Candidate Vaccine Strains and Potency Reagents: 2023-24 Northern Hemisphere Influenza Season

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Topics to Be Covered

- **WHO recommendations for 2023-24 northern hemisphere influenza vaccines**
- **Availability of potency reagents for each of the recommended strains**

Influenza A (H1N1)

- **WHO recommended viruses for 2023-24 NH season vaccines:**
  - ***Different from 2022-23 NH season***
  - ***Different from 2023 SH season***

- **For egg-based vaccines: A/Victoria/4897/2022 (H1N1)pdm09-like virus, egg derived**

- **For cell culture- or recombinant-based vaccines: A/Wisconsin/67/2022 (H1N1)pdm09-like virus, MDCK cell derived**

A(H1N1)pdm09 CVVs – Egg-based

Antigenically-like A/Victoria/4897/2022
Accession number (GISAID): EPI_ISL_16714268

CVV	Candidate Vaccine Virus	Type of virus or reassortant	Developing institute	Available from
A/Victoria/4897/2022	Wild type virus		VIDRL, Australia	VIDRL, Australia
	IVR-238	classical	Seqirus, Australia	VIDRL, Australia

A(H1N1)pdm09 CVVs – cell culture-based

Antigenically like A/Wisconsin/67/2022 (MDCK cell-derived)
Accession number (GISAID): EPI_ISL_15928563

ccCVV	Candidate Vaccine Virus	Type of virus or reassortant	Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available from
A/West Virginia/30/2022	Wild type virus		MDCK 33016 PF	CDC, USA	P2-P3	CDC, USA
A/Georgia/12/2022						

Potency reagents for the A(H1N1)pdm09 component of 2023-24 vaccines

- **Reference Antigen:**
  CBER will work with ERLs and manufacturers to prepare and calibrate the required reference antigens required for testing of egg, cell culture and rHA vaccines

- **CBER Antiserum:**
  Sheep antiserum production is being planned

Influenza A(H3N2)

- **WHO recommended viruses for 2023-24 NH season vaccines:**
  - ***Same as for 2022-23 NH season***
  - ***Same as for 2023 SH season***

- **For egg-based vaccines: A/Darwin/9/2021(H3N2)-like virus, egg derived**

- **For cell culture- or recombinant-based vaccines: A/Darwin/6/2021 (H3N2)-like virus, MDCK cell derived**

- **Candidate Vaccine Viruses (CVVs): many CVVs are available and have been used for past vaccine production campaigns**

Potency reagents for the A(H3N2) component of 2023-24 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/Darwin/9/2021 (SAN-010) (egg)	CBER MHRA	H3-Ag-2116 21/320	H3-Ab-2204 21/324
A/Darwin/9/2021 (IVR-228) (egg)	MHRA	21/318	21/324
A/Darwin/6/2021 (IVR-227) (egg)	TGA MHRA	2021/138B 21/314	AS445 21/324
A/Darwin/11/2021 (cell)	CBER	H3-Ag-2114	H3-Ab-2204
A/Darwin/6/2021 (rHA)	CBER	H3-Ag-2206	H3-Ab-2204

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

- **WHO recommended virus for 2023-24 NH season (for Trivalent and Quadrivalent Vaccines):**
  - ***Same as for 2022-23 NH season***
  - ***Same as for 2023 SH season***

- **For egg-based vaccines: B/Austria/1359417/2021 (B/Victoria lineage)-like virus, egg derived**

- **For cell culture- or recombinant-based vaccines: B/Austria/1359417/2021 (B/Victoria lineage)-like virus, MDCK cell derived**

- **Candidate Vaccine Viruses (CVVs): many CVVs are available and have been used for past vaccine production campaigns**

Potency reagents for the B/Victoria component of 2023-24 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Michigan/01/2021 (egg)	CBER MHRA	B(v)-Ag-2117 21/330	B(v)-Ab-2202 21/326
B/Austria/1359417/2021 (BVR-26) (egg)	TGA MHRA NIID	2021/139B 21/316 2022BVA 2022BVB	AS446 AS446-1 21/326 2022BV-1
B/Singapore/WUH4618/2021 (cell)	CBER	B(v)-Ag-2115	B(v)-Ab-2202
B/Austria/1359417/2021 (rHA)	CBER	B(v)-Ag-2207	B(v)-Ab-2202

Influenza B (2nd B-strain) (B/Yamagata/16/88 lineage)

- **WHO recommended virus for 2023-24 NH Season Quadrivalent Vaccines:**
  - ***Same as for 2022-23 NH season***
  - ***Same as for 2023 SH season***

- **For egg-based vaccine: B/Phuket/3073/2013 (B/Yamagata lineage)-like virus, egg derived**

- **For cell culture- or recombinant-based vaccines : B/Phuket/3073/2013 (B/Yamagata lineage)-like virus, MDCK cell derived**

- **Candidate Vaccine Viruses (CVVs): many CVVs are available and have been used for past vaccine production campaigns**

Potency reagents for the B/Yamagata component of 2023-2024 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
	TGA	2017/115B	AS434-1
	NIID	2021BYA	2021BY-1
B/Phuket/3073/2013 (BVR-1B) (egg)	TGA	2020/136B	AS426 AS434-1
B/Singapore/INFTT-16-0610/2016 (cell)	CBER	B(y)-Ag-2103	B(y)-Ab-2215
	MHRA	19/308	19/322
B/Utah/09/2014 (cell)	CBER	B(y)-Ag-1501	B(y)-Ab-2215
	MHRA	15/100	19/322
B/Phuket/3073/2013 (rHA)	CBER	B(y)-Ag-2001	B(y)-Ab-2215

Contact information

- **For CBER Reference Standards and Reagents availability and shipping, email: CBERshippingrequests@fda.hhs.gov**

- **For feedback/comments or general inquiries regarding reagents or testing, email: CBERinfluenzafeedback@fda.hhs.gov**

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Thank You