



Sofia[®]2

Technical Bulletin

Annual Reactivity Testing 2020 CDC Human Influenza Virus Panel Sofia Influenza A+B FIA with Sofia 2 – Swab Protocol

As required per 21 CFR 866.3328(b) for all rapid influenza diagnostic tests, Quidel Corporation performed annual reactivity testing with the contemporary influenza strains identified by FDA in consultation with the Centers for Disease Control and Prevention (CDC). Sofia Influenza A+B FIA with Sofia 2 detected all of the influenza viruses in the CDC panel:

Influenza Virus (Type/Subtype)	Virus Strain Name
A(H3N2)	A/Perth/16/2009
A(H3N2)	A/Hong Kong/2671/2019*
A(H1N1)pdm09	A/Christ Church/16/2010
A(H1N1)pdm09	A/Guangdong-Maonan/1536/2019*
B (Victoria Lineage)	B/Michigan/09/2011
B (Victoria Lineage)	B/Washington/02/2019*
B (Yamagata Lineage)	B/Texas/81/2016
B (Yamagata Lineage)	B/Phuket/3073/2013*
* WHO recommended vaccine strains for use in the 2020 – 2021 (northern hemisphere winter)	

All strains were obtained from the CDC and tested per the **swab** protocol recommended by the CDC. Test results generated for each influenza strain are listed below:

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution (N=5)						
A(H3N2)	A/Perth/16/2009	10 ^{9.3} EID ₅₀ /mL	2 x 10 ^{8.3}	4 x 10 ^{7.3}	8 x 10 ^{6.3}	1.6 x 10 ^{5.3}	3.2 x 10 ^{4.3}	6.4 x 10 ^{3.3}	1.28 x 10 ^{2.3}
		# detected	5/5	5/5	5/5	5/5	5/5	5-Jan	0/5
A(H3N2)	A/Hong Kong/2671/2019	10 ^{7.5} EID ₅₀ /mL	2 x 10 ^{6.5}	4 x 10 ^{5.5}	8 x 10 ^{4.5}	1.6 x 10 ^{3.5}	3.2 x 10 ^{2.5}	6.4 x 10 ^{1.5}	1.28 x 10 ^{0.5}
		# detected	5/5	5/5	2/5	0/5	0/5	NA	NA
A(H1N1)pdm09	A/Christ Church/16/2010	10 ^{10.2} EID ₅₀ /mL	2 x 10 ^{9.2}	4 x 10 ^{8.2}	8 x 10 ^{7.2}	1.6 x 10 ^{6.2}	3.2 x 10 ^{5.2}	6.4 x 10 ^{4.2}	1.28 x 10 ^{3.2}
		# detected	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/GuangDong-Maonan/1536/2019	10 ^{9.1} EID ₅₀ /mL	2 x 10 ^{8.1}	4 x 10 ^{7.1}	8 x 10 ^{6.1}	1.6 x 10 ^{5.1}	3.2 x 10 ^{4.1}	6.4 x 10 ^{3.1}	1.28 x 10 ^{2.1}
		# detected	5/5	5/5	5/5	5/5	0/5	0/5	NA
B (Victoria Lineage)	B/Michigan/09/2011	10 ^{6.9} EID ₅₀ /mL	2 x 10 ^{5.9}	4 x 10 ^{4.9}	8 x 10 ^{3.9}	1.6 x 10 ^{2.9}	3.2 x 10 ^{1.9}	6.4 x 10 ^{0.9}	1.28 x 10 ^{-0.1}
		# detected	5/5	5/5	5/5	5/5	0/5	0/5	NA
B (Yamagata Lineage)	B/Texas/81/2016	10 ^{8.3} EID ₅₀ /mL	2 x 10 ^{7.3}	4 x 10 ^{6.3}	8 x 10 ^{5.3}	1.6 x 10 ^{4.3}	3.2 x 10 ^{3.3}	6.4 x 10 ^{2.3}	1.28 x 10 ^{1.3}
		# detected	5/5	5/5	5/5	5/5	5/5	5/5	0/5
B (Victoria Lineage)	B/Washington/02/2019	10 ^{9.2} EID ₅₀ /mL	2 x 10 ^{8.2}	4 x 10 ^{7.2}	8 x 10 ^{6.2}	1.6 x 10 ^{5.2}	3.2 x 10 ^{4.2}	6.4 x 10 ^{3.2}	1.28 x 10 ^{2.2}
		# detected	5/5	5/5	5/5	5/5	5/5	0/5	0/5
B (Yamagata Lineage)	B/Phuket/3073/2013	10 ^{9.9} EID ₅₀ /mL	2 x 10 ^{8.9}	4 x 10 ^{7.9}	8 x 10 ^{6.9}	1.6 x 10 ^{5.9}	3.2 x 10 ^{4.9}	6.4 x 10 ^{3.9}	1.28 x 10 ^{2.9}
		# detected	5/5	5/5	5/5	5/5	0/5	0/5	NA

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Country	Phone	E Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
Austria	+43 316 231239	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
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Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858.552.1100	technicalsupport@quidel.com
Canada	437.266.1704 (main) 888.415.8764 (toll free)	technicalsupport@quidel.com
China	0400 920 9366 or +86 021 3217 8300	chinatechnicalservice@quidel.com

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