



# **Candidate Vaccine Strains and Potency Reagents for 2016-17 Influenza Season**

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# Topics To Be Covered

- **Currently used vaccine strains and WHO recommendation for 2016 – 17 Seasonal Vaccines (Trivalent and Quadrivalent)**
- **Available Reagents for each of the strains**
- **General Comments**

# Influenza A (H1N1)

- **Current Vaccine Strain (2015–16 Season) : A/California/7/2009 (H1N1)pdm09-like virus**
  - A/California/7/2009(H1N1) reassortants X-179A, X-181
  - A/Christ Church/16/2010 (H1N1)NIB-74 & NIB-74xp
  - A/Brisbane/10/2010 (H1N1)
  
- **WHO Recommended Strain for 2016–17: A/California/7/2009 (H1N1)pdm09-like virus**
  - Candidate Vaccine Viruses: A/California/7/2009; A/South Africa/3626/2013; A/ChristChurch/16/2010; A/Brisbane/10/2010;; A/California/4/2009; A/Texas/5/2009; A/England/195/2009; A/NewYork/18/2009
  - No change from 2015–16 strain
  - Was also recommended for 2016 SH campaign as well.

# CBER Authorized Reagents for H1N1

- **CBER Reference Antigen**
  - **For Egg Derived**
    - X-179A CBER Reference Antigen (Lot 76)
    - X-181 CBER Reference Antigen (Lot H1-Ag-1302)
    - *X-181 Reference Antigen from TGA\**
    - *NIB-74: Reference Antigen from NIBSC\**
  - **For Cell Derived**
    - *A/Brisbane/10/2010 (Cell Derived): Reference Antigen from NIBSC*
- **CBER Antiserum**
  - H1-Ab-1404
  - H1-Ab-1405
  - H1-Ab-1503

*\*(CBER approval of these reagents: case by case basis)*

# Influenza A (H3N2)

- **Current Vaccine Strain (2015–16 Season) : A/Switzerland/9715293/2013 (H3N2)-like virus**
  - A/Switzerland/9715293/2013 NIB-88 reassortant;
  - A/South Australia/55/2014 (IVR -175 reassortant) &
  - A/South Australia/55/2014 (Cell Derived)
  - **Reagents made available:**
    - **NIB-88 (egg):**, **CBER**, **NIBSC** & **NIID**
    - **IVR-175 (egg):** **TGA**
    - **A/South Australia (cell):** **CBER** & **NIBSC**
- **WHO Recommended Strain for 2016–17: A/Hong Kong/4801/2014 (H3N2)-like virus**
  - Candidate Vaccine Viruses: A/Victoria/673/2014; A/New Caledonia/71/2014; A/Hong Kong/7127/2014 and A/Hong Kong/4801/2014.
  - Has been recommended for 2016 southern hemisphere (SH) season.
  - **CBER is in process of getting reagent ready for A/Hong Kong/4801/2014 (X-263B). (Target availability May 2015)**
  - Reagents for
    - *A/Hong Kong/4801/2014 (X-263B): NIBSC\**
    - *A/New Caledonia/71/2014 (X-257A): TGA\* & NIBSC\**

*\*(CBER approval of these reagents: case by case basis)*

# Influenza B

- **Current Vaccine Strain (2015–16 Season): B/Yamagata/16/88-lineage-B/Phuket/3073/2013-like virus**
  - Wild Type (Wt.) B/Phuket/3073/2013 (used in vaccine)
  - Wt. B/Utah/09/2014 (used in vaccine)
  - **Reagents made available:**
    - B/Phuket (egg): **CBER**, *NIBSC* & *TGA*
    - B/Brisbane/9/2014 (egg): *NIBSC*
    - B/Utah/09/2014 (cell): **CBER** & *NIBSC*
  
- **WHO Recommended Strain for 2016–17: Victoria lineage-B/Brisbane/60/2008-like viruses**
  - Candidate Vaccine Viruses: B/Brisbane/33/2008; B/Bangladesh/5945/2009, B/Hong Kong/259/2010; B/Nevada/3/2011; B/Texas/2/2013; B/Brisbane/46/2015 & B/Brisbane/60/2008
  - This strain was included as “2<sup>nd</sup> B-Strain” for Quadrivalent Vaccine in 2015-16 season.
  - Has also been recommended for 2016 SH season.

## CBER Authorized Reagents for B-strain (Victoria Lineage)

- **CBER Reference Antigen**
  - **For Egg Derived**
    - B/Brisbane/60/2008 CBER Reference Antigen (Lot 77)
  - **For Cell Derived**
    - B/Brisbane/60/2008 CBER Reference Antigen: B(v)-Ag-1408
  - If manufacturers choose to use B-strain other than B/Brisbane/60/2008 CBER will work to generate homologous reference antigen standard. [Target availability May/June 2015](#)
- **CBER Antiserum**
  - B(v)-Ab-1406
  - B(v)-Ab-1407
  - New Lots: B(v)-Ab-1601 & B(v)-Ab-1602

*(In past CBER had authorized the use of B/Brisbane/60 Antibody Reagents from NIBSC and TGA. Consult with CBER)*

## Influenza B for Quadrivalent Formulations (2<sup>nd</sup> B-Strain)

- **Current Vaccine Strain (2015–16 Season): Victoria lineage – B/Brisbane/60/2008-like viruses**
  - B/Brisbane/60/2008 (used in vaccine)
  - Available Reagents :
    - B/Brisbane/60 (egg): **CBER**, *NIBSC & TGA*
    - B/Brisbane/60 (cell): **CBER**
  
- **WHO Recommended Second B Strain for 2016-17: B/Yamagata/16/88-lineage - B/Phuket/3073/2013-like virus**
  - Candidate Vaccine Viruses: B/California/12/2015; B/Phuket/3073/2013; B/Utah/09/2014 & B/Brisbane/9/2014
  - This strain was recommended as “B-Strain” for both trivalent and quadrivalent vaccines for 2015-16 NH season.
  - Has also been recommended for 2016 SH season.



## CBER Authorized Reagents for 2<sup>nd</sup> B-strain (Yamagata Lineage)

- **CBER Reference Antigen**
  - **For Egg Derived**
    - **Wt. B/Phuket/3073/2013 (Lot 80 )**
    - *Wt. B/Phuket/3073/2013 :NIBSC\* & TGA\**
    - *B/Brisbane/9/2014 : NIBSC\**
  - **For Cell Derived**
    - **Wild Type B/Utah/09/2014 : Lot B(y)-Ag-1501**
    - *Wild Type B/Utah/09/2014 : NIBSC\**
- **CBER Antiserum**
  - B(y)-Ab-1507
  - B(y)-Ab-1508
  - New Lots: B(y)-Ab-1605 & B(y)-Ab-1606

*\*(CBER approval of these reagents: case by case basis)*

## SRID Reagents: General Comments...1

- Only CBER authorized reagents should be used to test potency of vaccines marketed in the US (consult with CBER).
- CBER collaborates with other ERLs in calibration of reagents and can authorize the use of those reagents. Users have to obtain these reagents directly from the ERLs.
- To avoid discrepancies CBER recommends the use of reference antigen and reference antiserum from same source.

## SRID Reagents: General Comments...2

- Use of same reagents is desirable for Monovalent, Trivalent/Quadrivalent formulations (and follow-up stability studies).
- For new products - discuss with CBER about use of reagents (in early phase). Manufacturers and CBER can work together to ensure that required reagents are available to test new products.
- 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)**



# Thank You