

BioSign® Flu A + B

2021 Annual Reactivity Testing Results

The following tables summarize the results of annual reactivity testing performed using 2021 CDC influenza viruses panel (Cat: VP2021, Lot No.: 210601, Exp. Date: 2022-06-01) as required by 21 CFR 866.3328(b).

Using Swab Sample method

Influenza virus A

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)								
		10 ^{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}
A(H3N2)	A/Perth/16/2009	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	5/5	4/5	0/5	0/5
A(H3N2)	A/Tasmania/503/2020	10 ^{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}
		n/a	5/5	3/5	0/5	0/5	5/5	3/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church /16/2010	10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x10 ^{6.2}	3.2x10 ^{5.2}	6.4x10 ^{4.2}	n/a	n/a
		n/a	5/5	5/5	5/5	4/5	0/5	0/5	n/a	n/a
A(H1N1)pdm09	A/Victoria/2570/2019	10 ^{8.2}	2x10 ^{7.2}	4x10 ^{6.2}	8x10 ^{5.2}	1.6x10 ^{5.2}	3.2x10 ^{4.2}	6.4x10 ^{3.2}	n/a	n/a
		n/a	5/5	5/5	5/5	3/5	0/5	0/5	n/a	n/a

Influenza virus B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
		10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	6.4x10 ^{1.9}	n/a
B (Victoria lineage)	B/Michigan/09/2011	10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	6.4x10 ^{1.9}	n/a
		n/a	5/5	5/5	5/5	3/5	0/5	0/5	n/a
B (Victoria lineage)	B/Washington/02/2019	10 ^{9.3}	2x10 ^{8.3}	4x10 ^{7.3}	8x10 ^{6.3}	1.6x10 ^{6.3}	3.2x10 ^{5.3}	6.4x10 ^{4.3}	n/a
		n/a	5/5	5/5	5/5	4/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Texas/81/2016	10 ^{8.1}	2x10 ^{7.1}	4x10 ^{6.1}	8x10 ^{5.1}	1.6x10 ^{5.1}	3.2x10 ^{4.1}	6.4x10 ^{3.1}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Phuket/3073/2013	10 ^{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}
		n/a	5/5	5/5	3/5	5/5	1/5	0/5	0/5

Using Aspirate sample method

Influenza virus A

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)									
		10 ^{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}	5.12x10 ^{1.3}
A(H3N2)	A/Perth/16/2009	10 ^{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}	5.12x10 ^{1.3}
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Tasmania/503/2020	10 ^{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}	5.12x10 ^{1.5}
		n/a	5/5	5/5	0/5	0/5	5/5	5/5	3/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church /16/2010	10 ^{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}	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5	n/a
A(H1N1)pdm09	A/Victoria/2570/2019	10 ^{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}	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5	n/a

Influenza virus B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)									
		10 ^{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}	n/a	
B (Victoria lineage)	B/Michigan/09/2011	10 ^{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}	n/a	
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a	
B (Victoria lineage)	B/Washington/02/2019	10 ^{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}	n/a	
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a	
B (Yamagata lineage)	B/Texas/81/2016	10 ^{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}	
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5	
B (Yamagata lineage)	B/Phuket/3073/2013	10 ^{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}	
		n/a	5/5	5/5	5/5	1/5	5/5	4/5	0/5	0/5	

2020 Annual Reactivity Testing Results

The following tables summarize the results of annual reactivity testing performed using 2020 CDC influenza viruses panel (Lot No. 200330, exp. date 01/May/2021) as required by 21 CFR 866.3328(b).

Using Swab Sample method

Influenza virus A

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)						
		10 ^{9.3}	2x10 ^{8.3}	4x10 ^{7.3}	8x10 ^{6.3}	1.6x10 ^{6.3}	3.2x10 ^{5.3}	6.4x10 ^{4.3}
A(H3N2)	A/Perth/16/2009	10 ^{9.3}	2x10 ^{8.3}	4x10 ^{7.3}	8x10 ^{6.3}	1.6x10 ^{6.3}	3.2x10 ^{5.3}	6.4x10 ^{4.3}
		n/a	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Hong Kong/2671/2019	10 ^{7.5}	2x10 ^{6.5}	4x10 ^{5.5}	8x10 ^{4.5}	1.6x10 ^{4.5}	n/a	n/a
		n/a	5/5	3/5	0/5	0/5	n/a	n/a
A(H1N1)pdm09	A/Christ Church /16/2010	10 ^{10.2}	2x10 ^{9.2}	4x10 ^{8.2}	8x10 ^{7.2}	1.6x10 ^{7.2}	3.2x10 ^{6.2}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1)pdm09	A/Guangdong-Maonan/1536/2019	10 ^{9.1}	2x10 ^{8.1}	4x10 ^{7.1}	8x10 ^{6.1}	1.6x 10 ^{6.1}	3.2x10 ^{5.1}	n/a
		n/a	5/5	5/5	1/5	0/5	0/5	n/a

Influenza virus B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)						
		10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	n/a	n/a
B (Victoria lineage)	B/Michigan/09/2011	10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	n/a	n/a
		n/a	5/5	5/5	0/5	0/5	n/a	n/a
B (Victoria lineage)	B/Washington/02/2019	10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x 10 ^{6.2}	3.2x10 ^{5.2}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Texas/81/2016	10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}
		n/a	5/5	5/5	5/5	5/5	0/5	0/5
B (Yamagata lineage)	B/Phuket/3073/2013	10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{6.9}	3.2x10 ^{5.9}	n/a
		n/a	5/5	5/5	3/5	0/5	0/5	n/a

Using Aspirate sample method

Influenza virus A

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
		10 ^{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}
A(H3N2)	A/Perth/16/2009	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Hong Kong/2671/2019	10 ^{7.5}	2x10 ^{6.5}	4x10 ^{5.5}	8x10 ^{4.5}	1.6x10 ^{4.5}	n/a	n/a	n/a
		n/a	5/5	5/5	0/5	0/5	n/a	n/a	n/a
A(H1N1)pdm09	A/Christ Church /16/2010	10 ^{10.2}	2x10 ^{9.2}	4x10 ^{8.2}	8x10 ^{7.2}	1.6x10 ^{7.2}	3.2x10 ^{6.2}	6.4x10 ^{5.2}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1)pdm09	A/Guangdong-Maonan/1536/2019	10 ^{9.1}	2x10 ^{8.1}	4x10 ^{7.1}	8x10 ^{6.1}	1.6x 10 ^{6.1}	3.2x10 ^{5.1}	n/a	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a	n/a

Influenza virus B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
		10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	n/a	n/a
B (Victoria lineage)	B/Michigan/09/2011	10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{3.9}	3.2x10 ^{2.9}	n/a	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a	n/a
B (Victoria lineage)	B/Washington/02/2019	10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x 10 ^{6.2}	3.2x10 ^{5.2}	6.4x10 ^{4.2}	1.28x10 ^{4.2}
		n/a	5/5	5/5	5/5	5/5	4/5	0/5	0/5
B (Yamagata lineage)	B/Texas/81/2016	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5
B (Yamagata lineage)	B/Phuket/3073/2013	10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{6.9}	3.2x10 ^{5.9}	6.4x10 ^{4.9}	n/a
		n/a	5/5	5/5	5/5	1/5	0/5	0/5	n/a

2019 Annual Reactivity Testing Results

The following tables summarize the results of annual reactivity testing performed using 2019 CDC influenza viruses panel (Lot No. 190430, exp. date 01/May/2020) as required by 21 CFR 866.3328(b).

Using Swab Sample method

Influenza virus A

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)						
		10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}
A(H3N2)	A/Perth/16/2009	10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}
		n/a	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Kansas/14/2017	10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{5.9}	3.2x10 ^{4.9}	6.4x10 ^{3.9}
		n/a	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church /16/2010	10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{6.9}	3.2x10 ^{5.9}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1)pdm09	A/Brisbane/02/2018	10 ^{7.9}	2x10 ^{6.9}	4x10 ^{5.9}	8x10 ^{4.9}	1.6x 10 ^{4.9}	3.2x10 ^{3.9}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a

Influenza virus B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)						
		10 ^{8.5}	2x10 ^{7.5}	4x10 ^{6.5}	8x10 ^{5.5}	1.6x10 ^{5.5}	3.2x10 ^{4.5}	n/a
B (Victoria lineage)	B/Michigan/09/2011	10 ^{8.5}	2x10 ^{7.5}	4x10 ^{6.5}	8x10 ^{5.5}	1.6x10 ^{5.5}	3.2x10 ^{4.5}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a
B (Victoria lineage)	B/Colorado/06/2017	10 ^{8.3}	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x 10 ^{5.3}	3.2x10 ^{4.3}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a
B (Yamagata lineage)	B/New Hampshire /01/2016	10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{5.9}	3.2x 10 ^{4.9}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Phuket/3073/2013	10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{5.9}	3.2x10 ^{4.9}	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a

Using Aspirate sample method

Influenza virus A

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
		10 ^{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}
A(H3N2)	A/Perth/16/2009	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Kansas/14/2017	10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	1.28x10 ^{3.9}
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church /16/2010	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	4/5	0/5	0/5
A(H1N1)pdm09	A/Brisbane/02/2018	10 ^{7.9}	2x10 ^{6.9}	4x10 ^{5.9}	8x10 ^{4.9}	1.6x 10 ^{4.9}	3.2x10 ^{3.9}	6.4x10 ^{2.9}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a

Influenza virus B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
		10 ^{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}
B (Victoria lineage)	B/Michigan/09/2011	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	1/5	0/5	0/5
B (Victoria lineage)	B/Colorado/06/2017	10 ^{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}
		n/a	5/5	5/5	5/5	5/5	4/5	0/5	0/5
B (Yamagata lineage)	B/New Hampshire /01/2016	10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{5.9}	3.2x10 ^{4.9}	6.4x10 ^{3.9}	1.28x10 ^{3.9}
		n/a	5/5	5/5	5/5	5/5	3/5	0/5	0/5
B (Yamagata lineage)	B/Phuket/3073/2013	10 ^{8.9}	2x10 ^{7.9}	4x10 ^{6.9}	8x10 ^{5.9}	1.6x10 ^{5.9}	3.2x10 ^{4.9}	6.4x10 ^{3.9}	1.28x10 ^{3.9}
		n/a	5/5	5/5	5/5	5/5	2/5	0/5	0/5