

BioFire® FilmArray® Respiratory Panel (RP) EZ Influenza B Reactivity

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The BioFire RP EZ is a multiplexed nucleic acid test intended for use with BioFire® FilmArray® Systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. This includes the detection of influenza B.

Through in silico monitoring, a mutation has been identified in a circulating strain of influenza B that impacts the sequence detected by the BioFire RP EZ. This mutation is found in viruses of the influenza B/Victoria V1A.3 subclade. Additional testing has demonstrated a mild reduction in analytical sensitivity (estimated 10-100 fold difference in the limit of detection, approximated to be near 2000 copies per mL) in this mutated strain, as compared to strains without this specific mutation.

Current testing, in silico predictions, and previous reactivity studies demonstrate that the influenza B assay found in the BioFire RP EZ detects all currently-circulating influenza B strains, including the strain carrying this mutation. Due to the mild reduction in analytical sensitivity caused by this mutation, some specimens containing low-level influenza B concentrations may be missed when tested with the BioFire RP EZ but it is believed that this mutation is unlikely to impact the clinical sensitivity of this test.

This new influenza B subclade (B/Victoria V1A.3) emerged during the 2018-2019 influenza season and is the predominant influenza B strain of the 2019-2020 influenza season.

Conclusions:

1. The BioFire RP EZ may miss very low-level detections of certain influenza B strains due to a mutation identified under an assay primer.
2. The BioFire RP EZ is a highly sensitive and specific CLIA-waived molecular test. It is believed that the clinical sensitivity of the influenza B assay is not likely affected by the identified mutation.
3. The results of any BioFire Panel should be used to aid in the diagnosis of respiratory infection and should be used in conjunction with other clinical and epidemiological information.

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.

BioFire Technical Support

Email: support@biofiredx.com

Phone: +1-801-736-6354, select Option 5



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