

## Summary of 2020 Annual Flu Strain Reactivity testing

### Catalog 256045: BD Veritor™ System for Rapid Detection of Flu A + B, CLIA-Waived kit

A panel of eight human influenza viral strains was provided by the Centers for Disease Control for evaluating the reactivity of the BD Veritor™ System Flu A+B CLIA-waived 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. To create samples for testing, mock patient samples were prepared by pipetting 50 µL of each diluted sample onto a swab. Each swab was tested following the 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<sup>2</sup>:

Influenza Virus Type/(Subtype)	Virus Strain Name	Stock EID <sub>50</sub> /mL	Virus Serial Dilution Concentration (EID <sub>50</sub> /mL) and Number of Positive Results at Each Dilution							
			2x10 <sup>8.3</sup>	4x10 <sup>7.3</sup>	8x10 <sup>6.3</sup>	<b>1.6x10<sup>6.3</sup></b>	3.2x10 <sup>5.3</sup>	6.4x10 <sup>4.3</sup>	1.28x10 <sup>4.3</sup>	2.56x10 <sup>3.3</sup>
A (H3N2)	A/Perth/16/2009	10 <sup>9.3</sup>	2x10 <sup>8.3</sup>	4x10 <sup>7.3</sup>	8x10 <sup>6.3</sup>	<b>1.6x10<sup>6.3</sup></b>	3.2x10 <sup>5.3</sup>	6.4x10 <sup>4.3</sup>	1.28x10 <sup>4.3</sup>	2.56x10 <sup>3.3</sup>
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5		
	A/Hong Kong/2671/2019*	10 <sup>7.5</sup>	2x10 <sup>6.5</sup>	<b>4x10<sup>5.5</sup></b>	8x10 <sup>4.5</sup>	1.6x10 <sup>4.5</sup>	3.2x10 <sup>3.5</sup>	6.4x10 <sup>2.5</sup>	1.28x10 <sup>2.5</sup>	
			5/5	<b>4/5</b>	0/5	0/5	0/5			
A (H1N1)pdm09	A/Christ Church/16/2010	10 <sup>10.2</sup>	2x10 <sup>9.2</sup>	4x10 <sup>8.2</sup>	8x10 <sup>7.2</sup>	<b>1.6x10<sup>7.2</sup></b>	3.2x10 <sup>6.2</sup>	6.4x10 <sup>5.2</sup>	1.28x10 <sup>5.2</sup>	2.56x10 <sup>4.2</sup>
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5		
	A/Guangdon-Maonan/1536/2019*	10 <sup>9.1</sup>	2x10 <sup>8.1</sup>	4x10 <sup>7.1</sup>	<b>8x10<sup>6.1</sup></b>	1.6x10 <sup>6.1</sup>	3.2x10 <sup>5.1</sup>	6.4x10 <sup>4.1</sup>	1.28x10 <sup>4.1</sup>	2.56x10 <sup>3.1</sup>
			5/5	5/5	<b>3/5</b>	0/5	0/5			
B (Victoria lineage)	B/Michigan/09/2011	10 <sup>6.9</sup>	2x10 <sup>5.9</sup>	4x10 <sup>4.9</sup>	<b>8x10<sup>3.9</sup></b>	1.6x10 <sup>3.9</sup>	3.2x10 <sup>2.9</sup>	6.4x10 <sup>1.9</sup>	1.28x10 <sup>1.9</sup>	
			5/5	5/5	<b>1/5</b>	0/5	0/5	0/5	0/5	
	B/Washington/02/2019*	10 <sup>9.2</sup>	2x10 <sup>8.2</sup>	4x10 <sup>7.2</sup>	8x10 <sup>6.2</sup>	<b>1.6x10<sup>6.2</sup></b>	3.2x10 <sup>5.2</sup>	6.4x10 <sup>4.2</sup>	1.28x10 <sup>4.2</sup>	
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5		
B (Yamagata lineage)	B/Texas/81/2016	10 <sup>8.3</sup>	2x10 <sup>7.3</sup>	4x10 <sup>6.3</sup>	8x10 <sup>5.3</sup>	<b>1.6x10<sup>5.3</sup></b>	3.2x10 <sup>4.3</sup>	6.4x10 <sup>3.3</sup>	1.28x10 <sup>3.3</sup>	2.56x10 <sup>2.3</sup>
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5		
	B/Phuket/3073/2013*	10 <sup>9.9</sup>	2x10 <sup>8.9</sup>	4x10 <sup>7.9</sup>	<b>8x10<sup>6.9</sup></b>	1.6x10 <sup>6.9</sup>	3.2x10 <sup>5.9</sup>	6.4x10 <sup>4.9</sup>	1.28x10 <sup>4.9</sup>	
			5/5	5/5	<b>5/5</b>	0/5	0/5	0/5		

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

<sup>2</sup>all samples consisted of 50 µL of diluted viral sample on a swab identical to those contained in the BD Veritor™ CLIA Waived Flu kit. Results with actual patient samples may vary.