



**Working Standard**  
**NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant Dilution Series**

**NIBSC code: 21/B775**  
**Instructions for use**  
**(Version 2.0, Dated 16/06/2021)**

**This material is not for in vitro diagnostic use.**

## 1. INTENDED USE

NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant Dilution Series is step one for the approval process of DHSC for new assays by manufacturers. It consists of 6 dilutions of the Calibrant 20/162. Manufacturers will be issued with the dilution series blinded. They shall then test the series and return the results back to NIBSC. This dilution series is not to be used for any other purpose.

## 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 is blinded panel of the Diagnostic Calibrant (20/162). As this is a blinded dilution series there is no unitage associated with it.

## 4. CONTENTS

Country of origin of biological material: United Kingdom.  
The dilution series comprises of 6 dilutions of a mixed pool of convalescent plasma from 3 separate donors.

## 5. STORAGE

this reagent is to be stored at -20°C upon receipt until use.

**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 dilution series is to be used to assess relative sensitivities of assays.

## 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](mailto: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](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](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](mailto: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:<br>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](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

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|---|
| <b>Country of origin for customs purposes*:</b> 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. |
| <b>Net weight:</b> 22.8 g   |
| <b>Toxicity Statement:</b> Toxicity not assessed  |
| <b>Veterinary certificate or other statement</b> if applicable.   |
| <b>Attached:</b> No   |