



**CE Marked Material
HLA Class II Positive Control
NIBSC code: 08/148
Instructions for use
(Version 5.0, Dated 10/11/2017)**

This material is a self certified IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC".

1. INTENDED USE

This product is CE marked for use as an IVD within the UK, EU member states and EEA countries. In all other territories this product can be used for research purposes only.

This product should be used as an HLA Class II positive control material and should not be diluted.

Transfusion Related Acute Lung Injury (TRALI) was first described by Popovsky and Moore in 1985 and is now recognised as the most frequent cause of mortality and morbidity following blood transfusion both by the Serious Hazards of Transfusion (SHOT) haemovigilance scheme in the UK, (SHOT reports 2003, 2007 and 2008) and the Food and Drug Administration (FDA) in the USA (FDA 2009).

It occurs as a result of an immunological reaction between the recipient and the transfused donation(s). Antibodies in donor plasma against the recipient's white cells and/or endothelial cells lead to the trapping of leucocytes in the small blood vessels of the lung, damage to the pulmonary endothelium resulting in the leak of fluid and inflammatory cells into the lungs. The antibodies are typically directed against Human Leucocyte Antigen (HLA) class I, HLA class II or Human Neutrophil Antigens (HNA) expressed by the recipient.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

Each unit used for the production of this standard was individually tested and found to be negative for the presence of HBsAg and antibody to HCV and HIV 1 and 2. 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 should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts. The plasma was filtered through 0.2µm filters and stored under sterile conditions before filling into vials (1.0 ml/vial) and freeze-drying.

3. UNITAGE

No unitage assigned. This is a weak positive control for anti-HLA Class II relative to the negative control 10/142.

4. CONTENTS

Country of origin of biological material: United Kingdom. Freeze-dried residue of approximately 1.0ml of pooled human plasma.

5. STORAGE

Prior to reconstitution, this material has an expiry date of 2028-06. Accelerated degradation studies have indicated that this material is suitably stable when stored at 2-8°C prior to reconstitution. Reference materials should be stored on receipt as indicated on the label. Once reconstituted, users should determine the stability of the material according to their own method of preparation, storage and use. It is recommended this material be used on the day of reconstitution.

6. DIRECTIONS FOR OPENING

Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

To reconstitute this material, dissolve the entire contents of the ampoule in 1.0ml of sterile distilled water, keep at 2-8°C and use on the day of reconstitution. Once reconstituted, this material should be treated as an anti-HLA Class II positive human plasma. It is recommended that this standard is used alongside the negative human plasma standard 10/142 (Anti-HLA Control). For HLA serology multiplex assays, follow manufacturer's instructions. Users should be aware that by changing

assay conditions or reagents e.g. incubation times, results may vary. It is therefore important that each user validates this control using their own methods and reagents. It is recommended that aliquots should not be re-frozen after use.

The Preparation and Biological Activity please refer to page 2.

8. STABILITY

The expiry date is stated on the vial label. The stability of this preparation is monitored by NIBSC. Users who have data supporting any deterioration in the characteristics of this preparation are encouraged to contact NIBSC. Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

9. REFERENCES

Popovsky MA, Moore SB. Diagnostic and pathogenetic considerations in transfusion-related acute lung injury. *Transfusion* 1985; 25(6) :573-7.

Serious Hazards of Transfusion. Annual report 2003. Serious Hazards of Transfusion scheme, Manchester, UK, 2004 (www.shotuk.org).

Serious Hazards of Transfusion. Annual report 2007. Serious Hazards of Transfusion scheme, Manchester, UK, 2008 (www.shotuk.org).

Serious Hazards of Transfusion. Annual report 2008. Serious Hazards of Transfusion scheme, Manchester, UK, 2009 (www.shotuk.org).

Food and Drug Administration. Fatalities reported to FDA following blood collection and transfusion. Annual summary for the fiscal years 2005 and 2006.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/UCM129521.pdf> accessed 25/10/09.

10. ACKNOWLEDGEMENTS

11. FURTHER INFORMATION

Further information can be obtained as follows;

This material: enquiries@nibsc.org

WHO Biological Standards:

<http://www.who.int/biologicals/en/>

JCTLM Higher order reference materials:



<http://www.bipm.org/en/committees/jc/jctlm/>
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
<http://www.nibsc.org/products/ordering.aspx>
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Physical and Chemical properties	
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified Physical appearance: Freeze-dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of human origin
Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
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 ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.	

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 1.0g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable.
Attached: No

THE PREPARATION

The standard was prepared from a pool of 38 human AB+ plasma donations.

