

Summary of 2025 Annual Flu Strain Reactivity Testing

Catalogue 570-1886: One Step + Ultra Flu A&B Test, CLIA Waived Kit

A panel of eight human influenza viral strains was provided by the FDA Center for Biologics Evaluation and Research (CBER) for evaluating the reactivity of the One Step + Ultra Flu A&B Test. The viral isolates included four influenza A and four influenza B strains. Each sample was serially diluted in 5-fold dilutions from the stock provided and each dilution was assayed in replicates of five. To create samples for testing, mock patient samples were prepared by pipetting 50 µL of each diluted sample onto a swab. Each swab was tested following the procedure stated in the One Step + Ultra Flu A&B Test instructions for use. All strains were successfully detected. The minimally reactive concentration was identified as the lowest dilution at which any of the five replicates gave a positive reading.

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/Victoria/4897/2022	1x10 ^{9.25}	2x10 ^{8.25}	4x10 ^{7.25}	8x10 ^{6.25}	1.6x10 ^{6.25}	3.2x10 ^{5.25}	6.4x10 ^{4.25}	1.28x10 ^{4.25}	2.56x10 ^{3.25}
			5/5	5/5	5/5	5/5	5/5	0/5	0/5	not tested
	A/Victoria/2570/2019	1x10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}	1.28x10 ^{3.3}	2.56x10 ^{2.3}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
Influenza A/ H3N2	A/Croatia/10136RV/2023	1x10 ^{7.7}	2 x 10 ^{6.7}	4 x 10 ^{5.7}	8 x 10 ^{4.7}	1.6 x 10 ^{4.7}	3.2 x 10 ^{3.7}	6.4 x 10 ^{2.7}	1.28 x 10 ^{2.7}	2.56 x 10 ^{1.7}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
	A/Wisconsin/160/2024	1x10 ^{8.75}	2 x 10 ^{7.75}	4 x 10 ^{6.75}	8 x 10 ^{5.75}	1.6 x 10 ^{5.75}	3.2 x 10 ^{4.75}	6.4 x 10 ^{3.75}	1.28 x 10 ^{3.75}	2.56 x 10 ^{2.75}
			5/5	5/5	5/5	5/5	2/5	0/5	0/5	not tested
Influenza B/ Victoria Lineage	B/Austria/1359417/2021	1x10 ^{8.5}	2 x 10 ^{7.5}	4 x 10 ^{6.5}	8 x 10 ^{5.5}	1.6 x 10 ^{5.5}	3.2 x 10 ^{4.5}	6.4 x 10 ^{3.5}	1.28 x 10 ^{3.5}	2.56 x 10 ^{2.5}
			5/5	5/5	3/5	0/5	0/5	not tested	not tested	not tested
	B/Netherlands/10894/2022	1x10 ^{8.7}	2 x 10 ^{7.7}	4 x 10 ^{6.7}	8 x 10 ^{5.7}	1.6 x 10 ^{5.7}	3.2 x 10 ^{4.7}	6.4 x 10 ^{3.7}	1.28 x 10 ^{3.7}	2.56 x 10 ^{2.7}
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
Influenza B/ Yamagata Lineage	B/Phuket/3073/2013	1x10 ^{9.5}	2 x 10 ^{8.5}	4 x 10 ^{7.5}	8 x 10 ^{6.5}	1.6 x 10 ^{6.5}	3.2 x 10 ^{5.5}	6.4 x 10 ^{4.5}	1.28 x 10 ^{4.5}	2.56 x 10 ^{3.5}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
	B/Norway/2134/2019	1x10 ¹⁰	2 x 10 ⁹	4 x 10 ⁸	8 x 10 ⁷	1.6 x 10 ⁷	3.2 x 10 ⁶	6.4 x 10 ⁵	1.28 x 10 ⁵	2.56 x 10 ⁴
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested

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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/Victoria/4897/2022	1x10 ^{8.5}	2x10 ^{7.5}	4x10 ^{6.5}	8x10 ^{5.5}	1.6x10 ^{5.5}	3.2x10 ^{4.5}	6.4x10 ^{3.5}	1.28x10 ^{3.5}	2.56x10 ^{2.5}
			5/5	5/5	2/5	0/5	0/5	not tested	not tested	not tested
	A/Victoria/2570/2019	1x10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}	1.28x10 ^{3.3}	2.56x10 ^{2.3}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
Influenza A/ H3N2	A/California/122/2022	1x10 ^{8.5}	2 x 10 ^{7.5}	4 x 10 ^{6.5}	8 x 10 ^{5.5}	1.6 x 10 ^{5.5}	3.2 x 10 ^{4.5}	6.4 x 10 ^{3.5}	1.28 x 10 ^{3.5}	2.56 x 10 ^{2.5}
			5/5	5/5	5/5	5/5	5/5	0/5	0/5	not tested
	A/Georgia/02/2022	1x10 ^{9.5}	2 x 10 ^{8.5}	4 x 10 ^{7.5}	8 x 10 ^{6.5}	1.6 x 10 ^{6.5}	3.2 x 10 ^{5.5}	6.4 x 10 ^{4.5}	1.28 x 10 ^{4.5}	2.56 x 10 ^{3.5}
			5/5	5/5	5/5	2/5	0/5	0/5	not tested	not tested
Influenza B/ Victoria Lineage	B/Austria/1359417/2021	1x10 ^{8.5}	2 x 10 ^{7.5}	4 x 10 ^{6.5}	8 x 10 ^{5.5}	1.6 x 10 ^{5.5}	3.2 x 10 ^{4.5}	6.4 x 10 ^{3.5}	1.28 x 10 ^{3.5}	2.56 x 10 ^{2.5}
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
	B/Netherlands/10894/2022	1x10 ^{8.7}	2 x 10 ^{7.7}	4 x 10 ^{6.7}	8 x 10 ^{5.7}	1.6 x 10 ^{5.7}	3.2 x 10 ^{4.7}	6.4 x 10 ^{3.7}	1.28 x 10 ^{3.7}	2.56 x 10 ^{2.7}
			5/5	5/5	5/5	2/5	0/5	0/5	not tested	not tested
Influenza B/ Yamagata Lineage	B/Phuket/3073/2013	1x10 ^{9.5}	2 x 10 ^{8.5}	4 x 10 ^{7.5}	8 x 10 ^{6.5}	1.6 x 10 ^{6.5}	3.2 x 10 ^{5.5}	6.4 x 10 ^{4.5}	1.28 x 10 ^{4.5}	2.56 x 10 ^{3.5}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
	B/Norway/2134/2019	1x10 ¹⁰	2 x 10 ⁹	4 x 10 ⁸	8 x 10 ⁷	1.6 x 10 ⁷	3.2 x 10 ⁶	6.4 x 10 ⁵	1.28 x 10 ⁵	2.56 x 10 ⁴
			5/5	5/5	5/5	5/5	2/5	0/5	0/5	not tested

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			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
	A/Victoria/2570/2019	1x10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}	1.28x10 ^{3.3}	2.56x10 ^{2.3}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
Influenza A/ H3N2	A/Darwin/9/2021	1x10 ^{8.3}	2 x 10 ^{7.3}	4 x 10 ^{6.3}	8 x 10 ^{5.3}	1.6 x 10 ^{5.3}	3.2 x 10 ^{4.3}	6.4 x 10 ^{3.3}	1.28 x 10 ^{3.3}	2.56 x 10 ^{2.3}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
	A/Georgia/02/2022	1x10 ^{9.5}	2 x 10 ^{8.5}	4 x 10 ^{7.5}	8 x 10 ^{6.5}	1.6 x 10 ^{6.5}	3.2 x 10 ^{5.5}	6.4 x 10 ^{4.5}	1.28 x 10 ^{4.5}	2.56 x 10 ^{3.5}
			5/5	5/5	5/5	0/5	0/5	0/5	not tested	not tested
Influenza B/ Victoria Lineage	B/Austria/1359417/2021	1x10 ^{8.5}	2 x 10 ^{7.5}	4 x 10 ^{6.5}	8 x 10 ^{5.5}	1.6 x 10 ^{5.5}	3.2 x 10 ^{4.5}	6.4 x 10 ^{3.5}	1.28 x 10 ^{3.5}	2.56 x 10 ^{2.5}
			5/5	5/5	2/5	0/5	0/5	not tested	not tested	not tested
	B/Netherlands/10894/2022	1x10 ^{8.7}	2 x 10 ^{7.7}	4 x 10 ^{6.7}	8 x 10 ^{5.7}	1.6 x 10 ^{5.7}	3.2 x 10 ^{4.7}	6.4 x 10 ^{3.7}	1.28 x 10 ^{3.7}	2.56 x 10 ^{2.7}
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
Influenza B/ Yamagata Lineage	B/Phuket/3073/2013	1x10 ^{7.8}	2 x 10 ^{6.8}	4 x 10 ^{5.8}	8 x 10 ^{4.8}	1.6 x 10 ^{4.8}	3.2 x 10 ^{3.8}	6.4 x 10 ^{2.8}	1.28 x 10 ^{2.8}	2.56 x 10 ^{1.8}
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
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			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested