



**WHO International Standard
Immunoglobulin E (IgE), human serum
NIBSC code: 11/234
Instructions for use
(Version 1.0, Dated 31/10/2013)**

1. INTENDED USE

The measurement of serum IgE aids in the diagnosis and management of atopic allergic disease and hyper-IgE immunodeficiency syndromes. The 3rd International Standard for human serum IgE, 11/234, is intended to standardise assays for serum IgE. It replaces preparation 75/502. Its unitage was assigned relative to 75/502 following an international collaborative study.

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

6,750 IU/ampoule (13,500 IU/mL following reconstitution)

4. CONTENTS

Country of origin of biological material: United Kingdom.
Serum was prepared by UK NEQAS for Immunology from blood samples collected from consenting donors with raised levels of serum IgE according to local ethical practice. Frozen plasma samples were also kindly donated by Phadia AB, Sweden, and defibrinated at NIBSC. The sera and defibrinated plasma were pooled, dispensed in glass ampoules (~0.5 mL/ampoule), and lyophilised.

5. STORAGE

Store unopened ampoules at -20°C or below. Users should validate their own conditions of storage of reconstituted 11/234.

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufacturers instructions provided with the ampoule breaker.

7. USE OF MATERIAL

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

Reconstitute the entire contents of the ampoule with 0.5 mL distilled or deionised water. Allow several minutes for complete dissolution, mix gently.

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. Accelerated degradation studies have shown that lyophilised 11/234 will be sufficiently stable to allow long-term storage at -20°C or below,

and shipment at ambient temperature. Once reconstituted, users should validate their own conditions of storage.

NIBSC follows the policy of WHO with respect to its reference materials. It is not the policy of WHO to assign expiry dates to their reference materials.

9. REFERENCES

N/A

10. ACKNOWLEDGEMENTS

We are very grateful to Phadia AB, Sweden, and UK NEQAS for Immunology for providing bulk materials, and the participants of the collaborative study.

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: Lyophilisate | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: No | Irritant: Unknown |
| Flammable: No | Handling: See caution, Section 2 |
| Other (specify): | Contains human serum |
| 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: 0.04g

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.