

Technical Brief

May 7, 2024

Circulating SARS-CoV-2 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 SARS-CoV-2 virus strains.¹

Pfizer performs routine surveillance of circulating COVID-19 strains by periodically evaluating *in silico* reactivity against sequences submitted to the GISAID database.²

An evaluation was conducted on sequences submitted to the database between January 1, 2024, and April 22, 2024. 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 SARS-CoV-2 viruses for the period sampled, meeting the pre-specified reactivity threshold based on guidance from the FDA.³ This evaluation included but is not limited to the following lineages: BA.2.86, EG.5, JN.1, JN.1.4.3, JN.1.7, JN.1.8.1, JN.1.11.1, JN.1.13.1, JN.1.16, JN.1.18, KP.1.1, KP.2, XBB.1.5, and XBB.1.16. This ensures that the COVID-19 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 COVID-19. 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 April 22, 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.