



**WHO Reference Reagent
First WHO Reference Reagent for Anti-malaria (Plasmodium
falciparum) human serum
NIBSC code: 10/198
Instructions for use
(Version 2.01, Dated 16/11/2017)**

1. INTENDED USE

This preparation is derived from individuals based in Kimusu Kenya with a history of malaria. Single plasma donations were collected by the Kisumu Blood Bank, Kenya. Samples were screened for antibodies against 5 Plasmodium falciparum antigens, MSP-1-19 (K1), MSP-1-42 (3D7), MSP-2 (3D7), MSP-3 (K1), AMA-1 (3D7, FC27, FP3), 77% positive for at least one antigen. Each ampoule contains a freeze-dried residue comprising, under an atmosphere of nitrogen, of diluted human plasma containing antibodies to P. falciparum. The intended uses of this Reference reagent, a single multivalent preparation, are (1) to allow cross-comparisons of results of vaccine trials performed in different centers / with different products; (2) to facilitate standardization and harmonization of immunological assays used in epidemiology research; and (3) to allow optimization and validation of immunological assays used in malaria vaccine development. This material is not intended for in vitro diagnostic use.

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

The content of this preparation has been assessed by a collaborative study to have an immunological reactivity of 100 units to malaria P. falciparum antigens.

4. CONTENTS

Country of origin of biological material: Kenya
Pooled plasma collected from a malaria endemic area was defibrinated and diluted (1: 5) with sterile water and filled at 1 ml/ ampoule. This gives a content equivalent to 0.2 ml serum/ ampoule..

5. STORAGE

This preparation should be stored at -20°C in the dark for long-term storage to preserve activity.

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 manufacturers 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

Dissolve the total contents of the ampoules with 1 ml of deionised water. Ensure that the entire freeze dried residue is dissolved in this solution.

Reconstituted ampoules should be used immediately or can be stored between 2°- 8°C for 3 months without loss of activity.

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

Bryan D, Silva N, Rigsby P, Dougall T, Corran P, Bowyer PW, Ho MM; Collaborative study group.

Malar J. 2017 Aug 5;16(1):314

Bryan D, Silva N, Rigsby P, Dougall T, Corran P and Ho M. M (2014) International collaborative study to evaluate and establish the 1st WHO Reference Reagent for anti-malaria (Plasmodium falciparum) human serum. WHO/BS/2014.2235

10. ACKNOWLEDGEMENTS

Special thanks are due to the National Blood Bank in Kisumu and to CDC/ KEMRI malaria laboratory for sourcing and donating the material used in this preparation. Thanks also go to NIAID/ NIH for donating purified malaria antigen preparations used in this study. Special thanks also due to all the participating laboratories and scientists involved in the collaborative study.

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: White freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains material of human origin	
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: 0.0185g
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_bi_olefstandardsrev2004.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.