Incompatibility of the College of American Pathologists SARS-CoV-2 Molecular Proficiency Testing Panel with the BioFire® COVID-19 Test

Purpose

The purpose of this technical note is to inform users of the incompatibility of the College of American Pathologists SARS-CoV-2 Molecular Proficiency Panel when used with the BioFire® COVID-19 Test.

Background

The College of American Pathologists (CAP) has released a panel for laboratories wishing to perform proficiency testing on Sudden Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) molecular diagnostics tests. The current version of the panel (COV2-A 2020) consists of simulated clinical samples containing gene fragments of the SARS-CoV-2 genome, including the N, E, RdRP, ORF1a, and S regions.

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, only proficiency panels or controls that contain all three targeted regions should be used. Proficiency panels or controls that only contain specific genes or gene fragments are not compatible and will give inaccurate results.

Incompatibility of the CAP SARS-CoV-2 Molecular Proficiency Panel

BioFire Defense has determined that the CAP SARS-CoV-2 Molecular Proficiency Panel does not include targets for two of the three assays on the BioFire® COVID-19 Test and is therefore incompatible. BioFire Defense does not recommend using the CAP SARS-CoV-2 Molecular Proficiency Panel for proficiency testing or laboratory verifications when using the BioFire® COVID-19 Test. The following 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 control 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
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