Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA REFERENCE ANTIGEN

INFLUENZA VIRUS HAEMAGGLUTININ – A/Croatia/10136RV/2023 (NYMC X-425A)

Lot: 2024/148B (DOM: OCT 2024)

1. Introduction

Influenza antigen reagent TGA Lot 2024/148B is prepared for single radial immunodiffusion assay (SRID) of A/Croatia/10136RV/2023 (NYMC X-425A) using an appropriate antiserum reagent.

2. Unitage

Assigned potency of Lot 2024/148B:

> **109 µg (microgram) of HA per mL**, after reconstitution of the lyophilized reagent in 0.5 mL of distilled water, or:
>
> **54.5 µg (microgram) of HA per vial**.

Lot 2024/148B was calibrated using sheep antiserum Lot AS460 raised against egg-derived A/Croatia/10136RV/2023-like haemagglutinin.

For further information please contact: influenza.reagents@health.gov.au

3. Contents

Country of origin of biological material: Australia

Lot 2024/148B was produced in embryonated eggs and the material inactivated with 0.1% v/v beta-propiolactone (βPL). The antigen was subjected to diafiltration prior to dilution with an equal volume of 6% w/v dextran (in 0.9% w/v sodium chloride). It was thoroughly mixed and dispensed for freeze-drying in 0.5 mL volumes as described by Campbell, PJ, Journal of Biological Standardization, 1974, 2, 249-267.

The mean of vials weights was 0.515 g with a coefficient of variation of 0.67%.

4. Caution

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.

The preparation does not contain material of human 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 probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

5. Use of material

For all practical purposes each vial contains the same quantity of the substance listed above. Reconstitute the total contents of one vial of reagent with 0.5 mL of distilled water. Allow to stand for a minimum of 5 minutes before use to allow for complete solubilisation of freeze-dried material. Lot 2024/148B should be used according to the method described by Wood, JM, Schild, GC, Newman, RW, and Seagroatt, VA, Journal of Biological Standardization, 1977, 5, 237-247, with the following modification.

It is recommended that Lot 2024/148B and test virus antigens be treated with Zwittergent 3-14 detergent (Calbiochem-Behring, La Jolla, CA, USA) before the SRID assay. Suitable incubation conditions are as follows: add 50 microlitres of 10% (w/v) Zwittergent 3-14 to 450 microlitres of antigen and incubate for 30 minutes at room temperature (20-25°C). Dilutions of Zwittergent 3-14 treated antigens are then added to wells in the SRID plates and incubated at 20-25°C.

Lot 2024/148B should be used to assay antigens using a suitable antiserum reagent.

No attempt should be made to weigh out any portion of the freeze-dried material. Unopened vials should be store at below −60°C but storage of reconstituted reagent is not recommended. To remove the reconstituted material from the vial, it is necessary to use some form of transfer pipette rather than a volumetric pipette. The contents of the vials should not be assumed to be sterile.

6. Stability

It is the policy of WHO not to assign an expiry date to their international reference materials which remain valid with the assigned potency and status until withdrawn or amended. TGA follows the policy of WHO with respect to its reference materials. Reference materials should be stored as indicated on the label. In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

7. Citation

In all publications (or data sheets for immunoassay kits) in which this preparation is used as an assay calibrant, it is important that the title of the preparation, vial code and the name and address of TGA are cited correctly.

8. Product liability

Information emanating from TGA is given after the exercise of all reasonable care and skill in its compilation, preparation and issue, but is provided without liability in its application and use.

This product is intended for use as a standard or reference material in laboratory work in relation to biological research, manufacturing or quality control testing of biological products or in the field of *in vitro* diagnostics. It is the responsibility of the user to ensure that they have the necessary technical skills to determine the appropriateness of this product for the proposed application. Results obtained from this product are likely to be dependent on conditions of use and the variability of materials beyond the control of TGA.

TGA accepts no liability whatsoever for any loss or damage arising from the use of this product, whether loss of profits, or indirect or consequential loss or otherwise, including, but not limited to, personal injury other than as caused by the negligence of TGA. In particular, TGA accepts no liability whatsoever for:

(i) results obtained from this product; and/or

(ii) non-delivery of goods or for damages in transit.

In the event of any replacement of goods following loss or damage a customer accepts as a condition of receipt of a replacement product, acceptance of the fact that the replacement is not to be construed as an admission of liability on TGA's behalf.

9. Material Safety Sheet

Physical properties (at room temperature)			
Physical appearance:	White powder		
Fire hazard:	None		
Chemical properties			
Stable:	Yes	Corrosive:	No
Hygroscopic:	No	Oxidising:	No
Flammable:	No	Irritant:	No
Other (specify):	Contains inactivated human influenza virus		
Handling:	See caution, section 4		
Toxicological properties			
Effects of inhalation:	No adverse effects have been reported		
Effects of ingestion:	No adverse effects have been reported		
Effects of skin absorption:	No adverse effects have been reported		
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 vial contents should be taken up with absorbent material wetted with a virucidal agent. Rinse area with a virucidal agent followed by water. Absorbent materials used to treat spillage should be treated as biologically hazardous waste.			

10. Further information

For further information regarding this product please email: influenza.reagents@health.gov.au

Version 2.0

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