Proposal (title)	1st WHO International Standard for anti-SARS-CoV-2 antibodies		
Proposer (name of Institution)	NIBSC	**Principal contact**	Giada Mattiuzzo
Rationale	Severe acute respiratory syndrome coronavirus -2 (SARS-CoV-2) previously known as novel coronavirus 2019 (nCOV-2019) is the aetiological agent of the Coronavirus Disease 2019 (COVID-19). It causes mild symptoms in the majority of cases, however ~10% cases are requiring medical intervention, with a small percentage progressing to severe pneumonia and death. The World Health Organization declared COVID-19 a Public Health Emergency of International Concern on 30th January 2020, and a Pandemic on 11th March 2020. As of 31st March 2020, there are over 850,000 confirmed cases and 42,000 deaths. Serological assays are needed to understand the real impact of COVID-19, as most of the cases with mild symptoms are undetected. Urgent and rapid vaccine development is underway; currently there are 44 vaccine candidates and two vaccines have entered phase I clinical trials. The scientific and clinical community requires a COVID-19 antibody standard urgently for serological assay development, evaluation of vaccine efficacy, and for epidemiological studies. Plasma or serum from convalescent patients is the preferred candidate standard as these are commutable, due to most closely representing clinical samples that are analysed in the assay. These samples have consistently been able to reduce inter-assay variability when used as a calibrant for a range of tests, as shown for many other viruses, including MERS-CoV.		
Anticipated uses and users	Standardisation of serological assay (e.g. ELISA, neutralisation assays) for identification and/or potency test of anti-SARS-CoV-2 antibodies in: Clinical and public health laboratories Vaccine manufacturers - Vaccine studies Therapeutic Ab producers Assay Kit manufacturers Research laboratories		
Source/type of materials	Donated human serum or plasma from convalescent individuals will be preferred. The project is supported by the Coalition for Epidemic Preparedness Innovations. Donors have been identified from affected countries (UK, Norway, Italy, USA, Singapore).		

	Materials issued by NIBSC will have undergone treatment steps for virus inactivation, to be shipped as non-infectious. All clinical and other samples will have undergone screening for blood-borne viruses.		
Outline of proposed collaborative study	Collaborative study will involve 20+ laboratories worldwide, performing a range of serological assays for SARS-CoV-2, and representing control laboratories, vaccines and kit manufacturers, clinical and academic laboratories. The aims will be to assess the suitability of different antibody preparations to serve as the International standard with an assigned unitage per ampoule for use in the harmonisation of SARS-CoV-2 serology assays by: • characterisation of the antibody preparations in terms of reactivity/specificity in different assay systems. • assessing each preparation's potency i.e. readout in a range of typical assays performed in different laboratories • assessing commutability i.e. to establish the extent to which each preparation is suitable to serve as an interim standard for the variety of different samples and assay types.		
Issues raised by the proposal	The study is taking place during COVID-19 pandemic, and logistics could be difficult. Personnel may also be an issue due to mobility restrictions and self isolation.		
Action required	ECBS to endorse proposal		
Proposer's project reference		**Date proposed:**	31 March 2020
CONSIDERATIONS FOR ASSIGNMENT OF PRIORITIES (TRS932)			
Approval status of medicine or in vitro diagnostic method	Several licensed drugs are under investigation to be re-purposed for COVID-19 treatment. Clinical trials are taking place. 44 vaccine candidates have been developed and 2 of them are in phase I.		
Number of products or methods	Commercial kits and in-house assays are available; some CE-marked, EQA scheme has been organised. Majority of in-house assays are neutralisation assay using either the virus in CL3 or pseudotyped systems. ELISA format is the most prevalent commercial assay format. Rapid point of care testing is also being developed.		
Public health importance	The World Health Organization declared COVID-19 a Public Health Emergency of International Concern on 30th January 2020, and a Pandemic on 11th March 2020.		
Global importance	The World Health Organization declared COVID-19 a Public Health Emergency of International Concern on 30th January 2020, and a Pandemic on 11th March 2020. Proposed standard is essential for		

	evaluation of vaccines and other biologicals developed for prevention and control of COVID-19 disease.
Global need from regulatory & scientific considerations	Standardised and calibrated assays are vital for accurate evaluation of treatments, including antibody therapies and vaccine, and for case management and surveillance.
ECBS outcome	[BLANK]

Running Title: **1st anti-SARS-CoV-2 antibody standard**