



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

ANTISERUM REAGENT – A/Darwin/1454/2025-like
For Single Radial Immunodiffusion Assay of
Influenza Virus Haemagglutinin
Lot: AS469 (DOM: Mar 2026)

1. Introduction

Influenza antiserum reagent TGA Lot AS469 is prepared for single radial immunodiffusion (SRID) assay of A/Darwin/1454/2025-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 were slaughtered in Australia.

The purified haemagglutinin (HA) used to immunise the sheep was derived from a formalin inactivated pool of A/Darwin/1499/2025 (IVR-284). The HA was purified with a protease treatment step prior to immunisation. 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 was diluted 1:1 with phosphate-buffered saline (PBS) and contains 0.05% sodium azide as a 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

This antiserum is suitable for SRID testing of A/Darwin/1454/2025-like antigens. For antigens containing approximately 30 µg HA per mL, add 2.0 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 AS469 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.

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policy of WHO with respect to its reference materials and they remain valid with the assigned potency and status until withdrawn or amended.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 below -20°C 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.

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. Safety Data Sheet

Please refer to the hardcopy of the safety data sheet (SDS) supplied with the product.

10. Further information

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

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