




NOTICE OF AWARD

State Of Missouri
Office Of Administration
Division Of Purchasing
PO Box 809
Jefferson City, MO 65102-0809
<http://oa.mo.gov/purchasing>

CONTRACT NUMBER CS202236001	CONTRACT TITLE COVID-19 Testing
	CONTRACT PERIOD April 14, 2020 through October 13, 2020
REQUISITION/REQUEST NUMBER N/A	SAM II VENDOR NUMBER/MissouriBUYS SYSTEM ID 43174696000/MB0009700
CONTRACTOR NAME AND ADDRESS PTC Laboratories, Inc. 300 Portland Street Columbia, MO 65201	STATE AGENCY'S NAME AND ADDRESS STATEWIDE -Various State Agency Locations
ACCEPTED BY THE STATE OF MISSOURI AS FOLLOWS: In accordance with section 34.045, RSMo, the State of Missouri, Division of Purchasing hereby establishes Contract CS202236001 for use by all state agencies COVID-19 Testing, pursuant to all terms, conditions, prices, and provisions of the attached agreement, including the two attached emails from Joe Gorman dated 4/14/2020. All transactions between the state agency and the contractor shall reference the State of Missouri contract number.	
BUYER N/A	BUYER CONTACT INFORMATION Email: karen.boeger@oa.mo.gov Phone: (573) 751- 1699 Fax: (573) 526-9816
SIGNATURE OF BUYER N/A	DATE
DIRECTOR OF PURCHASING Karen S. Boeger 	

Covid-19 Testing Agreement

This Covid-19 Testing Agreement (the "Agreement"), effective as of the 14th day of April 2020 (the "Effective Date"), is entered into by and between PTC Laboratories, Inc. (PTC), having a business address at 300 Portland Street, Suite 300, Columbia, MO 65201 (hereinafter "Provider") and the State of Missouri, Office of Administration, Division of Purchasing, having a business address at 301 West High Street, Room 630, P.O. Box 809 Jefferson City, MO 65102 on behalf of all Missouri state entities providing direct care or custody services (the "Client"). Provider and Client may be individually referred to herein as a "Party" and collectively as the "Parties."

WHEREAS, Provider is the provider of certain genetic testing laboratory services, including testing to detect the presence of the SARS-CoV-2 virus, also known as the novel coronavirus (the "Virus Testing" or "Services," sometimes referred to as a "laboratory test"); and

WHEREAS, Client wishes to obtain or prescribe Services for patients, individuals under Client custody, or employees of the State of Missouri;

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, the Parties do agree as follows:

1. Scope.

- a. Provider agrees to provide Virus Testing for specimens collected by or on behalf of Client. Client agrees to collect or provide for the collection of specimens and provide such specimens to Provider for the purpose of Virus Testing.
- b. If requested, the Provider will supply specimen collection materials ("Specimen Collection Kits") and instructions ("Specimen Collection Instructions") for collecting and submitting specimens to the Provider for testing, as further described in Exhibit A.
- c. Provider will supply Client with a Test Requisition Form to use for requesting each individual test. Client must furnish Provider with a completed Test Requisition Form (in the form agreed to by Provider and Client) with or in connection with each specimen. Client acknowledges that Provider has no obligation to process specimens without a properly completed Test Requisition Form.
- d. Client shall collect and label specimens in accordance with the Specimen Collection Instructions agreed by Provider and Client.
- e. Client acknowledges and agrees that Provider (i) does not provide genetic counseling services to patients, and (ii) is only obligated to deliver test results of the Services to the applicable state agency that utilizes the Services.

2. Fees.

- a. For each Virus Test that Provider performs on a specimen from Client, the Client shall pay Provider one hundred twenty-five dollars (\$125.00).
- b. Once per calendar month, Provider will submit an invoice documenting amounts due for the services provided by Provider to each Client state agency during the prior calendar month pursuant to this Agreement. Each invoice shall include sufficient information to aid Client state agency in tracking the specimens.

Such information may include but is not limited to the first and last name; date of birth; and the date on which the specimen was collected.

- c. Client shall pay Provider within forty-five (45) days from the receipt of the invoice. In the case of a dispute, both parties will make commercially reasonable efforts to resolve the issue within fifteen (15) calendar days of receipt and Client will use reasonable efforts to submit the agreed upon payment within fifteen (15) calendar days thereafter.
- d. All payments to Provider shall be made in full by check or electronic funds transfer in U.S. dollars available at Provider's U.S. bank, or otherwise as Provider may direct in advance. The Parties acknowledge that on-time payment for the Services is a material requirement of this Agreement and that failure to make on-time payments shall constitute a material breach of this Agreement. Payments due from Client to Provider, and not received by Provider within forty-five (45) days of Provider emailing the invoice to Client state agency shall be subject to late penalties as permitted by section 34.055 RSMo. Provider shall apply payments from Client state agency first to any interest due hereunder. Provider shall be registered in the State of Missouri payment system.

3. Representations and Warranties.

- a. Provider hereby represents, warrants and covenants that: (i) Provider, its employees and contractors shall have and maintain during the term of this Agreement all U.S. federal and state licenses or certificates that are required by applicable law, rule, or regulation to perform the Services; and (ii) Provider will perform the Services in a professional and workmanlike manner, and in accordance with such applicable laws and regulations.
- b. Client hereby represents, warrants and covenants that: (i) Client, its employees and contractors shall have and maintain during the term of this Agreement all licenses or certificates that are required by law or regulations to perform its obligations under this Agreement; and (ii) Client will perform its obligations under this Agreement in a professional and workmanlike manner, and in accordance with such applicable laws and regulations.
- c. Without limiting the generality of the foregoing representations, warranties, and covenants, each Party, including its employees and contractors, shall comply with all laws and regulations preventing fraud and abuse within the healthcare industry, including but not limited to the federal Anti-Kickback Statute and the federal Physician Self-Referral (Stark) Law.
- d. This Agreement is intended to be in compliance with all applicable laws as of the Effective Date. The Parties agree to amend this Agreement to bring it into compliance with future applicable law as may be required.

4. Term and Termination.

- a. The term of this Agreement shall begin on the Effective Date and shall terminate six (6) months thereafter unless one Party receives prior written notice from the other Party of an election to terminate.
- b. The termination of this Agreement shall not affect any rights or obligations of either Party accruing prior to such termination.

5. Miscellaneous.

a. **Indemnification.**

i. By Provider.

1. Provider agrees to indemnify, defend and hold harmless Client, its parent company and affiliates, their officers, directors, representatives and employees (Client and each of the foregoing a "Client Indemnitee") against any and all claims or actions brought by a third party arising out of any personal injury, death, or other harm to any of Client's patients caused by Provider's negligence or willful misconduct in performing Services (referred to as a "Client Claim"). The obligation of Provider to indemnify, defend and hold harmless a Client Indemnitee from a Client Claim does not apply to the extent that such Client Claim is attributable to the fraud, negligence, gross negligence, or willful misconduct of a Client Indemnitee.
2. If Provider is made liable for a claim under the preceding paragraph then, subject to the requirements of subsection (iii) below regarding the handling of claims, Provider shall pay all settlements entered into, and all final judgments and costs awarded against such Client Indemnitee in connection with such Client Claim.

ii. By Client.

1. To the extent permitted by law and without waiving sovereign immunity, Client agrees to indemnify, defend and hold harmless Provider, its parent company and affiliates, their respective officers, directors, representatives and employees (Provider and each of the foregoing a "Provider Indemnitee") against any and all claim or action brought by a third party arising out of any personal injury, death, or other harm to any of Client's patients caused by Client's negligence or willful misconduct in performing its obligations under this Agreement (referred to as a "Provider Claim"). The obligation of Client to indemnify, defend and hold harmless a Provider Indemnitee from a Provider Claim does not apply to the extent such Provider Claim is attributable to the fraud, negligence, gross negligence, or willful misconduct of a Provider Indemnitee.
2. If Client is made liable for a claim under the preceding paragraph then, subject to the requirements of subsection (iii) below regarding the handling of claims, Client shall pay all settlements entered into, and all final judgments and costs awarded against such Provider Indemnitee in connection with such Provider Claim.

- iii. The Parties' indemnification obligations under Section 5(a) are subject to the Party seeking indemnification (a) notifying the indemnifying Party promptly in writing of the claim, (b) giving indemnifying Party exclusive control and authority over the defense of such claim, (c) not admitting infringement of any intellectual property right without prior written consent of the indemnifying Party, (d) not entering into any settlement or compromise of any such action without the indemnifying Party's prior written consent, and (e) providing all reasonable assistance to the indemnifying Party that the indemnifying Party requests and ensuring that its officers, directors, representatives and employees and other indemnitees likewise

provide assistance (provided that indemnifying Party reimburses the indemnified Party(ies) for its/their reasonable out-of-pocket expenses incurred in providing such assistance). An indemnifying Party will not enter into or otherwise consent to an adverse judgment or order, or make any admission as to liability or fault that would adversely affect the indemnified party, or settle a dispute without the prior written consent of the indemnified Party, which consent shall not be unreasonably withheld, conditioned, or delayed.

- b. **Independent Contractor.** Each Party is an independent party and shall not be construed to be an agent or representative of the other Party. In addition, neither Party, nor any of its employees, agents, or subcontractors, shall be deemed to be employees or agents of the other Party. Therefore, neither Party nor any of its employees, agents or subcontractors, shall be entitled to compensation, workers compensation, or employee benefits of the other Party by virtue of this Agreement. Furthermore, neither Party shall be deemed an agent nor employee of the other and neither shall have actual, apparent or implied authority to bind the other to any obligation whatsoever.
- c. **Confidentiality.** Provider and Client shall comply with applicable federal and state laws regarding the confidentiality of medical records, including but not limited to applicable provisions of the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations. This provision shall not preclude access to records to confirm the proper performance under this Agreement in accord with applicable law. The Parties acknowledge that in connection with this Agreement, each may receive or have access to proprietary and confidential information of the other. As used herein, "**Confidential Information**" means any business, financial, customer, product, technology or service information received by a Party from the other Party, or information that is marked as Confidential or with another similar confidentiality legend or if disclosed orally is identified as confidential at the time of disclosure and reduced to a written summary, also marked as Confidential, that is provided to the recipient Party within 30 days (email acceptable) other than: (a) information which at the time of disclosure is published or otherwise generally known or available to the public; (b) information which, after disclosure by the other Party, is published or becomes generally known or available to the public through no fault of the receiving Party; (c) information in the possession of the receiving Party without obligation of confidentiality; or (d) information that is independently developed by or for the receiving Party without use of or reference to the Confidential Information of the disclosing Party. Each Party agrees that, during the term of this Agreement and for a period of 5 years thereafter (the "**Confidentiality Term**"), it shall not disclose the other Party's Confidential Information, directly or indirectly, to any third party without the consent of the other Party, except as expressly permitted herein or unless disclosure is required by law. Each Party further agrees that during the Confidentiality Term it shall not use such Confidential Information except as is necessary to perform its obligations under this Agreement. Notwithstanding the foregoing, Provider may disclose Client's Confidential Information to its parent company and affiliates as necessary to perform hereunder or for administration of

its business, but only upon such parent company and affiliates prior written agreement to be bound by the confidentiality requirements contained in this Agreement.

- d. **Referrals.** The Parties agree that any payments required hereunder represent fair market value for the services rendered by the Parties and that the payment of monies hereunder in no way represents the division, sharing, splitting or other allocation of fees for medical services. The Parties further agree that any benefit, consideration or remuneration conferred upon one Party under this Agreement is not in any way contingent upon or related to, directly or indirectly, the solicitation of or the referral of or any other arrangement for the provision of, any item or service offered by the other Party or their parent companies or affiliates.
- e. **Notices.** Unless otherwise provided, any notice required under this Agreement shall be given in writing and shall be deemed effectively given upon personal delivery to the Party to be notified, or upon receipt when sent by a National Post Office (for dispatch by registered or certified mail, postage prepaid) or by recognized express courier (all charges prepaid). All such notices shall be addressed to the Party to be notified at the address set forth below, or at such other address as such Party may designate by 10 days' advance written notice to the other Party.

If to the Client:
(To be provided by each
department at time of
account setup)

If to the Provider:
John Beckwith
PTC Laboratories
300 Portland St., Suite.
300
Columbia, MO 65201

With a copy to:
Karen Boeger, Director
Office of Administration,
Division of Purchasing
301 West High, Room 630,
P.O. Box 809
Jefferson City, MO 65102

With a copy to:
Joseph M. Gorman
PTC Laboratories
300 Portland St., Suite
300
Columbia, MO 65201

- f. **Governing Law.** This Agreement shall be governed by the laws of the State of Missouri. The Parties hereby consent to personal jurisdiction of, and venue within, the state courts of the State of Missouri.
- g. **Successors and Assigns.** This Agreement and the provisions hereof shall be binding upon each of the Parties and their respective successors and assigns.
- h. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

- i. **No Exclusion.** No Party, and no officer, employee, agent or contractor thereof, is currently or has in the past been suspended, excluded, or debarred from, or is otherwise ineligible to participate in, any Federal Health Care Program.
- j. **Insurance.** The Parties shall procure or utilize a self-funded program and maintain adequate policies of professional and general liability insurance, in amounts of not less than one million dollars (\$1 m) per claim and three million dollars (\$3m) in the annual aggregate. In addition, each Party shall maintain property insurance and workers' compensation insurance. Upon request, each Party will furnish the other Party with evidence of such coverage. Each Party shall make reasonable business efforts to notify the other party thirty (30) days in advance of any substantial reduction, cancellation or termination of any insurance coverage.
- k. **Federal Funds.** The contractor shall understand and agree that the contract may involve the use of federal funds. The contractor shall comply with applicable Federal Funds requirements identified by the federal government.
- l. **Entire Agreement.** This Agreement (together with all exhibits and appendices attached hereto) contains, and is intended as, a complete statement of all of the terms of this Agreement between the Parties with respect to the matters provided for herein and supersedes any previous agreements and understandings (whether written or oral) between the parties. (NOTE: The agreements with Department of Mental Health and Missouri Veterans Commission shall continue to apply for tests completed under those agreements for those agencies as long as they remain in effect.) All Exhibits and Attachments, including the business associate agreement attached to this Agreement, shall be deemed part of this Agreement and incorporated as if fully set forth herein.
- m. **Healthcare Disclosures.** Both Parties acknowledge and agree that as healthcare companies, and notwithstanding anything in this Agreement to the contrary, the Parties, and their affiliates, may be required by applicable law and regulation ("Healthcare Laws") to disclose the existence of this Agreement, the terms of this Agreement, including without limitation, the financial terms and the subject matter (e.g., the U.S. Sunshine Act, and state and foreign equivalents).
- n. **Survival.** The following sections of this Agreement shall survive any expiration or termination of this Agreement: (2) Fees, (3) Representations and Warranties, 4(b) accrued rights and obligations, 5(a) Indemnification and 5(c) Confidentiality, along with all payment obligations established hereunder.

Signature Page Immediately Follows

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Provider

PTC Laboratories, Inc.

by Kim Gorman
Name: Kim Gorman
Title: President

Client

State of Missouri, Office of
Administration, Division of Purchasing
(on behalf of Missouri State Agencies) *

Acceptance includes Joe Gorman's attached
two emails dated 4/14/2020 (10:39am and 12:15pm)
by Karen Boeger
Name: Karen Boeger
Title: Director, Division of Purchasing

EXHIBITS

Exhibit A-Provider Response to State Questions: Provider is requested to provide responses to the following questions:

1. Provider is requested to explain whether a physician's signature is required on each Test Requisition form. **RESPONSE:** The FDA requires that in order to perform a test, Provider must have a test request authorized by a licensed practitioner. In order to expedite the administration of testing and turn-around time for results, PTC requests that each agency designate one doctor as the authorizing physician for all Covid-19 tests submitted by that agency. The agency may have the doctor actually sign each test request, or may use its discretion to determine more efficient methods of providing written authorization from the doctor for each patient, such as an order signed by the doctor for a list of patients. Provider will proceed with each test using a Test Requisition form with the printed name of the agency's designated doctor. Client must ultimately furnish Provider with printed documents signed by the doctor that include the names of all patients.
2. Provider is requested to explain the availability of test kits to be provided for the state to use for specimen collection. **RESPONSE:** Provider will provide test kits to Client, containing the elements outlined in Response number 3, below, to the greatest extent possible. Provider is able to procure adequate supply of all elements of the test kits except the nasal pharyngeal swabs. Both parties shall continue to use their best efforts to obtain additional nasal pharyngeal swabs.

3. In the event the state must secure test kits, Provider is requested to identify any specifications for what specific test kits the state should obtain for specimen collection to accomplish the intentions outlined herein. **RESPONSE:** A test kit shall contain: (1) one nasal pharyngeal swab, (2) a collection tube with viral transport media, (3) Test Requisition form (added by Client at time of specimen collection), and (4) specimen biohazard bag.

4. Provider is requested to explain whether special shipping materials must be used for delivering the specimens to the Provider and whether the Provider supplies those as part of their service to the Client. **RESPONSE:** Client is responsible for furnishing shipping materials for the transportation of specimens. Specimens must be kept cold in shipping using, for example, ice or ice packs. Various types of insulated bags or Styrofoam containers may be used. If shipped by overnight delivery service, a special outer container such as a FedEx Clinical Pak must be used.

In some cases various clients of Provider have organized couriers from other cities making daily or even twice-daily runs to Provider's facility. Using couriers both simplifies and expedites shipping of specimens, and expedites test results. Provider will use its best efforts to advise state agencies of courier services among both state agencies and non-state entities in specific locations, to facilitate the sharing of courier services for shipping specimens.

ATTACHMENTS (see next page)

**Attachment A (Business Associate Agreement)
(rev 06.07.13)**

1. Health Insurance Portability and Accountability Act of 1996, as amended - The Department of Mental Health and the contractor are both subject to and must comply with provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) (PL-111-5) (collectively, and hereinafter, HIPAA) and all regulations promulgated pursuant to authority granted therein. The contractor constitutes a "Business Associate" of the Department. Therefore, the term, "contractor" as used in this section shall mean "Business Associate."
2. The contractor agrees that for purposes of the Business Associate Provisions contained herein, terms used but not otherwise defined shall have the same meaning as those terms defined in 45 CFR Parts 160 and 164 and 42 U.S.C. §§ 17921 *et. seq.* including, but not limited to the following:
 - a. "Access", "administrative safeguards", "confidentiality", "covered entity", "data aggregation", "designated record set", "disclosure", "hybrid entity", "information system", "physical safeguards", "required by law", "technical safeguards", "use" and "workforce" shall have the same meanings as defined in 45 CFR 160.103, 164.103, 164.304, and 164.501 and HIPAA.
 - b. "Breach" shall mean the unauthorized acquisition, access, use, or disclosure of Protected Health Information which compromises the security or privacy of such information, except as provided in 42 U.S.C. § 17921. This definition shall not apply to the term "breach of contract" as used within the contract.
 - c. "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean the contractor.
 - d. "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean the Department.
 - e. "Electronic Protected Health Information" shall mean information that comes within paragraphs (1)(i) or (1)(ii) of the definition of Protected Health Information as specified below.
 - f. "Enforcement Rule" shall mean the HIPAA Administrative Simplification: Enforcement; Final Rule at 45 CFR Parts 160 and 164.
 - g. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
 - h. "Individual" shall have the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502 (g).
 - i. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

- j. "Protected Health Information" as defined in 45 CFR 160.103, shall mean individually identifiable health information:
 - 1) Except as provided in paragraph (2) of this definition, that is: (i) Transmitted by electronic media; or (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium.
 - 2) Protected Health Information excludes individually identifiable health information in (i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and (iii) Employment records held by a covered entity (Department) in its role as employer.
 - k. "Security Incident" shall be defined as set forth in the "Obligations of the Contractor" section of the Business Associate Provisions.
 - l. "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 164, Subpart C.
 - m. "Unsecured Protected Health Information" shall mean Protected Health Information that is not secured through the use of a technology or methodology determined in accordance with 42 U.S.C. § 17932 or as otherwise specified by the secretary of Health and Human Services.
- 3. The contractor agrees and understands that wherever in this document the term Protected Health Information is used, it shall also be deemed to include Electronic Protected Health Information.
 - 4. The contractor must appropriately safeguard Protected Health Information which the contractor receives from or creates or receives on behalf of the Department. To provide reasonable assurance of appropriate safeguards, the contractor shall comply with the business associate provisions stated herein, as well as the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) (PL-111-5) and all regulations promulgated pursuant to authority granted therein.
 - 5. The Department and the contractor agree to amend the contract as is necessary for the parties to comply with the requirements of HIPAA and the Privacy Rule, Security Rule, Enforcement Rule, and other rules as later promulgated (hereinafter referenced as the regulations promulgated thereunder). Any ambiguity in the contract shall be interpreted to permit compliance with the HIPAA Rules.
 - 6. **Permitted Uses and Disclosures of Protected Health Information by the Contractor**

- 6.1 The contractor may not use or disclose Protected Health Information in any manner that would violate Subpart E of 45 CFR Part 164 if done by the Department, except for the specific uses and disclosures in the contract.
- 6.2 The contractor may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, the Department as specified in the contract, provided that such use or disclosure would not violate HIPAA and the regulations promulgated thereunder.
- 6.3 The contractor may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1) and shall notify the Department by no later than ten (10) calendar days after the contractor becomes aware of the disclosure of the Protected Health Information.
- 6.4 If required to properly perform the contract and subject to the terms of the contract, the contractor may use or disclose Protected Health Information if necessary for the proper management and administration of the contractor's business.
- 6.5 If the disclosure is required by law, the contractor may disclose Protected Health Information to carry out the legal responsibilities of the contractor.
- 6.6 If applicable, the contractor may use Protected Health Information to provide Data Aggregation services to the Department as permitted by 45 CFR 164.504(e)(2)(i)(B).
- 6.7 The contractor may not use Protected Health Information to de-identify or re-identify the information in accordance with 45 CFR 164.514(a)-(c) without specific written permission from the Department to do so.
- 6.8 The contractor agrees to make uses and disclosures and requests for Protected Health Information consistent with the Department's minimum necessary policies and procedures.

7. Obligations and Activities of the Contractor

- 7.1 The contractor shall not use or disclose Protected Health Information other than as permitted or required by the contract or as otherwise required by law, and shall comply with the minimum necessary disclosure requirements set forth in 45 CFR § 164.502(b).
- 7.2 The contractor shall use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by the contract. Such safeguards shall include, but not be limited to:
 - a. Workforce training on the appropriate uses and disclosures of Protected Health Information pursuant to the terms of the contract;
 - b. Policies and procedures implemented by the contractor to prevent inappropriate uses and disclosures of Protected Health Information by its workforce and subcontractors, if applicable;
 - c. Encryption of any portable device used to access or maintain Protected Health Information or use of equivalent safeguard;

- d. Encryption of any transmission of electronic communication containing Protected Health Information or use of equivalent safeguard; and
 - e. Any other safeguards necessary to prevent the inappropriate use or disclosure of Protected Health Information.
- 7.3 With respect to Electronic Protected Health Information, the contractor shall use appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Electronic Protected Health Information that contractor creates, receives, maintains or transmits on behalf of the Department and comply with Subpart C of 45 CFR Part 164, to prevent use or disclosure of Protected Health Information other than as provided for by the contract.
- 7.4 In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), the contractor shall require that any agent or subcontractor that creates, receives, maintains, or transmits Protected Health Information on behalf of the contractor agrees to the same restrictions, conditions, and requirements that apply to the contractor with respect to such information.
- 7.5 By no later than ten (10) calendar days after receipt of a written request from the Department, or as otherwise required by state or federal law or regulation, or by another time as may be agreed upon in writing by the Department, the contractor shall make the contractor's internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, created by, or received by the contractor on behalf of the Department available to the Department and/or to the Secretary of the Department of Health and Human Services or designee for purposes of determining compliance with the HIPAA Rules and the contract.
- 7.6 The contractor shall document any disclosures and information related to such disclosures of Protected Health Information as would be required for the Department to respond to a request by an individual for an accounting of disclosures of Protected Health Information in accordance with 42 USCA §17932 and 45 CFR 164.528. By no later than five (5) calendar days of receipt of a written request from the Department, or as otherwise required by state or federal law or regulation, or by another time as may be agreed upon in writing by the Department, the contractor shall provide an accounting of disclosures of Protected Health Information regarding an individual to the Department. If requested by the Department or the individual, the contractor shall provide an accounting of disclosures directly to the individual. The contractor shall maintain a record of any accounting made directly to an individual at the individual's request and shall provide such record to the Department upon request.
- 7.7 In order to meet the requirements under 45 CFR 164.524, regarding an individual's right of access, the contractor shall, within five (5) calendar days following a Department request, or as otherwise required by state or federal law or regulation, or by another time as may be agreed upon in writing by the Department, provide the Department access to the Protected Health Information in an individual's designated record set. However, if requested by the Department, the contractor shall provide access to the Protected Health Information in a designated record set directly to the individual for whom such information relates.

- 7.8 At the direction of the Department, the contractor shall promptly make any amendment(s) to Protected Health Information in a Designated Record Set pursuant to 45 CFR 164.526.
- 7.9 The contractor shall report to the Department's Security Officer any security incident immediately upon becoming aware of such incident and shall take immediate action to stop the continuation of any such incident. For purposes of this paragraph, security incident shall mean the attempted or successful unauthorized access, use, modification or destruction of information or interference with systems operations in an information system. This does not include trivial incidents that occur on a daily basis, such as scans, "pings," or unsuccessful attempts that do not penetrate computer networks or servers or result in interference with system operations. By no later than five (5) days after the contractor becomes aware of such incident, the contractor shall provide the Department's Security Officer with a description of any remedial action taken to mitigate any harmful effect of such incident and a proposed written plan of action for approval that describes plans for preventing any such future security incidents.
- 7.10 The contractor shall report to the Department's Privacy Officer any unauthorized use or disclosure of Protected Health Information not permitted or required as stated herein immediately upon becoming aware of such use or disclosure and shall take immediate action to stop the unauthorized use or disclosure. By no later than five (5) calendar days after the contractor becomes aware of any such use or disclosure, the contractor shall provide the Department's Privacy Officer with a written description of any remedial action taken to mitigate any harmful effect of such disclosure and a proposed written plan of action for approval that describes plans for preventing any such future unauthorized uses or disclosures.
- 7.11 The contractor shall report to the Department's Security Officer any breach immediately upon becoming aware of such incident and shall take immediate action to stop the continuation of any such incident. By no later than five (5) days after the contractor becomes aware of such incident, the contractor shall provide the Department's Security Officer with a description of the breach, the information compromised by the breach, and any remedial action taken to mitigate any harmful effect of such incident and a proposed written plan for approval that describes plans for preventing any such future incidents.
- 7.12 The contractor's reports required in the preceding paragraphs shall include the following information regarding the security incident, improper disclosure/use, or breach, (hereinafter "incident"):
- a. The name, address, and telephone number of each individual whose information was involved if such information is maintained by the contractor;
 - b. The electronic address of any individual who has specified a preference of contact by electronic mail;
 - c. A brief description of what happened, including the date(s) of the incident and the date(s) of the discovery of the incident;
 - d. A description of the types of Protected Health Information involved in the incident (such as full name, Social Security Number, date of birth, home

address, account number, or disability code) and whether the incident involved Unsecured Protected Health Information; and

The recommended steps individuals should take to protect themselves from potential harm resulting from the incident.

- 7.13 Notwithstanding any provisions of the Terms and Conditions attached hereto, in order to meet the requirements under HIPAA and the regulations promulgated thereunder, the contractor shall keep and retain adequate, accurate, and complete records of the documentation required under these provisions for a minimum of six (6) years as specified in 45 CFR Part 164.
- 7.14 Contractor shall not directly or indirectly receive remuneration in exchange for any Protected Health Information without a valid authorization.
- 7.15 If the contractor becomes aware of a pattern of activity or practice of the Department that constitutes a material breach of contract regarding the Department's obligations under the Business Associate Provisions of the contract, the contractor shall notify the Department's Security Officer of the activity or practice and work with the Department to correct the breach of contract.
- 7.16 The contractor shall indemnify the Department from any liability resulting from any violation of the Privacy Rule or Security Rule or Breach arising from the conduct or omission of the contractor or its employee(s), agent(s) or subcontractor(s). The contractor shall reimburse the Department for any and all actual and direct costs and/or losses, including those incurred under the civil penalties implemented by legal requirements, including but not limited to HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act, and including reasonable attorney's fees, which may be imposed upon the Department under legal requirements, including but not limited to HIPAA's Administrative Simplification Rules, arising from or in connection with the contractor's negligent or wrongful actions or inactions or violations of this Agreement.
- 7.17 Notwithstanding the language in this Agreement set forth above in the Section 7.16, the parties recognize that certain Business Associates and/or contractors may be entities that are sovereign political subdivisions of the State of Missouri – including but not limited to a department, board or other governmental unit of a city, county, township, etc. In that instance, the Business Associate or contractor, by entering into this agreement, is not thereby waiving or limiting the rights or defenses it may have with respect to sovereign or governmental immunity, official immunity or any other legal protections applicable under federal or state law, which are afforded to that Business Associate or contractor and its employees by virtue of the entity's status as a political subdivision of the State of Missouri.

8. Obligations of the Department

- 8.1 The Department shall notify the contractor of limitation(s) that may affect the contractor's use or disclosure of Protected Health Information, by providing the contractor with the Department's notice of privacy practices in accordance with 45 CFR 164.520.
- 8.2 The Department shall notify the contractor of any changes in, or revocation of, authorization by an Individual to use or disclose Protected Health Information.

- 8.3 The Department shall notify the contractor of any restriction to the use or disclosure of Protected Health Information that the Department has agreed to in accordance with 45 CFR 164.522.
- 8.4 The Department shall not request the contractor to use or disclose Protected Health Information in any manner that would not be permissible under HIPAA and the regulations promulgated thereunder.

9. Expiration/Termination/Cancellation

Except as provided in the subparagraph below, upon the expiration, termination, or cancellation of the contract for any reason, the contractor shall, at the discretion of the Department, either return to the Department or destroy all Protected Health Information received by the contractor from the Department, or created or received by the contractor on behalf of the Department, and shall not retain any copies of such Protected Health Information. This provision shall also apply to Protected Health Information that is in the possession of subcontractor or agents of the contractor.

In the event the Department determines that returning or destroying the Protected Health Information is not feasible, the contractor shall extend the protections of the contract to the Protected Health Information for as long as the contractor maintains the Protected Health Information and shall limit the use and disclosure of the Protected Health Information to those purposes that made return or destruction of the information infeasible. If at any time it becomes feasible to return or destroy any such Protected Health Information maintained pursuant to this paragraph, the contractor must notify the Department and obtain instructions from the Department for either the return or destruction of the Protected Health Information.

10. Breach of Contract

In the event the contractor is in breach of contract with regard to the business associate provisions included herein, the contractor agrees that in addition to the requirements of the contract related to cancellation of contract, if the Department determines that cancellation of the contract is not feasible, the State of Missouri may elect not to cancel the contract, but the Department shall report the breach of contract to the Secretary of the Department of Health and Human Services.

Boeger, Karen

From: Joe Gorman <jgorman@ptclabs.com>
Sent: Tuesday, April 14, 2020 10:39 AM
To: Boeger, Karen
Cc: Tim McCarty
Subject: State of Missouri Request to Establish Emergency Testing Services Contract

Ms. Boeger,

I am working on your contract, and appreciate very much that you started with the PTC model. That is helping to greatly expedite completion.

We have identified a number of items that could or should be added, but if that would require individual agency approvals and hold up the process, we can simply operate the contract on the understanding that these additional provisions will be followed. Please let me know if I should find a place for these in the contract. In the meantime we continue to work on the rest of the contract.

1. PTC is required to disclose the results of each Covid-19 test to the Missouri State Public Health Laboratory.
2. PTC will also notify a central contact for each agency of the results of tests received from that agency. Each agency shall designate a contact for this purpose. Each agency shall be responsible for notifying the respective medical practitioners of the results of tests for their patients, as appropriate. PTC will not notify individual practitioners or patients of results.
3. PTC shall bill each agency for completed tests, ~~or shall bill a central state office, as directed by the State.~~ *KB 4/14/20*
4. PTC shall use its best efforts to have test results available within twenty-four hours of the time that PTC receives specimens, and notes that PTC has been successful thus far in always providing test results within twenty-four hours and often in much less time. In the unlikely event that any test ever takes more than ninety-six hours to complete, following receipt of specimen, PTC will not bill for that test.

We will wait for you to advise whether these provisions should be incorporated into the contract, or should simply be an understanding between the parties.

Thank you.

Joe

--

Joseph M. Gorman
General Counsel
GeneTrait Laboratories and
PTC Laboratories
300 Portland Street
Columbia, MO 65201
Telephone: (888) 837-8323
Local/Interntl: (573) 442-9948
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E-mail: jgorman@ptclabs.com

Web: www.ptclabs.com

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Boeger, Karen

From: Joe Gorman <jgorman@ptclabs.com>
Sent: Tuesday, April 14, 2020 12:53 PM
To: Tim McCarty; Boeger, Karen
Subject: Re: FW: State of Missouri Request to Establish Emergency Testing Services Contract
Attachments: Statewide - PTC Covid-19.pdf

Ms. Boeger,

Here is the signed Covid-19 Statewide Agreement. In addition to the answers provided by PTC in Exhibit A, the only changes are in section 1(b), incorporating Exhibit A regarding kits, and in section 4(a) inserting the word "prior" to make the last sentence make sense.

Please let us know if you need anything further.

Thank you for all of your work on this contract.

Joe Gorman

On 4/14/2020 12:46 PM, Tim McCarty wrote:

> Hi Karen,
>
> Thank you for reaching out.
>
> I apologize for the confusion. PTC's attorney Joseph Gorman, copied
> here, sent a message to your email address earlier this morning. I
> should have responded directly as well, to make sure you received it.
>
> Joe also has the agreement signed and ready to send to you now. I will
> let him respond to this email directly.
>
> Below is his message from earlier.
>
> Thank you,
> Tim
>
> --
>
> Ms. Boeger,
>
> I am working on your contract, and appreciate very much that you
> started with the PTC model. That is helping to greatly expedite completion.
>
> We have identified a number of items that could or should be added,
> but if that would require individual agency approvals and hold up the
> process, we can simply operate the contract on the understanding that
> these additional provisions will be followed. Please let me know if I
> should find a place for these in the contract. In the meantime we
> continue to work on the rest of the contract.
>
> 1. PTC is required to disclose the results of each Covid-19 test to

> the Missouri State Public Health Laboratory.
>
> 2. PTC will also notify a central contact for each agency of the
> results of tests received from that agency. Each agency shall
> designate a contact for this purpose. Each agency shall be
> responsible for notifying the respective medical practitioners of the
> results of tests for their patients, as appropriate. PTC will not
> notify individual practitioners or patients of results.
>
> 3. PTC shall bill each agency for completed tests, or shall bill a
> central state office, as directed by the State.
>
> 4. PTC shall use its best efforts to have test results available
> within twenty-four hours of the time that PTC receives specimens, and
> notes that PTC has been successful thus far in always providing test
> results within twenty-four hours and often in much less time. In the
> unlikely event that any test ever takes more than ninety-six hours to
> complete, following receipt of specimen, PTC will not bill for that test.
>
> We will wait for you to advise whether these provisions should be
> incorporated into the contract, or should simply be an understanding
> between the parties.
>
> Thank you.
>
> Joe
>
> --
> Joseph M. Gorman
> General Counsel
> GeneTrait Laboratories and
> PTC Laboratories
> 300 Portland Street
> Columbia, MO 65201
> Telephone: (888) 837-8323
> Local/Interntl: (573) 442-9948
> Facsimile: (573) 442-9870
> E-mail: jgorman@ptclabs.com
> Web: www.ptclabs.com
>
> --
>
> On Tue, Apr 14, 2020 at 12:36 PM Boeger, Karen
> <Karen.Boeger@oa.mo.gov>
> wrote:
>
>> Tim, just wanted to confirm whether you saw my email from early this AM?
>> ...Karen
>>
>>
>>
>> *Karen Boeger, CPPB*

>>
>> Director, Division of Purchasing
>>
>> State of Missouri, Office of Administration
>>
>> karen.boeger@oa.mo.gov
>>
>> 573-751-1699 (office); 573-257-7003 (cell)
>>
>> Division of Purchasing's Website: <https://oa.mo.gov/purchasing>
>>
>> MissouriBUYS Website: <https://missouribuys.mo.gov>
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>>
>> *From:* Boeger, Karen
>> *Sent:* Tuesday, April 14, 2020 1:20 AM
>> *To:* 'tmccarty@ptclabs.com' <tmccarty@ptclabs.com>
>> *Cc:* Dawson, Stacia L. <Stacia.Dawson@oa.mo.gov>; Stafford, Cindy <
>> Cindy.Stafford@oa.mo.gov>; Lambert, Beth <Beth.Lambert@doc.mo.gov>;
>> McDonald, Wade S <Wade.S.McDonald@dss.mo.gov>; Duemmel, Corey <
>> Corey.Duemmel@dmh.mo.gov>; McCune, Stacey
>> <Stacey.McCune@mvc.dps.mo.gov>; Steelman, Sarah
>> <Sarah.Steelmann@oa.mo.gov>; Dixon, Cindy <Cindy.Dixon@oa.mo.gov>;
>> Long, Mark <Mark.Long@oa.mo.gov>; Hall, John <John.Hall@oa.mo.gov>
>> *Subject:* State of Missouri Request to Establish Emergency Testing
>> Services Contract
>> *Importance:* High
>>
>>
>>
>> Tim,
>>
>>
>>
>> As we discussed on the phone Monday, the State of Missouri desires to
>> enter into an Emergency Statewide Contract with PTC for COVID-19
>> Virus Testing of Specimens pursuant to the state's emergency
>> procurement statute outlined in section 34.045 RSMo
>> <<https://revisor.mo.gov/main/OneSection.aspx?section=34.045>> for a
>> period of six months to be used on an as needed, if needed basis for
>> all state agencies who provide direct health care or custody services in the state.
>> I understand the Department of Mental Health (DMH) and the Missouri
>> Veterans Commission (MVC) have already entered into agreements with PTC.
>> It is not my intention to disrupt those agreements; however, to the
>> extent the resulting agreement serves those entities' needs, they
>> would be welcome to transition to the resulting statewide contract.
>>

>>
>>
>> The existing agreements with DMH and MVC were used as a base in
>> drafting the attached agreement so almost all of this will look very
>> familiar. If at all possible I would appreciate PTC reviewing the
>> attached agreement and completing the questions outlined in Exhibit A
>> and signing and returning the agreement to me *TUESDAY, APRIL 14,
>> BEFORE NOON*. Upon receipt of your response, I will apply the
>> state's final acceptance and provide a copy of the final executed
>> agreement to PTC so that services can begin immediately. Please let
>> me know if you have any questions. I sincerely appreciate PTC's
>> willingness to assist the State of Missouri in providing these important emergency services!

>>
>>
>>
>> ...Karen

>>
>>
>>
>> *Karen Boeger, CPPB*
>>
>> Director, Division of Purchasing
>>
>> State of Missouri, Office of Administration
>>
>> karen.boeger@oa.mo.gov
>>
>> 573-751-1699 (office); 573-257-7003 (cell)
>>
>> Division of Purchasing's Website: <https://oa.mo.gov/purchasing>
>>
>> MissouriBUYS Website: <https://missouribuys.mo.gov>

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>>
>> *From:* Boeger, Karen
>> *Sent:* Monday, April 13, 2020 5:09 PM
>> *To:* 'tmccarty@ptclabs.com' <tmccarty@ptclabs.com>
>> *Cc:* Dawson, Stacia L. <Stacia.Dawson@oa.mo.gov>; Stafford, Cindy <
>> Cindy.Stafford@oa.mo.gov>
>> *Subject:* Status Update

>>
>>
>>
>> Tim, just a status update – still working with the agencies here to
>> finish up the document before I send it your way. Will be a little later this
>> evening. Sorry for the delay. Will still appreciate as quick of
>> turnaround as you can after you receive.

>>
>>
>>
>> *Karen Boeger, CPPB*
>>
>> Director, Division of Purchasing
>>
>> State of Missouri, Office of Administration
>>
>> karen.boeger@oa.mo.gov
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