

Technical Brief

January 19, 2024

Circulating Influenza Strains and Detection by the LUCIRA® by Pfizer COVID-19 & Flu Test and COVID-19 & Flu Home Test

The Global Initiative on Sharing All Influenza Data (GISAID) Science Initiative promotes the rapid sharing of global data for priority pathogens, including viral genomic sequences of circulating Influenza virus strains.¹

Pfizer performs routine surveillance of circulating Influenza strains by periodically evaluating *in silico* reactivity against H1N1, H3N2, and Flu B sequences submitted to the GISAID database.²

An evaluation was conducted on sequences submitted to the database between May 15, 2023, and October 25, 2023. This evaluation confirmed that the LUCIRA® by Pfizer COVID-19 & Flu Test and COVID-19 & Flu Home Test (OTC) by *in silico* analysis are predicted reactive to circulating Influenza A/H1N1, A/H3N2, and Influenza B for the period sampled, meeting the pre-specified reactivity threshold based on guidance from the FDA.³ This ensures that the Flu assays in the LUCIRA® by Pfizer tests maintain the stated level of performance established during the clinical study.²

Pfizer will continue to monitor the situation with circulating strains of Influenza. If you have any questions on the above, please reach out to LUCIRA® by Pfizer Customer Support at luciracustomersupport@pfizer.com.

¹ Global Initiative on Sharing All Influenza Data. About Us and mission. <https://gisaid.org/about-us/mission/>. Accessed January 12, 2024.

² Data on file.

³ Guidance for Industry and FDA Staff: Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses, 15 July 2011.

