To reconstitute this material, dissolve the entire contents of the ampoule in 1ml 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+ plasma 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;
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 and the expiry date are referenced, it is important that the preparation’s title, its status, the NIBSC code and the expiry date are included. For this product, the title is CE Marked Material Negative Control For FCXM NIBSC code: 09/112

(Version 11.0, Dated 10/11/2017)
14. MATERIAL SAFETY SHEET

**Physical and Chemical properties**

<table>
<thead>
<tr>
<th>Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008:</th>
<th>Not applicable or not classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freeze-dried powder</td>
<td>Corrosive: No</td>
</tr>
</tbody>
</table>

**Stable:** Yes  
**Hygroscopic:** Yes  
**Flammable:** No  
**Oxidising:** No  
**Irritant:** 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. |

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**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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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

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**THE PREPARATION**

The standard was prepared from a pool of 38 donations of AB+ plasma. Prior to pooling, each donation was confirmed negative for anti-HLA antibodies. The plasma pool was filtered through 0.2μm filters and stored under sterile conditions before distribution into vials (1.0 ml/vial) and lyophilized.

**BIOLOGICAL ACTIVITY**

Donor lymphocytes incubated with FCMX Negative Control standard 09/112 and minimum potency Positive Control standard 07/214.

**- - - - - - -**  
**09/112 (Negative)**  
**07/214 (Minimum potency positive control)**

Lymphocyte gate  
T cells (CD3 gate)  
B cells (CD19 gate)