

BioSign® Flu A + B

2018 Annual Reactivity Testing Results

The following tables summarize the results of annual reactivity testing performed using 2018 CDC influenza viruses panel (Lot No. 180430, exp. date 01/May/2019) 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 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	1.28x10 ^{3.9}
A(H3N2)	A/Perth/16/2009	10 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{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(H3N2)	A/Singapore/INFIMH-16-0019/2016	10 ^{8.2}	2x 10 ^{7.2}	4x 10 ^{6.2}	8x 10 ^{5.2}	1.6x 10 ^{5.2}	3.2x 10 ^{4.2}	6.4x 10 ^{3.2}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1)pdm09	A/California/07/2009	10 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1)pdm09	A/Michigan/45/2015	10 ^{8.2}	2x 10 ^{7.2}	4x 10 ^{6.2}	8x 10 ^{5.2}	1.6x 10 ^{5.2}	3.2x 10 ^{4.2}	6.4x 10 ^{3.2}	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}	2x 10 ^{7.5}	4x 10 ^{6.5}	8x 10 ^{5.5}	1.6x 10 ^{5.5}	3.2x 10 ^{4.5}	6.4x 10 ^{3.5}	n/a
(Victoria lineage)	B/Brisbane/60/2008	10 ^{8.5}	2x 10 ^{7.5}	4x 10 ^{6.5}	8x 10 ^{5.5}	1.6x 10 ^{5.5}	3.2x 10 ^{4.5}	6.4x 10 ^{3.5}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
(Victoria lineage)	B/Colorado/06/2017	10 ^{9.4}	2x 10 ^{8.4}	4x 10 ^{7.4}	8x 10 ^{6.4}	1.6x 10 ^{6.4}	3.2x 10 ^{5.4}	6.4x 10 ^{4.4}	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
(Yamagata lineage)	B/Wisconsin/1/2010	10 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{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
(Yamagata lineage)	B/Phuket/3073/2013	10 ^{8.5}	2x 10 ^{7.5}	4x 10 ^{6.5}	8x 10 ^{5.5}	1.6x 10 ^{5.5}	3.2x 10 ^{4.5}	6.4x 10 ^{3.5}	1.28x10 ^{3.5}
		n/a	5/5	5/5	5/5	5/5	5/5	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 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	1.28x10 ^{3.9}	2.56x10 ^{2.9}
A(H3N2)	A/Perth/16/2009	10 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	1.28x10 ^{3.9}	2.56x10 ^{2.9}
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Singapore/INFIMH-16-0019/2016	10 ^{8.2}	2x 10 ^{7.2}	4x 10 ^{6.2}	8x 10 ^{5.2}	1.6x 10 ^{5.2}	3.2x 10 ^{4.2}	6.4x 10 ^{3.2}	1.28x10 ^{3.2}	n/a
		n/a	5/5	5/5	5/5	5/5	2/5	0/5	0/5	n/a
A(H1N1)pdm09	A/California/07/2009	10 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	1.28x10 ^{3.9}	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1)pdm09	A/Michigan/45/2015	10 ^{8.2}	2x 10 ^{7.2}	4x 10 ^{6.2}	8x 10 ^{5.2}	1.6x 10 ^{5.2}	3.2x 10 ^{4.2}	6.4x 10 ^{3.2}	1.28x10 ^{3.2}	n/a
		n/a	5/5	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}	2x 10 ^{7.5}	4x 10 ^{6.5}	8x 10 ^{5.5}	1.6x 10 ^{5.5}	3.2x 10 ^{4.5}	6.4x 10 ^{3.5}	1.28x10 ^{3.5}	2.56x10 ^{2.5}
(Victoria lineage)	B/Brisbane/60/2008	10 ^{8.5}	2x 10 ^{7.5}	4x 10 ^{6.5}	8x 10 ^{5.5}	1.6x 10 ^{5.5}	3.2x 10 ^{4.5}	6.4x 10 ^{3.5}	1.28x10 ^{3.5}	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a
(Victoria lineage)	B/Colorado/06/2017	10 ^{9.4}	2x 10 ^{8.4}	4x 10 ^{7.4}	8x 10 ^{6.4}	1.6x 10 ^{6.4}	3.2x 10 ^{5.4}	6.4x 10 ^{4.4}	1.28x10 ^{4.4}	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a
(Yamagata lineage)	B/Wisconsin/1/2010	10 ^{8.9}	2x 10 ^{7.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{5.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	1.28x10 ^{3.9}	2.56x10 ^{2.9}
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
(Yamagata lineage)	B/Phuket/3073/2013	10 ^{8.5}	2x 10 ^{7.5}	4x 10 ^{6.5}	8x 10 ^{5.5}	1.6x 10 ^{5.5}	3.2x 10 ^{4.5}	6.4x 10 ^{3.5}	1.28x10 ^{3.5}	2.56x10 ^{2.5}
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5

2017 Annual Reactivity Testing Results

The following tables summarize the results of annual reactivity testing performed using 2017 CDC influenza viruses panel (Lot No. 170428, exp. date 01/May/2018) 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}	4x 10 ^{7.3}	8x 10 ^{6.3}	1.6x 10 ^{5.3}	3.2x 10 ^{5.3}	6.4x 10 ^{4.3}	1.28x10 ^{4.3}	2.56x10 ^{3.3}	n/a
A(H1N1)	A/Brisbane/59/2007	10 ^{9.3}	4x 10 ^{7.3}	8x 10 ^{6.3}	1.6x 10 ^{5.3}	3.2x 10 ^{5.3}	6.4x 10 ^{4.3}	1.28x10 ^{4.3}	2.56x10 ^{3.3}	n/a
		n/a	5/5	5/5	5/5	5/5	4/5	0/5	0/5	n/a
A(H1N1)	A/Fujian Gulou/1896/2009	10 ^{9.2}	4x 10 ^{7.2}	8x 10 ^{6.2}	1.6x 10 ^{5.2}	3.2x 10 ^{5.2}	6.4x 10 ^{4.2}	1.28x10 ^{4.2}	2.56x10 ^{3.2}	5.12x10 ^{2.2}
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Perth/16/2009	10 ^{8.9}	4x 10 ^{6.9}	8x 10 ^{5.9}	1.6x 10 ^{4.9}	3.2x 10 ^{4.9}	n/a	n/a	n/a	n/a
		n/a	5/5	5/5	0/5	0/5	n/a	n/a	n/a	n/a
A(H3N2)	A/Hong Kong/4801/2014	10 ^{7.9}	4x 10 ^{5.9}	8x 10 ^{4.9}	1.6x 10 ^{3.9}	3.2x 10 ^{3.9}	6.4x 10 ^{2.9}	1.28x10 ^{2.9}	2.56x10 ^{1.9}	5.12x10 ^{0.9}
		n/a	5/5	5/5	5/5	5/5	5/5	4/5	0/5	0/5
A(H1N1)pdm09	A/California/07/2009	10 ^{9.5}	4x 10 ^{7.5}	8x 10 ^{6.5}	1.6x 10 ^{5.5}	3.2x 10 ^{5.5}	6.4x 10 ^{4.5}	n/a	n/a	n/a
		n/a	5/5	5/5	2/5	0/5	0/5	n/a	n/a	n/a
A(H1N1)pdm09	A/Michigan/45/2015	10 ^{8.3}	4x 10 ^{6.3}	8x 10 ^{5.3}	1.6x 10 ^{4.3}	3.2x 10 ^{4.3}	n/a	n/a	n/a	n/a
		n/a	5/5	3/5	0/5	0/5	n/a	n/a	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 ^{9.9}	2x 10 ^{8.9}	4x 10 ^{7.9}	8x 10 ^{6.9}	1.6x 10 ^{5.9}	3.2x 10 ^{5.9}	6.4x 10 ^{4.9}	1.28x 10 ^{3.9}	n/a
(Victoria lineage)	B/Brisbane/60/2008	10 ^{9.9}	2x 10 ^{8.9}	4x 10 ^{7.9}	8x 10 ^{6.9}	1.6x 10 ^{5.9}	3.2x 10 ^{5.9}	6.4x 10 ^{4.9}	1.28x 10 ^{3.9}	n/a
		n/a	5/5	5/5	5/5	5/5	2/5	0/5	0/5	n/a
(Victoria lineage)	B/Texas/02/2013	10 ^{9.1}	2x 10 ^{8.1}	4x 10 ^{7.1}	8x 10 ^{6.1}	1.6x 10 ^{5.1}	3.2x 10 ^{5.1}	6.4x 10 ^{4.1}	1.28x 10 ^{3.1}	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a
(Yamagata lineage)	B/Wisconsin/1/2010	10 ^{6.9}	2x 10 ^{5.9}	4x 10 ^{4.9}	8x 10 ^{3.9}	1.6x 10 ^{2.9}	3.2x 10 ^{2.9}	6.4x 10 ^{1.9}	n/a	n/a
		n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a	n/a
(Yamagata lineage)	B/Phuket/3073/2013	10 ^{9.9}	2x 10 ^{8.9}	4x 10 ^{7.9}	8x 10 ^{6.9}	1.6x 10 ^{5.9}	3.2x 10 ^{5.9}	n/a	n/a	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a	n/a	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}	8x 10 ^{6.3}	1.6x 10 ^{5.3}	3.2x 10 ^{5.3}	6.4x 10 ^{4.3}	1.28x10 ^{4.3}	2.56x10 ^{3.3}	5.12x10 ^{2.3}	n/a	n/a
A(H1N1)	A/Brisbane/59/2007	10 ^{9.3}	8x 10 ^{6.3}	1.6x 10 ^{5.3}	3.2x 10 ^{5.3}	6.4x 10 ^{4.3}	1.28x10 ^{4.3}	2.56x10 ^{3.3}	5.12x10 ^{2.3}	n/a	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a	n/a
A(H1N1)	A/Fujian Gulou/1896/2009	10 ^{9.2}	8x 10 ^{6.2}	1.6x 10 ^{5.2}	3.2x 10 ^{5.2}	6.4x 10 ^{4.2}	1.28x10 ^{4.2}	2.56x10 ^{3.2}	5.12x10 ^{2.2}	1.02x10 ^{2.2}	2.05x10 ^{1.2}
		n/a	5/5	5/5	5/5	5/5	5/5	4/5	0/5	0/5	0/5
A(H3N2)	A/Perth/16/2009	10 ^{8.9}	8x 10 ^{5.9}	1.6x 10 ^{4.9}	3.2x 10 ^{4.9}	6.4x 10 ^{3.9}	n/a	n/a	n/a	n/a	n/a
		n/a	5/5	5/5	0/5	0/5	n/a	n/a	n/a	n/a	n/a
A(H3N2)	A/Hong Kong/4801/2014	10 ^{7.9}	8x 10 ^{4.9}	1.6x 10 ^{3.9}	3.2x 10 ^{3.9}	6.4x 10 ^{2.9}	1.28x10 ^{2.9}	2.56x10 ^{1.9}	5.12x10 ^{0.9}	1.02x10 ^{0.9}	2.05x10 ^{-0.1}
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5	0/5
A(H1N1)pdm09	A/California/07/2009	10 ^{9.5}	8x 10 ^{6.5}	1.6x 10 ^{5.5}	3.2x 10 ^{5.5}	6.4x 10 ^{4.5}	1.28x10 ^{4.5}	n/a	n/a	n/a	n/a
		n/a	5/5	5/5	5/5	0/5	0/5	n/a	n/a	n/a	n/a
A(H1N1)pdm09	A/Michigan/45/2015	10 ^{8.3}	8x 10 ^{5.3}	1.6x 10 ^{4.3}	3.2x 10 ^{4.3}	6.4x 10 ^{3.3}	n/a	n/a	n/a	n/a	n/a
		n/a	5/5	4/5	0/5	0/5	n/a	n/a	n/a	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 ^{9.9}	4x 10 ^{7.9}	8x 10 ^{6.9}	1.6x 10 ^{5.9}	3.2x 10 ^{5.9}	6.4x 10 ^{4.9}	1.28x 10 ^{4.9}	2.56x10 ^{3.9}	n/a	n/a
(Victoria lineage)	B/Brisbane/60/2008	10 ^{9.9}	4x 10 ^{7.9}	8x 10 ^{6.9}	1.6x 10 ^{5.9}	3.2x 10 ^{5.9}	6.4x 10 ^{4.9}	1.28x 10 ^{4.9}	2.56x10 ^{3.9}	n/a	n/a
		n/a	5/5	5/5	5/5	5/5	4/5	0/5	0/5	n/a	n/a
(Victoria lineage)	B/Texas/02/2013	10 ^{9.1}	4x 10 ^{7.1}	8x 10 ^{6.1}	1.6x 10 ^{5.1}	3.2x 10 ^{5.1}	6.4x 10 ^{4.1}	1.28x 10 ^{4.1}	2.56x10 ^{3.1}	5.12x10 ^{2.1}	1.02x10 ^{2.1}
		n/a	5/5	5/5	5/5	5/5	5/5	3/5	2/5	0/5	0/5
(Yamagata lineage)	B/Wisconsin/1/2010	10 ^{6.9}	4x 10 ^{4.9}	8x 10 ^{3.9}	1.6x 10 ^{2.9}	3.2x 10 ^{2.9}	6.4x 10 ^{1.9}	1.28x10 ^{0.9}	2.56x10 ^{0.9}	n/a	n/a
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5	n/a	n/a
(Yamagata lineage)	B/Phuket/3073/2013	10 ^{9.9}	4x 10 ^{7.9}	8x 10 ^{6.9}	1.6x 10 ^{5.9}	3.2x 10 ^{5.9}	6.4x 10 ^{4.9}	1.28x 10 ^{4.9}	n/a	n/a	n/a
		n/a	5/5	5/5	5/5	2/5	0/5	0/5	n/a	n/a	n/a