



Australian Government

Department of Health
Therapeutic Goods Administration

TGA REFERENCE ANTIGEN (CELL PROPAGATED)

INFLUENZA VIRUS HAEMAGGLUTININ A/Singapore/GP1908/2015 (IVR-180)

Lot: 2017/119B (DOM: November 2017)

1. Introduction

Influenza antigen reagent TGA Lot 2017/119B is prepared for single radial immunodiffusion assay (SRID) of A/Singapore/GP1908/2015 (IVR-180) (A/Michigan/45/2015 H1N1 pdm09-like virus) cell propagated haemagglutinin (HA) using an appropriate antiserum reagent; it should only be used for the estimation of HA content of cell-propagated antigens.

2. Unitage

Assigned potency of Lot: 2017/119B:

70 µg (microgram) of HA per mL, after reconstitution of the lyophilized reagent in 0.5 mL of distilled water, or:

35 µg (microgram) of HA per vial.

Lot: 2017/119B was calibrated using sheep antiserum Lot: AS418 raised against egg derived A/Singapore/GP1908/2015 (IVR-180). The calibration of this reagent involved the use of a primary liquid standard (PLS), the HA content of which, was estimated by Isotope Dilution Mass-Spectroscopy (IDMS).

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

3. Contents

Country of origin of biological material: USA

Lot: 2017/119B was produced in cultured MDCK cells. The material has been inactivated by 0.05% v/v beta-propiolactone (βPL). The cell propagated antigen was purified by diafiltration prior to dilution with an equal volume of 6% w/v dextran in 0.9% w/v sodium chloride, which after thorough mixing was dispensed for freeze-drying in 0.5 mL volumes as described by Campbell, P.J.; Journal of Biological Standardisation, 1974, 2, 249-267.

The mean of vials weights was 0.521 g with a coefficient of variation of 1.18 %.

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 substances 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 solution of freeze-dried material. Lot: 2017/119B should be used according to the method described by Wood, JM, Schild, GC, Newman, RW, and Seagroatt, VA, Journal of Biological Standardisation, 1977, 5, 237-247, with the following modification:

It is recommended that Lot: 2017/119B and test virus antigens should be treated with Zwittergent 3-14 detergent (Calbiochem-Behring, La Jolla, CA, USA) before single-radial-immunodiffusion assay. Suitable incubation conditions are as follows: 450 microlitres of antigen are added to 50 microlitres of 10% (w/v) Zwittergent detergent and incubated in covered containers for 30 minutes at room temperature (20-25°C). Dilutions of detergent treated antigens are then added to wells in single-radial-immunodiffusion plates and incubated at 20-25°C. Lot: 2017/119B should only be used to assay cell propagated antigens using an appropriate antiserum reagent.

No attempt should be made to weigh out any portion of the freeze-dried material. Unopened vials should be stored 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, lot 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.

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- (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: | <i>White powder</i> | | | | | |
| Fire hazard: | <i>None</i> | | | | | |
| Chemical properties | | | | | | |
| Stable: | <i>Yes</i> | Corrosive: | <i>No</i> | | | |
| Hygroscopic: | <i>No</i> | Oxidising: | <i>No</i> | | | |
| Flammable: | <i>No</i> | Irritant: | <i>No</i> | | | |
| Other (specify): | <i>Contains inactivated human influenza virus</i> | | | | | |
| Handling: | <i>See caution, section 4</i> | | | | | |
| Toxicological properties | | | | | | |
| Effects of inhalation: | <i>No adverse effects have been reported</i> | | | | | |
| Effects of ingestion: | <i>No adverse effects have been reported</i> | | | | | |
| Effects of skin absorption: | <i>No adverse effects have been reported</i> | | | | | |
| Suggested First Aid | | | | | | |
| Inhalation: | <i>Seek medical advice</i> | | | | | |
| Ingestion: | <i>Seek medical advice</i> | | | | | |
| Contact with eyes: | <i>Wash with copious amounts of water. Seek medical advice</i> | | | | | |
| Contact with skin: | <i>Wash thoroughly with water.</i> | | | | | |
| Action on Spillage and Method of Disposal | | | | | | |
| <p><i>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.</i></p> <p><i>Absorbent materials used to treat spillage should be treated as biologically hazardous waste.</i></p> | | | | | | |

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