Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
VASCULAR ENDOTHELIAL GROWTH FACTOR
NIBSC code: 01/424
Instructions for use
(Version 5.0, Dated 04/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

NOTE: The WHO Reference Reagent for vascular endothelial growth factor-165 (VEGF165) is available, code 02/286.

Preparation 01/424 contains human sequence recombinant vascular endothelial growth factor-165 (VEGF165) synthesized in Escherichia coli. It was formulated and lyophilized at NIBSC and has been distributed since 2002 as a NIBSC research reagent,. However, it shows variation between ampoules in the volume and crystalline appearance of the lyophilized plug. A second preparation, coded 02/286, was subsequently lyophilized in a different formulation and was established by the World Health Organization (WHO) in 2005 as the WHO reference reagent (RR) for human VEGF165. To provide continuity for laboratories previously using preparation 01/424, it is intended to maintain availability of 01/424 as a NIBSC research reagent at least until October 2010 to permit laboratories to make direct comparison of the two preparations in their own assay systems.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. 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

This material is issued on the understanding that it has no official status and has no definitive unitage or content ascribed to it.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 1ml of a solution that contained:

VEGF 165	10	microgram	
NaH2PO4	4.0	mg/ml	pH 5.3
Trehalose	30.0	mg/ml	
Arginine	3.0	mg/ml	
Tween 20	0.1	mg/ml	
NaCl	4.5	mg/ml	

5. STORAGE

The ampoules are shipped at ambient temperature. Unopened ampoules should be stored at minus 20 degrees C in the dark. It may be possible to store frozen aliquots of the reconstituted preparations for subsequent use but this should be validated for the user's particular laboratory, storage and assay conditions. Repeated freezing and thawing should be avoided. The ampoules do not contain bacteriostat and solutions of the ampouled material should not be assumed to be sterile.
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 all practical purposes, each ampoule contains the same quantity of VEGF165. The entire contents of each ampoule should be completely dissolved in a known volume of suitable solvent. It is recommended that, when possible, buffer containing carrier protein should be used to minimize loss by surface adsorption. The solvent should be compatible with the assay system used.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities and they should be stored on receipt as indicated on the label. Extensive stability studies were not performed on preparation 01/424 as the WHO Reference Reagent for vascular endothelial growth factor-165 (VEGF165), code 02/286, was subsequently made available. Preparation 01/424 is made available for laboratories who may wish to compare the two preparations. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

The World Health Organization Reference Reagent for Vascular Endothelial Growth Factor, VEGF165
Robinson CJ, Gaines Das R, Stammers R, Rafferty B
Growth Factors (2006) 24 (4) 285-290

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Genentech, Inc., South San Francisco, CA, USA, for the donation of the bulk preparation of recombinant VEGF165

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.

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

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: No	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	
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: 40mg
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No