Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Virus Infectious NYMC X-243
NIBSC code: 14/306
Instructions for use
(Version 3.0, Dated 18/03/2016)

1. INTENDED USE

Reagent 14/306 is prepared from NYMC X-243 which was processed for freeze drying in 250µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267. The known passage history of NYMC X-243 is attached

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

No unitage is assigned to this material

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains 250µl (nominal) of infectious influenza virus as allantoic fluid from SPF embryonated hen's eggs.

5. STORAGE

Store in the dark at -20^{0}C or below
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

Reconstitute the contents of one ampoule of reagent with 250µl of sterile distilled water. Leave for a minimum of 5 minutes before use to allow for complete solution of freeze-dried material. A range of dilutions (e.g. 10^{-3} to 10^{-5}) should be made in a suitable medium for initial cultivation.

8. STABILITY

Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

NA

10. ACKNOWLEDGEMENTS

NA

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties			
Physical appearance: white powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Live influenza virus		

Toxicological properties	
Effects of inhalation:	Likelihood of influenza virus infection
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin

Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.

Action on Spillage and Method of Disposal
Spillage of contents should be taken up with absorbent material wetted with an appropriate virucidal agent. Rinse area with an appropriate virucidal agent followed by water. Absorbent materials used to treat spillage should be treated as biologically hazardous waste.

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.
Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: NA
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

Passage history of NYMC X-243 (Post mixed infection)

Passage	Lot	Laboratory
E1-E10		NYMC, New York, USA
E11	E#6087	NYMC, New York, USA
E12		Francis Crick Institute, London, UK
E13	40180	NIBSC, Hertfordshire, UK

June 4, 2014

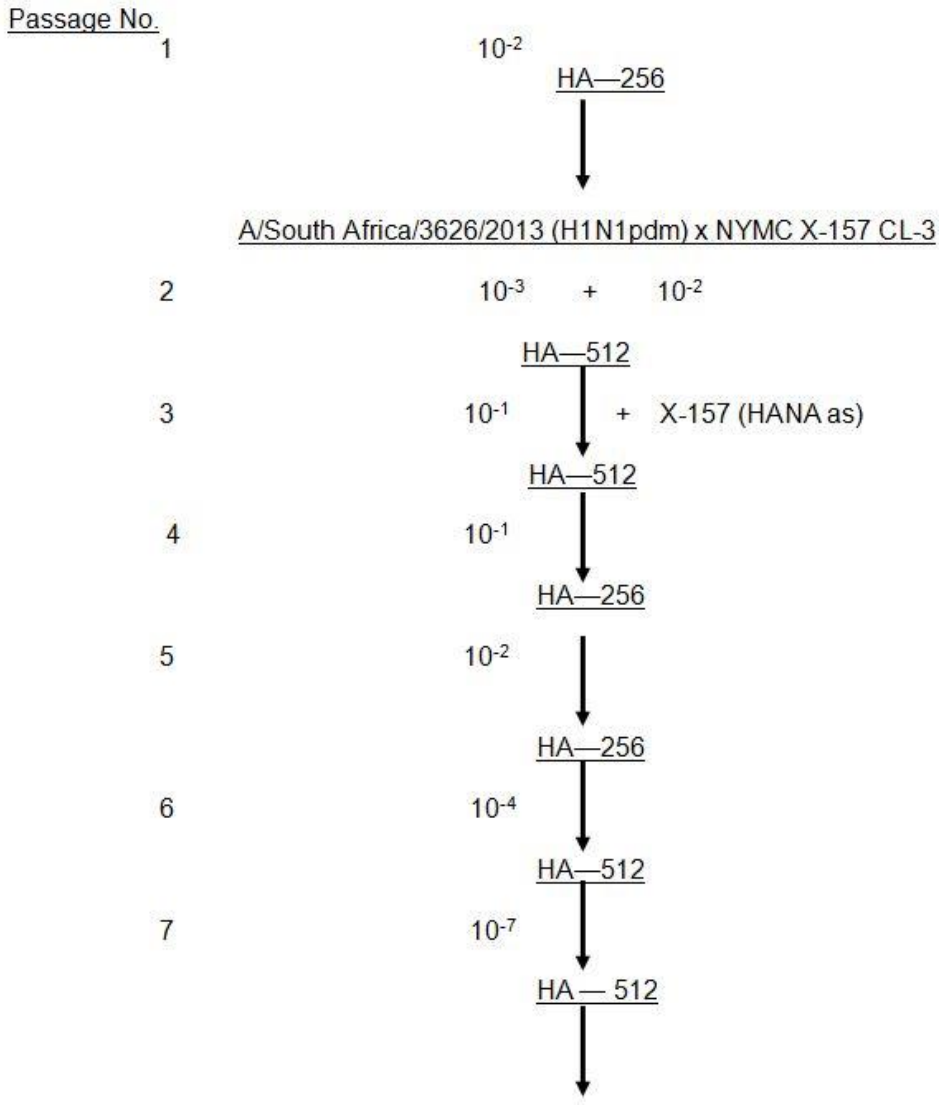
Derivation of NYMC X-243

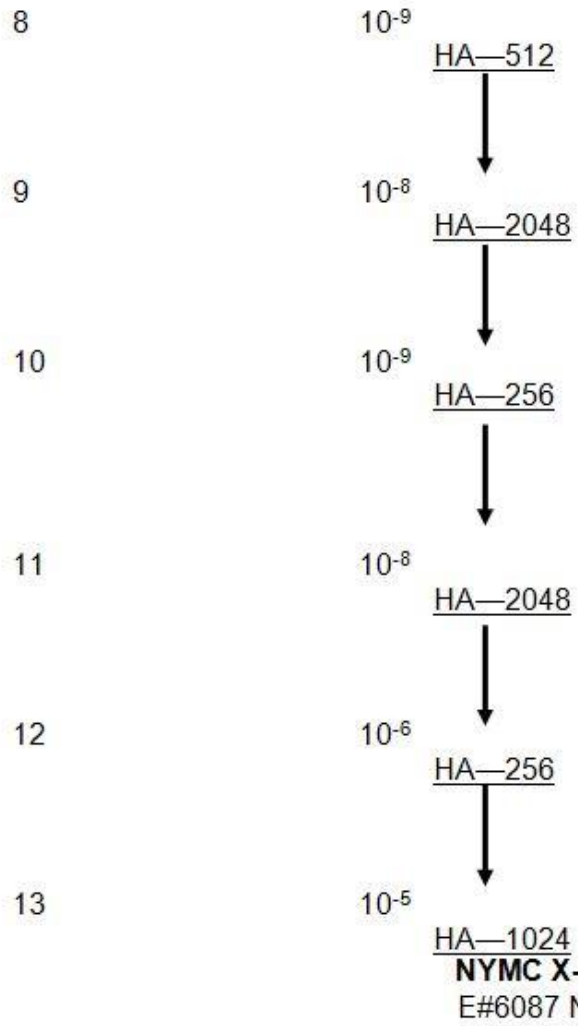
A/South Africa/3626/2013 (H1N1pdm) reassorted with NYMC X-157 CL-3, an H3N2 hyr (5:3) as hy donor

X-243 has A/PR/8/34 PB2, PA, NP, M and NS genes and wt South Africa PB1, HA and NA genes—5:3 H1N1pdm hyr

Exper. # 4737 (2/10/14)
A/South Africa/3626/2013
#132473
E1/E2
HA: 256 (tRBC)

Passages at New York Medical College





HA, NA, and PB1 genes were identified as A/South Africa/3626/2013 by RT-PCR/RFLP gene analysis. PB2, PA, NP, M and NS genes were identified as A/PR/8/34 by RT-PCR/RFLP analysis. Therefore, NYMC X-243 is a 5:3 reassortant.

SPF eggs were used for all reassortant passages.

All HA titers were tested using chicken red blood cells (cRBC) at room temperature.

Virus seed was shown to be sterile. Sterility testing was performed by streaking the sample on blood agar plates and incubating for 48 hours at 37 °C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

9/22/2015

Doris Bucher, Ph.D
Department of Microbiology and Immunology
New York Medical College
Basic Science Building
Valhalla, NY 10595

Dear Dr. Bucher,

We appreciate your submission of influenza reassortants to CDC for analysis. Data from your laboratory and other collaborating laboratories worldwide contribute significantly towards the influenza vaccine recommendations made each year by WHO.

Your reassortants were characterized by a "two-way" hemagglutination-inhibition test using post-infection ferret antisera.

The results we obtained with your reassortants are listed and interpreted below.

CDC ID#	Specimen ID#	Results
2014768824	A/SOUTH AFRICA/3626/2013 X-243	CONSISTENT WITH A/SOUTH AFRICA/3626/2013; TWO-WAY PASS

Your reassortant had an HI reactivity pattern that was consistent with its corresponding wild type virus and is A/California/07/2009-like. In addition, ferret antiserum raised against the A/South Africa/3626/2013 virus inhibited the majority of recently circulating viruses in the HI assay with HI titers equal to or within a four-fold difference to the homologous HI titer of the virus, therefore, this reassortant has passed the two-way test.

If you have any questions, please contact us.

Sincerely,

Dr. Xiyan Xu

Deputy Director
WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza
Influenza Division, CDC

Dr. Jacqueline Katz

Director
WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza
Influenza Division, CDC

HEMAGGLUTINATION INHIBITION REACTIONS OF INFLUENZA A(H1N1)pdm09 VIRUSES*

TWO-WAY TEST

DATE TESTED: 8/28/2015

	STRAIN DESIGNATION	REFERENCE FERRET ANTISERUM					
					X-243		DATE
	REFERENCE ANTIGENS	CA/7	CA/7	SA/3626	SA/3626	PASSAGE	COLLECTED
1	A/CALIFORNIA/07/2009	**1280**	2560	2560	2560	E3(3/31/14)	4/9/2009
2	A/CALIFORNIA/07/2009	1280	**2560**	2560	2560	C2(3/31/14)	4/9/2009
3	A/SOUTH AFRICA/3626/2013	1280	2560	**2560**	2560	E1E2/E3(3/13/15)	6/6/2013
	TEST ANTIGEN						
4	A/SOUTH AFRICA/3626/2013 X-243	2560	2560	2560	**2560**	EX	REASS

*A virus is considered consistent with the wild type if it reacted with ferret antisera raised to the reference strain giving an HI titer equal to or within two-fold of the HI titer of the wild type reference strain.

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