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Summary of 2020 Annual Analytical Reactivity Testing

Thermo Scientific Remel Xpect Flu A & B Test

A panel of 8 human influenza viral strains was provided by the Centers for Disease Control to evaluate the reactivity of the Thermo Scientific[TM] Remel[TM] Xpect[TM] Flu A & B Test (R24600). The viral isolates included 4 x Influenza A and 4 x Influenza B strains. Each sample was serially diluted in 5 fold dilutions. Each dilution was assayed in replicates of 5, using the standard test procedure detailed in the Instructions For Use (IFU).

All strains were successfully detected. The minimally reactive concentration was identified as the lowest dilution at which any of the replicates gave a positive reading.

Testing was performed as per 21 CFR 866.3328 for Influenza virus antigen detection test systems.

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID_{50}/mL)	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at each Dilution (End point highlighted)								
A (H3N2)	A/Perth/16/2009	$10^{9.3}$	$2 \times 10^{8.3}$	$4 \times 10^{7.3}$	$8 \times 10^{6.3}$	$1.6 \times 10^{6.3}$	$3.2 \times 10^{5.3}$	$6.4 \times 10^{4.3}$	$1.28 \times 10^{4.3}$	$2.56 \times 10^{3.3}$	$5.12 \times 10^{2.3}$
			5/5	5/5	5/5	**5/5**	0/5	0/5	0/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID_{50}/mL)	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at each Dilution (End point highlighted)								
A (H3N2)	A/Hong Kong/2671/2019*	$10^{7.5}$	$2 \times 10^{6.5}$	$4 \times 10^{5.5}$	$8 \times 10^{4.5}$	$1.6 \times 10^{3.5}$	$3.2 \times 10^{3.5}$	$6.4 \times 10^{2.5}$	$1.28 \times 10^{2.5}$	$2.56 \times 10^{1.5}$	$5.12 \times 10^{0.5}$
			5/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID_{50}/mL)	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at each Dilution (End point highlighted)								
A (H1N1)pdm09	A/Christ Church/16/2010	$10^{10.2}$	$2 \times 10^{9.2}$	$4 \times 10^{8.2}$	$8 \times 10^{7.2}$	$1.6 \times 10^{7.2}$	$3.2 \times 10^{6.2}$	$6.4 \times 10^{5.2}$	$1.28 \times 10^{5.2}$	$2.56 \times 10^{4.2}$	$5.12 \times 10^{3.2}$
			5/5	**4/5**	0/5	0/5	0/5	0/5	0/5	0/5	0/5

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Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID$_{50}$/mL)	Virus Serial Dilution Concentration (EID$_{50}$/mL) and Number of Positive Results at each Dilution (End point highlighted)								
A (H1N1)pdm09	A/Guangdong-Maonan/1536/2019*	$10^{9.1}$	$2 \times 10^{8.1}$	$4 \times 10^{7.1}$	$8 \times 10^{6.1}$	$1.6 \times 10^{6.1}$	$3.2 \times 10^{5.1}$	$6.4 \times 10^{4.1}$	$1.28 \times 10^{4.1}$	$2.56 \times 10^{3.1}$	$5.12 \times 10^{2.1}$
			5/5	**5/5**	0/5	0/5	0/5	0/5	0/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID$_{50}$/mL)	Virus Serial Dilution Concentration (EID$_{50}$/mL) and Number of Positive Results at each Dilution (End point highlighted)								
B (Victoria lineage)	B/Michigan/09/2011	$10^{6.9}$	$2 \times 10^{5.9}$	$4 \times 10^{4.9}$	$8 \times 10^{3.9}$	$1.6 \times 10^{3.9}$	$3.2 \times 10^{2.9}$	$6.4 \times 10^{1.9}$	$1.28 \times 10^{1.9}$	$2.56 \times 10^{0.9}$	$5.12 \times 10^{-0.1}$
			5/5	5/5	**3/5**	0/5	0/5	0/5	0/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID$_{50}$/mL)	Virus Serial Dilution Concentration (EID$_{50}$/mL) and Number of Positive Results at each Dilution (End point highlighted)								
B (Victoria Lineage)	B/Washington/02/2019*	$10^{9.2}$	$2 \times 10^{8.2}$	$4 \times 10^{7.2}$	$8 \times 10^{6.2}$	$1.6 \times 10^{6.2}$	$3.2 \times 10^{5.2}$	$6.4 \times 10^{4.2}$	$1.28 \times 10^{4.2}$	$2.56 \times 10^{3.2}$	$5.12 \times 10^{2.2}$
			5/5	5/5	5/5	**1/5**	0/5	0/5	0/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID$_{50}$/mL)	Virus Serial Dilution Concentration (EID$_{50}$/mL) and Number of Positive Results at each Dilution (End point highlighted)								
B (Yamagata Lineage)	B/Texas/81/2016	$10^{8.3}$	$2 \times 10^{7.3}$	$4 \times 10^{6.3}$	$8 \times 10^{5.3}$	$1.6 \times 10^{5.3}$	$3.2 \times 10^{4.3}$	$6.4 \times 10^{3.3}$	$1.28 \times 10^{3.3}$	$2.56 \times 10^{2.3}$	$5.12 \times 10^{1.3}$
			5/5	5/5	5/5	**5/5**	0/5	0/5	0/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock concentration (EID$_{50}$/mL)	Virus Serial Dilution Concentration (EID$_{50}$/mL) and Number of Positive Results at each Dilution (End point highlighted)								
B (Yamagata Lineage)	B/Phuket/3073/2013*	$10^{9.9}$	$2 \times 10^{8.9}$	$4 \times 10^{7.9}$	$8 \times 10^{6.9}$	$1.6 \times 10^{6.9}$	$3.2 \times 10^{5.9}$	$6.4 \times 10^{4.9}$	$1.28 \times 10^{4.9}$	$2.56 \times 10^{3.9}$	$5.12 \times 10^{2.9}$
			5/5	5/5	5/5	3/5	**1/5**	0/5	0/5	0/5	0/5

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