire® COVID-19 Test.