Biosafety when Testing Suspected SARS-CoV-2 Samples on the BioFire® FilmArray® System

TECHNICAL ::: NOTE

Introduction

The purpose of this technical note is to provide the user with guidance regarding handling of suspected severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) respiratory samples during testing on the BioFire System.

Safety with Potential SARS-CoV-2 Positive Samples

General Information

SARS-CoV-2 is an enveloped virus with a single-stranded, positive-sense RNA genome. Coronavirus Disease 2019 (COVID-19) is an emerging pandemic respiratory illness caused by SARS-CoV-2 first discovered in China in 2019. The highly pathogenic nature of this virus requires special caution when handling patient samples suspected of containing SARS-CoV-2. The recommendations outlined below do not apply to all respiratory samples, ONLY to potential SARS-CoV-2 positives. When handling potentially positive samples, always follow applicable and recommended guidelines from all applicable regulatory agencies, including the WHO (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance) and the Centers for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html).

Sample Handling

Patient samples suspected of being positive for SARS-CoV-2 need to be handled appropriately with biosafety laboratory level 2 procedures and associated personal protective equipment. It is recommended that all potential SARS-CoV-2 positive samples be handled in a class II or higher biosafety cabinet. If a biosafety cabinet is unavailable, handing of suspected SARS-CoV-2 positive samples should include additional precautions to provide a protective barrier between specimen manipulation and personnel performing sample processing and BioFire pouch loading.[1,2] According to the WHO, all work surfaces should be decontaminated after use with an appropriate disinfectant with proven activity against enveloped viruses (e.g. hypochlorite (bleach), alcohol,

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hydrogen peroxide, quaternary ammonium compounds and phenolic compounds)[1] because free SARS-CoV-2 virions have been observed to survive for up to 72 hours on both steel and plastic surfaces.[3]

Organism Inactivation during Sample Manipulation

In general, guanidine salt-based buffers, like BioFire® FilmArray® Sample Buffer, are effective at inactivating enveloped viruses.[4–6] For example, the Qiagen® nucleic acid extraction buffer AVL has been shown to effectively inactivate MERS-CoV in culture media.[7] BioFire has also demonstrated rapid inactivation of Ebola virus after contact with the BioFire Sample Buffer.[8] Based on the available information, once the potential SARS-CoV-2 sample is added to BioFire Sample Buffer, the sample mix is not expected to contain viable virus. This supports the concept that the sample loading workflow of the BioFire® System is safe for laboratory personnel as soon as the specimen is in contact with the BioFire Sample Buffer and after specimen injection into the self-contained pouch.

References

1. Organization, W. H. Laboratory biosafety guidance related to coronavirus disease (COVID-19): interim guidance, 19 March 2020. (2020).

2. Siddharta, A. *et al.* Virucidal Activity of World Health Organization-Recommended Formulations Against Enveloped Viruses, Including Zika, Ebola, and Emerging Coronaviruses. *J. Infect. Dis.* **215**, 902–906 (2017).

3. van Doremalen, N. *et al.* Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. *N. Engl. J. Med.* **0**, null (2020).

4. Blow, J. A., Dohm, D. J., Negley, D. L. & Mores, C. N. Virus inactivation by nucleic acid extraction reagents. *J. Virol. Methods* **119**, 195–198 (2004).

5. Roberts, P. L. & Lloyd, D. Virus inactivation by protein denaturants used in affinity chromatography. *Biol. J. Int. Assoc. Biol. Stand.* **35**, 343–347 (2007).

6. Rosenstierne, M. W. *et al.* Rapid Bedside Inactivation of Ebola Virus for Safe Nucleic Acid Tests. *J. Clin. Microbiol.* **54**, 2521–2529 (2016).

7. Kumar, M. *et al.* Inactivation and safety testing of Middle East Respiratory Syndrome Coronavirus. *J. Virol. Methods* **223**, 13–18 (2015).

8. Ferraris, O. *et al.* Complete ebola and vaccina virus inactivation during lysis in the FilmArray Biothreat-E Assay demonstrates the biosafety of the test. (2016).

Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the BioFire Technical Support team for assistance.

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