



**CE Marked Material  
Anti-HLA Control  
NIBSC code: 10/280  
Instructions for use  
(Version 4.0, 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 standard is intended for use as a negative control for flow cytometry cross matching (FCXM) and Luminex based assays for anti-HLA antibodies. Prior to organ transplantation, flow cytometry cross-matching is performed to detect anti-HLA antibodies that may be detrimental to the performance of the organ. Findings from multicentre studies have shown not only the importance of the selection and standardization of the methods used for cross-matching, but also that the selection of the control sera is fundamental to the cross-match, as they are the negative controls on which the definition of positivity is based (Harmer et al 1996; Shenton et al 1997). Transplants known to have taken place after a positive FCXM result may have impaired survival (Scornik et al 2001).

**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 negative for the mandatory microbiological tests HBsAg, HBV NAT, HCV NAT, anti-HCV, anti-HTLV, anti-HIV 1 and 2 and HIV p24 antigen and syphilis antibodies. 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.

**3. UNITAGE**

No unitage assigned. This is an anti-HLA negative control.

**4. CONTENTS**

Country of origin of biological material: United Kingdom. Freeze-dried residue of approximately 0.5ml of pooled normal human AB+ serum.

**5. STORAGE**

Prior to reconstitution, this material has an expiry date of 2021/03. 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 screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

**7. USE OF MATERIAL**

To reconstitute this material, dissolve the entire contents of the ampoule in 0.5ml of sterile distilled water, keep at 2-8°C and use on the day of reconstitution. Once reconstituted, this material should be treated as normal human AB+ serum for use as a negative control for flow cytometry cross matching (FCXM). Different instruments and different assays may

yield varying results, therefore it is important that each user validates this control using their own platform(s). It is not intended for use in calibration of individual laboratory standards. No attempt should be made to weigh out a portion of the freeze-dried material, nor should aliquots be re-frozen after use. It is recommended that this standard be used in combination with 07/214 Positive Control for FCXM (minimum potency positive control standard). Users should be aware that by changing assay conditions or reagents e.g. incubation times or secondary antibodies, assay results may vary. It is therefore important that each user validates this control using their own methods and reagents.

**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**

1. Harmer, A.W., Garner, S., Bell, A.E. et al (1996). Evaluation of the flow cytometric crossmatch. Preliminary results of a multicentre study. Transplantation 61, 1108-1111.
2. Shenton, B.K., Bell, A.E., Harmer, A.W. et al (1997). Importance of methodology in the flow cytometric crossmatch: a multicentre study. Transplantation Proceedings 29, 1454-1455.
3. Scornik, J.C., Clapp, W., Patton, P.R. et al (2001). Outcome of kidney transplants in patients known to be flow cytometry crossmatch positive. Transplantation 71, 1098-1102.

**10. ACKNOWLEDGEMENTS**

**11. FURTHER INFORMATION**

Further information can be obtained as follows:  
This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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 | Corrosive: No |
| Physical appearance: Freeze-dried powder   |               |





|   |   |            |                        |
|---|---|------------|------------------------|
| Stable:   | Yes   | Oxidising: | No                     |
| Hygroscopic:  | Yes   | Irritant:  | No                     |
| Flammable:  | No  | Handling:  | See caution, Section 2 |
| Other (specify):  | Contains material of human origin                       |            |                        |
| <b>Toxicological properties</b>   |   |            |                        |
| Effects of inhalation:  | Not established, avoid inhalation                       |            |                        |
| Effects of ingestion:   | Not established, avoid ingestion                        |            |                        |
| Effects of skin absorption:   | Not established, avoid contact with skin                |            |                        |
| <b>Suggested First Aid</b>  |   |            |                        |
| 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.                             |            |                        |
| <b>Action on Spillage and Method of Disposal</b>  |   |            |                        |
| 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](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**

|   |
|---|
| <b>Country of origin for customs purposes*:</b> 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. |
| <b>Net weight:</b> 0.5g   |
| <b>Toxicity Statement:</b> Non-toxic  |
| <b>Veterinary certificate or other statement</b> if applicable.   |
| <b>Attached:</b> No   |

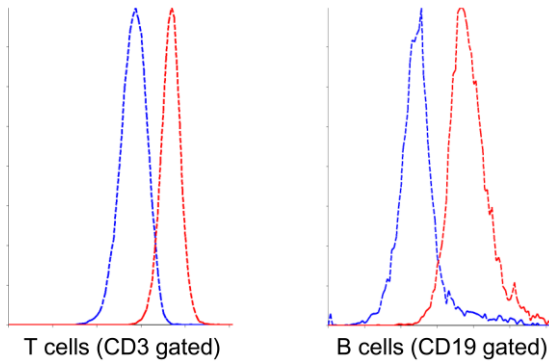
**THE PREPARATION**

The standard was prepared from a pool of 18 human AB<sup>+</sup> serum donations. Prior to pooling, each donation was filtered through 0.2µm filters, confirmed negative for anti-HLA antibodies and stored under sterile conditions before distribution into vials (0.5ml/vial) and lyophilized.

**BIOLOGICAL ACTIVITY**

Donor lymphocytes incubated with Anti-HLA Control 10/280 and minimum potency Positive Control 07/214

- 10/280 - Anti-HLA Control (Negative control sera)
- - - 07/214 - Positive Control for FCXM (Minimum potency control)



**Incorrect label**



**Correct label**



**PLEASE NOTE:** 10/280 vial labels may show incorrect symbol positions as highlighted above.

