



Summary of 2025 Annual Flu Strain Reactivity Testing

Catalogue 1032: OSOM® Ultra Plus 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 OSOM® Ultra Plus 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 OSOM® Ultra Plus 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. www.sekisuidiagnostics.com

Influenza Virus	Virus Strain Name	Stock Concentration	Virus 5-Fold Serial Dilutions (EID₅₀/mL) and Number of Positive Results at Each Dilution								
(Type/Subtype)		(EID ₅₀ /mL)	5х	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}	
		IXIU	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}	2.56x10 ^{2.3}	
		1X108.3	5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested	
Influenza A/ H3N2	A/Croatia/10136RV/2023	1.1077	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}	
		1x10 ^{7.7}	5/5	5/5	5/5	5/5	0/5	0/5	1.28×10 ^{4.25} 2.56×10 0/5 not test 1.28×10 ^{3.3} 2.56×10 not tested not test 1.28 × 10 ^{2.7} 2.56 × 1 not tested not test 1.28 × 10 ^{3.75} 2.56 × 1 0/5 not test 1.28 × 10 ^{3.5} 2.56 × 1 not tested not test 1.28 × 10 ^{3.7} 2.56 × 1 not tested not test 1.28 × 10 ^{3.7} 2.56 × 1 not tested not test 1.28 × 10 ^{4.5} 2.56 × 1 not tested not test	not tested	
	A/Wisconsin/160/2024	1108.75	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}	
		1x10 ^{8.75}	5/5	5/5	5/5	5/5	2/5	0/5	0/5	not tested	
	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}	
Influenza B/ Victoria Lineage		1X100.5	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}	
		TXTO	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 10⁴	
			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}
		1X10	5/5	5/5	2/5	0/5	0/5	not tested	78,125x 390,625 1.28x10 ^{3.5} 2.56x10 not tested not tested 1.28x10 ^{3.3} 2.56x10 not tested not tested 1.28 x 10 ^{3.5} 2.56 x 10 0/5 not tested 1.28 x 10 ^{4.5} 2.56 x 10 not tested not tested 1.28 x 10 ^{3.5} 2.56 x 10 not tested not tested 1.28 x 10 ^{3.5} 2.56 x 10 not tested not tested 1.28 x 10 ^{3.7} 2.56 x 10 not tested not tested 1.28 x 10 ^{4.5} 2.56 x 10 not tested not tested 1.28 x 10 ^{4.5} 2.56 x 10 not tested not tested 1.28 x 10 ^{4.5} 2.56 x 10 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
	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}
Influenza B/ Victoria Lineage			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 10⁴
		TXTO ₁₀	5/5	5/5	5/5	5/5	2/5	0/5	0/5	not tested



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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}	
		1X10	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} not tested not tested	2.56x10 ^{2.3}	
		1X10	5/5	5/5	5/5	5/5	0/5	0/5		not tested	
	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}	
Influenza A/ H3N2		1X10	5/5	5/5	5/5	5/5	0/5	0/5	1.28x10 ^{3.5} 2.56x1 not tested not tes 1.28x10 ^{3.3} 2.56x1 not tested not tes 1.28 x 10 ^{3.3} 2.56 x 3 not tested not tes 1.28 x 10 ^{4.5} 2.56 x 3 not tested not tes 1.28 x 10 ^{3.5} 2.56 x 3 not tested not tes 1.28 x 10 ^{3.7} 2.56 x 3 not tested not tes 1.28 x 10 ^{3.7} 2.56 x 3 not tested not tes 1.28 x 10 ^{3.7} 2.56 x 3 not tested not tes 1.28 x 10 ^{2.8} 2.56 x 3 not tested not tes 1.28 x 10 ^{2.8} 2.56 x 3 not tested not tes	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}	
		IXIO	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}	
		1x10**	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}	
		TXTO.	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}	
		IXIO	5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested	
	B/Norway/2134/2019	D/N /0404/0400 1 1205	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}
		1X10	5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested	