



Non WHO Reference Material
NIBSC Reference Reagent for Respiratory Microbiome Analysis
by Next-Generation Sequencing (DNA-Respiratory-HiLo)
NIBSC code: 24/152
Instructions for use
(Version 1.0, Dated 02/12/2024)

This material is not for in vitro diagnostic use

1. INTENDED USE

This material is a mix of purified nucleic acids isolated from bacterial strains that reside in the human respiratory tract (see Table 1). This reference preparation is intended as a control reagent for Next Generation Sequencing analysis of respiratory microbiome samples, and more broadly to assess the quality of laboratory methods and software analysis used in these studies.

2. CAUTION

The material is not of human or bovine origin. This preparation is not for administration to humans or animals

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.

0.25 ml of freeze-dried material consisting of DNA from 20 bacterial strains (see Table 1) and are at a final concentration of between 4-6 ng/µl upon reconstitution with 50 µl.

Table 1

Strain Number	Strain name	% content (genome size adjusted)
NCTC 10301	<i>Actinomyces naeslundii</i>	0.10
NCTC 11326	<i>Fusobacterium nucleatum</i> subsp. <i>Fusifforme</i>	17.51
NCTC 8143	<i>Haemophilus influenzae</i>	17.02
NCTC 13368	<i>Klebsiella pneumoniae</i>	0.58
NCTC 12456	<i>Leptotrichia buccalis</i>	13.05
NCTC 12454	<i>Leptotrichia buccalis</i>	0.11
NCTC 11020	<i>Moraxella (branhameella) catarrhalis</i>	16.86
NCTC 10394	<i>Mycobacterium fortuitum</i>	0.51
NCTC 10617	<i>Neisseria lactamica</i>	1.46
NCTC 10025	<i>Neisseria meningitidis</i>	0.15
DSM 23539	<i>Neisseria sicca</i>	1.28
DSM 17245	<i>Oribacterium sinus</i>	11.79
NCTC 11834	<i>Porphyromonas gingivalis</i>	0.14
NCTC 13070	<i>Prevotella intermedia</i>	0.12
NCTC 12963	<i>Prevotella melaninogenica</i>	1.02
NCTC 10332	<i>Pseudomonas aeruginosa</i>	5.09
NCTC 10917	<i>Rothia dentocariosa</i>	0.13
NCTC 8532	<i>Staphylococcus aureus</i>	11.40
NCTC 7465	<i>Streptococcus pneumoniae</i>	1.52
NCTC 8618	<i>Streptococcus salivarius</i> subsp. <i>Savilivarius</i>	0.15

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

Upon receipt, ampoules should be stored at -20 C until use. Prior to use in assays, freeze-dried material are to be reconstituted with 50 µl 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. Before reconstitution, please ensure the whole freeze-dried material is at the bottom of the ampoule, improper reconstitution will result in a reagent of lower concentration. 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.

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

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

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	
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 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