AGREEMENT FOR COVID-19 TESTING

This Agreement for COVID-19 Testing (“Agreement”) is made and entered this ___ day of April, 2020, by and between University of Louisville Research Foundation, Inc., a Kentucky non-profit corporation (“ULRF”), located at Clinical and Translational Research Building (“CTRB”), 505 S Hancock St, Louisville, KY 40202, and the following healthcare facility (“Facility”):

____________________________________________________________________.
(Name and address of Facility)

Introduction. The novel coronavirus known as SARS-CoV-2 causes a respiratory disease and illness called COVID-19 that can range from mild to severe, including illness resulting in death. Many cases of COVID-19 have been confirmed in the Louisville community, Kentucky and the nation as a whole.

One of the key elements of the strategies to contain the spread of COVID-19 is an extensive testing program which has not yet been available to healthcare facilities in the Louisville area.

ULRF has developed a test for COVID-19 and desires to make this testing available to Facility in order to expedite the testing of patients and Facility desires to obtain this testing for its patients and/or workers in order to provide better treatment and mitigate the spread of this disease.

Accordingly, in consideration of the mutual promises set forth in this Agreement, ULRF and Facility agree as follows:

1. Obligations of Facility. Facility shall be responsible for collecting samples from patients for testing.

   The samples shall be collected and maintained in accordance with the requirements set forth in Section 5, below. It is the responsibility of the Facility to maintain sample integrity until samples are delivered to the testing location (CTRB or Regional Biosafety Laboratory (RBL) Hurstbourne Lane site.

   Facility shall either (check one)
   ___ (a) deliver the samples to ULRF at the location specified above in a timely manner, or
   ___ (b) timely notify ULRF that samples are ready for pick-up, for which the applicable transportation fee shall be charged.

   Facility further agrees to pay to ULRF for the testing in accordance with Section 4, below.
2. **Obligations of ULRF.** ULRF agrees to perform the testing in a manner consistent with that degree of care, skill and diligence as is ordinarily exercised by a professional laboratory testing contractor under similar conditions and circumstances, and each individual whom ULRF intends to engage to perform the testing will possess the qualifications, licenses, skills and experience needed to perform such testing.

ULRF will provide Facility with Cycle threshold values (Ct) for the primer targets of N1, N2, and the endogenous control, and a short description of the result (e.g., positive, negative, inconclusive, or invalid). Where the results are inconclusive or invalid, ULRF will consult with Facility as to the potential causes for the inconclusive or invalid results and, where appropriate, will retest the sample or request that a new sample be obtained and submitted for testing.

In performing the testing:

(i) ULRF will be responsible for the professional quality, technical accuracy, completeness and coordination of all tests, analyses and reports performed, conducted or prepared by or on behalf of ULRF;

(ii) ULRF will use reasonable efforts in a diligent manner to perform the testing on a timely basis in accordance with the timing agreed to by the parties;

(iii) ULRF will have sole control and discretion over the means, methods, techniques, equipment, sequences and procedures its uses to perform the testing, without having to confer with, or obtain the consent or approval of, Facility;

recognizing that ULRF is in the process of ramping up its testing capacity and cannot commit to providing test results within any specific timeframe at present.

ULRF will comply with all federal, state and local laws, rules and regulations applicable to the performance of its obligations under this Agreement.

3. **Limitations on Test Results.**

(a) ULRF represents and Facility acknowledges that the testing to be performed by ULRF has been developed in a research setting and that ULRF is not currently a CLIA-certified lab. Nevertheless, the test has proven reliable by comparative, paired testing with an FDA-approved test using CDC-approved methods run in parallel with another FDA-approved test performed in a CLIA-approved lab. While the testing has been developed for surveillance purposes and is not technically qualified as a diagnostic test, it has been shown to be reliable with no known incidence of false negatives.

(b) EXCEPT TO THE EXTENT OF THE LIMITED WARRANTIES SET FORTH IN SECTION 2, ABOVE, AND IN THIS SECTION 3, AND NOTWITHSTANDING ANY PROVISION TO THE CONTRARY CONTAINED HEREIN, OR IN ANY REPORT OR OTHER STATEMENT OR INSTRUMENT, ULRF MAKES NO WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, WITH RESPECT TO THE TESTING, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
(c) Any work product produced by ULRF as part of the testing performed hereunder (x) will relate only to those specific samples actually tested by ULRF, and (y), in no way, can be taken or relied upon as being representative of any other portion of the lot or batch from which such samples were taken;

(d) ULRF assumes no responsibility for the purposes for which Facility or any third party uses any work product from the testing; and

(e) Facility may not and will not, under any circumstances, hold out or represent to any third party that ULRF has in anyway whatsoever certified, guaranteed or otherwise passed judgment on the efficacy of any results derived from the performance of the testing hereunder, except to the extent ULRF has certified that it has performed the testing in accordance with the provisions of this Agreement.

4. Fees.

(a) The basic fee for the testing shall be $150 per test, but fees and other charges for the testing may be modified by ULRF from time to time with notice from ULRF to Facility. The fees will be invoiced by ULRF to Facility. ULRF will submit invoices to Facility on a regular basis and will send a final invoice to Facility upon completion of the testing. Unless otherwise specified, payment for the amount invoiced will be due upon presentation of the applicable invoice and all undisputed amounts will be paid within thirty (30) days of the date of invoice.

(b) If there is a dispute regarding an invoice, the issue will first be addressed by email, a meeting or telephone conference, within thirty (30) days after the date of invoice, between the representatives representing each party for the applicable project, and the parties agree to cooperate in good faith to attempt to resolve the dispute. Payment of all amounts due, if any, upon resolution of such dispute will be made within thirty (30) days after resolution of such dispute. Facility will continue to pay ULRF for all testing set forth hereunder except those disputed in good faith.

(c) A one percent (1%) per month (12% per annum) service charge will be added to all undisputed amounts remaining unpaid after the date on which they were due to ULRF. A $40.00 charge will apply to all returned checks.

5. Samples.

(a) Sample Requirements. Samples delivered to ULRF will be clearly identified with all information deemed reasonably necessary by ULRF, and as submitted by Facility to ULRF and agreed to and executed by representatives of both parties.

(b) Delivery of Samples. Unless otherwise noted in Section 1, above, Facility will deliver, or cause to be delivered, each sample to ULRF’s testing facilities. Notwithstanding anything to the contrary herein, Facility will retain the risk of loss or damage to all samples during shipment to ULRF.

(c) Storage. While in ULRF’s control or possession and while not undergoing testing, URLF will store all samples in current good industry practices. Notwithstanding the foregoing, ULRF will not be liable for any loss or theft of any samples.
ULRF will retain all samples following completion of the relevant testing for at least twenty-four hours after reporting results and will retain all positive samples for a minimum of seven (7) days. ULRF shall be responsible for the proper disposal of each sample.

6. **Regulatory Changes.** In the event any changes or additions to the laws, rules or regulations of the U.S. Food and Drug Administration or any other regulatory authority (each, a “Regulatory Authority”):

   (i) require that ULRF change the manner in which it performs the testing;
   and/or

   (ii) impose additional expenses, charges, fees and costs applicable to ULRF and/or the testing,

Facility will promptly reimburse ULRF for any and all incremental costs incurred by ULRF under this Agreement.

7. **Term.** This Agreement shall be effective as of the first date on which Facility provides samples to ULRF for testing, which was March ____, 2020 (“Effective Date”) and shall continue in effect indefinitely unless terminated by either party on not less than ten (10) days notice.

8. **Damages.** Facility acknowledges that many tests or other procedures performed by ULRF in connection with the testing may be hazardous and agrees that, except as such injury or damage relates to the gross negligence or willful misconduct of ULRF, ULRF will not be liable for any injury or damage to any property, products, employees, agents or other representatives of Facility or any third party (acting on behalf or at the request of Facility) that may occur during, or as a result of, the performance of the testing or any onsite visit at any of ULRF’s or any of its subcontractors’ facilities conducted in connection with this Agreement. In addition, Facility will indemnify and hold each ULRF affiliate harmless from and against any and all damages which such entity may incur as a result of any proceeding, directly or indirectly, arising out of or in any way related to such injury or damage.

9. **Entire Agreement.** This Agreement attached hereto from time to time, constitutes the complete and exclusive statement of the terms, conditions and agreements between the parties and supersedes all prior understandings and agreements, oral and written, between the parties relating to this Agreement, the Testing or other matters set forth herein. This Agreement may not be modified or altered except by written instrument duly executed by both parties.

10. **Governing Law.** The parties agree that this Agreement is entered into and will be governed by and constructed in accordance with the laws of Kentucky, without regard to its choice of laws principles.

11. **Relationship of the Parties.** ULRF is an independent contractor of Facility and not an employee, franchisee, agent, partner or joint venture of Facility. Neither party has
the authority to bind the other party without the express written authorization of the other party. Nothing herein may be construed so as to create an employer-employee, franchisor-franchisee, agency, partnership, or joint venture relationship between the parties hereto.

12. **HIPAA Compliance.** To the extent applicable, the parties agree to comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 USC § 1320d (“HIPAA”) and any current and future regulations promulgated thereunder. The parties further agree not to use or disclose any Protected Health Information (as defined in 45 C.F.R. § 164.501) or Individually Identifiable Health Information (as defined in 42 USC § 1320d), other than as permitted by HIPAA. The parties shall also comply with any other applicable federal and state laws and regulations, and all rules, regulations and policies of Facility and its affiliated medical staffs, regarding the confidentiality of patient information.

In witness whereof, the parties have entered into this Agreement as of the date first above written

**UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.**

By: ________________________________

Title: ________________________________

______________________________________________

**FACILITY**

By: ________________________________

Title: ________________________________