



# Sofia<sup>2</sup>

## Technical Bulletin

### Annual Reactivity Testing 2021 CDC Human Influenza Virus Panel Sofia Influenza A+B FIA with Sofia 2 – Aspirate 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/Tasmania/503/2020*
A(H1N1)pdm09	A/Christ Church/16/2010
A(H1N1)pdm09	A/Victoria/2570/2019*
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 2021 – 2022 (northern hemisphere winter)	

All strains were obtained from the CDC and tested per the **aspirate** 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 <sub>50</sub> /mL) and Number of Positive Results at Each Dilution (N=5)						
A(H3N2)	A/Perth/16/2009	10 <sup>8.3</sup> EID <sub>50</sub> /mL	2 x 10 <sup>7.3</sup>	4 x 10 <sup>6.3</sup>	8 x 10 <sup>5.3</sup>	1.6 x 10 <sup>5.3</sup>	3.2 x 10 <sup>4.3</sup>	6.4 x 10 <sup>3.3</sup>	1.28 x 10 <sup>3.3</sup>
		# detected	5/5	5/5	5/5	5/5	5/5	5/5	0/5
A(H3N2)	A/Tasmania/503/2020	10 <sup>8.5</sup> EID <sub>50</sub> /mL	2 x 10 <sup>7.5</sup>	4 x 10 <sup>6.5</sup>	8 x 10 <sup>5.5</sup>	1.6 x 10 <sup>5.5</sup>	3.2 x 10 <sup>4.5</sup>	6.4 x 10 <sup>3.5</sup>	1.28 x 10 <sup>3.5</sup>
		# detected	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church/16/2010	10 <sup>8.2</sup> EID <sub>50</sub> /mL	2 x 10 <sup>8.2</sup>	4 x 10 <sup>7.2</sup>	8 x 10 <sup>6.2</sup>	1.6 x 10 <sup>6.2</sup>	3.2 x 10 <sup>5.2</sup>	6.4 x 10 <sup>4.2</sup>	1.28 x 10 <sup>4.2</sup>
		# detected	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/Victoria/2570/2019	10 <sup>8.2</sup> EID <sub>50</sub> /mL	2 x 10 <sup>7.2</sup>	4 x 10 <sup>6.2</sup>	8 x 10 <sup>5.2</sup>	1.6 x 10 <sup>5.2</sup>	3.2 x 10 <sup>4.2</sup>	6.4 x 10 <sup>3.2</sup>	1.28 x 10 <sup>3.2</sup>
		# detected	5/5	5/5	5/5	5/5	5/5	0/5	0/5
B (Victoria Lineage)	B/Michigan/09/2011	10 <sup>8.9</sup> EID <sub>50</sub> /mL	2 x 10 <sup>5.9</sup>	4 x 10 <sup>4.9</sup>	8 x 10 <sup>3.9</sup>	1.6 x 10 <sup>3.9</sup>	3.2 x 10 <sup>2.9</sup>	6.4 x 10 <sup>1.9</sup>	1.28 x 10 <sup>0.9</sup>
		# detected	5/5	5/5	5/5	5/5	0/5	0/5	NA
B (Yamagata Lineage)	B/Washington/02/2019	10 <sup>8.3</sup> EID <sub>50</sub> /mL	2 x 10 <sup>8.3</sup>	4 x 10 <sup>7.3</sup>	8 x 10 <sup>6.3</sup>	1.6 x 10 <sup>6.3</sup>	3.2 x 10 <sup>5.3</sup>	6.4 x 10 <sup>4.3</sup>	1.28 x 10 <sup>4.3</sup>
		# detected	5/5	5/5	5/5	5/5	0/5	0/5	NA
B (Victoria Lineage)	B/Texas/81/2016	10 <sup>8.1</sup> EID <sub>50</sub> /mL	2 x 10 <sup>7.1</sup>	4 x 10 <sup>6.1</sup>	8 x 10 <sup>5.1</sup>	1.6 x 10 <sup>5.1</sup>	3.2 x 10 <sup>4.1</sup>	6.4 x 10 <sup>3.1</sup>	1.28 x 10 <sup>3.1</sup>
		# detected	5/5	5/5	5/5	5/5	0/5	0/5	NA
B (Yamagata Lineage)	B/Phuket/3073/2013	10 <sup>9.9</sup> EID <sub>50</sub> /mL	2 x 10 <sup>8.9</sup>	4 x 10 <sup>7.9</sup>	8 x 10 <sup>6.9</sup>	1.6 x 10 <sup>6.9</sup>	3.2 x 10 <sup>5.9</sup>	6.4 x 10 <sup>4.9</sup>	1.28 x 10 <sup>4.9</sup>
		# detected	5/5	5/5	5/5	5/5	5/5	0/5	0/5

If you have any questions regarding the use of this product or to report a problem, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com). If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference [quidel.com](http://quidel.com) to see more options for Support.

Country	Phone	E-Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	<a href="mailto:emeatechnicalsupport@quidel.com">emeatechnicalsupport@quidel.com</a>
Austria	+43 316 231239	
Belgium	+32 (2) 793 0180	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Ireland	+353 (91) 412 474	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858.552.1100	
Canada	437.266.1704 (main) 888.415.8764 (toll free)	<a href="mailto:technicalsupport@quidel.com">technicalsupport@quidel.com</a>
China	0400 920 9366 or +86 021 3217 8300	<a href="mailto:chinatechnicalservice@quidel.com">chinatechnicalservice@quidel.com</a>

You may also visit our website at [quidel.com](http://quidel.com) for information on Quidel's line of Rapid Diagnostics, Molecular Diagnostics, Cell Culture and Specialty Products (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, SDS, and Package Inserts.

TB202181200EN00 (10/21)