



WHO International Standard
1st International Standard for Anti Thyroid Peroxidase Antibodies
NIBSC code: 19/260
Instructions for use
(Version 1.0, Dated 11/11/2021)

1. INTENDED USE

The 1st International Standard for anti-thyroid peroxidase antibodies, coded 19/260, is intended for use in the calibration of immunoassays for anti-thyroid peroxidase. It replaces the NIBSC Reference Reagent (NRR), coded 66/387, for anti-thyroid microsome serum, which was produced in the 1960's as a research reagent for anti-thyroid microsome activity. This activity has since been determined to be autoimmunity to the thyroid peroxidase (TPO) enzyme. The material coded 19/260 was established as the 1st International Standard for anti-thyroid peroxidase antibodies by the Expert Committee on Biological Standardisation of the World Health Organisation at their 74th meeting held 18-22 October 2021.

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 the International Standard contains 555 IU of anti-thyroid peroxidase antibodies.

4. CONTENTS

Country of origin of biological material: Germany.

Each ampoule contains the residue after freeze-drying of 1 mL of a solution that contained:

Human plasma, defibrinated
HEPES, 40 mM

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

For practical purposes each ampoule contains the same quantity of the substances listed above. The entire content of each ampoule should be dissolved completely in an accurately measured volume of a suitable diluent. Users should make their own investigations into the type of diluent suitable, dependent on their use. The use of water to reconstitute ampoule

contents is not recommended. If extensive dilutions are prepared, a carrier protein should be added. The material has not been sterilised and the ampoules do not contain bacteriostat.

COLLABORATIVE STUDY

A batch of human serum containing high anti-TPO antibodies was produced by pooling defibrinated plasma from three donors, purchased from TCS Biosciences Ltd (Buckingham, UK) to produce a total volume of 1909 mL. This serum was buffered with 40 mM HEPES and aliquots of 1.0 mL were then dispensed into glass ampoules, lyophilised and sealed according to procedures recommended by WHO and stored at -20°C in the dark at NIBSC, Potters Bar, UK.

This batch of ampoules, coded 19/260, was evaluated in a collaborative study to value assign the standard in International Units, by immunoassay, in terms of the NRR 66/387, and to assess its suitability to serve as an International Standard. The results of the study yielded an assigned content for 19/260 of 555 IU/ampoule. Reference details of the study are provided in Section 9.

It should be noted that due to the inherent nature of autoantibodies, the replacement standard will not consist of identical autoantibody populations and it is therefore not a direct replacement of the material from which 66/387 was produced. Users are recommended to perform their own assessments to determine the impact of this new material in their own assays.

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.

Data from an accelerated thermal degradation study performed as part of the collaborative study found that 19/260 is likely to be highly stable under long term storage conditions at -20°C, indicating that the standard is sufficiently stable to serve as an International Standard.

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Moore, M., Hockley, J. and Burns, C. (2021) Proposed 1st WHO International Standard for anti-Thyroid Peroxidase Antibodies. WHO/BS/2021.2404. Expert Committee on Biological Standardization, 18-22 October 2021 (Expert Committee on Biological Standardization (who.int)).

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the important contributions of all the participants to 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: Yellowish 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, see caution, section 2
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: 78 mg
Toxicity Statement: Non-toxic
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_biol_efstandardsrev2004.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.