

HABERSHAM COUNTY BOARD OF COMMISSIONERS
EXECUTIVE SUMMARY

SUBJECT: Pro-geneX & Habersham County Emergency Services Laboratory Agreement

DATE: 04/18/2022

(X) RECOMMENDATION

() POLICY DISCUSSION

BUDGET INFORMATION:

() STATUS REPORT

ANNUAL-

() OTHER

CAPITAL-

COMMISSION ACTION REQUESTED ON: April 18, 2022

PURPOSE:

Seek commission approval for Laboratory Agreement between ProgeneX and Habersham County Emergency Services.

BACKGROUND / HISTORY:

- a. One of the services provided by ProgeneX, is laboratory testing on a person's DNA to determine the best medication to be prescribed.
 - b. The HCES Community Paramedicine program has several individuals this testing may benefit.
 - c. Pro-geneX will bill Medicare for the testing.
 - d. The Community Paramedicine staff will take the samples and submit them for testing.
 - e. Pro-GeneX will pick up samples.
 - f. No out-of-pocket expense for the county.
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FACTS AND ISSUES:

- a. Patients have often been prescribed medications their body does not use appropriately. For example, 30% of the population does not respond appropriately to the commonly used medication Plavix, commonly used for stroke and cardiac patients.
 - b. The Community Paramedicine program has several patients they have cared for over a long period, which may benefit from the testing.
 - c. Pro-GenX is responsible for maintaining the security of the patient's medical information.
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OPTIONS:

- 1) Approve recommendation
 - 2) Deny recommendation
 - 3) Commission defined alternative
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RECOMMENDED SAMPLE MOTION: Make a motion for the approval for Pro-GeneX to provide services for the Habersham County Emergency Services Community Paramedicine patients for the testing as described in the agreement.

DEPARTMENT:

Prepared by:

Jeffrey D. Adams

Director: _____

**ADMINISTRATIVE
COMMENTS:**_____

_____ **DATE:** _____

County Manager

Pro-GeneX & Habersham County Emergency Services Laboratory Agreement

This Laboratory Agreement (this “Agreement”) is entered into as of **March 28, 2022**, between **Pro-GeneX Laboratories Incorporated** (“Pro-GeneX”) a Georgia corporation, and **Habersham County Emergency Services** located in Clarksville, Georgia

Pro-GeneX owns and operates a CLIA-certified clinical laboratory, which performs tests and examinations on human body materials for the purpose of providing information for the diagnosis, prevention, or treatment of disease, or the assessment of medical conditions; and

Provider desires to contract with Pro-GeneX to provide laboratory services, for Provider patients, and Pro-GeneX desires to perform such services for Provider in an economically prudent manner, pursuant to the terms and conditions set forth herein.

Therefore, in reliance upon and in consideration of the above facts and the terms and conditions set forth below, the parties agree as follows:

1. Terms and Termination

- a. **Term.** This Agreement will remain in effect for an initial term of 12 months (the “Initial Term”) from the date hereinafter first written and will automatically renew for additional terms of one year each.
- b. **Termination upon Breach.** This Agreement may be terminated by either party in the event of a material breach by the other party, upon the giving of thirty days written notice setting forth such breach. However, if such breach is cured within thirty days of such notice, then such notice will be deemed to be withdrawn.
- c. **Termination Without Cause.** After expiration of the Initial Term, either party may terminate this Agreement, with or without cause, upon thirty days prior written notice to the other party.

2. Duties of Pro-GeneX

- a. Pro-GeneX will perform clinical laboratory testing services required by Provider for Provider’s patients, employees, and subcontractors for the benefit of Provider’s operations in accordance with the terms of this Agreement.
- b. Pro-GeneX will perform testing on specimens received from Provider Monday through Friday of each week, except holidays. Pro-GeneX guarantees that SARS-COVID-19 test results will be available within 48 hours provided that specimens are collected, transported, and maintained appropriately, and all laboratory requisition forms are completed accurately.
- c. Pro-GeneX will transmit patient reports via a cloud-based portal. Pro-GeneX will grant Provider electronic access to such cloud-based portal and Provider will be responsible for the proper use and confidentiality of any usernames, unique identifiers, passwords, or pins that are used in conjunction with the Pro-GeneX cloud-based portal. Copies of transmitted reports will not be mailed, emailed, or hand delivered by courier.
- d. Under this Agreement, Pro-GeneX will provide to Provider certain specimen collection supplies, at no charge, to be used solely for the collection of specimens that are to be returned to Pro-

GeneX for analysis or testing by. The type and amount of such supplies are subject to Pro-GeneX decisions and procedures of what is reasonable or appropriate in the particular circumstances, including without limitation its particular contractual relationships with equipment suppliers and others.

- e. In accordance with federal law (42 C.F.R. § 411.351) supplies identified as “dual use” will not be provided. Pro-GeneX reserves the right to reduce the quantity of any supply item ordered by Provider to reflect the historical volume of testing referred to Pro-GeneX.
- f. Because needles or similar devices used for blood collection procedures may be governed by federal and state laws, for example, OSHA’s Bloodborne Pathogen Standard, Provider will use the needles or cause them to be used in an appropriate manner, in accordance with the manufacturer’s instructions and all applicable laws and regulations. Pro-GeneX is not responsible for any claims arising out of the use or misuse of any needles or any other supplies provided hereunder. Pro-GeneX makes no warranties, express or implied, including but not limited to implied warranties or merchantability and fitness for a particular purpose, with respect to any specimen collection supplies provided hereunder.
- g. Pro-GeneX warrants to Provider that all services provided hereunder will be performed in accordance with established and recognized clinical laboratory testing procedures and with reasonable care in accordance with applicable federal, state, and local laws. Except as expressly set forth herein, no other warranties are made by Pro-GeneX. In no event will Pro-GeneX be responsible for any punitive damages or any consequential, incidental, indirect, or special damages of Provider or any third party.
- h. If specimens cannot be analyzed because of improper collection or degradation in transit or if Pro-GeneX is unable to obtain satisfactory test results on an apparently acceptable specimen, Pro-GeneX will promptly notify Provider. In either case, Provider will not be charged for the unacceptable specimen or nonviable results.

3. Duties of Provider

- a. **Patient Demographics and Insurance Information.** Provider will provide all information to Pro-GeneX required for billing, compliance, and performance of laboratory services. Pro-GeneX will bill Provider directly and Provider will promptly pay, for all such requested services at the rates set forth in **Exhibit A**, other than when Provider requests that Pro-GeneX bills insurance or a third-party payor for the laboratory services.
- b. **Completion of Forms.** In addition to the foregoing, Provider is responsible for correctly completing and submitting requisition forms to Pro-GeneX for all provider requested laboratory services, including all patient demographics, diagnostics, and billing information necessary to maintain an accurate and sufficient medical record for each patient.
- c. **Submission of Specimens.** Pro-GeneX will facilitate the daily collection of specimens from Provider at one single location or drop-box to be determined jointly by Provider and Pro-GeneX.
- d. Provider will send specimens to Pro-GeneX via FedEx courier service. Provider will ensure that patient specimens referred to Pro-GeneX are collected in an appropriate container, in adequate quantity, and properly packaged for transport, in accordance with Pro-GeneX policies and procedures or as otherwise communicated to Provider from time to time, and in accordance with all applicable federal, state and local statutes, rules, and regulations.

- e. **Specimen Collection.** Provider is responsible for specimen collection, labeling of specimens, **submission of full patient demographics and insurance information**, and other collection-related activities that are performed by Provider employees or other qualified individuals acting on Provider's behalf as well as delivery of test specimens to Pro-GeneX's facility. Specimens must be collected in accordance with the instructions provided with the test kit shipments used by Pro-GeneX and such other instructions that Pro-GeneX may provide. Each collected specimen must be placed in an individual biohazard bag, and the bagged specimen, properly labeled (in accordance with Pro-GeneX's instructions) must be placed in a second biohazard bag. Each specimen must be marked with the date and time of collection, and initialed by the individual collecting the specimen and must be delivered to Pro-GeneX test facility within 48 hours of collection. Collected specimens are to be kept at certain temperatures until delivered to Pro-GeneX. Collected specimens must be maintained as established in instructions, or other procedures, provided by Pro-GeneX until delivered to the Pro-GeneX testing facility. Pro-GeneX may reject, for testing, any specimen that does not satisfy its criteria for patient demographics and insurance information, specimen acceptability or specimen otherwise unsuitable for testing. Pro-GeneX will promptly notify the Provider of the rejection or inability to use any test specimen.
- f. **Specimen Delivery Cutoff Time.** Specimens may be delivered to Pro-GeneX laboratory testing facility on regular business days between the hours of 8:30 am and 5:00 pm. COVID-19 specimens received by the testing facility before 2:00 pm will likely be processed the same day. Specimens received at or after 2:00 pm will be processed the following business day.
- g. **Authorized Provider Order.** Each specimen must be accompanied by a valid order from a healthcare provider who is authorized to order such test under the laws of the State of Georgia and who will satisfy applicable requirements for Pro-GeneX to bill and receive payment from third-party payers, including, but not limited to, federal health care programs and commercial insurers, or, as appropriate, the Provider, for the fees associated with Pro-GeneX's performance of testing under this Agreement. Provider is responsible for ensuring that all orders for laboratory services and tests are made by an Authorized Provider.
- h. **Patient Consent, Authorization, and Notices.** Provider must obtain all consents and authorizations from individuals and patients, such as No Surprise Act required notice for out-of-network healthcare services, as may be required by applicable law to enable Pro-GeneX to perform laboratory services and tests for such patients and report the results thereof to Provider, the Authorized Provider who ordered the test, and/or the individual for whom the test was performed. Submission of a test order by Provider or its providers or Authorized Provider will be deemed to be confirmation by Provider that authorization and consent was obtained from patient and/or employee and will be maintained in accordance with law to allow the collection by Provider, testing by Pro-GeneX, and release of results by Pro-GeneX to Provider, Authorized Provider or any person accessing the Pro-GeneX test results portal, other Laboratory databank, or any Laboratory report containing patient information. Upon request, the Provider must provide Pro-GeneX with a copy of consents and authorizations signed by the individual for whom the test was performed or his/her guardian or personal representative.
- i. Provider will assume full professional and administrative responsibility for all services provided for Provider's patients. Provider is also ultimately responsible for ensuring that any service provided pursuant to this Agreement complies with all pertinent provisions of federal, state and

local statutes, rules, and regulations such as the Health Insurance Portability and Accountability Act of 1996, codified at 42 U.S.C. §§ 1320d through 1320d-8 ("HIPAA") and its implementing regulations (the "HIPAA Regulations"); Health Information Technology for Economic and Clinical Health Act (HITECH Act); the Genetic Information Nondiscrimination Act of 2008 (GINA) and all subsequent amendments; all other privacy laws, and employer's responsibilities to keep health records separate from employee records.

4. **Compensation**

- a. **Third-Party Billing and Billing Assignment.** Pro-GeneX will bill Provider directly for all laboratory services requested by Provider, except laboratory services where Provider requests that Pro-GeneX bills insurers or third-party payors for payment. In situations when Pro-GeneX bills commercial insurance, Medicare, Medicaid, private payors, or other third parties for laboratory services, Pro-GeneX accepts those assignments if Provider provides all patient demographic and insurance information to Pro-GeneX as requested at the time of services. No fees will be paid by Pro-GeneX to Provider for services that Pro-GeneX bills the insurer or third-party payor. If Provider is billed for a laboratory service, Pro-GeneX will not bill commercial insurance, Medicare, Medicaid, Provider patients, private payors, or other third parties for such laboratory services.
- b. **Billing and Fee Provider Schedule.** Pro-GeneX will submit to Provider a monthly statement reflecting such laboratory services furnished to Provider by Pro-GeneX. Such statement will reflect charges included on the Fee schedule set forth in **Exhibit A**, which is expressly incorporated herein by reference. Any amendments or changes to the Fee Schedule or **Exhibit A** will become effective 60 days after Provider's receipt of notice advising Provider of such amendments, unless the parties expressly agree to a different effective date. Provider will be required to pay Pro-GeneX the full amount due within 30 days of receipt of a Pro-GeneX statement. In the event it becomes necessary to bring collection proceedings to collect amounts owed to Pro-GeneX hereunder, Provider will be responsible for all reasonable costs associated with such collection efforts, including attorneys' fees, late fees, interest, and court costs.
- c. **Pricing is Confidential.** The parties agree that all information and matters regarding pricing represent the confidential information of Pro-GeneX ("Confidential Information"). The Provider must maintain the confidentiality of all pricing and fee information and must not divulge such information to any third-party, except as required by applicable law.
- d. **Amendments to Fee Provider Schedule.** Any amendments or changes to the Fee Provider Schedule or information found in **Exhibit A** does not need signatures by the parties and will automatically become part of this Agreement.

5. **Independent Contractor.** In the performance of the work, duties and obligations of Pro-GeneX under this Agreement, it is mutually understood and agreed that Pro-GeneX is at all times acting and performing as an independent contractor. Provider will neither have nor exercise any control or direction over the methods by which Pro-GeneX or its employees will perform their work and functions. Neither party can act as the agent or employee of the other with regard to the subject of this Agreement or any other matter.

6. **Confidentiality**

- a. **Confidentiality of Agreement.** All provisions in this Agreement, including all exhibits hereto, are strictly confidential. Provider is prohibited from communicating or permitting to be communicated by any of its agents, employees, or contractors any of the contents of this Agreement to any third party except in an instance when expressly required by law. Access to the contents of this Agreement must be strictly limited to only those employees who have a definite “need to know” its contents, as necessary to the performance of this Agreement. The provisions of this paragraph will survive the termination of this Agreement.
 - b. **Confidentiality of Patient Information.** Provider and Pro-GeneX agree that clinical records of patients related to the ordering of laboratory tests and/or test reports will be regarded as confidential and as protected health information. Both parties will comply with all applicable federal and state laws and regulations regarding the use and disposition of such information, including without limitation the provisions of the Health Insurance Portability and Accountability Act 1996, codified at 42 U.S.C. §§ 1320d through 1320d-8 (“HIPAA”) and its implementing regulations (the “HIPAA Regulations”). Without the prior written consent of Pro-GeneX, Provider will not manipulate, aggregate, integrate, compile, merge, reorganize, regenerate or otherwise use the information (except for its own internal purposes and original intention for services) and will not provide the information to any person or entity, except as required or authorized by applicable law. The provisions of this paragraph will survive the termination of this Agreement.
7. **Access to Records.** For a period of six years following the last date Pro-GeneX furnishes services pursuant to this Agreement, Pro-GeneX will make available, upon written request by the Secretary of the United States Department of Health and Human Services (“HHS”), the Comptroller General of the United States or any of their duly authorized representatives, all contracts, books, documents and other records of Provider or Pro-GeneX, as applicable, which are necessary to verify the nature and extent of the costs of the services provided hereunder
 8. **Insurance.** Each party will maintain professional liability insurance in the amount of \$1,000,000 per incident and \$3,000,000 annual aggregate, which covers professional services rendered pursuant to this Agreement. Pro-GeneX will provide a certificate of insurance upon request.
 9. **Liability.** Each party will be responsible for the acts and omissions of itself and its employees and will not be responsible for the acts and omissions of the other parties or its employees.
 10. **Disputes.** Any dispute arising under this Agreement that is not disposed of by agreement of the parties will be subject to the following process. The party raising the dispute will notify the other party of the dispute in writing. The party’s notification must detail the nature of the dispute, seek specific relief, and be accompanied by any documentation supporting the party’s position. A resolution to the dispute will first be attempted between Pro-GeneX and the Provider by utilizing the notice information provided herein. Any resolution will be formalized in writing by the parties. In the event the dispute is not resolved within 30 business days of the written notification of the dispute, the party which did not raise the dispute will provide a written response and attach thereto any documentation supporting that party’s position. Thereafter, the parties will meet in good faith to attempt to resolve the dispute. Any resolution will be formalized in writing by the parties. If, for any reason, the parties have not resolved the dispute within 45 calendar days, either party may pursue appropriate administrative remedies and/or file suit according to the Choice of Law and Jurisdiction provisions found herein.

11. Indemnification.

- a. To the extent permitted by law, Provider will defend, indemnify and hold harmless Pro-GeneX and all of its officers, agents, and employees from and against any and all claims, loss, damage, injury, and cost resulting from or arising out of any negligent acts or omissions of Provider in connection with Provider's obligations in this Agreement.
- b. Pro-GeneX will defend, indemnify, and hold harmless the Provider and all of its elected or appointed officials and employees from and against any and all claims, loss, damage, injury, and cost resulting from or arising out of any negligent acts or omissions or willful misconduct of Pro-GeneX in connection with Pro-GeneX obligations in this Agreement. Pro-GeneX's liability in connection with any cause of action, costs or damages relating to the indemnity provision above is limited to the liability insurance maintained by Pro-GeneX, in no case will the liability be greater than the aggregate value of all laboratory services performed by Pro-GeneX and requested by Provider in the last 12 months.

12. Choice of Law & Jurisdiction. This Agreement is governed by and construed in accordance with the laws of the State of Georgia and the federal laws of the United States of America. The parties will attempt in good faith to resolve all disputes, disagreements, or claims between the parties relating to this Agreement. In the case of a dispute concerning this Agreement, the Parties consent and submit to the jurisdiction and forum of the state and federal courts in Hall County, Georgia. Either party may apply to any court for any equitable relief such as injunctions.

13. Compliance with Laws

- a. This Agreement is intended to comply with any and all federal and state statutes, regulations and rules, including but not limited to HIPAA, 42 U.S.C. § 1320a-7b(b) (the "Fraud and Abuse Statute") and 42 U.S.C. § 1395nn and 42 U.S.C. § 1395nn (the "Stark Law") and the safe harbors and exceptions promulgated pursuant to the Fraud and Abuse Statute and the Stark Law, as amended from time to time. In the event that any law, regulation, or administrative or judicial interpretation is adopted, amended, promulgated, modified or issued, which prohibits or restricts all or any party of this Agreement, the parties will either: (i) renegotiate this Agreement in the manner intended to comply with such law, regulation, or decision; or (ii) terminate the Agreement without penalty to either party.
- b. Pro-GeneX represents and warrants to Provider, with respect to all protected health information (as that term is defined under HIPAA), that it is a covered entity (and not a business associate of Provider) under the HIPAA Regulations and that it will protect the privacy, integrity, security, confidentiality, and availability of the protected health information disclosed to, used by, or exchanged by the parties by implementing appropriate privacy and security policies, procedures, and practices and physical and technological safeguards and security mechanisms, all as required by, and set forth more specifically in the HIPAA Regulations. The provisions of this paragraph will survive the termination of this Agreement.
- c. The amounts to be paid hereunder represent the fair market value of the services to be provided as established by arms-length negotiations by the parties and have not been determined in any manner that takes into account the volume or value of any potential referrals between the parties. No amount paid hereunder is intended to be, nor will it be construed to be, an inducement or payment for referral of patients by any party to any other party. In addition, the amounts charged hereunder do not include any discount, rebate,

kickback or other reduction in charges, unless an exception applies to the Anti-kickback Statute or the Eliminating Kickbacks Recovery Act. The amount charged is not intended to be, nor will it be construed to be an inducement or payment for referral of patients by any party to any other party.

14. **Non-Exclusion.** Each party represents and warrants that it is not an Excluded Provider. For purposes of this Section, the term “Excluded Provider” means a person or entity that either (i) has been convicted of a crime related to health care, or (ii) is currently listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federally funded programs (including without limitation, federally funded health care programs such as Medicare and Medicaid). Each party will notify the other party within 5 days after it receives notice of Exclusion. The party receiving the notice will have the right to terminate this Agreement at any time after learning that notifying party is an Excluded entity or individual.
15. **Force Majeure.** Pro-GeneX will not be liable for any claims or damages if such claims or damages result or arise out of a failure or delay that is due to any act beyond the reasonable control of the Pro-GeneX – including natural disasters, information technology or information systems failure, or acts of God.
16. **Miscellaneous**
 - a. This Agreement, along with **Exhibit A**, set forth the entire understanding between the parties with respect to the subject matter hereof, and prior or contemporaneous written or oral agreements are merged herein.
 - b. If any part of this Agreement is determined to be unenforceable in a court of competent jurisdiction for any reason, such part will be deemed severable from the remainder hereof and this Agreement will be construed in all respects as if such invalid or unenforceable provision were omitted.
 - c. Neither party will assign its rights or delegate its duties under this Agreement without the prior written consent of the other party. Notwithstanding the foregoing, Pro-GeneX may assign this Agreement to an affiliate of Pro-GeneX.
 - d. No waiver of any term, provision, or condition of this Agreement, whether by conduct or otherwise, in any one or more instances, will be deemed to be or construed as a further and continuing waiver of any such term, provision, or condition of this Agreement. No amendment to any provision of this Agreement will be effective unless in writing and signed by each party other than the Fee Provider schedule found in **Exhibit A**.
 - e. Should any litigation be commenced by any party concerning any provision of this Agreement or the right and duties of any party, the prevailing party will be entitled, in addition to such other relief as may be granted, to reasonable attorney’s fees and court costs.
 - f. Pro-GeneX certifies that all requirements have been met for coverage of services under Title XVIII of the Social Security Act.
 - g. In accordance with Title VI of the Civil Rights Act of 1964, Pro-GeneX does not refuse, limit, or terminate services to patients based on race, color, sex, national origin, or handicap. Services will be provided to all patients equally based on individual need for the service.

- h. This Agreement may be executed in any number of counterparts, each of which will be an original, but all of which together will constitute one instrument.
- i. **Notices.** All notices required or permitted to be given hereunder will be in writing and deemed to have been given upon delivery if hand-delivered or delivered by receipted overnight courier, **or** three days after deposit in the U.S. Mail if sent by certified or registered mail, return receipt requested, **or** by electronic mail. All such notices will be addressed as set forth below:

Pro-GeneX Laboratory Incorporated
Brett Grauss, President & CEO
Brett.Grauss@Pro-GeneX.com
999 Chestnut Street, Suite 16, Gainesville, GA, 30501

Habersham Emergency Services
Jeff Adams
jadams@habershamga.com
P.O. Box 1555 Clarkesville, Ga. 30523

The parties hereto have executed this Agreement to be effective as of the day and year first above written.

Pro-GeneX Laboratories Incorporated

Signature: 
DocuSigned by:
18E492E4A65B4EC...
Name: Brett Grauss
Title: President & CEO

Habersham County Emergency Services

Signature: _____
Name: Jeff Adams
Title: _____

EXHIBIT A

PAYMENT AND PRICING INFORMATION

Price List:

Test	Price
Amphetamines	\$12.75
Barbiturates	\$13.86
Benzodiazepines	\$13.90
Buprenorphine	\$22.50
Cannabinoid (THC)	\$12.75
Carisoprodol/Meprobamate	\$22.50
Cocaine metabolite	\$22.50
Fentanyl	\$22.50
Heroin metabolite	\$22.50
MDMA	\$22.50
Meperidine	\$22.50
Methadone	\$22.50
Opiates	\$13.86
Oxycodone/Oxymorphone	\$22.50
Phencyclidine (PCP)	\$12.75
Propoxyphene	\$22.50
Tapentadol	\$22.50
Tramadol	\$22.50

Urine Drug Screen (UDS) Toxicology	\$72.00
Molecular UTI/Urinary Tract Microbiota Test (UTI/UTM)	\$229.00
RPP including influenza	\$229.00
PGx Behavioral Panel	\$289.00
Vaginal Microbiota	\$229.00
SARS-COVID-19 PCR Guaranteed 24-hour turnaround.	\$80.00

*The prices above do not apply when Pro-GeneX bills the patient or the patient's insurance directly.

*Tests, and associated pricing, that are invoiced directly to the Facility are billed on a Net 10 basis.

Third-Party Billing and Billing Assignment. Pro-GeneX will bill commercial insurance, Medicare, Medicaid, private payors, or other third parties for the laboratory services applicable to this Agreement. Pro-GeneX accepts those assignments if Provider provides all patient demographic and insurance information to Pro-GeneX as requested at the time of services. If Provider is billed for a laboratory service, Pro-GeneX will not bill commercial insurance, Medicare, Medicaid, patients, private payors, or other third parties for such laboratory services.