



Australian Government
Department of Health
Therapeutic Goods Administration

ANTISERUM REAGENT – B/Phuket/3073/2013-like
FOR SINGLE RADIAL IMMUNODIFFUSION (SRID) ASSAY OF INFLUENZA VIRUS
HAEMAGGLUTININ

TGA Lot: AS434 (DOM: September 2019)

1. Introduction

Influenza antiserum reagent TGA Lot AS434 is prepared for Single Radial Immunodiffusion (SRID) assay of B/Phuket/3073/2013 (B/Phuket/3073/2013-like) antigens.

2. Unitage

No unitage is assigned to this material.

3. Contents

Country of origin of biological material: Australia

Animal Species: Domestic sheep (*Ovis aries*)

Donor Sheep Breed: Australian Merino Cross

The sheep originated, were continuously reared and slaughtered in Australia.

The purified haemagglutinin (HA) used to immunise sheep was derived from a beta-propiolactone (β PL) inactivated pool of B/Phuket/3073/2013 (BVR-1B) virus. The HA was purified using a protease treatment step prior to further downstream purification. All sheep used in the production of antisera were inspected by a veterinary surgeon prior to terminal bleed to confirm 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 SRID testing of influenza virus antigens; this antiserum is suitable for the testing of B/Phuket/3073/2013-like antigens. For antigen preparation containing approximately 20-30 µg HA per mL of B/Phuket/3073/2013 antigen, add 4.5 µL of the undiluted antiserum to 1 mL of agarose. It may be necessary to change the antiserum concentration according to local laboratory conditions.

Antiserum reagent AS434 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. TGA follows the policy of WHO with respect to its reference materials and 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.

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.

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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. Safety Data Sheet (SDS) OR Material Safety Sheet

Please refer to the hardcopy of the SDS supplied with the product.

10. Further information

For further information regarding this product please email:

influenza.reagents@health.gov.au.

Version 1.0

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