Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

**Non WHO Reference Material**
**Human Anti GM-CSF Plasma**
**NIBSC code: 97/538**
**Instructions for use**
**(Version 5.0, Dated 01/02/2008)**

**This material is not for in vitro diagnostic use.**

## 1. INTENDED USE

This material is intended for use as an internal control in assays for detection of neutralizing antibodies to human GM-CSF in serum/plasma.

## 2. CAUTION

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

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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

The following information is provided as a guide, based on bioassays performed at NIBSC. After reconstitution, a 1/50 dilution of the vial contents completely neutralised at least 5 IU/ml of the International Standard for GM-CSF (88/646) in a bioassay using the TF-1 cell line.

## 4. CONTENTS

Country of origin of biological material: United Kingdom.
The Plasma in this vial was obtained from a patient with Myasthenia Gravis like symptoms.Each vial contains the residue after freeze drying of 0.5 ml of human plasma diluted 1 in 4 with phosphate buffered saline, pH 7.0.

## 5. STORAGE

Dilutions should be made in a protein-containing medium. Vials should be stored at -20ºC and when reconstituted in aliquots at -40ºC or below. The vials do not contain bacteriostat and solutions of the preparation should not be assumed to be sterile.
**Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.**

## 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
Reconstitute the vial with 0.5 ml of sterile distilled water. After reconstitution, the solution should be treated as a 1 in 4 dilution of whole plasma.

## 8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials.

## 9. REFERENCES

1. Meager A, Wadhwa M, Bird C, Dilger P, Thorpe R, Newsom-Davis J, Willcox N (1999). Spontaneously occurring neutralizing antibodies against granulocyte-macrophage colony-stimulating factor in patients with autoimmune disease. Immunology, 97,526-532.

2. Wadhwa M, Bird C Fagerberg J, Gaines-Das R, Ragnhammar P, Mellstedt H, Thorpe R. (1996).Production of neutralizing granulocyte-macrophage colony-stimulating factor (GM-CSF) antibodies in carcinoma patients following GM-CSF combination therapy, Clin Exp Immunol, 104, 351-8.

## 10. ACKNOWLEDGEMENTS

N/A

## 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

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

| **Physical and Chemical properties** | |
|---|---|
| Physical appearance: Lyophilised powder | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic:No | Irritant: No |
| Flammable:No | Handling: See caution, Section 2 |
| Other (specify): | Contains material of human origin |
| **Toxicological properties** | |
| Effects of inhalation: | No adverse effects reported for this material |
| Effects of ingestion: No adverse effects reported for this material | |

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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| Effects of skin absorption: No adverse effects reported for this material |
| **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.<br>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**

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|---|
| **Country of origin for customs purposes*:** United Kingdom<br>* 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:** 4.6g |
| **Toxicity Statement:** Toxicity not assessed |
| **Veterinary certificate or other statement** if applicable**.**<br>**Attached:** No |