CLARITY

APPENDIX

2026 Annual Analytical Reactivity Testing Results
Swab Sample Protocol
Clarity Influenza A&B Test

As required per 21 CFR 866.3328(b), annual analytical reactivity testing was performed with the contemporary influenza strains identified by FDA in consultation with the Centers for Disease Control and Prevention (CDC) using the 2026 CBER influenza virus panel (Cat: VP2026, Lot No.: VP2026-001, Exp. Date: June 1st, 2027).

All strains from FDA CBER were tested per the swab sample protocol. Test results for each influenza strain are listed below. Clarity Influenza A&B Test detected all the influenza viruses in the panel.

Type/Subtype	Virus Strain Name	Virus Serial Dilution Concentration (EID_{50}/mL)							
		Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
A (H1N1) pdm09	A/Missouri/11/2025	$10^{7.8}$	$1.26x10^{7}$	$2.52x10^{6}$	$5.05x10^{5}$	$1.01x10^{5}$	$2.02x10^{4}$	$4.04x10^{3}$	$8.08x10^{2}$
		N/A	5/5	5/5	5/5	5/5	5/5	0/5	0/5
	A/Victoria/4897/2022	$10^{9.25}$	$3.56x10^{8}$	$7.11x10^{7}$	$1.42x10^{7}$	$2.85x10^{6}$	$5.69x10^{5}$	$1.14x10^{5}$	$2.28x10^{4}$
		N/A	5/5	5/5	5/5	5/5	0/5	0/5	N/A
A (H3N2)	A/Michigan/105/2025	$10^{8.5}$	$6.32x10^{7}$	$1.26x10^{7}$	$2.53x10^{6}$	$5.06x10^{5}$	$1.01x10^{5}$	$2.02x10^{4}$	$4.05x10^{3}$
		N/A	5/5	5/5	5/5	0/5	0/5	N/A	N/A
	A/Wisconsin/160/2024	$10^{8.75}$	$1.12x10^{8}$	$2.25x10^{7}$	$4.5x10^{6}$	$9x10^{5}$	$1.8x10^{5}$	$3.6x10^{4}$	$7.2\ x10^{3}$
		N/A	5/5	5/5	5/5	5/5	5/5	0/5	0/5
B (Victoria lineage)	B/Tokyo/EIS13-175/2025	$10^{8.75}$	$1.12x10^{8}$	$2.25x10^{7}$	$4.5x10^{6}$	$9x10^{5}$	$1.8x10^{5}$	$3.6x10^{4}$	$7.2\ x10^{3}$
		N/A	5/5	5/5	5/5	2/5	0/5	0/5	N/A
	B/Austria/1359417/2021	$10^{8.5}$	$6.32x10^{7}$	$1.26x10^{7}$	$2.53x10^{6}$	$5.06x10^{5}$	$1.01x10^{5}$	$2.02x10^{4}$	$4.05x10^{3}$
		N/A	5/5	5/5	5/5	2/5	0/5	0/5	N/A