# PRODUCT RESTRICTION AGREEMENTS

Certain products purchased from Zalgen Labs require that the Purchaser/User agree to specific terms and conditions concerning the use of these products.

Each time the Purchaser/User purchases restricted products on the ZalgenLabs.com website, the Purchaser/User will be promoted to acknowledge acceptance and agreement to the appropriate restriction(s) listed below for that particular product. Failure to accept these restrictions will limit the Purchaser/User from purchasing the restricted products.

Some products also require that the Purchaser/User agree to the restricted terms and conditions in writing prior to the initial purchase.

## I. PURCHASE OF DIAGNOSTIC TEST KITS AND MATERIALS LABELED FOR RESEARCH USE ONLY.

- Products sold by Zalgen Labs LLC labeled Research Use Only (RUO) are referred to as "RUO Version Products".
- RUO Version Products are "For Research Use Only". RUO Version Products are not US Food and Drug Administration ("FDA") cleared or approved for diagnostic, prognostic, or any other clinical use. They are not authorized for emergency use.
- RUO Version Products do not bear a CE mark. RUO Version Products are not to be used to compare to an IVD that bears a CE mark. If the Purchaser/User intends to compare it to a test with the CE mark, Zalgen must be notified in writing for review and approval, and to obtain the appropriate labeled product that conforms to the requirements of the European Union IVD Directive ("IVDD").
- RUO Version Products have no intended investigational use and the testing performed is not to be used to provide data addressing or demonstrating safety or effectiveness.
- RUO Version Products are not to be used to report patient results for diagnostic, prognostic, or any clinical purposes, or to make treatment decisions, except as permitted by applicable law.
- RUO Version Products are not to be used in an independent clinical study. If the Purchaser/User wishes to conduct an independent clinical study, Zalgen shall be notified in writing for review and approval, and to obtain the appropriately labeled product.
- The Purchaser/User understands RUO Version Products are subject to change at any time.
- By purchasing RUO Version Products, the Purchaser/User verifies the intention to use these products for Research Use Only, except as otherwise expressly permitted by applicable law.

## II. PURCHASE OF DIAGNOSTIC TEST KITS LABELED FOR INVESTIGATIONAL USE ONLY

- Products sold by Zalgen Labs LLC labeled Investigational Use Only (IUO) are referred to as "IUO Version Products".
- IUO Version Products are specifically for use in designated clinical studies. Prior to purchase of IUO Version Products from Zalgen, the clinical investigators and all others directly responsible for use of the IUO Version Products in a specific clinical study (the "Clinical Study"), hereby designated as the "Investigators", must provide a copy of the clinical protocol to Zalgen.
- The Investigators certify that they have all governmental approvals to conduct the Clinical Study including use of the IUO Version Products.
- IUO Version Products are "For Investigational Use Only". IUO Version Products are not cleared or approved by the US Food and Drug Administration ("FDA") for diagnostic, prognostic, or any other clinical use. IUO Version Products are not authorized for emergency use. IUO Version Products are not CE Marked.
- The performance characteristics of the IUO Version Products have not been established.
- IUO Version Products are IVD product being provided for product testing that is not subject to the FDA 21 CFR part 812 prior to full commercial marketing for testing of specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful.
- Testing using IUO Version Products must be performed and used to generate clinical data and assess safety or effectiveness as specified in the Clinical Study.
- IUO Version Products are not to be used to report patient results for diagnostic, prognostic, or any clinical purposes, or to make treatment decisions, except as permitted by applicable law other than as specified in the Clinical Study.
- The Investigators understand IUO Version Products are subject to change at any time.

## III. PURCHASE OF ReSARS CoV-2 TEST KITS LABELED FOR EMERGENCY AUTHORIZED USE ONLY

- Zalgen Labs ReSARS CoV-2 are antibody tests authorized by the FDA for the detection of antibodies to SARSCoV-2 in human serum and/or plasma. The tests detect human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and are to be performed on only plasma or serum specimens.
- ReSARS-CoV-2 Antibody Tests are authorized for use in the United States in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.
- ReSARS-CoV-2 Antibody Tests are limited for use outside the United States only where allowed by law.
- Purchasers/Users intending to use the ReSARS-CoV-2 Antibody Tests must review the Fact Sheet for Healthcare Providers provided by Zalgen.
- All individuals whose specimens are tested with the ReSARS-CoV-2 Antibody Tests must receive the Fact Sheet for Recipients: Emergency Use of ReSARS CoV-2 Antibody Tests provided by Zalgen.

## IV. PURCHASE OF VIRAL ANTIGENS, VIRAL ANTIBODIES AND OTHER PRODUCTS REQUIRING A MATERIAL TRANSFER AGREEMENT

- Purchaser/User must have in place a written Material Transfer Agreement ("MTA") with Zalgen Labs specifying restrictions to the use of Viral Antigens, Viral Antibodies, and certain other products prior to purchasing those restricted products from Zalgen.
- See example below of an MTA template.
- Each Purchaser/User wishing to establish an MTA to obtain such limited products are to proceed as follows:
  - Contact Zalgen at admin@zalgenlabs.com with a request to preparee an MTA, providing basic information including list of Zalgen product(s) of interest and information highlighted in yellow in the template below.
  - Zalgen will prepare and return a draft MTA for further discussion. Conference calls will be scheduled as appropriate.
  - Following completion and execution of the MTA by both parties, the Purchaser/User will have access to purchasing the designated products.

### EXAMPLE OF MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (this "Agreement") is between Zalgen Labs, L.L.C., a Maryland limited liability corporation with a principal place of business located at 20271 Goldenrod Lane, Suite 2083, Germantown, Maryland 20876, ("Zalgen"), and [Name of Recipient] a _____ with an address at _____ ("Recipient"), in response to a request from Dr. [Name] ("Recipient Scientist") for research materials controlled by Zalgen. This Agreement is effective as of the date of the last party to sign below ("Effective Date").

I. Definitions

1. Original Material: [describe]

2. Material: Original Material, Progeny, Unmodified Derivatives, and Modifications.

3. Progeny: Unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism.

4. Unmodified Derivatives: Substances created by the Recipient that constitute an unmodified functional subunit or product expressed by the Original Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Original Material, proteins expressed by DNA/RNA supplied by Zalgen, or monoclonal antibodies secreted by a hybridoma cell line.

5. Modifications: Substances created by the Recipient which contain and/or incorporate the Original Material, Progeny, or Unmodified Derivatives.

6. Commercial Purposes: The sale, lease, license, or other transfer of the Material to a for-profit organization. Commercial Purposes also includes uses of the Material

by any organization, including Recipient, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material to a for-profit organization. However, industrially sponsored academic research will not be considered a use of the Material for Commercial Purposes per se, unless any of the above conditions of this definition are met.

7. Research: The research program described in Appendix A.

II. Terms and Conditions of this Agreement

1. Zalgen controls all Material. The Recipient may not make, manufacture, derive, or otherwise create Modifications or other substances through the use of the Material that are not Progeny, Unmodified Derivatives, or Modifications (i.e., do not contain the Original Material, Progeny, Unmodified Derivatives, or Modifications). If the Recipient makes, manufactures, derives, or otherwise creates Modifications or such other substances, Modifications and such other substances will be owned by Zalgen and Recipient will have no rights in or to such substances.

2. The Recipient agrees and the Recipient Scientist acknowledges that the Material:
   (a) is to be used solely for internal research purposes;
   (b) will not be used in human subjects, in clinical trials or for diagnostic purposes involving human subjects;
   (c) is to be used only at the Recipient organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his direct supervision;
   (d) is to be used only for the Research as described in Appendix A and will not be used for any other research or purpose without the prior written consent of Zalgen; and
   (e) will not be transferred to anyone else within the Recipient organization without the prior written consent of Zalgen.

3. All Material and any information relating to the Material ("Confidential Information") that is disclosed by Zalgen to Recipient is confidential. No Confidential Information will be disclosed to anyone within the Recipient organization who is not under the direct supervision of the Recipient Scientist. Recipient will use reasonable efforts to prevent the disclosure of Confidential Information to third parties for a period of ten (10) years from receipt, except for any Confidential Information that is expressly marked as a trade secret. As such, a trade secret will be maintained in confidence for so long as it is considered confidential and its trade secret status remains, provided that if it is no longer confidential, its entry into the public domain was through no fault of the Recipient. Recipient will not use Confidential Information for any purpose other than the Research. Recipient's obligations of confidentiality and non-use will not apply to Confidential Information that:
   (a) is already in the Recipient's possession at the time of disclosure by Zalgen under this Agreement, as evidenced by the Recipient's written records;
   (b) is or later becomes part of the public domain through no fault of the Recipient;
   (c) is received by the Recipient from a third party having no obligations of confidentiality to Zalgen; or

(d) is independently developed by the Recipient without reference to information disclosed by Zalgen to Recipient under this Agreement, as evidenced by the Recipient's written records.

In the event that Recipient receives a subpoena, a notice to produce, or information submissions or filings required by government agencies demanding Confidential Information, the Recipient will, to the extent possible and permissible under applicable law, promptly notify Zalgen in writing of such a demand to disclose. Such notice will include, without limitation, identification of the information to be so disclosed and a copy of the order. Zalgen may seek an appropriate protective order and/or waive the Recipient's obligations of nondisclosure under this Agreement. If requested by Zalgen, the Recipient will reasonably cooperate with Zalgen, at Zalgen's expense. If the Recipient is nonetheless compelled to disclose the Confidential Information, the Recipient will disclose only that portion of the Confidential Information which the Recipient, in its good faith judgment, is legally required to disclose. Upon Zalgen's request and at Zalgen's expense, the Recipient will use reasonable efforts to obtain assurances that confidential treatment will be accorded to such Confidential Information to the extent such treatment is available. The act of such disclosure will not operate to render Confidential Information non-confidential, unless the making of such required disclosure renders the Confidential Information public record.

4. The Recipient agrees and the Recipient Scientist acknowledges that any request for the Material from anyone other than those persons working under the Recipient Scientist's direct supervision will be referred to Zalgen.

5. The Recipient acknowledges that the Material is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of Zalgen, including any proprietary rights of Zalgen relating to any altered forms of the Material. In particular, no express or implied licenses or other rights are provided to use the Material, or any related patents controlled by Zalgen for Commercial Purposes or for any purposes other than the Research.

6. If the Recipient desires to use or license the Material for Commercial Purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with Zalgen to establish the terms of a commercial license. It is understood by the Recipient that Zalgen has no obligation to grant such a license to the Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the Material to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government. Nothing contained in this Agreement obligates or may be construed to obligate in any way Zalgen to proceed with any negotiation or transaction or to establish any business relationship, whether expressly contemplated by this Agreement or otherwise.

7. Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. ZALGEN MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR

PURPOSE, OR THAT THE USE OF THE MATERIAL OR CONFIDENTIAL INFORMATION WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

8. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material. Zalgen will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of Zalgen.

9. Recipient will inform Zalgen of the results of the Research, in confidence, by providing Zalgen with a written report describing such results. The Recipient agrees and acknowledges that no manuscript, abstract, presentation, or other publication disclosing Research results may be submitted to a third party or otherwise disclosed to a third parry without Zalgen's prior written approval. Confidential Information that has been expressly marked as a trade secret may NOT be included in any manuscript, abstract, presentation, or other publication disclosing Research results. The Recipient agrees and the Recipient Scientist acknowledges that appropriate acknowledgement of the source of the Material will be included in any publication that results from the Research.

10. The Recipient agrees to use the Material in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines, such as those relating to research involving the use of animals or recombinant DNA, for example.

11. Recipient further agrees that it will not export any Material received under this Agreement to any countries for which the United States government requires an export license or other supporting documentation at the time of export or transfer.

12. This Agreement will terminate on the earliest of the following dates: (a) one (1) year from the Effective Date, or (b) on completion of the Research, or (c) on thirty (30) days' written notice by either party to the other. Upon any expiration or termination of this Agreement, the Recipient will discontinue its use of the Material and will, upon direction of Zalgen, return or destroy any remaining Material and Confidential Information.

13. This Agreement is not assignable, whether by operation of law or otherwise, without the prior written consent of Zalgen. Any purported assignment that does not comply with Section 13 is null and void. This Agreement is binding upon and will inure to the benefit of and be enforceable by the parties, their successors, and their permitted assignees.

14. Sections 3, 5, 7, 8, 9, 12, 14, 16, 17, 18, 19, and 20 of Part II will survive any expiration or termination of this Agreement.

15. Each of the parties represents that it has full and unrestricted power and authority to enter into this Agreement and to adhere to the obligations. Each of the parties represents that to the best of its knowledge, the terms of this Agreement do not

conflict with, violate, or constitute a breach or default under any other agreement to which it may be a party.

16. In the event that Confidential Information, including Material, is inadvertently or accidentally disclosed, the Recipient will notify Zalgen as promptly as possible and will take all necessary precautions to avoid further dissemination of the Confidential Information disclosed, as well as precautions to prevent disclosure of any additional information.

17. This Agreement embodies the entire agreement and understanding between the parties hereto and supersedes all prior agreements and understandings relating to the subject matter. This Agreement may not be changed, modified, or extended except by written amendment executed by an authorized representative of each party.

18. This Agreement, and all matters arising out of or relating to this Agreement, will be interpreted, construed, and enforced in accordance with the laws of the State of Louisiana, without giving effect to its conflicts of law principles.

19. If any provision of this Agreement is held to be illegal, invalid, or unenforceable, then such illegality, invalidity or unenforceability will attach only to such provision and will not in any manner affect or render illegal, invalid, or unenforceable any other provision of this Agreement, and this Agreement will be carried out as if any such illegal, invalid, or unenforceable provision were not contained herein.

20. The Recipient acknowledges that money damages would be both incalculable and an insufficient remedy for any breach of this Agreement and that any such breach would cause Zalgen irreparable harm. Accordingly, the Recipient agrees that in the event of any breach or threatened breach of this Agreement, Zalgen will be entitled, without the requirement of posting a bond or other security, to equitable relief, including injunctive relief and specific performance, in addition to any other remedies at law or in equity it may have.

21. This Agreement may be executed in several counterparts, each of which, when executed and delivered, will be deemed to be an original, and all of which together will constitute and be deemed to be one and the same instrument. Transmission by facsimile, email, or other form of electronic transmission of an executed counterpart of this Agreement will be deemed to constitute due and sufficient delivery of such counterpart.

22. All notices, requests, and other communications hereunder will be in writing and will be personally delivered or by registered or certified mail, return receipt requested, postage prepaid, in each case to the respective address specified above, or such other address as may be specified in writing to the other party, and will be deemed to have been given upon receipt.

23. It is agreed that no waiver by either party of any provision, or of any breach or default of any of the covenants or agreements set forth herein, will be deemed a waiver as to any subsequent and/or similar breach or default, nor will any delay or omission on the part of either party to exercise or avail itself of any right, power or

privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such party.

24. The Material is provided at no cost, or with an optional transmittal fee solely to reimburse Zalgen for its preparation and distribution costs. If a transmittal fee is requested by Zalgen, the amount is so indicated: $TBD.

***Remainder of this page intentionally left blank. Signature page to follow.***

**ZALGEN LABS LLC**

By: _____
Name:
Title:
Date: _____

**RECIPIENT**

By: _____
Name:
Title:

Date: _____

Read and understood:

_____
Signature of Recipient Scientist

## APPENDIX A

Description of the research to be conducted with the Material: