Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
Anti-HNA-3a (minimum potency)
NIBSC code: 19/114
Instructions for use
(Version 1.0, Dated 25/01/2022)

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1. INTENDED USE

This preparation, when reconstitutes and diluted as described below, should be used as a reference reagent for minimum acceptable potency for the detection of IgG antibodies against Human Neutrophil Antigen-3a (HNA-3a).

2. CAUTION

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. This preparation is not for administration to humans or animals

3. UNITAGE

No units are assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying 0.5 ml of plasma. The plasma was collected from three consenting donors with anti-HNA-3a antibodies resulting from pregnancy. The immunoglobulin class of HNA-3a antibodies is IgG. Antibodies against other HNA antigens have not been detected in this preparation.

5. STORAGE

Store unopened ampoules at -20 **ºC** or below.
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 one ampoule with 0.5 ml distilled water immediately before use, mix gently until fully reconstituted. Dilute immediately before use by adding 1 volume of reconstituted material to 7 volumes of diluent. Diluted material should be tested for the presence of anti-HNA-3a antibodies using HNA-3a/3a cells (or beads) using a relevant method, for example, the GIFT, LIFT, GAT. This dilution (1 in 8) is the minimum dilution expected to give a positive result. However, many laboratories can detect anti-HNA-3a at larger dilutions of 19/114, as shown in the histogram.

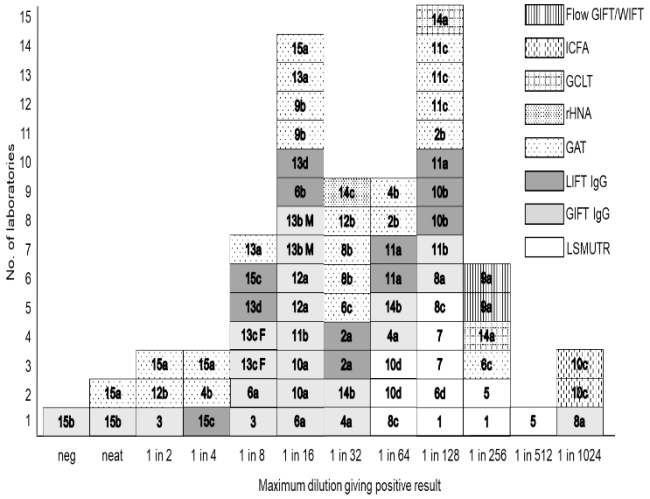

Figure 1 shows the last dilution of 19//114 in a series of two-fold dilutions giving a positive result as reported by laboratories using HNA-3a/3a cells or beads. Numbers in boxes refer to laboratory codes used in the collaborative study.

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.

Accelerated degradation studies have shown this material is suitably stable, when stored at **-20ºC** or below, for the minimum potency to remain valid until the material is withdrawn or replaced. The studies have shown the material is suitably stable for shipment at ambient temperature without any effect on the minimum potency value.

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

9. REFERENCES

1. P. Metcalfe, P. Rigsby, H. Pearson & G. Lucas. An International Reference Reagent for the detection of anti-human neutrophil antigen-1a, Vox sanguinis (2013) 104, 153-158.

10. ACKNOWLEDGEMENTS

We thank the H&I Department, NHSBT, Filton and the Platelet & Leukocyte Department, Sanquin Diagnostic Services for their laboratory support and advice throughout the study. We also thank the ISBT Granulocyte Immunobiology Working Party and UK NEQAS H&I Wales for distributing the collaborative study invitations and finally, we thank the participants of the 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:

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

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: Pale yellow freeze-dried 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:	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_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.