



Data Sheet

Research reagent for

anti-SARS-CoV-2 Ab

NIBSC code 20/130

(Version 2, Dated 17/01/2021)

INTENDED USE

The research reagent for anti-SARS-CoV-2 antibody is intended to be used for the development and evaluation of serological assays for the detection of antibodies against SARS-CoV-2, as a positive control.

This material is for research use only.

CONTENTS

Each vial contains 0.1 mL of frozen human plasma from a donor recovered from COVID-19. The material has been solvent-detergent treated, to inactivate any envelope virus present, using a method validated at NIBSC [1,2].

CAUTION

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

The preparation contains material of human origin. It has 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.

DESCRIPTION

The material was obtained by plasmapheresis from a COVID-19 PCR positive-confirmed patient, at least 4 weeks after symptoms and recovery. No information was provided on the severity of the symptoms. The project

was approved by the National Institute for Biological Standards and Control (NIBSC) Human Material Advisory Committee (project 16/005MP). Plasma was donated to NIBSC anonymised by the UK National Health Service Blood and Transplant (NHSBT). The donor patient signed an informed consent for the use of their plasma.

STORAGE

Vials should be stored at -20°C upon receipt or below. Avoid freeze/thaw cycles. No stability studies have been conducted on this material yet.

USE OF THE MATERIAL

Thaw the research reagent at ambient temperature. The research reagent should be processed according to the end user's method.

REPRESENTATIVE DATA

The research reagent 20/130 has been characterised as part of the collaborative study for the establishment of the First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (NIBSC code 20/136) [3]. The results provided below are the mean value for the assays used the in collaborative study.

	GM	95% CI	
Neut Ab	1300	981-1719	IU/mL
anti-RBD IgG	502	382-660	BAU/mL
anti-S1 IgG	588	398-870	BAU/mL
anti-Spike IgG	476	418-542	BAU/mL
anti-N IgG	747	214-2606	BAU/mL

Neut Ab: neutralising antibody activity; CI: confidence interval; IU: International Unit; BAU: binding antibody units.

ACKNOWLEDGEMENTS

We would like to wholeheartedly thank the anonymous donor of the plasma sample for their consent which has allowed this reagent



to be prepared. We would like to express our gratitude to Dr H. Harvala Simmonds and colleagues at the UK National Health Service Blood and Transplant (NHSBT) for the collection of the plasma sample.

This work has been funded and facilitated by the Coalition for Epidemic Preparedness Innovations (CEPI).

REFERENCES

[1] Dichtelmuller, H.O., et al., Robustness of solvent/detergent treatment of plasma derivatives: a data collection from Plasma Protein Therapeutics Association member companies. *Transfusion*, 2009. 49(9): p. 1931-43.

[2] Wilkinson, D.H., et al., WHO collaborative study to assess the suitability of the 1st International Standard and the 1st International Reference Panel for antibodies to Ebola virus. 2017.

[3] Mattiuzzo G, et al. Establishment of the WHO International Standard and Reference Panel for anti-SARS-CoV-2 antibody. 2020. WHO/BS/2020.2403

CUSTOMER FEEDBACK

Customer are encouraged to provide feedback on the suitability or use of the research reagent 20/130. Please send any comments to Standards@nibsc.org.

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CITATION

In any publication making reference to the materials, the acknowledgment should read: "The research reagent for SARS-CoV-2 RNA (NIBSC 20/130) was obtained from the National Institute for Biological Standards and Control, UK".



MATERIAL SAFETY SHEET

Physical properties (at room temperature)			
Physical appearance	Pale yellow, frozen liquid		
Fire hazard	None		
Chemical properties			
Stable	Yes	Corrosive:	No
Hygroscopic	No	Oxidising:	No
Flammable	No	Irritant:	No
Other: Contains material of human origin			
Handling:	See caution section		
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			
<p>Spillage of ampoule or vial contents should be taken up with absorbent material wetted with a virucidal agent. Rinse area with a virucidal agent followed by water.</p> <p>Absorbent materials used to treat spillage should be treated as biologically hazardous waste.</p>			