

## Summary of 2023 Annual Flu Strain Reactivity Testing

### Catalogue 23-200-279: Sure-Vue Signature Test Influenza A&B, CLIA Waived Kit

A panel of eight human influenza viral strains was provided by the FDA Center for Biologics Evaluation and Research (CBER) for evaluating the reactivity of the Sure-Vue Signature Test Influenza A&B. The viral isolates included four influenza A and four influenza B strains. Each sample was serially diluted in 5-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 stated in Sure-Vue Signature Test Influenza A&B instructions for use. All strains were successfully detected. The minimally reactive concentration was identified as the lowest dilution at which any of the five replicates gave a positive reading.

Influenza Virus	Virus Strain Name	Stock Concentration	Virus 5-Fold Serial Dilutions (EID <sub>50</sub> /mL) and Number of Positive Results at Each Dilution							
(Type/Subtype)		(EID <sub>50</sub> /mL)	5x	25x	125x	625x	3,125x	15,625x	78,125x	390,625x
Influenza A/ H1N1pdm09	A/Victoria/4897/2022	1x10 <sup>8.5</sup>	2x10 <sup>7.5</sup>	4x10 <sup>6.5</sup>	8x10 <sup>5.5</sup>	1.6x10 <sup>5.5</sup>	3.2x10 <sup>4.5</sup>	6.4x10 <sup>3.5</sup>	1.28x10 <sup>3.5</sup>	2.56x10 <sup>2.5</sup>
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
	A/Victoria/2570/2019	1x10 <sup>8.3</sup>	2x10 <sup>7.3</sup>	4x10 <sup>6.3</sup>	8x10 <sup>5.3</sup>	1.6x10 <sup>5.3</sup>	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	5/5	0/5	0/5	not tested	not tested
Influenza A/ H3N2	A/Darwin/9/2021	1x10 <sup>8.3</sup>	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>	2.56 x 10 <sup>2.3</sup>
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
	A/Georgia/02/2022	1x10 <sup>9.5</sup>	2 x 10 <sup>8.5</sup>	4 x 10 <sup>7.5</sup>	8 x 10 <sup>6.5</sup>	1.6 x 10 <sup>6.5</sup>	3.2 x 10 <sup>5.5</sup>	6.4 x 10 <sup>4.5</sup>	1.28 x 10 <sup>4.5</sup>	2.56 x 10 <sup>3.5</sup>
			5/5	5/5	5/5	0/5	0/5	0/5	not tested	not tested
Influenza B/ Victoria Lineage	B/Austria/1359417/2021	1x10 <sup>8.5</sup>	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>	2.56 x 10 <sup>2.5</sup>
			5/5	5/5	2/5	0/5	0/5	not tested	not tested	not tested
	B/Netherlands/10894/2022	1x10 <sup>8.7</sup>	2 x 10 <sup>7.7</sup>	4 x 10 <sup>6.7</sup>	8 x 10 <sup>5.7</sup>	1.6 x 10 <sup>5.7</sup>	3.2 x 10 <sup>4.7</sup>	6.4 x 10 <sup>3.7</sup>	1.28 x 10 <sup>3.7</sup>	2.56 x 10 <sup>2.7</sup>
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
Influenza B/ Yamagata Lineage	B/Phuket/3073/2013	1x10 <sup>7.8</sup>	2 x 10 <sup>6.8</sup>	4 x 10 <sup>5.8</sup>	8 x 10 <sup>4.8</sup>	1.6 x 10 <sup>4.8</sup>	3.2 x 10 <sup>3.8</sup>	6.4 x 10 <sup>2.8</sup>	1.28 x 10 <sup>2.8</sup>	2.56 x 10 <sup>1.8</sup>
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
	B/Norway/2134/2019	1x10 <sup>9.5</sup>	2 x 10 <sup>8.5</sup>	4 x 10 <sup>7.5</sup>	8 x 10 <sup>6.5</sup>	1.6 x 10 <sup>6.5</sup>	3.2 x 10 <sup>5.5</sup>	6.4 x 10 <sup>4.5</sup>	1.28 x 10 <sup>4.5</sup>	2.56 x 10 <sup>3.5</sup>
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested

## Summary of 2021 Annual Flu Strain Reactivity Testing

### Catalogue 23-200-279: Sure-Vue Signature Test Influenza 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 Sure-Vue Signature Test Influenza A&B. The viral isolates included four influenza A and four influenza B strains. Each sample was serially diluted in 5-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 stated in the Sure-Vue Signature Test Influenza A&B instructions for use. All strains were successfully detected. The minimally reactive concentration was identified as the lowest dilution at which any of the five replicates gave a positive reading.

Influenza Virus	Virus Strain Name	Stock Concentration	Virus 5-Fold Serial Dilutions (EID <sub>50</sub> /mL) and Number of Positive Results at Each Dilution							
(Type/Subtype)		(EID <sub>50</sub> /mL)								
A(H3N2)	A/Perth/16/2009	1x10 <sup>8.3</sup>	2x10 <sup>7.3</sup>	4x10 <sup>6.3</sup>	8x10 <sup>5.3</sup>	1.6x10 <sup>5.3</sup>	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	5/5	5/5	5/5	5/5	0/5
	A/Tasmania/503/2020	1x10 <sup>8.5</sup>	2x10 <sup>7.5</sup>	4x10 <sup>6.5</sup>	8x10 <sup>5.5</sup>	1.6x10 <sup>5.5</sup>	3.2x10 <sup>4.5</sup>	6.4x10 <sup>3.5</sup>	1.28x10 <sup>3.5</sup>	2.56x10 <sup>2.5</sup>
			5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/Christ Church/16/2020	1x10 <sup>9.2</sup>	2x10 <sup>8.2</sup>	4x10 <sup>7.2</sup>	8x10 <sup>6.2</sup>	1.6x10 <sup>6.2</sup>	3.2x10 <sup>5.2</sup>	6.4x10 <sup>4.2</sup>	1.28x10 <sup>4.2</sup>	2.56x10 <sup>3.2</sup>
			5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
	A/Victoria/2570/2019	1x10 <sup>8.2</sup>	2x10 <sup>7.2</sup>	4x10 <sup>6.2</sup>	8x10 <sup>5.2</sup>	1.6x10 <sup>5.2</sup>	3.2x10 <sup>4.2</sup>	6.4x10 <sup>3.2</sup>	1.28x10 <sup>3.2</sup>	2.56x10 <sup>2.2</sup>
			5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
B (Victoria lineage)	B/Michigan/09/2011	1x10 <sup>6.9</sup>	2x10 <sup>5.9</sup>	4x10 <sup>4.9</sup>	8x10 <sup>3.9</sup>	1.6x10 <sup>3.9</sup>	3.2x10 <sup>2.9</sup>	6.4x10 <sup>1.9</sup>	1.28x10 <sup>1.9</sup>	2.56x10 <sup>0.9</sup>
			5/5	5/5	5/5	5/5	5/5	0/5	0/5	not tested
	B/Washington/02/2019	1x10 <sup>9.3</sup>	2x10 <sup>8.3</sup>	4x10 <sup>7.3</sup>	8x10 <sup>6.3</sup>	1.6x10 <sup>6.3</sup>	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	5/5	3/5	0/5	0/5	not tested
B (Yamagata lineage)	B/Texas/81/2016	1x10 <sup>8.1</sup>	2x10 <sup>7.1</sup>	4x10 <sup>6.1</sup>	8x10 <sup>5.1</sup>	1.6x10 <sup>5.1</sup>	3.2x10 <sup>4.1</sup>	6.4x10 <sup>3.1</sup>	1.28x10 <sup>3.1</sup>	2.56x10 <sup>2.1</sup>
			5/5	5/5	5/5	5/5	5/5	2/5	0/5	0/5
	B/Phuket/3073/2013	1x10 <sup>9.9</sup>	2x10 <sup>8.9</sup>	4x10 <sup>7.9</sup>	8x10 <sup>6.9</sup>	1.6x10 <sup>6.9</sup>	3.2x10 <sup>5.9</sup>	6.4x10 <sup>4.9</sup>	1.28x10 <sup>4.9</sup>	2.56x10 <sup>3.9</sup>
			5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5

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Influenza Virus	Virus Strain Name	Stock Concentration	Virus 5-Fold Serial Dilutions (EID <sub>50</sub> /mL) and Number of Positive Results at Each Dilution							
(Type/Subtype)		(EID <sub>50</sub> /mL)								
A(H3N2)	A/Perth/16/2009	1x10 <sup>9.3</sup>	2x10 <sup>8.3</sup>	4x10 <sup>7.3</sup>	8x10 <sup>6.3</sup>	1.6x10 <sup>6.3</sup>	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	5/5	4/5	0/5	0/5	not tested
	A/Hong Kong/2671/2019	1x10 <sup>7.5</sup>	2x10 <sup>6.5</sup>	4x10 <sup>5.5</sup>	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>	2.56x10 <sup>1.5</sup>
			5/5	5/5	0/5	0/5	not tested	not tested	not tested	not tested
A(H1N1)pdm09	A/Christ Church/16/2010	1x10 <sup>10.2</sup>	2x10 <sup>9.2</sup>	4x10 <sup>8.2</sup>	8x10 <sup>7.2</sup>	1.6x10 <sup>7.2</sup>	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	5/5	3/5	0/5	0/5	not tested
	A/Guangdong-Maonan/1536/2019	1x10 <sup>9.1</sup>	2x10 <sup>8.1</sup>	4x10 <sup>7.1</sup>	8x10 <sup>6.1</sup>	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	5/5	0/5	0/5	not tested	not tested	not tested
B (Victoria lineage)	B/Michigan/09/2011	1x10 <sup>6.9</sup>	2x10 <sup>5.9</sup>	4x10 <sup>4.9</sup>	8x10 <sup>3.9</sup>	1.6x10 <sup>3.9</sup>	3.2x10 <sup>2.9</sup>	6.4x10 <sup>1.9</sup>	1.28x10 <sup>1.9</sup>	2.56x10 <sup>0.9</sup>
			5/5	5/5	5/5	0/5	0/5	not tested	not tested	not tested
	B/Washington/02/2019	1x10 <sup>9.2</sup>	2x10 <sup>8.2</sup>	4x10 <sup>7.2</sup>	8x10 <sup>6.2</sup>	1.6x10 <sup>6.2</sup>	3.2x10 <sup>5.2</sup>	6.4x10 <sup>4.2</sup>	1.28x10 <sup>4.2</sup>	2.56x10 <sup>3.2</sup>
			5/5	5/5	5/5	5/5	0/5	0/5	not tested	not tested
B (Yamagata lineage)	B/Texas/81/2016	1x10 <sup>8.3</sup>	2x10 <sup>7.3</sup>	4x10 <sup>6.3</sup>	8x10 <sup>5.3</sup>	1.6x10 <sup>5.3</sup>	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	5/5	5/5	0/5	0/5	not tested
	B/Phuket/3073/2013	1x10 <sup>9.9</sup>	2x10 <sup>8.9</sup>	4x10 <sup>7.9</sup>	8x10 <sup>6.9</sup>	1.6x10 <sup>6.9</sup>	3.2x10 <sup>5.9</sup>	6.4x10 <sup>4.9</sup>	1.28x10 <sup>4.9</sup>	2.56x10 <sup>3.9</sup>
			5/5	5/5	5/5	5/5	2/5	0/5	0/5	not tested

## Summary of 2019 Annual Flu Strain Reactivity Testing

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		(EID <sub>50</sub> /mL)								
A(H3N2)	A/Perth/16/2009	1x10 <sup>8.3</sup>	2x10 <sup>7.3</sup>	4x10 <sup>6.3</sup>	8x10 <sup>5.3</sup>	1.6x10 <sup>5.3</sup>	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	5/5	5/5	<b>1/5</b>	0/5	0/5
	A/Kansas/14/2017*	1x10 <sup>8.9</sup>	2x10 <sup>7.9</sup>	4x10 <sup>6.9</sup>	8x10 <sup>5.9</sup>	1.6x10 <sup>5.9</sup>	3.2x10 <sup>4.9</sup>	6.4x10 <sup>3.9</sup>	1.28x10 <sup>3.9</sup>	2.56x10 <sup>2.9</sup>
			5/5	5/5	5/5	5/5	5/5	<b>1/5</b>	0/5	0/5
A(H1N1)pdm09	A/Christ Church/16/2010	1x10 <sup>9.9</sup>	2x10 <sup>8.9</sup>	4x10 <sup>7.9</sup>	8x10 <sup>6.9</sup>	1.6x10 <sup>6.9</sup>	3.2x10 <sup>5.9</sup>	6.4x10 <sup>4.9</sup>	1.28x10 <sup>4.9</sup>	2.56x10 <sup>3.9</sup>
			5/5	5/5	5/5	5/5	5/5	<b>5/5</b>	0/5	0/5
	A/Brisbane/02/2018*	1x10 <sup>7.9</sup>	2x10 <sup>6.9</sup>	4x10 <sup>5.9</sup>	8x10 <sup>4.9</sup>	1.6x10 <sup>4.9</sup>	3.2x10 <sup>3.9</sup>	6.4x10 <sup>2.9</sup>	1.28x10 <sup>2.9</sup>	2.56x10 <sup>1.9</sup>
			5/5	5/5	5/5	5/5	5/5	<b>2/5</b>	0/5	0/5
B (Victoria lineage)	B/Michigan/09/2011	1x10 <sup>8.5</sup>	2x10 <sup>7.5</sup>	4x10 <sup>6.5</sup>	8x10 <sup>5.5</sup>	1.6x10 <sup>5.5</sup>	3.2x10 <sup>4.5</sup>	6.4x10 <sup>3.5</sup>	1.28x10 <sup>3.5</sup>	2.56x10 <sup>2.5</sup>
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5	0/5	not tested
	B/Colorado/06/2017*	1x10 <sup>8.3</sup>	2x10 <sup>7.3</sup>	4x10 <sup>6.3</sup>	8x10 <sup>5.3</sup>	1.6x10 <sup>5.3</sup>	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	5/5	<b>4/5</b>	0/5	0/5	not tested
B (Yamagata lineage)	B/New Hampshire/01/2016	1x10 <sup>8.9</sup>	2x10 <sup>7.9</sup>	4x10 <sup>6.9</sup>	8x10 <sup>5.9</sup>	1.6x10 <sup>5.9</sup>	3.2x10 <sup>4.9</sup>	6.4x10 <sup>3.9</sup>	1.28x10 <sup>3.9</sup>	2.56x10 <sup>2.9</sup>
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5	0/5	not tested
	B/Phuket/3073/2013*	1x10 <sup>8.9</sup>	2x10 <sup>7.9</sup>	4x10 <sup>6.9</sup>	8x10 <sup>5.9</sup>	1.6x10 <sup>5.9</sup>	3.2x10 <sup>4.9</sup>	6.4x10 <sup>3.9</sup>	1.28x10 <sup>3.9</sup>	2.56x10 <sup>2.9</sup>
			5/5	5/5	5/5	<b>5/5</b>	0/5	0/5	0/5	not tested

\*CDC recommended strains for use in the 2019-2020 influenza season vaccine (northern hemisphere).