Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
NIBSC Reference Reagent for Gut Microbiome Analysis by Next-Generation Sequencing (DNA-Gut-HiLo)
NIBSC code: 21/128
Instructions for use
(Version 2.0, Dated 02/11/2021)

1. INTENDED USE

This material is a mix of purified nucleic acids isolated from bacterial strains that reside in the human intestine (see Table). This a reference preparation is intended as a control reagent for Next Generation Sequencing analysis of gut microbiome samples, and more broadly to assess the quality of laboartory methods and software analaysis used in these studies.

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

No unitage is assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom.
0.25ml of freeze-dried material consisting of DNA from 20 bacterial strains (see Table) and are at a final concentration of between 6-9ng/µl upon reconstitution with 50µl.

Table

Strain number	Strain name	% content
DSM 22959	Akkermansia muciniphila	0.13
DSM 17242	Alistipes finegoldii	1.3
DSM 3319	Anaerostipes hadrus	1.3
DSM 2079	Bacteroides thetaiotaomicron	13
DSM 6597	Bacteroides uniformis	1.3
DSM 20088	Bifidobacterium longum subsp. infantis	13
DSM 20219	Bifidobacterium longum subsp. Longum	13
DSM 19850	Blautia wexlera	0.13
DSM 10702	Clostridium butyricum	13
DSM 13712	Collinsella aerofaciens	1.3
DSM 1103	Escherichia coli	13
DSM 3353	Eubacterium hallii	1.3
DSM 17677	Faecalibacterium praunitzii	0.13
DSM 20077	Lactobacillus gasserii	0.13
DSM 20701	Parabacteroides distasonis	13
DSM 18205	Prevotella copri	13
DSM 7089	Prevotella melaninogenica	1.3
DSM 16839	Roseburia hominis	1.3
DSM 14610	Roseburia intestinalis	0.13
DSM 19829	Ruminococcus gauvreauii	0.13

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

Upon receipt, ampoules should be stored at -20°C until use. Prior to use in assays, freeze-dried material are to be reconstituted with 50µl of sterile nuclease-free water. To ensure complete reconstitution of samples it is recommended that samples are gently but thoroughly mixed by pipetting material up and down at least 10 times. Samples should be reconstituted on the day of the assay.

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.

Accelerated degradation studies performed suggest that this material will be stable when stored at the recommended storage temperature of -20°C.

Users who have any data supporting any change in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

https://doi.org/10.1186/s40168-020-00856-3

10. ACKNOWLEDGEMENTS

We would like to express our thanks to SPD (NIBSC) for assistance in the determination of freeze drying conditions and for moisture and oxygen determinations of the ampouled material and the staff of CBRM for assistance with the filling procedure.

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

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

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: Yes
Flammable: No	Handling: See caution, Section 2
Other (specify): see caution, section 1	
Toxicological properties	
Effects of inhalation: Not established, avoid inhalation	
Effects of ingestion: Irritating to mouth, throat and stomach, avoid ingestion	
Effects of skin absorption: May cause skin irritation, avoid contact with skin	
Suggested First Aid	
Inhalation: Move to fresh air and seek medical advice.	
Ingestion: Wash out mouth with water, provided person is conscious and seek medical advice	
Contact with eyes: Wash with copious amounts of water. Seek medical advice	
Contact with skin: Wash thoroughly with water. Seek medical advice if symptoms occur.	
Action on Spillage and Method of Disposal	
Absorbent materials used to treat spillage should be treated as biologically hazardous 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: 0.25 - 0.5 g
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_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.