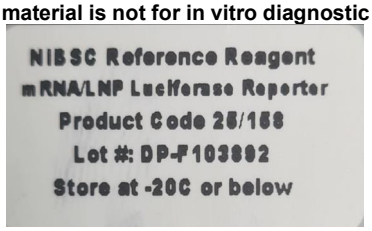
Working Standard
mRNA/LNP Luciferase Reporter
NIBSC code: 25/158
Instructions for use
(Version2.0, Dated 01/09/2026)

This material is not for in vitro diagnostic use.



1. INTENDED USE

This mRNA/LNP reference reagent has a firefly luciferase reporter and is intended to help users develop and/or monitor performance of analytical methods that are used to characterise and control mRNA/LNP products. Sub-lot ID: DP-F103892

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 assigned value

Results for some parameters obtained from testing at MHRA are provided for information only as a guide for users in Appendix 1 of this IFU

4. CONTENTS

Country of origin of biological material: USA.

Each vial contains the freeze-dried pellet of a 0.63 mL fill of the mRNA/LNP in a Tris (16.6 mM) Acetate (4.3 mM) Sucrose (72.1 g/L) Sodium Chloride (8.3 g/L) buffer pH 7.5

The mean fill weight is 0.651 g (CV% = 0.41)
The water content is 0.22%

25/158 contains the following lipids: SM-102, Cholesterol, DSPC, PEG2000-DMG with a total lipid content of 3173 µg/vial

5. STORAGE

Product coded 25/158 should be stored at -20 or below
Product coded 25/158 will be shipped on dry ice

6. DIRECTIONS FOR OPENING

Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

The results from testing at MHRA, shown in Appendix 1, were obtained after reconstitution of vials with 0.63 mL water

8. STABILITY

Data from an accelerated thermal stability study conducted at MHRA suggests that 25/158 will be stable when stored at the recommended storage conditions.

9. REFERENCES

United States Pharmacopoeia. Analytical Procedures for Quality of mRNA Vaccines and Therapeutics (Draft Guidelines: 3rd Edition) (https://go.usp.org/mRNAVaccineQuality

10. ACKNOWLEDGEMENTS

N/A

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: off white dry powder		**Corrosive:**	**No**
Stable:	**Yes**	**Oxidising:**	**No**
Hygroscopic:	**Yes**	**Irritant:**	**No**
Flammable:	**No**	**Handling:**	**See caution, Section 2**
Other (specify):	**N/A**		
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 discarded according to local procedures.			

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*: USA * 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: 0.63g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** N/A

APPENDIX 1. RESULTS OBTAINED AT MHRA (n=15 vials tested in groups of 5 across 3 separate runs, each vial reconstituted in 0.63 mL water))

Parameter	Analytical Method[1]	Mean (95% confidence interval)	RSD
Particle size diameter (nm) PDI	Dynamic scanning fluorimetry	104.1 (103.0 – 105.2) 0.39 (0.39 – 0.40)	1.85 1.91
Total RNA concentration (mg/mL) RNA encapsulation (%)	Ribogreen assay	0.222 (0.217 – 0.227) 90.0 (89.6 – 90.4)	3.96 0.84
RNA integrity – main peak %	Capillary electrophoresis	90.9 (90.6 – 91.2)	0.00
RNA purity – main peak %	Ion-pair reverse phase HPLC	91.3 (91.2 – 91.4)	0.64

[1]testing performed using in-house methods based on USP *Analytical Procedures for Quality of mRNA Vaccines and Therapeutics (Draft Guidelines: 3rd Edition)* (https://go.usp.org/mRNAVaccineQuality)