

Candidate Vaccine Strains and Potency Reagents: 2025-26 Northern Hemisphere Influenza Season

**Laboratory of Biochemistry, Virology & Immunochemistry
Division of Biological Standards & Quality Control
OCBQ, CBER, FDA**

Manju Joshi, Ph.D.

**Prepared for
Interagency Meeting 13th March 2025**

Recommended influenza virus strains for 2025 SH seasonal influenza vaccines



Influenza A(H1N1)pdm09:

- For egg-based vaccines: A/Victoria/4897/2022-like virus
- For cell culture- or recombinant-based vaccines: A/Wisconsin/67/2022-like virus

Influenza A(H3N2):

- For egg-based vaccines: A/Croatia/10136RV/2023-like virus
- For cell culture- or recombinant-based vaccines: A/District of Columbia/27/2023-like virus

Influenza B (B/Victoria/2/87 Lineage):

- For egg-based vaccines: B/Austria/1359417/2021-like virus
- For cell culture- or recombinant-based vaccines: B/Austria/1359417/2021-like virus

Candidate Vaccine Viruses (CVVs): many available

Data collected and reviewed by the Global Influenza Surveillance and Response System (GISRS) support the same vaccine composition for 2025-2026 NH seasonal vaccines

Potency reagents for the A(H1N1)pdm09 component



Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/Victoria/4897/2022 (IVR-238) (egg)	CBER	H1-Ag-2303	H1-Ab-2214*; H1-Ab-2316
	MHRA	22/320	23/100
	TGA	2023/146B	AS454
	NIID	2024AH1A; 2024AH1B	2023AH1-1
A/Georgia/12/2022 CVR-167 (cell)	CBER	H1-Ag-2307	H1-Ab-2214*; H1-Ab-2316
A/West Virginia/30/2022 (rHA)	CBER	H1-Ag-2304	H1-Ab-2214*; H1-Ab-2316

**anti-A/Sydney/05/2021 antiserum*



Potency reagents for the A(H3N2) component

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/Croatia/10136RV/2023 NYMC X-425 (egg)	CBER	H3-Ag-2411	H3-Ab-2412
	MHRA	24/174	24/176
	TGA	2024/148B	AS460
A/District of Columbia/27/2023 (cell)	CBER	H3-Ag-2410	H3-Ab-2412
A/District of Columbia/27/2023 (rHA)	CBER	H3-Ag-2504* (planned)	H3-Ab-2412

** will be calibrated*

Potency reagents for the B/Victoria component

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Michigan/01/2021 (egg)	CBER	B(v)-Ag-2117	B(v)-Ab-2202; B(v)-Ab-2308
	MHRA	21/330	22/228
B/Austria/1359417/2021 (BVR-26) (egg)	MHRA	21/316	22/228
	TGA	2021/139B	AS446-1 AS452
	NIID	2023BVA 2023BVB	2022BV-1
B/Singapore/WUH4618/2021 (cell)	CBER	B(v)-Ag-2402	B(v)-Ab-2202 B(v)-Ab-2308
B/Austria/1359417/2021 (rHA)	CBER	B(v)-Ag-2306	B(v)-Ab-2202; B(v)-Ab-2308

General Comments

- **CBER will work with manufacturers to prepare and calibrate any additional reference antigens as needed.**
- **Some manufacturers can no longer use CBER reagents because their license stipulates reagents should be obtained from another Essential Regulatory Laboratory (ERL) (e.g., MHRA, NIID, or TGA).**

Thank You