

Summary of 2026 Annual Flu Strain Reactivity Testing

Catalogue 1099: OSOM® COVID-19/Flu A&B Combo Test, CLIA Waived Kit

The FDA Center for Biologics Evaluation and Research (CBER) provided six human influenza virus strains to evaluate the reactivity of the OSOM® COVID-19/Flu A&B Combo Test. The panel included four influenza A strains and two influenza B strains. Each strain was serially diluted fivefold from the provided stock and tested in five replicates at each dilution. To prepare each mock patient sample, 50 µL of diluted virus was pipetted onto a swab. Each swab was tested according to the OSOM® COVID-19/Flu A&B Combo Test instructions for use. The test detected all six strains. The lowest concentration at which at least one of five replicates tested positive was defined as the minimally reactive concentration and is shaded gray.

Influenza Virus	Virus Strain Name	Stock Concentration	Virus 5-Fold Serial Dilutions (EID ₅₀ /mL) and Number of Positive Results at Each Dilution							
(Type/Subtype)		(EID ₅₀ /mL)	5x	25x	125x	625x	3,125x	15,625x	78,125x	390,625x
Influenza A/ H1N1pdm09	A/Missouri/11/2025	1 x 10 ^{3.6}	10 ^{7.1}	10 ^{6.4}	10 ^{5.7}	10 ^{5.0}	10 ^{4.3}	10 ^{3.6}	10 ^{2.9}	10 ^{2.2}
			5/5	5/5	5/5	5/5	5/5	2/5	0/5	0/5
	A/Victoria/4897/2022	1 x 10 ^{5.05}	10 ^{8.55}	10 ^{7.85}	10 ^{7.15}	10 ^{6.45}	10 ^{5.75}	10 ^{5.05}	10 ^{4.35}	10 ^{3.65}
			5/5	5/5	5/5	5/5	5/5	2/5	0/5	0/5
Influenza A/ H3N2	A/Michigan/105/2025	1 x 10 ^{5.7}	10 ^{7.8}	10 ^{7.1}	10 ^{6.4}	10 ^{5.7}	10 ^{5.0}	10 ^{4.3}	N/A	N/A
			5/5	5/5	5/5	1/5	0/5	0/5	Not Tested	Not Tested
	A/Wisconsin/160/2024	1 x 10 ^{4.55}	10 ^{8.05}	10 ^{7.35}	10 ^{6.65}	10 ^{5.95}	10 ^{5.25}	10 ^{4.55}	10 ^{3.85}	10 ^{3.15}
			5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5
Influenza B/ Victoria Lineage	B/Tokyo/EIS13-175/2025	1 x 10 ^{5.95}	10 ^{8.05}	10 ^{7.35}	10 ^{6.65}	10 ^{5.95}	10 ^{5.25}	10 ^{4.55}	N/A	N/A
			5/5	5/5	5/5	5/5	0/5	0/5	Not Tested	Not Tested
	B/Austria/1359417/2021	1 x 10 ^{5.7}	10 ^{7.8}	10 ^{7.1}	10 ^{6.4}	10 ^{5.7}	10 ^{5.0}	10 ^{4.3}	N/A	N/A
			5/5	5/5	5/5	1/5	0/5	0/5	Not Tested	Not Tested