



Working Standard
NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant
NIBSC code: 20/162
Instructions for use
(Version 1.0, Dated 30/07/2020)

This material is not for in vitro diagnostic use.

1. INTENDED USE

NIBSC Anti-SARSCoV-2 Antibody Diagnostic Calibrant reagent should be used to monitor the sensitivity of assays. Data obtained with this reagent can be used to confirm that the chosen assay is acceptable for clinical use. It can also be used to investigate the following:

- check performance of equipment, such as automated analysers
 - check sensitivity of assays, such as Enzyme Immuno Assays (EIA) and chemiluminescence immunoassays (CLIA)
- check variance between kit lots and kit batches.

This reagent has been used to estimate the end-point dilutions of the following assays:

- DiaSorin LIAISON SARS-CoV2 S1/S2 IgG
- Abbott Architect SARS-CoV-2 IgG
- Roche Elecsys Anti-SARS-CoV-2 (e411)
- Roche Elecsys Anti-SARS-CoV-2 (e801)
- EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)
- Siemens Atellica SARS-CoV-2 Total
- Siemens Atellica SARS-CoV-2 IgG
- Fortress COVID-19 Total Antibody

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

This reagent has been assigned an arbitrary unitage of 1000U.

4. CONTENTS

Country of origin of biological material: United Kingdom.
This reagent is from convalescent plasma positive for Ant-SARS-CoV-2 from 3 separate donors. The volume of this reagent is 0.3 ml.

5. STORAGE

This reagent is to be stored at -20.° C upon receipt until use. Do not repeat freeze/thaw.

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

This reagent is intended for single use only.

Allow reagent to come to room temperature prior to use.
Use suitable PPE when handling this product

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

10. ACKNOWLEDGEMENTS

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: Frozen liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	
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: 3.8 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. Attached: No