Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
Blood group genotyping, genomic DNA
NIBSC code: 11/214; 10/232; 10/236; 10/238; 10/234
Instructions for use
(Version 7.0, Dated 24/02/2020)

1. INTENDED USE

To standardise and control blood group genotyping procedures for common Caucasian and Black African alleles The Reagents are available individually and as a Panel (code 11/214) containing one ampoule of each of 10/232, 10/236, 10/238 and 10/234.

2. CAUTION

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

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. 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

N/A

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains 2.5 µg DNA and 0.75 mg trehalose. Upon reconstitution with 50 µl distilled or de-ionised water, the final concentration of DNA will be 50 ng/µl in 10 mM Tris 1 mM EDTA containing 15 µg/µl trehalose. The DNA was prepared from lymphoblastoid cell lines established from phenotyped and genotyped consenting blood donors.

5. STORAGE

Store unopened ampoules at -20°C 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 with 50 µl distilled or deionised water. Allow the material to stand for 1 h at RT and pipette well to mix before use.

Reagents RBC1, RBC4, RBC5 and RBC12 have been validated for blood group genotyping in an international collaborative study. The genotypes are shown in Table 1.

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.

9. REFERENCES

N/A

10. ACKNOWLEDGEMENTS

These reagents were produced under the auspices of the International Society for Blood Transfusion in collaboration with Dr Geoff Daniels, Dr Sylvia Armstrong-Fisher, and Professor Stan Urbaniak.

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
NIBSC Genomic Reference Materials:
http://www.nibsc.org/science_and_research/advanced_therapies/genomic_reference_materials.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: Lyophilisate		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	Unknown
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains human DNA		
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.			

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

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: 0.0015 g
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.

TABLE 1

+ indicates genes present; - indicates genes absent

Gene	Reference Reagent			
	RBC1 (OR_1R_2)	RBC4 (AR_1R_1)	RBC5 (Brr)	RBC12 (OψD)
	10/232	10/236	10/238	10/234
GYPA*M	+	+	-	+
GYPA*N	-	+	+	+
GYPB*S	+	-	-	-
GYPB*s	+	+	+	+
RHD	+	+	-	-
RHDΨ	-	-	-	+
RHCE*C	+	+	-	-
RHCE*c	+	-	+	+
RHCE*E	+	-	-	-
RHCE*e	+	+	+	+
KEL*1	+	-	+	-
KEL*2	+	+	-	+
FY*A	-	-	+	-
FY*B	+	+	+	+
FY*BNull	-	-	-	+
JK*A	-	+	+	+
JK*B	+	+	-	+
DO*A	-	-	-	-
DO*B	+	+	+	+