

Candidate Vaccine Strains and Potency Reagents: 2021-22 Northern Hemisphere Influenza Season

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

Manju Joshi, Ph.D.

**Prepared for
Vaccines and Related Biological Products Advisory Committee
5th March 2021**



Topics to Be Covered

- **WHO virus recommendations for 2021-22 seasonal influenza vaccines**
- **Available potency reagents for the recommended components**
- **Planning for 2021-22 Northern Hemisphere Influenza Season**
- **General Comments**

Influenza A (H1N1)

- **WHO Recommended Virus for 2021-22 NH Season Vaccines:**
 - *Different from 2020-21 NH season*
 - *Same as for 2021 SH season*
- **For egg-propagated vaccines: A/Victoria/2570/2019 (H1N1)pdm09-like virus**
- **For cell culture-propagated or recombinant vaccines: A/Wisconsin/588/2019 (H1N1)pdm09-like virus**
- **Candidate Vaccine Viruses (CVVs) are listed at the WHO web site:**
https://www.who.int/influenza/vaccines/virus/candidates_reagents/2021_22_north/en/

Potency reagents for the A(H1N1)pdm09 component of 2021-22 vaccines

Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
A/Victoria/2570/2019 (IVR-215) (egg)	CBER	H1-Ag-2016	H1-Ab-2101
	TGA	2020/134B	AS443
	NIBSC	20/232	20/234
A/Delaware/55/2019 (cell)	CBER	H1-Ag-2017	H1-Ab-2101

Influenza A(H3N2)

- **WHO Recommended Virus for 2021-22 NH Season Vaccines:**
 - *Different from for 2020-21 NH season*
 - *Different from for 2021 SH season*

- **For egg-propagated vaccines: A/Cambodia/e826360/2020 (H3N2)-like virus**

- **For cell culture-propagated or recombinant vaccines: A/Cambodia/e826360/2020 (H3N2)-like virus**

- **Candidate Vaccine Viruses (CVVs) listed at the WHO web site:**
https://www.who.int/influenza/vaccines/virus/candidates_reagents/2021_22_north/en/

Candidate Vaccine Viruses for A(H3N2) Vaccine Component



CVVs antigenically like - A/Cambodia/e0826360/2020 (egg-derived)

Parent virus	CVV	Type of reassortant	Available from
A/Cambodia/e0826360/2020	Wild type IVR-224	N/A Classical	WHO CCs; NIBSC, UK WHO CCs; NIBSC, UK
A/Tasmania/503/2020	Wild type IVR-221	N/A Classical	WHO CCs; NIBSC, UK WHO CCs; NIBSC, UK

Cell culture (cc)-based CVVs antigenically like - A/Cambodia/e0826360/2020 (MDCK-SIAT derived, EPI_ISL_944639)

ccCVV	Certified cell line used for isolation and propagation	Passage level available	Available from
A/Cambodia/e0826360/2020	MDCK 33016 PF	P2	VIDRL, Australia
A/Tasmania/503/2020	MDCK 33016 PF	P2	VIDRL, Australia

Potency reagents for the A(H3N2) component of 2021-22 vaccines

CBER will work with ERLs and manufacturers to prepare and calibrate the reagents for measuring the potency of the A/Cambodia/e826360/2020 (H3N2)-like component of vaccines produced using different platforms.

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



- **WHO Recommended Virus for 2021-22 NH Season Trivalent and Quadrivalent Vaccines:**
 - *Same as for 2020-21 NH season*
 - *Same as for 2021 SH season*
- **For egg-propagated vaccines: B/Washington/02/2019-like virus**
- **For cell culture-propagated or recombinant vaccines: B/Washington/02/2019-like virus**
- **Candidate Vaccine Viruses (CVVs) are listed at the WHO web site:**
https://www.who.int/influenza/vaccines/virus/candidates_reagents/2021_22_north/en/

Potency reagents for the B/Victoria component of 2021-22 vaccines



Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Washington/02/2019 (wild-type) (egg)	CBER	B(v)-Ag-1912	B(v)-Ab-2014
	NIBSC	19/238	19/218
B/Victoria/705/2018 (BVR-11) (egg)	TGA	2019/130B	AS 436
	NIBSC	19/208	19/218
	NIID	2020BVA; 2020BVB	2020BV-1
B/Darwin/7/2019 (cell)	CBER	B(v)-Ag-2002	B(v)-Ab-2014
	NIBSC	19/210	19/218
B/Washington/02/2019 (rHA)	CBER	B(v)-Ag-2004	B(v)-Ab-2014

Influenza B (B/Yamagata/16/88 lineage)



- **WHO Recommended Virus for 2021-22 NH Season Quadrivalent Vaccines:**
 - *Same as for 2020-21 NH season*
 - *Same as for 2021 SH season*
- **For egg-propagated Vaccine: B/Phuket/3073/2013-like virus**
- **For cell culture-propagated or recombinant vaccines :**
B/Phuket/3073/2013-like virus
- **Candidate Vaccine Viruses (CVVs) listed at the WHO web site:**
https://www.who.int/influenza/vaccines/virus/candidates_reagents/2021_22_north/en/

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



Virus/Reassortant	Source	Reference Antigen Lot#	Antiserum Lot#
B/Phuket/3073/ 2013 (wild-type) (egg)	CBER	80	B(y)-Ab-1808
	NIBSC	16/158	17/214
	TGA	2017/115B	AS425; AS434
	NIID	2020BYA; 2020BYB	2017BY-1
B/Phuket/3073/ 2013 (BVR-1B) (egg)	TGA	2017/117B	AS425; AS434
B/Singapore/INFTT-16-0610/2016 (cell)	CBER	B(y)-Ag-1817	B(y)-Ab-1808
	NIBSC	19/308	17/214
B/Utah/09/2014 (wild type) (cell)	CBER	B(y)-Ag-1501	B(y)-Ab-1808
	NIBSC	15/100	17/214
B/Phuket/3073/ 2013 (rHA)	CBER	B(y)-Ag-2001	B(y)-Ab-1808



Planning for 2021-22 Influenza Season

- Manufacturers to provide the following information to DBSQC for each strain used in manufacturing (ASAP following VRBPAC on 5th March 2021)

Strain Name	Reassortant/ Candidate Vaccine Virus used in manufacturing	Ref Antigen Supplier & Lot No.	Ref Antiserum Supplier & Lot No.
-------------	--	--------------------------------------	--

This information is very important for DBSQC to plan

- Reagent calibration activities
- Importing reagents from other ERLs
- Monovalent 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; Maryna.Eichelberger@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