



**WHO International Standard**  
**Serum Amyloid A (Second WHO International Standard)**  
**NIBSC code: 23/148**  
**Instructions for use**  
**(Version 1.0, Dated 06/11/2024)**

This material is not for in vitro diagnostic use

**1. INTENDED USE**

The WHO International Standard for Serum Amyloid A is intended for the calibration of immunoassays measuring human Serum Amyloid A (SAA). This preparation, coded 23/148, was established as the Second WHO International Standard for SAA by the Expert Committee for Biological Standardisation of the WHO in October 2024. It replaces the First WHO International Standard, coded 92/680.

Users of this standard are advised to read the accompanying WHO ECBS report (see Section 9: References) prior to use. In this report, conclusions regarding the commutability of this preparation with patient samples are limited by a lack of individual patient samples. Therefore, it is advised that users perform their own assessment of the commutability of this preparation with patient samples in their chosen assay.

**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**

Each ampoule of 23/148 contains 56 µg SAA per ampoule. This value has 95% confidence intervals of 52-60 µg.

**4. CONTENTS**

Country of origin of biological material: United Kingdom.  
Each ampoule of 23/148 contains the residue after freeze-drying 0.5 mL of pooled human serum

**5. STORAGE**

Unopened ampoules should be stored at -20°C.  
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 manufactures 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**

Dissolve the total contents of the ampoule in a known volume of water or a suitable assay diluent. The ampoules do not contain bacteriostat and solutions of the reagent should not be assumed to be sterile.

**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**

2<sup>nd</sup> WHO International Standard for human Serum Amyloid A. B Cowper, M Moore, E Atkinson, P Rigsby, Sir MB Pepys, GA Tennent & C Burns. WHO/BS/2024.2478

**10. ACKNOWLEDGEMENTS**

We gratefully acknowledge the important contributions of all the participants in the collaborative study, the UCL Centre for Amyloidosis who donated the bulk material, and MHRA colleagues for preparation and dispatch of the ampouled materials

**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**

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

Physical and Chemical properties	
Physical appearance: freeze-dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): N/A	



<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> 0.5 g
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> 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 ([https://www.who.int/publications/m/item/annex2-trs932\(revised2004\)](https://www.who.int/publications/m/item/annex2-trs932(revised2004))). 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.