Annual Influenza Reactivity Testing

AccessBio

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test

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REF RCNM-02071

As influenza viruses change over time, the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test / CareSuperb™ COVID-19/Flu A&B Antigen Combo Test is tested each year against a panel of recently circulating influenza A and B viruses supplied by the FDA Center for Biologics Evaluation and Research (CBER).

2026 Annual Reactivity Testing Results

Each virus was diluted in a five-fold series, and each dilution was tested in five replicates, following the CBER panel testing procedure. Testing continued until two consecutive dilutions produced no positive results. The table below shows the lowest concentration at which the test gave a positive result for each virus.

The following tables summarize the results of annual analytical reactivity testing performed with the 2026–2027 CBER Influenza Virus Panel (Cat. No. VP2026, Lot No. VP2026-001, Exp. Date 2027-06-01), as required by 21 CFR 866.3987.

Table 1. Summary of Minimum Reactive Concentration (MRC) by Strains

Influenza Virus (Type/Subtype)	Virus Strain Name	CBER Lot No.	Stock Titer (EID_{50}/mL)	Dilution at MRC	MRC (EID_{50}/mL)	No. Positive / 5 at MRC
A(H1N1)pdm09	A/Missouri/11/2025*	273	$10^{7.8}$	15,625x	**$10^{3.61}$**	2/5 (40%)
A(H1N1)pdm09	A/Victoria/4897/2022	263	$10^{9.25}$	3,125x	**$10^{5.76}$**	5/5 (100%)
A(H3N2)	A/Michigan/105/2025*	274	$10^{8.5}$	125x	**$10^{6.40}$**	5/5 (100%)
A(H3N2)	A/Wisconsin/160/2024	265	$10^{8.75}$	15,625x	**$10^{4.56}$**	1/5 (20%)
B (Victoria lineage)	B/Tokyo/EIS13-175/2025*	276	$10^{8.75}$	3,125x	**$10^{5.26}$**	5/5 (100%)
B (Victoria lineage)	B/Austria/1359417/2021	228	$10^{8.5}$	625x	**$10^{5.70}$**	5/5 (100%)

Table 2. 2026 Annual Reactivity Testing – Influenza A

Influenza Virus (Type/Subtype) / Virus Strain Name	Dilution	5x	25x	125x	625x	3,125x	15,625x	78,125x	390,625x
A(H1N1)pdm09 A/Missouri/11/2025*	Titer (EID_{50}/mL)	$10^{7.10}$	$10^{6.40}$	$10^{5.70}$	$10^{5.00}$	$10^{4.31}$	**$10^{3.61}$**	$10^{2.91}$	$10^{2.21}$
	No. Positive / 5	5/5	5/5	5/5	5/5	5/5	**2/5**	0/5	0/5
	Positive Rate (%)	100	100	100	100	100	**40**	0	0
A(H1N1)pdm09 A/Victoria/4897/2022	Titer (EID_{50}/mL)	$10^{8.55}$	$10^{7.85}$	$10^{7.15}$	$10^{6.45}$	**$10^{5.76}$**	$10^{5.06}$	$10^{4.36}$	N/A
	No. Positive / 5	5/5	5/5	5/5	5/5	**5/5**	0/5	0/5	N/A
	Positive Rate (%)	100	100	100	100	**100**	0	0	N/A
A(H3N2) A/Michigan/105/2025*	Titer (EID_{50}/mL)	$10^{7.80}$	$10^{7.10}$	**$10^{6.40}$**	$10^{5.70}$	$10^{5.01}$	N/A	N/A	N/A
	No. Positive / 5	5/5	5/5	**5/5**	0/5	0/5	N/A	N/A	N/A
	Positive Rate (%)	100	100	**100**	0	0	N/A	N/A	N/A
A(H3N2) A/Wisconsin/160/2024	Titer (EID_{50}/mL)	$10^{8.05}$	$10^{7.35}$	$10^{6.65}$	$10^{5.95}$	$10^{5.26}$	**$10^{4.56}$**	$10^{3.86}$	$10^{3.16}$
	No. Positive / 5	5/5	5/5	5/5	5/5	5/5	**1/5**	0/5	0/5
	Positive Rate (%)	100	100	100	100	100	**20**	0	0

Table 3. 2026 Annual Reactivity Testing – Influenza B

Influenza Virus (Type/Subtype) / Virus Strain Name	Dilution	5x	25x	125x	625x	3,125x	15,625x	78,125x	390,625x
B (Victoria lineage) B/Tokyo/EIS13-175/2025*	Titer (EID_{50}/mL)	$10^{8.05}$	$10^{7.35}$	$10^{6.65}$	$10^{5.95}$	**$10^{5.26}$**	$10^{4.56}$	$10^{3.86}$	N/A
	No. Positive / 5	5/5	5/5	5/5	5/5	**5/5**	0/5	0/5	N/A
	Positive Rate (%)	100	100	100	100	**100**	0	0	N/A
B (Victoria lineage) B/Austria/1359417/2021	Titer (EID_{50}/mL)	$10^{7.80}$	$10^{7.10}$	$10^{6.40}$	**$10^{5.70}$**	$10^{5.01}$	$10^{4.31}$	N/A	N/A
	No. Positive / 5	5/5	5/5	5/5	**5/5**	0/5	0/5	N/A	N/A
	Positive Rate (%)	100	100	100	**100**	0	0	N/A	N/A

* FDA-recommended influenza virus for the composition of influenza vaccines for the 2026–2027 U.S. (Northern Hemisphere) influenza season.

EID_{50} = 50% egg infectious dose.

MRC = minimum reactive concentration: the titer of the most dilute level with at least 1 of 5 replicates positive, immediately preceding two consecutive dilution levels with 0 of 5 positive.

N/A = dilution level not tested (endpoint already reached).

Shaded cells mark the MRC for each strain.

Limitation

Although this test was reactive with the influenza viruses listed above when tested with cultured virus, the performance characteristics of this test with clinical specimens that are positive for these influenza viruses have not been established. Test sensitivity may vary with new or emerging influenza strains. A negative result does not rule out influenza infection.

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