

# **Candidate Vaccine Strains and Potency Reagents: 2024-25 Northern Hemisphere Influenza Season**

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# Topics to Be Covered

- **WHO recommendations for 2024-25 northern hemisphere influenza vaccines**
  - **Trivalent Vaccines**
  - **Quadrivalent**
- **Availability of potency reagents for each of the recommended strains**
- **General comments**

# Influenza A (H1N1)pdm09



- **WHO recommended viruses for 2024-25 NH season vaccines:**
  - *Same as for 2023-24 NH season*
  - *Same as for 2024 SH season*
- **For egg-based vaccines: A/Victoria/4897/2022 (H1N1)pdm09-like virus**
- **For cell culture- or recombinant-based vaccines: A/Wisconsin/67/2022 (H1N1)pdm09-like virus**
- **Candidate Vaccine Viruses (CVVs): many CVVs are available; CVVs and source are listed at [Global Influenza Programme](https://www.who.int/global-influenza-programme) (who.int)**

# Potency reagents for the A(H1N1)pdm09 component of 2024-25 vaccines



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	2023/143B;2023/146B	AS451-1: AS454
	NIID	2023AH1A; 2023AH1B	2023AH1-1
A/Georgia/12/2022 (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*

# Influenza A(H3N2)

- **WHO recommended viruses for 2024-25 NH season vaccines:**
  - *Different from 2023-24 NH season*
  - *Same as for 2024 SH season*
- **For egg-based vaccines: an A/Thailand/8/2022 (H3N2)-like virus**
- **For cell culture- or recombinant-based vaccines: an A/Massachusetts/18/2022 (H3N2)-like virus**
- **Candidate Vaccine Viruses (CVVs): many CVVs are available; CVVs and source are listed at [Global Influenza Programme](https://www.who.int/global-influenza-programme) (who.int)**



# Potency reagents for the A(H3N2) component of 2024-25 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/California/122/2022 (SAN-022) (egg)	CBER	H3-Ag-2314	H3-Ab-2315
	MHRA	23/226	23/222
A/Thailand/8/2022 (IVR-237) (egg)	TGA	2023/145B	AS450
	MHRA	23/220	23/222
A/Sydney/1304/2022 (cell)	CBER	H3-Ag-2312	H3-Ab-2315

***Note: CBER will work with manufacturers and ERLs to prepare and calibrate any additional reference antigens as needed.***



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

- **WHO recommended virus for 2024-25 NH season**
  - *Same as for 2023-24 NH season*
  - *Same as for 2024 SH season*
- **For egg-based vaccines: B/Austria/1359417/2021 (B/Victoria lineage)-like virus**
- **For cell culture- or recombinant-based vaccines: B/Austria/1359417/2021 (B/Victoria lineage)-like virus**
- **Candidate Vaccine Viruses (CVVs): many CVVs are available; CVVs and source are listed at [Global Influenza Programme \(who.int\)](https://www.who.int)**

# Potency reagents for the B/Victoria component of 2024-25 vaccines



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)	TGA	2021/139B	AS446-1 AS452
	MHRA	21/316	22/228
	NIID	2023BVA 2023BVB	2022BV-1
B/Singapore/WUH4618/2021 (cell)	CBER	B(v)-Ag-2115	B(v)-Ab-2202 B(v)-Ab-2308
B/Austria/1359417/2021 (rHA)	CBER	B(v)-Ag-2207; B(v)-Ag-2306	B(v)-Ab-2202; B(v)-Ab-2308



# Influenza B (2<sup>nd</sup> B-strain for Quadrivalent Vaccines) (B/Yamagata/16/88 lineage)

- In the regions where Quadrivalent Vaccines are used B/Yamagata lineage component remains unchanged from previous seasons
  - *Same as for 2023-24 NH season*
  - *Same as for 2024 SH season*
- For egg-based, cell culture- or recombinant-based vaccines vaccine: B/Phuket/3073/2013 (B/Yamagata lineage)-like virus
- Candidate Vaccine Viruses (CVVs): many CVVs are available; CVVs and source are listed at [Global Influenza Programme](https://www.who.int/global-influenza-programme) (who.int)

# Potency reagents for the B/Yamagata component of 2024-2025 vaccines



Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Phuket/3073/ 2013 (egg)	CBER	B(y)-Ag-2112	B(y)-Ab-2215
	MHRA	21/136	19/322; 22/132
	TGA	2017/115B	AS425; AS426; AS449
	NIID	2023BYA; 2023BYB	2021BY-1
B/Phuket/3073/ 2013 (BVR-1B) (egg)	TGA	2020/136B; 2023/142B	AS425; AS426; AS449
B/Singapore/INFTT-16-0610/2016 (cell)	CBER	B(y)-Ag-2103	B(y)-Ab-2215
	MHRA	19/308	19/322; 22/132
B/Utah/09/2014 (cell)	CBER	B(y)-Ag-1501	B(y)-Ab-2215
	MHRA	15/100	19/322; 22/132
B/Phuket/3073/ 2013 (rHA)	CBER	B(y)-Ag-2001	B(y)-Ab-2215

# General Comments (for vaccine manufacturers)



- Communicate with DBSQC regarding potency testing reagents that you plan to use in new campaign. Only CBER authorized reagents should be used to test potency of vaccines marketed in the US
- Monovalent samples must be submitted to DBSQC. Please email [Manju.Joshi@fda.hhs.gov](mailto:Manju.Joshi@fda.hhs.gov) regarding dispatch of samples, test results etc. (cc: [Muhammad.Shahabuddin@fda.hhs.gov](mailto:Muhammad.Shahabuddin@fda.hhs.gov))
- For any inquires regarding CBER Reference Standards and Reagents availability and shipping, contact CBER Standards at [CBERshippingrequests@fda.hhs.gov](mailto:CBERshippingrequests@fda.hhs.gov)
- Send feedback/comments on the suitability or use of the reagents provided, and other aspects of our service to [CBERinfluenzafeedback@fda.hhs.gov](mailto:CBERinfluenzafeedback@fda.hhs.gov)

**Thank You**