NIBSC is seeking partners for sourcing serum or plasma from individuals vaccinated against and/or recovered from infection with SARS-CoV-2 variants for the development of antibody working standards and reference panels

Background

Through a joint effort in 2020, the Coalition for Epidemic Preparedness Innovations (CEPI), the National Institute for Biological Standards and Control (NIBSC), and the World Health Organization (WHO) provided COVID-19 vaccine developers and the entire scientific community with a research reagent for an anti-SARS-CoV-2 antibody, an International Reference Panel and the first WHO International Antibody Standard for assay calibration (https://www.who.int/news-room/feature-stories/detail/standardization-of-vaccines-for-coronavirus-disease-covid-19). These materials are constituted of plasma samples sourced from SARS-CoV-2 convalescent patients.
The emergence of SARS-CoV-2 variants which appear to be serologically diverse from the original VIC-01 isolate has raised questions on the suitability of current assays, the efficacy of candidate vaccines, and the suitability of WHO-endorsed International Standard established in December 2020.

Request for collaboration

To address these questions, NIBSC, with the support of CEPI and WHO, is looking for partners for sourcing serum or plasma from vaccinated individuals and/or recovered patients for the development of working standards for each of the SARS-CoV-2 variants of concern. Such material will be evaluated in a multi-center collaborative study in parallel with the first WHO International Antibody Standard. This will bridge between the WHO International Antibody Standard and a possible replacement should one be needed. This initial outreach is focusing on the collection of B.1.1.7, B.1.351 and P1 variant serum collection, but we seek partners that would be able to support collection of other emerging variant-specific serum/plasma as well.
NIBSC, in its role as a WHO-designated International Laboratory for Biological Standards, prepares and tests candidate biological standards, coordinates collaborative studies involving such candidate materials and acts as custodian and distributor of International Standards and other biological reference materials. Provision of the serum/plasma must be compliant with such use.

Product Profile

Category	Minimal	Preferred	Evidence required
Origin	Undiluted sera/plasma from human recovered individuals confirmed with SARS-COV-2 infection and/or vaccinated against SARS-COV-2 in a geographic area where one of the variants of concern is dominating. The serum/plasma must not be pooled.	Undiluted sera/plasma from several individuals confirmed with SARS-CoV-2 variant infection by sequencing. The serum/plasma must not be pooled.	Required: country of origin; ethical approval and informed consent forms (unsigned, unidentified). If available: Description of clinical illness; diagnostic details; time between discharge and sampling; virus strain identity or sequence data.
Product characteristic	Serum/plasma confirmed to contain antibodies against SARS-COV-2	Serum/plasma analyzed and confirmed with high antibody titer and neutralizing activity against SARS-COV-2 virus and/or pseudo typed virus	Describe laboratory capacity and assays performed on site Alternatively, which type of assays will be performed on samples at other sites. Sequencing confirmation of the SARS-CoV-2 variant.
Volume of serum/plasma collected per donor	Minimum 10 mL of serum/plasma	100 mL or more of serum/plasma	Confirm and describe if collection is projected to be done by blood collection or plasmapheresis
Total volume of serum/plasma collection	500 mL	Collection from more than one site, 500 mL or more from each site; 2.5-liter total volume	Confirm and describe
Safety	Laboratory-confirmed absence of SARS-COV-2 virus through accepted methods (RT-PCR)	Also tested for other blood borne pathogens and possible contaminants such as HIV, HCV and HBV.	Describe measures taken and methods to be used. If considering pathogen inactivated sera, then it needs to be shown that antibody function is unaffected.

Additional Guidance

Timelines: Partners will be selected on a rolling basis in 2021.
Compensation: Serum/plasma collection and shipment expenses will be fully covered.
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