Terms and Conditions

CLINICAL LABORATORY SERVICES AGREEMENT

1. Services.

The parties agree that Facility is to provide clinical laboratory services for the patients of Client under the terms and conditions of this Agreement and in accordance with all applicable requirements of federal, state or local laws, rules, and/or regulations, third-party reimbursement sources (public or private), or other reimbursement sources covering Facility services. Clinical laboratory services will include virology (the COVID-19 Test, HCPCS U0002) testing performed on samples to provide information for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition (the “Service”).

2. Term & Termination.

A. Term of Agreement. This Agreement shall commence on the date of last signature (the “Effective Date”), and shall continue for a period of two (2) year(s) (the “Initial Term”). [NOTE: The Effective Date cannot be a date that occurs before the dates that both Facility and Client signed the Agreement. If the Agreement is submitted for approval with an Effective Date that occurs before the last party (Facility or Client) signed the Agreement, the Effective Date will automatically be changed to the date that Client or Facility signed, whichever is later. Facility will not be compensated for services provided to Client prior to the Effective Date.] This Agreement will automatically renew for successive twelve-month periods after the expiration of the Initial Term (an “Extended Term”), provided, however, that any Extended Term may be terminated upon (a) the full execution of a new agreement between the parties covering the same services; or (b) not less than thirty (30) days prior written notice of termination by either party to the other party during the Extended Term. As used herein, “Term” shall mean the Initial Term and any Extended Term.

B. Termination. Either party may terminate this Agreement, without cause, by providing not less than thirty (30) days’ prior written notice stating the intended date of termination. In the event that either party terminates this Agreement during the first year of the Initial Term, the parties shall not enter into a different agreement for the same services until the first anniversary of the Effective Date.


A. Procedures for Billing Client directly. Facility will bill Client monthly, and Client agrees to reimburse Facility at the rate set forth in Exhibit A as the current fees to be charged to Client for services rendered hereunder. No tests or services will be priced below the fair market value.

i. Facility will submit to Client on a monthly basis an invoice, which will reflect services rendered. Client agrees to pay Facility within thirty days of receipt of Facility’s invoice. Such invoice shall include the name of each patient to whom supplies, equipment and/or services were provided, the date each service was provided, and the total charge.

B. Compliance with Laws. Facility and Client will comply with all applicable federal and state laws and regulations applicable to the provision and billing of laboratory services, including, without limitation, any laws or regulations prohibiting the mark-up of the charges for laboratory services billed by Facility to Client.
4. **Test Information.**

Facility will provide Client with (i) laboratory name and address, (ii) laboratory phone and fax number, (iii) medical director’s name and phone number, and (iv) tests offered, including test name, pricing, CPT/HCPCS code, and specimen requirements.

5. **Test Orders and Forms.**

   A. **Orders.** All tests ordered by Client will be performed by or referred to another laboratory by Facility. All test orders must be accompanied with a diagnosis, sign, symptom, and/or ICD-9-CM (or other updated system) code associated with the test(s) being ordered. Verbal test orders must be authenticated as specified in accordance with Facility’s medical staff by-laws and/or state rules and regulations. Written confirmation of verbal orders must be received within twenty-four (24) hours. Standing orders must be written, authenticated and renewed every year, or in accordance with Facility’s medical staff bylaws.

6. **Records.**

   A. Facility agrees to keep and maintain any and all records, including, but not limited to, medical and financial records, for services rendered by Facility as may be required by federal, state, or local government agency, or payor guidelines.

   B. Facility agrees to deliver a copy of the original laboratory report in a timely manner to Client. The laboratory test report will include, at a minimum, patient’s name, date of test, test name, test result, normal values, laboratory name and address. Facility shall report all abnormal and STAT reports to Client or to the patient’s attending physician, as directed by Client.

   C. If applicable, pursuant to Section 1395X(V)(1)(I) of Title 42 of the United States Code, until the expiration of four years after the termination of this contract, Facility shall make available, upon written request to the Secretary of the United States Department of Health and Human Services, or upon request to the Comptroller General of the United States General Accounting Office, or any of their duly authorized representatives, a copy of this contract and such books, documents and records as are necessary to certify the nature and extent of costs of the services provided by Facility under this Agreement.

   D. Facility further agrees that, in the event Facility carries out any of the duties under this Agreement through a subcontract with a value of cost of Ten Thousand Dollars ($10,000) or more over a twelve-month period, with a related organization, such contract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request to the Secretary of the United States Department of Health and Human Services, or upon request to the Comptroller General of the United States General Accounting Office, or any of their duly authorized representatives, a copy of such subcontract and such books, documents and records of such organization as are necessary to verify the nature and extent of such costs.

7. **Laboratory Qualifications.**

Upon request, Facility shall provide Client with proof that Facility is approved by Medicare to provide laboratory services and is licensed or registered in its state of operation. Facility will perform all tests in compliance with any standard, ruling, or regulation of The Joint Commission, the State Department of Health.
and Human Services, CMS’s Clinical Laboratory Improvement Act, or any other governmental agency responsible for administering, regulating, or accrediting healthcare facilities or professionals.

**Supplies & Equipment.**

8. **Equipment.** Equipment provided by Facility to Client free of charge must be used exclusively in conjunction with ordering and testing of laboratory services provided by Facility.

9. **Specimen Transport & Courier Service.**

Under normal conditions, Facility will not be responsible for transport of specimens from Client to Facility. Transported specimens must be packaged and handled by Client and Facility according to OSHA guidelines.

10. **Independent Contractor.**

In performing the services herein specified, Facility is acting as an independent contractor, and neither Facility nor any Facility staff shall be considered employees of Client. In no event shall this Agreement be construed as establishing a partnership or joint venture or similar relationship between the parties hereto, and nothing herein contained shall be construed to authorize either party to act as agent for the other.

11. **Confidentiality.**

Each party warrants and covenants to the other that neither shall disclose to any third party, except where permitted or required by law, any patient or medical record information, and each shall comply with all federal and state laws and regulations regarding the confidentiality of such information.

12. **Insurance.**

Each party shall, at its sole cost and expense at all time during the term of this Agreement, procure and maintain comprehensive general and professional liability insurance (including personal injury, property damage, products liability, and completed operations liability) in an amount not less than required by Client’s medical staff bylaws.

13. **Miscellaneous.**

A. **Assignment.** This Agreement and the rights and interests hereunder may be transferred or assigned only with the prior written consent of the other party.

B. **Waiver.** The waiver of any breach of any term or condition of this Agreement shall not be deemed to constitute the waiver of any other breach of the same or any other term or condition.

C. **Entire Agreement.** This Agreement contains the entire contractual understanding between the parties and supersedes and terminates any prior agreement(s) between the parties hereto. No amendments or additions to this Agreement shall be binding unless such amendments or additions are in writing and signed by each party, except as herein otherwise provided.
D. **Regulatory Requirements.** The parties expressly agree that nothing contained in this Agreement shall require Facility or Client to refer or admit any patients to, or order any goods or services from Facility. Notwithstanding any unanticipated effect of any provision of this Agreement, neither party will knowingly or intentionally conduct himself in such a manner as to violate the prohibition against fraud and abuse in connection with the Medicare and Medicaid programs (42 USC Section 1320a-7b).

E. **Amendments.** No modifications of or amendment to this Agreement or its attachments shall be effective or binding on either party unless mutually agreed to in writing signed by both parties.

F. **Compliance.** Facility represents and warrants that as of the date of this Agreement: (i) it is not excluded, debarred or otherwise ineligible to participate in Medicare, Medicaid or any other federal or state healthcare programs or in any federal or state procurement or non-procurement programs; or (ii) it has not been convicted of a criminal offense related to the provision of federal health care items or services that could lead to debarment or exclusion. Further, Facility agrees to immediately notify the Client to the contract in the event the foregoing representation and warranty is no longer completely accurate. Facility acknowledges and agrees this is a material term of the Agreement and any breach or nonfulfillment of same will entitle Client to immediately terminate this Agreement.

G. **Alternate Dispute Resolution.** The parties firmly desire to resolve all disputes arising hereunder without resort to litigation in order to protect their respective business reputations and the confidential nature of certain aspects of their relationship. Accordingly, any controversy or claim arising out of or relating to this Agreement shall be settled by arbitration administered by the American Health Lawyers Association in accordance with its rules. The award or decision rendered by the arbitrator will be final, binding, and conclusive, and judgment may be entered upon such award by any court of competent jurisdiction. The arbitration process itself, and any other information or disclosures revealed by either party to the arbitrator or to the other party during the arbitration process will be confidential. No disclosure of the award shall be made by the parties except as required by the law or as necessary or appropriate to effectuate the terms thereof. The location of such arbitration shall be in the city where the Facility is located, unless the parties mutually agree to another location. The dispute shall be governed by the laws of the State in which Facility is located. Further, the prevailing party shall be entitled to recover all costs and expenses associated with arbitration, including reasonable attorneys’ fees. If the arbitrator determines that neither party has substantively prevailed, the parties shall bear equally the fees and costs of the arbitrator and the related expense of arbitration. This section specifically survives the termination of this Agreement.

H. **Governing Law.** This Agreement shall be governed by the laws of the state in which Facility is located.

I. **Third-Party Beneficiaries.** This Agreement is entered into for the sole benefit of Facility and Client. Nothing contained herein or in the parties’ course of dealings shall be construed as conferring any third-party beneficiary status on any person or entity not a party to this Agreement.

J. **Master Contract Database.** To the extent required by 42 C.F.R. section 411.357 (d) (1) (ii), all service agreements between Facility and Client (or an immediate family member of Client) are maintained electronically in a master contract database that is maintained and updated centrally and is available for review upon request by an authorized governmental official.
14. **Notice.**

Any notice required or permitted to be given hereunder shall be in writing and may be given by: (1) hand delivery and shall be deemed given on the date of delivery; (2) registered or certified mail and shall be deemed given the third day following the date of mailing; or (3) overnight delivery by reputable overnight delivery services such as Federal Express or UPS and shall be deemed given the following day.

**FACILITY:** Michigan Technological University  
1400 Townsend Drive  
Houghton, MI 49931  
Attn: Administration  
And Via E-mail shschult@mtu.edu, ddreed@mtu.edu and dcyrus@mtu.edu

15. **HIPAA Requirements.**

Both parties agree to comply with the applicable provisions of the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act"), the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. §1320d through d-8, as amended from time to time ("HIPAA"), and the requirements of any regulations promulgated under either the HITECH Act or HIPAA, including, without limitation, the federal privacy regulations as contained in 45 CFR Parts 160 and 164 (the “Federal Privacy Regulations”), the federal security standards as contained in 45 CFR Parts 160, 162 and 164 (the “Federal Security Regulations”), and the federal standards for electronic transactions contained in 45 C.F.R. Parts 160 and 162 (the "Federal Electronic Transactions Regulations"), all as amended from time to time and all collectively referred to herein as "HIPAA Requirements." Both parties acknowledge that each party constitutes a “covered entity,” as that term is defined at 45 CFR §164.103, and both parties are engaged in “covered functions,” as that term is defined at 45 CFR §164.501.

Both parties agree not to use or further disclose any “protected health information,” as defined at 45 CFR §164.103, or “individually identifiable health information,” as defined at 42 U.S.C. §1320d (collectively, the “Protected Health Information”), concerning a patient other than as permitted by the provisions of this Agreement and the requirements of HIPAA and the regulations promulgated pursuant to HIPAA, including without limitation the Federal Privacy Regulations and the Federal Security Regulations. Both parties shall implement appropriate safeguards to prevent the use or disclosure of protected health information other than as provided for by this Agreement. Either party shall promptly report to the other party any use or disclosure of protected health information not in accordance with this Agreement or in violation of HIPAA Requirements of which that party becomes aware. In the event either party, with the prior approval of the other party in writing, contracts with any other parties or agents to whom the party furnishes protected health information received from the party, that party shall include provisions in such agreements whereby that party and the other party or agent agree to the same restrictions and conditions that apply to that party with respect to such protected health information. Either party shall return to the other party or properly dispose of any protected health information in accordance with federal and state law and regulations after the expiration or termination of this Agreement. Either party shall make its internal practices, books, and records relating to the use and disclosure of protected health information available to the Secretary of Health...
Submission of the requisition form certifies:

1) This Agreement constitutes a binding agreement to perform services as and may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument;

2) The compensation arrangement is established at fair market value for the services to be rendered, and this Agreement is for services that are needed and reasonable in scope;

3) This Agreement supersedes all prior agreements, contracts and understandings, whether written or otherwise, between the parties relating to the subject matter hereof and does not condition the payment or the arrangement on the volume or value of any referrals or other business generated between the parties;

4) Until the Agreement is listed in Client’s Master Contract Database to the extent required by 42 C.F.R. § 411.357(d)(1)(ii), no payment shall be made nor services accepted under this Agreement; and

5) Upon the Effective Date of this Agreement, no payments shall be made and no services accepted beyond the terms of this Agreement or the terms of other company-approved agreements between the parties.
Exhibit A

Fee Schedule

One Hundred Percent (100%) the Medicare Fee Schedule, as amended from time to time by Medicare. Facility shall provide a copy to Client upon request.