Australian Government

Department of Health

Therapeutic Goods Administration

ANTISERUM REAGENT FOR SINGLE-RADIAL-DIFFUSION ASSAY OF H5N1 A/Egypt/N03072/2010 (IDCDC-RG29) INFLUENZA VIRUS HAEMAGGLUTININ TGA Lot: AS414 (DOM: August 2016)

1. Introduction

Influenza antiserum reagent TGA Lot AS414 is prepared for single radial immunodiffusion (SRID) assay of A/Egypt/N03072/2010 (IDCDC-RG29) TGA antigen.

2. Unitage

No unitage is assigned to this material.

3. Contents

Country of origin of biological material: Australia

Animal Species: Domestic sheep (*Ovis aires*)

Donor Sheep Breed: Australian Merino Cross

The sheep originated, were continuously reared and slaughtered in Australia

The purified HA used to immunise sheep was derived from a beta-propiolactione (βPL) inactivated virus pool. The HA was purified using a protease treatment step prior to further downstream purification. This antiserum was prepared in sheep to the purified HA of A/Egypt/N03072/2010 (IDCDC-RG29) virus. All sheep used in the production of antisera were inspected by a veterinary surgeon prior to terminal bleed confirming their disease free status. The antiserum contains 0.1% sodium azide as preservative.

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 testing antigens containing approximately 20-30 µg HA per mL, approximately:

> **3 µL** of the undiluted antiserum should be added to 1 mL of agarose for the SRID assay of **A/Egypt/N03072/2010 (IDCDC-RG29) TGA antigen (Lot 2016/110B)**.

However, it may be necessary to change the antiserum concentration according to local laboratory conditions.

Antiserum reagent AS414 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.

6. Stability

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

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

Storage: Antiserum should be stored at or below -20°C.

Note: This material is shipped on dry ice.
The temperature range for shipping is -80 to -70°C.

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 he/she has 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:	*Frozen Liquid*		
Fire hazard:	*None*		
Chemical properties			
Stable:	*Yes*	Corrosive:	*No*
Hygroscopic:	*No*	Oxidising:	*No*
Flammable:	*No*	Irritant:	*No*
Other (specify):	*Contains sheep serum and sodium azide (0.1 %w/v)*		
Handling:	*See caution, section 4*		
Toxicological properties			
Effects of inhalation:	*Toxic*		
Effects of ingestion:	*Toxic*		
Effects of skin absorption:	*Toxic*		
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

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