Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Data Sheet

COVID-19 convalescent plasma panel, human

NIBSC code 20/118

(Version 1, Dated 30/04/2020)

INTENDED USE

The COVID-19 convalescent plasma panel is composed of 5 members: 4 plasma samples from COVID-19 recovered patients: 20/120, 20/122, 20/124, 20/126 and a negative plasma pool from healthy donors collected before 2019, 20/128-negative. The antibody panel is intended to be used for the development and evaluation of serological assays for the detection of antibodies against SARS-CoV-2.
This material is for research use only, and it has only been characterised in-house.

CONTENTS

Each vial contains 0.1mL of frozen human plasma from one or multiple donors recovered from COVID-19. The material has been solvent-detergent treated, to inactivate any enveloped 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 COVID-19 PCR positive confirmed patients, 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 Institutes for Biologicals 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) and through the ISARIC4C Consortium. The donor patients 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 panel at ambient temperature. The reagents should be processed according to the end user's method. In our in-house characterisation, 20/120 has the highest anti-SARS-CoV-2 antibody titer, 20/122 has a mid-antibody titer, 20/124 and 20/126 have the lowest titers; 20/124 has a relatively high response to SARS-CoV-2 N protein.

REPRESENTATIVE DATA

The panel 20/118 has only been characterised in-house. The following results are for information only, it is the end user's responsibility to assess performance of each panel member in their assays.

1) Neutralisation assay

Potencies are reported as the reciprocal of the endpoint titer dilution. Experiments were run once in quadruplicate.

	20/120	20/122	20/124	20/126	20/128
Live virus (CPE)	200	70	40	35	<20
VSV-PV	267	90	20	<20	<20
$PRNT_{50}$	107	33	13	<20	<20

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CPE: Cytopathic effect; VSV-PV: SARS-CoV-2 pseudotyped vesicular stomatitis virus; PRNT50: 50% plaque reduction neutralisation

2) ELISA

The antibody panel 20/118 was tested once in both a commercial and in-house ELISA.

	20/120	20/122	20/124	20/126	20/128
EuroImmun IgG*	pos (8.59)	pos (3.47)	pos (1.62)	neg (0.64)	neg (0.21)
EuroImmunIgA*	pos (10.1)	pos (1.1)	pos (1.84)	pos (1.63)	neg (0.02)
IgG S1**	5580	3202	1636	1181	<50
IgG N**	3417	2425	3296	995	<50
IgG sSpike***	2693	1488	118	8	<50
IgM	+	+	-	+	-

*results are based on a ratio calculated against the kit calibrator; ** S1 and N proteins kindly provided by Dr P. Cherepanov (The Francis Crick Institute, London, UK) deposited in CFAR cat. no. 100979; ***stabilised Spike protein produced in house from plasmid kindly donated by Dr B. Graham (NIAID/NIH, Bethesda, MD, USA).

ACKNOWLEDGEMENTS

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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.

CUSTOMER FEEDBACK

Customer are encouraged to provide feedback on the suitability or use of the antibody panel 20/118. Please send any comments to Covid19_reagents@nibsc.org.

LIABILITY AND LOSS

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CITATION

In any publication making reference to the materials, the acknowledgment should read: “The COVID-19 convalescent plasma panel (NIBSC 20/118) 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			
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. Absorbent materials used to treat spillage should be treated as biologically hazardous waste.			