

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

## TECHNICAL ::: NOTE

### Purpose

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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

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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<sup>1</sup>
- BioFire® COVID-19 External Control Kit<sup>2</sup>

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

### Technical Support Contact Information

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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](mailto:support@biofiredefense.com)

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Technical Note

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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.

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