MATERIAL TRANSFER AGREEMENT

FCG-IGC whose principal place of business is Avenida de Berna no. 45-A, 1059-039 Lisboa, represented by Mónica Bettencourt Dias, in the capacity of Instituto Gulbenkian Ciência Director (“Supplier”), has developed the materials known as SarsCov-2 RBD and/or Spike protein and includes any constructs, strains, progeny, derivatives, portions, improvements, modifications and components (as the case may be) obtained from or as a result of the use of the materials (the “Materials”) using plasmids expressing the SARS-COV-2 RBD and Spike protein (“Original Materials”) received from Icahn School of Medicine of Mount Sinai (the “Original Provider”).

X who is an employee of PLEASE INSERT NAME AND ADDRESS OF SCIENTIST’S INSTITUTION, here represented by XXX in his/her role of XXX (the “Recipient”). The Recipient wishes to receive a sample of the Materials and the Supplier agrees to provide such materials, under the terms and conditions defined herein.

The Recipient wishes to receive for a sample of the materials for the following purposes (PLEASE TICK THE BOX(ES) THAT APPLY):

[ ]  Academic research purposes only relating to: INSERT DESCRIPTION OF ACADEMIC RESEARCH FOR WHICH MATERIALS ARE TO BE USED (the “Research Programme”, details of which provided in Annex I)

[ ]  Testing own staff (details of which provided in Annex II)

The Supplier is willing to provide a sample of the following materials and quantities – (PLEASE TICK THE BO(XES) THAT APPLY AND FILL WITH PROTEIN QUANTITIES BEING REQUESTED; PLEASE CONSIDER MAXIMUM AMOUNT TO BE DISTRIBUTED IS 1MG OF RBD AND 1MG OF SPIKE)

[ ]  RBD \_XXX\_mg for academic research purposes and \_XXX\_mg for testing own staff purposes

[ ]  Spike \_XXX\_mg for academic research purposes and \_XXX\_mg for testing own staff purposes

The materials are provided within the scope of the Serology4COVID consortium efforts led by IGC Instituto Gulbenkian Ciência – Fundação Calouste Gulbenkian in collaboration with iBET - Instituto de Biologia Experimental e Tecnológica; CEDOC – NOVA Medical School, Universidade Nova de Lisboa; ITQB NOVA – Instituto de Tecnologia Química e Biológica António Xavier – Universidade Nova de Lisboa and iMM – Instituto de Medicina Molecular João Lobo Antunes and funded by Camara Municipal de Oeiras. This Consortium implemented the method described by Krammer and his team (Stadlbauer et al, Curr Protoc Microbiol 2020, 57(1):e100). The Original Materials were obtained from the Original Provider, through a material transfer agreement for research purposes, that acts as an ancillary agreement and to whose conditions the Recipient need to agree to (Annex IV).

The materials are provided alongside the standard operation procedure (SOP) optimized by the Serology4COVID for the use of the materials. No other use of materials is allowed if not following the SOP. A Copy of the SOP can be found in Annex III. Questions can be forwarded to serology4covid@colife.eu. Materials are provided only for non-commercial legitimate purpose required to rapidly prevent, detect, prepare for, and respond to, the spread or transmission of SARS-CoV-2 only.

Term: this agreement has a period of two years duration, or until the end of the Research Programme, whatever ends earlier. When provided for the purposes of testing own staff, this agreement will finish on the situations mention above and upon the ELISA test developed with Consortium technology being commercially available, whatever earlier. The Recipient agrees to comply with all the Terms and Conditions of this agreement.

Terms and Conditions:

1. The Recipient shall keep the Materials secure at the Recipient’s laboratory and ensure that no-one other than the Recipient and authorised co-workers (“Co-workers”) have access to them. In this Agreement “the Materials” shall include any and all materials, documents and information that Supplier may provide to the Recipient under or in connection with this Agreement, and including any constructs, strains, progeny, derivatives, portions, improvements, modifications and components obtained from or as a result of using any item provided by the Supplier.

2. The Recipient shall use the Materials only for the purposes specified above and only in combination with the SOP, and not for any commercial purpose or commercially-sponsored research without the prior written consent of the Supplier even if those purposes are being pursued in the Recipient’s laboratory without the prior written consent of Supplier.

3. The Recipient and the Institution shall not supply the Materials to any other party. The Materials shall under no circumstances be used in humans.

4. The Term may be extended with the written agreement of the Supplier. Permission to extend the term of this Agreement must be sought by the Recipient three (3) months before the expiry of the Term.

5. The Recipient shall acknowledge Supplier as the source of the Materials in any publication which mentions them, by using the following sentence: Materials and SOP produced by Serology4COVID consortium and provided by FCG-IGC on their behalf, with funding from Câmara Municipal de Oeiras. The Recipient shall inform the Supplier in advance of making any reports or publications public. Recipient shall make available on request any raw data.

6. The Materials (and any copies thereof made by or in possession of or under the control of the Recipient pursuant to this Agreement) shall be and remain the property of Supplier or Original Provider as applicable, and shall be immediately returned (or if the Supplier so requires, destroyed) (i) on termination of this Agreement, or (ii) in the event that the Recipient or Institution is in breach of any of the conditions of this Agreement, and (iii) at any other time on request of the Supplier.

7. The Materials shall at all times remain the property of the Supplier or Original Provider, as applicable, and will not be removed from the Recipient’s address. No licence under any Supplier or Original Provider intellectual property is granted or implied by this Agreement.

8. In the event that the Recipient or Co-workers make or observe any new discovery, improvement or invention (“Invention”) relating to the Materials or as a direct result of the Research Programme then the Recipient will bring this to the attention of the Supplier and Original Provider. The Recipient shall not make or seek to make actual commercial gain from such an Invention, nor make any patent application or secure any other proprietary rights to legally protect any such Invention without the prior written consent of the Supplier and Original Provider. The Supplier will, at all times, retain the right to use Invention for non-commercial research purposes.

10. The Recipient and Co-workers shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials.

11. The Materials are supplied without cost but the Recipient shall reimburse the Supplier for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to the Recipient.

12. The Materials are experimental in nature and Supplier and Original Provider makes no representation and gives no warranty or undertaking, in relation to them. As examples, but without limiting the foregoing, the Supplier and Original Provider give no warranty: (i) that it owns all necessary property and other rights in the Materials and that their use will not infringe any patent, copyright, trade mark or other right owned by any third party; or (ii) that the Materials are of merchantable or satisfactory quality or fit for any particular purpose, have been developed with reasonable care and skill or tested, for the presence of pathogens or otherwise, or are viable, safe, or non-toxic.

13. The Supplier and Original Provider shall have no liability to the Recipient, whether in contract, tort or otherwise, in relation to the supply of the Materials to the Recipient or their use or keeping by the Recipient or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law. The Recipient shall indemnify and hold harmless the Indemnified Parties from and against all Claims and Losses arising from such supply, use or keeping, including without limitation Claims and Losses arising from: (i) breach of this Agreement; (ii) injury to the Institution’s employees and third parties; (iii) infringement of third party intellectual property rights; and (iv) use of the Materials or any results (including data) created using the Materials within or outside the scope of this Agreement.

14. For the purposes of this Agreement: (i) “Indemnified Parties” shall mean Supplier and Original Provider and their associated undertakings and their respective directors, officers, employees and representatives; (ii) “Claims” shall mean all demands, claims, proceedings, penalties, fines and liability (whether criminal or civil, in contract, tort or otherwise); and (iii) “Losses” shall mean all losses including without limitation financial losses, damages, legal costs and other expenses of any nature whatsoever.

15. The Recipient agree to be bound by this Agreement in consideration of the Supplier making the Materials available to the Recipient.

16. Portuguese law shall apply to this Agreement, and the Portuguese courts shall have exclusive jurisdiction. This Agreement does not create any right enforceable by any person that is not a party to it.

AGREED by the parties through their authorised signatories:

|  |  |  |
| --- | --- | --- |
| For and on behalf of Supplier | For and on behalf of Recipient | Acknowledged by the Recipient Scientist (who is not a part of this agreement) |
| Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date (DD/MM/YY)Contact: serology4covid@colife.eu | Date (DD/MM/YY)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date (DD/MM/YY)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

***Annex I – Research Programme***

*PLEASE INSERT DESCRITION OF RESEARCH PROGRAMME (MAX 1 PAGE)*

*Project Title*

*Please fill*

*Project Objectives*

*Please fill*

*Location*

*Please fill*

*Tasks to be carried out*

*Please fill*

*Timetable*

*Please fill*

*Results Anticipated*

*Please fill*

***Annex II – Testing own staff***

*Description of efforts of testing own staff*

*Please fill*

*Subjects that will be tested*

*Please fill*

*Timelines for the test(s)*

*Please fill*

***Annex III - The Standard Operation Procedure optimized by the Serology4COVID***

**Anti-spike SARSCoV2 - ELISA standard operation procedure**

Adapted from Stadlbauer et al, Current Protocols in Microbiology e100, Volume 57,

by IBET, IMM, CEDOC and IGC.

*This SOP is based on Florian Krammer protocol and further development and adaptations by the Serology4COVID and regroups the minor variations adopted for practicality by each Serology4COVID Member.*

**COATING**

* RBD: 2µg/ml in 1x PBS or Spike: 2 or 0.5µg/ml in 1xPBSa
* 50µl/well on high binding 96 well/plate
* 4ºC ON

**WASHING**

* 1xPBS 0.1%Tween20, 3-5 times

**BLOCKING**

* 1xPBS, 0.05%Tween20, 2%BSA (or 3% low-fat milk powder)b
* 150µl/well
* 1h at RT

**WASHING (optional)**

* 1xPBS 0.1%Tween20, 3-5 times

**SAMPLE**

* inactivated serum or plasma diluted 1:50 (and optionally at 1:100) in 1xPBS, 0.0,5% Tween-20, 2%BSA (or 1% low-fat milk powder)b
* 50 (or optionally 100) µl/well)
* 1h at RT

**WASHING**

* 1xPBS 0.1%Tween20, 3-5 times

**SECONDARY ANTIBODY**

* HRP-conjugated secondary antibody diluted in 1xPBS 2%BSA (or 1% low-fat milk powder)b,c
* 50µl/well
* 1h at RT

**WASH**

* 1xPBS 0.1%Tween20, 3-5 times

**SUBSTRATE AND MEASUREMENT**

* TMB substrate (50 or optionally 100µl/well)
* 10 min at RT in the dark
* 1M H2SO4 stop solution (50µl/well)
* Photometric measurement at 450nm within 30 minutes.

**CONTROLS AND CALIBRATORS**

* Negative: 1/50 pre-COVID19 sample pool,
* Positive: 1/50 high-titre COVID19 sample pool
* Calibrators: serial dilution high titre, and 1/50 low titre COVID19 sample pool.
* Blank: 1xPBS, 0.05% Tween-20, 2%BSA (or 1% low-fat milk powder)

Notes:

a spike at 0.5µg/ml discriminates better high, intermediate and low titre sera diluted at 1/50

b low fat milk may interfere with specific IgM detection

c enzyme conjugated secondary antibody concentration varies according to provider and lot. S4C screens uses Goat Anti-Human IgG Fc (HRP), ab97225, Abcam, at 1:25000 or 1:40000 final.

***Annex IV - Ancillary Agreement for RBD and Spike protein constructs***

By agreeing to this Ancillary Agreement, the RECIPIENT and RECIPIENT SCIENTIST acknowledge they recognize and commit to abide to the same rules and conditions of the ancillary MTA defined below:

Icahn School of Medicine at Mount Sinai, One Gustave Levy Place, New York, NY 10029 (“MOUNT SINAI”) is the owner of plasmid RBD SARS-CoV-2 and plasmid Spike SARS-CoV-2 (protein constructs), and retains ownership rights of protein constructs material incorporated in any derivative materials made by the Recipient. Protein constructs material is or may be the subject of a patent applications.