

Summary of 2021 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 Centers for Disease Control 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 μ L 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 (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus 5-Fold Serial Dilutions (EID ₅₀ /mL) and Number of Positive Results at Each Dilution							
		(EID ₅₀ /mL)								
A(H3N2)	A/Perth/16/2009	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	5/5	5/5	0/5	0/5
	A/Tasmania/503/2020	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	5/5	5/5	5/5	0/5	0/5	not tested
A(H1N1)pdm09	A/Christ Church/16/2020	1x10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x10 ^{6.2}	3.2x10 ^{5.2}	6.4x10 ^{4.2}	1.28x10 ^{4.2}	2.56x10 ^{3.2}
			5/5	5/5	5/5	5/5	5/5	0/5	0/5	not tested
	A/Victoria/2570/2019	1x10 ^{8.2}	2x10 ^{7.2}	4x10 ^{6.2}	8x10 ^{5.2}	1.6x10 ^{5.2}	3.2x10 ^{4.2}	6.4x10 ^{3.2}	1.28x10 ^{3.2}	2.56x10 ^{2.2}
			5/5	5/5	5/5	5/5	5/5	0/5	0/5	not tested
B (Victoria lineage)	B/Michigan/09/2011	1x10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	6.4x10 ^{1.9}	1.28x10 ^{1.9}	2.56x10 ^{0.9}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
	B/Washington/02/2019	1x10 ^{9.3}	2x10 ^{8.3}	4x10 ^{7.3}	8x10 ^{6.3}	1.6x10 ^{6.3}	3.2x10 ^{5.3}	6.4x10 ^{4.3}	1.28x10 ^{4.3}	2.56x10 ^{3.3}
			5/5	5/5	5/5	3/5	0/5	0/5	not tested	not tested
B (Yamagata lineage)	B/Texas/81/2016	1x10 ^{8.1}	2x10 ^{7.1}	4x10 ^{6.1}	8x10 ^{5.1}	1.6x10 ^{5.1}	3.2x10 ^{4.1}	6.4x10 ^{3.1}	1.28x10 ^{3.1}	2.56x10 ^{2.1}
			5/5	5/5	5/5	5/5	2/5	0/5	0/5	not tested
	B/Phuket/3073/2013	1x10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{6.9}	3.2x10 ^{5.9}	6.4x10 ^{4.9}	1.28x10 ^{4.9}	2.56x10 ^{3.9}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested

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		(EID ₅₀ /mL)								
A(H3N2)	A/Perth/16/2009	1x10 ^{9.3}	2x10 ^{8.3}	4x10 ^{7.3}	8x10 ^{6.3}	1.6x10 ^{6.3}	3.2x10 ^{5.3}	6.4x10 ^{4.3}	1.28x10 ^{4.3}	2.56x10 ^{3.3}
			5/5	5/5	5/5	5/5	4/5	0/5	0/5	not tested
	A/Hong Kong/2671/2019	1x10 ^{7.5}	2x10 ^{6.5}	4x10 ^{5.5}	8x10 ^{4.5}	1.6x10 ^{4.5}	3.2x10 ^{3.5}	6.4x10 ^{2.5}	1.28x10 ^{2.5}	2.56x10 ^{1.5}
			5/5	5/5	0/5	0/5	not tested	not tested	not tested	not tested
A(H1N1)pdm09	A/Christ Church/16/2010	1x10 ^{10.2}	2x10 ^{9.2}	4x10 ^{8.2}	8x10 ^{7.2}	1.6x10 ^{7.2}	3.2x10 ^{6.2}	6.4x10 ^{5.2}	1.28x10 ^{5.2}	2.56x10 ^{4.2}
			5/5	5/5	5/5	5/5	3/5	0/5	0/5	not tested
	A/Guangdong-Maonan/1536/2019	1x10 ^{9.1}	2x10 ^{8.1}	4x10 ^{7.1}	8x10 ^{6.1}	1.6x10 ^{6.1}	3.2x10 ^{5.1}	6.4x10 ^{4.1}	1.28x10 ^{4.1}	2.56x10 ^{3.1}
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
B (Victoria lineage)	B/Michigan/09/2011	1x10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	6.4x10 ^{1.9}	1.28x10 ^{1.9}	2.56x10 ^{0.9}
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
	B/Washington/02/2019	1x10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x10 ^{6.2}	3.2x10 ^{5.2}	6.4x10 ^{4.2}	1.28x10 ^{4.2}	2.56x10 ^{3.2}
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
B (Yamagata lineage)	B/Texas/81/2016	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	5/5	0/5	0/5	not tested
	B/Phuket/3073/2013	1x10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{6.9}	3.2x10 ^{5.9}	6.4x10 ^{4.9}	1.28x10 ^{4.9}	2.56x10 ^{3.9}
			5/5	5/5	5/5	2/5	0/5	0/5	not tested	not tested

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(Type/Subtype)		(EID ₅₀ /mL)								
A(H3N2)	A/Perth/16/2009	1x10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{4.3}	3.2x10 ^{3.3}	6.4x10 ^{2.3}	1.28x10 ^{1.3}	2.56x10 ^{0.3}
			5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5
	A/Kansas/14/2017*	1x10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{4.9}	3.2x10 ^{3.9}	6.4x10 ^{2.9}	1.28x10 ^{1.9}	2.56x10 ^{0.9}
			5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church/16/2010	1x10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{5.9}	3.2x10 ^{4.9}	6.4x10 ^{3.9}	1.28x10 ^{2.9}	2.56x10 ^{1.9}
			5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
	A/Brisbane/02/2018*	1x10 ^{7.9}	2x10 ^{6.9}	4x10 ^{5.9}	8x10 ^{4.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	6.4x10 ^{1.9}	1.28x10 ^{0.9}	2.56x10 ^{-0.1}
			5/5	5/5	5/5	5/5	5/5	2/5	0/5	0/5
B (Victoria lineage)	B/Michigan/09/2011	1x10 ^{8.5}	2x10 ^{7.5}	4x10 ^{6.5}	8x10 ^{5.5}	1.6x10 ^{4.5}	3.2x10 ^{3.5}	6.4x10 ^{2.5}	1.28x10 ^{1.5}	2.56x10 ^{0.5}
			5/5	5/5	5/5	5/5	0/5	0/5	0/5	not tested
	B/Colorado/06/2017*	1x10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{4.3}	3.2x10 ^{3.3}	6.4x10 ^{2.3}	1.28x10 ^{1.3}	2.56x10 ^{0.3}
			5/5	5/5	5/5	5/5	4/5	0/5	0/5	not tested
B (Yamagata lineage)	B/New Hampshire/01/2016	1x10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{4.9}	3.2x10 ^{3.9}	6.4x10 ^{2.9}	1.28x10 ^{1.9}	2.56x10 ^{0.9}
			5/5	5/5	5/5	5/5	0/5	0/5	0/5	not tested
	B/Phuket/3073/2013*	1x10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{4.9}	3.2x10 ^{3.9}	6.4x10 ^{2.9}	1.28x10 ^{1.9}	2.56x10 ^{0.9}
			5/5	5/5	5/5	5/5	0/5	0/5	0/5	not tested

*CDC recommended strains for use in the 2019-2020 influenza season vaccine (northern hemisphere).