Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
Ferritin (Human, Recombinant)
NIBSC code: 19/118
Instructions for use
(Version 3.0, Dated 25/01/2022)

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1. INTENDED USE

Preparation 19/118, the 4th International Standard for ferritin, is for use in immunoassays for human serum ferritin.

The recombinant ferritin preparation, 19/118, was evaluated by 12 laboratories in 9 countries for its suitability as an International Standard (IS) (1). The preparation was assayed in a wide range of commercial immunoassays against the 3rd IS for ferritin (94/572) (2). The recombinant ferritin was immunologically similar to the 3rd IS in the majority of assays, and demonstrated adequate stability in accelerated degradation studies. On the basis of these results, and with the overall agreement of the participants of the collaborative study, the World Health Organization (WHO) Expert Committee on Biological Standardization established 19/118 as the 4th IS for ferritin, recombinant, with an ASSIGNED CONTENT OF 10.5 MICROGRAMS/AMPOULE.

Uncertainty: the expanded uncertainty limits are 10.2-10.8 µg/ampoule (95% confidence; k=2.23).

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.

3. UNITAGE

Each ampoule contains 10.5 micrograms ferritin

4. CONTENTS

Country of origin of biological material: United Kingdom.
Recombinant human ferritin was expressed in an E Coli strain transformed with the plasmid pET-21a which encodes the full human ferritin L-chain amino acid sequence. Details of its purification and characterization are described in reference 1.

The recombinant ferritin was diluted in human AB serum (pooled from individual donations which had been tested and found negative for HBsAg, anti-HIV and anti-HCV;before distribution into ampoules and lyophilization.

5. STORAGE

Store unopened ampoules at or below -20ºC.
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.

Reconstitute the contents of each ampoule with 1.0 ml distilled water. Store at 4ºC (short term only since the preparation does not contain sodium azide).

THE FERRITIN CONCENTRATION OF THE RECONSTITUTED MATERIAL IS 10.5 MICROGRAMS/ML.

8. STABILITY

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. Accelerated degradation studies have indicated that this standard is suitably stable, when stored at -20ºC or below, for the assigned values to remain valid until the standard is withdrawn or replaced. These studies have also shown that the standard is suitably stable for shipment at ambient temperature without any effect on the assigned values.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. For information specific to a particular biological standard, contact the Technical Information Officer or, where known, the appropriate NIBSC scientist.

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

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

1. Fox Bernard, Roberts Graham, Atkinson Eleanor, Rigsby Peter and Ball Christina. "International collaborative study to evaluate and calibrate two recombinant L chain Ferritin preparations for use as a WHO International Standard" Clinical Chemistry and Laboratory Medicine (CCLM) , no. (2021). https://doi.org/10.1515/cclm-2021-1139.
2. S J Thorpe, D Walker, P Arosio, A Heath, J Cook and M Worwood. Clin Chem (1997) 43:1582-1587

10. ACKNOWLEDGEMENTS

We thank the participants of the collaborative study to assign unitage.

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

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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:	No
Flammable:	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.

Action on Spillage and Method of Disposal
Spillage of 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: 0.08g
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_biolefstandardsrev2004.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.