

Candidate Vaccine Strains and Potency Reagents: 2022-23 Northern Hemisphere Influenza Season

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Topics to Be Covered

- **WHO recommendations for 2022-23 northern hemisphere influenza vaccines**
- **Availability of potency reagents for each of the recommended strains**
- **Planning for 2022-23 northern hemisphere influenza season**
- **General comments**

Influenza A (H1N1)

- **WHO recommended viruses for 2022-23 NH season vaccines:**
 - *Same as for 2021-22 NH season*
 - *Same as for 2022 SH season*
- **For egg-based vaccines: A/Victoria/2570/2019 (H1N1)pdm09-like virus**
- **For cell culture- or recombinant-based vaccines: A/Wisconsin/588/2019 (H1N1)pdm09-like virus**
- **Candidate Vaccine Viruses (CVVs) are listed at the WHO web site:**
<https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations>



Potency reagents for the A(H1N1)pdm09 component of 2022-23 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/Victoria/2570/2019 (IVR-215) (egg)	CBER	H1-Ag-2118	H1-Ab-2109
	TGA	2020/137B	AS443; AS443-1
	NIBSC	20/232	20/234
A/Victoria/1/2020 (IVR-217) (egg)	NIID	2021AH1A 2021AH1B	2021AH1-1
A/Delaware/55/2019 (cell)	CBER	H1-Ag-2017	H1-Ab-2109
A/Washington/19/2020 (cell)	CBER	H1-Ag-2106	H1-Ab-2109
A/Wisconsin/588/2019 (rHA)	CBER	H1-Ag-2102	H1-Ab-2109

Influenza A(H3N2)

- **WHO recommended viruses for 2022-23 NH season vaccines:**
 - *Different than for 2021-22 NH season*
 - *Same as for 2022 SH season*
- **For egg-based vaccines: A/Darwin/9/2021(H3N2)-like virus**
- **For cell culture- or recombinant-based vaccines: A/Darwin/6/2021 (H3N2)-like virus**
- **Candidate Vaccine Viruses (CVVs) listed at the WHO web site:**
<https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations>

Potency reagents for the A(H3N2) component of 2022-23 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/Darwin/9/2021 (SAN-010) (egg)	CBER	H3-Ag-2116	H3-Ab-2120*
	NIBSC	21/320	21/324
A/Darwin/9/2021 (IVR-228) (egg)	NIBSC	21/318	21/324
A/Darwin/6/2021 (IVR-227) (egg)	TGA	2021/138B	AS445
	NIBSC	21/314	21/324
A/Darwin/11/2021 (cell)	CBER	H3-Ag-2114	H3-Ab-2120*

* Replacement lot in preparation

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



- **WHO recommended virus for 2022-23 NH season (for Trivalent and Quadrivalent Vaccines):**
 - *Different than for 2021-22 NH season*
 - *Same as for 2022 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) are listed at the WHO web site:**
<https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations>

Potency reagents for the B/Victoria component of 2022-23 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Michigan/01/2021 (egg)	CBER	B(v)-Ag-2117	B(v)-Ab-2119 B(v)-Ab-2202
	NIBSC	21/330	21/326
B/Austria/1359417/2021 (BVR-26) (egg)	TGA	2021/139B	AS446
	NIBSC	21/316	21/326
B/Singapore/WUH4618/2021 (cell)	CBER	B(v)-Ag-2115	B(v)-Ab-2119 B(v)-Ab-2202



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

- **WHO recommended virus for 2022-23 NH Season Quadrivalent Vaccines:**
 - *Same as for 2021-22 NH season*
 - *Same as for 2022 SH season*
- **For egg-based vaccine: B/Phuket/3073/2013 (B/Yamagata lineage)-like virus**
- **For cell culture- or recombinant-based vaccines : B/Phuket/3073/2013 (B/Yamagata lineage)-like virus**
- **Candidate Vaccine Viruses (CVVs) listed at the WHO web site:**
<https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations>

B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)



Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Phuket/3073/2013 (egg)	CBER	B(y)-Ag-2112	B(y)-Ab-1808
	NIBSC	21/136	19/322
	TGA	2017/115B	AS425; AS426; AS434
	NIID	2021BYA; 2021BYB	2021BY-1
B/Phuket/3073/2013 (BVR-1B) (egg)	TGA	2020/136B	AS425; AS426; AS434
B/Singapore/INFTT-16-0610/2016 (cell)	CBER	B(y)-Ag-1817 B(y)-Ag-2103	B(y)-Ab-1808
	NIBSC	19/308	19/322
B/Utah/09/2014 (cell)	CBER	B(y)-Ag-1501	B(y)-Ab-1808
	NIBSC	15/100	19/322
B/Phuket/3073/2013 (rHA)	CBER	B(y)-Ag-2001	B(y)-Ab-1808

Preparation and Calibration of New Reagents

- **CBER will work with ERLs and the manufacturer to prepare and calibrate the reagents required for potency testing of**
 - **A/Darwin/6/2021-like component in recombinant HA (rHA) influenza vaccine.**
 - **B/Austria/1359417/2021-like component in recombinant HA (rHA) influenza vaccine.**
- **CBER will be ready to calibrated reagent for any new strain....etc.**

Planning for 2022-23 Influenza Season

- **Manufacturers to provide the following information to DBSQC for each strain used in manufacturing (ASAP following VRBPAC on 3rd March 2022)**

Strain Name	Reassortant/ Candidate Vaccine Virus used in manufacturing	Ref Antigen Supplier & Lot No.	Ref Antiserum Supplier & Lot No.
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Having this information is very important to plan laboratory activities:

- **Reagent calibration**
- **Importing reagents from other ERLs**
- **Monovalent bulk testing**
- **Lot release testing**



General Comments

- Only CBER authorized reagents should be used to test potency of vaccines marketed in the US (consult with CBER)
- Monovalent samples must be submitted to DBSQC. Please email Manju.Joshi@fda.hhs.gov regarding dispatch of samples, test results etc. (cc: 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
- Send feedback/comments on the suitability or use of the reagents provided, and other aspects of our service to CBERinfluenzafeedback@fda.hhs.gov

Thank You