

Summary of 2019 Annual Flu Strain Reactivity testing

Catalog 256041: BD Veritor™ System for Rapid Detection of Flu A + B, Laboratory kit

A panel of eight human Influenza viral strains was provided by the Centers for Disease Control in order to evaluate the reactivity of the BD Veritor™ System Flu A+B test, as required by CFR 866.3328. The viral isolates included four Influenza A and four Influenza B strains. Each sample was serially diluted in five-fold dilutions from the stock provided and each dilution was assayed in replicates of five, using the standard test procedure included in the BD product package insert.

All strains were successfully detected. The concentrations highlighted below identify the lowest dilution at which any of the five replicates gave a positive reading.

Results with actual patient samples may vary.

Influenza Virus Type/(Subtype)	Virus Strain Name	Stock EID ₅₀ /mL	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution							
A (H3N2)	A/Perth/16/2009	10 ^{8.3}	2×10 ^{7.3}	4×10 ^{6.3}	8×10 ^{5.3}	1.6×10 ^{5.3}	3.2×10 ^{4.3}	6.4×10^{3.3}	1.28×10 ^{3.3}	2.56×10 ^{2.3}
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
	A/Kansas/14/2017 *	10 ^{8.9}	2×10 ^{7.9}	4×10 ^{6.9}	8×10 ^{5.9}	1.6×10 ^{5.9}	3.2×10 ^{4.9}	6.4×10^{3.9}	1.28×10 ^{3.9}	2.56×10 ^{2.9}
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
A (H1N1)pdm09	A/Christ Church/16/201	10 ^{9.9}	2×10 ^{8.9}	4×10 ^{7.9}	8×10 ^{6.9}	1.6×10 ^{6.9}	3.2×10 ^{5.9}	6.4×10^{4.9}	1.28×10 ^{4.9}	2.56×10 ^{3.9}
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
	A/Brisbane/02/2018 *	10 ^{7.9}	2×10 ^{6.9}	4×10 ^{5.9}	8×10 ^{4.9}	1.6×10 ^{4.9}	3.2×10 ^{3.9}	6.4×10^{2.9}	1.28×10 ^{2.9}	2.56×10 ^{1.9}
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
B (Victoria lineage)	B/Michigan/09/2011	10 ^{8.5}	2×10 ^{7.5}	4×10 ^{6.5}	8×10 ^{5.5}	1.6×10 ^{5.5}	3.2×10^{4.5}	6.4×10 ^{3.5}	1.28×10 ^{3.5}	
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
	B/Colorado/06/2017 *	10 ^{8.3}	2×10 ^{7.3}	4×10 ^{6.3}	8×10 ^{5.3}	1.6×10 ^{5.3}	3.2×10^{4.3}	6.4×10 ^{3.3}	1.28×10 ^{3.3}	
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
B (Yamagata lineage)	B/New Hampshire/01/2016	10 ^{8.9}	2×10 ^{7.9}	4×10 ^{6.9}	8×10 ^{5.9}	1.6×10 ^{5.9}	3.2×10^{4.9}	6.4×10 ^{3.9}	1.28×10 ^{3.9}	
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5
	B/Phuket/3073/2013 *	10 ^{8.9}	2×10 ^{7.9}	4×10 ^{6.9}	8×10 ^{5.9}	1.6×10 ^{5.9}	3.2×10^{4.9}	6.4×10 ^{3.9}	1.28×10 ^{3.9}	
			5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5

* Strains recommended by CDC for inclusion in Northern Hemisphere vaccine for 2019-2020