INTENDED USE

This product is CE marked for use as an IVD within the 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 2-8ºC 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 2-8ºC 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


10. ACKNOWLEDGEMENTS

11. FURTHER INFORMATION

Further information can be obtained as follows;

WHO Biological Standards:
http://www.who.int/biologicals/en/

JCTLM Higher order reference materials:

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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification in accordance with Directive 2000/54/EC.</td>
</tr>
<tr>
<td>Regulation (EC) No 1272/2008: Not applicable or not classified</td>
</tr>
</tbody>
</table>

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.

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**THE PREPARATION**

The standard was prepared from a pool of 18 human AB⁺ 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)

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**Incorrect label**

![Incorrect label image]

**Correct label**

![Correct label image]

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