



BOARD OF SUPERVISORS AGENDA ITEM REPORT
CONTRACTS / AWARDS / GRANTS

☐ Award ☒ Contract ☐ Grant

Requested Board Meeting Date: 10/20/20

* = Mandatory, information must be provided

or Procurement Director Award ☐

***Contractor/Vendor Name/Grantor (DBA):**

Paradigm Laboratories, LLC dba P2 Diagnostic, LLC

***Project Title/Description:**

COVID-19 Test Kits, Processing, and Reporting

***Purpose:**

Amendment of Award: Master Agreement No. MA-PO-20-166, Amendment No. 4. This Amendment provides the additional requirements for COVID-19 Rapid Response Testing Teams. Administering Department: Health.

***Procurement Method:**

Pursuant to Pima County Procurement Code 11.12.060, Emergency and other limited competition procurement, award for MA-PO-20-166 was made to Paradigm Laboratories, LLC dba P2 Diagnostic, LLC, with which the County has negotiated a satisfactory agreement.

On May 7, 2020, the Procurement Director approved Amendment No.1, which increased the annual award amount by \$1,500,000.00 from \$1,500,000.00 to \$3,000,000.00 for a cumulative not-to-exceed contract amount of \$3,000,000.00.

On June 24, 2020, the Procurement Director approved Amendment No. 2, which increased the annual award amount by \$1,800,000.00 from \$3,000,000.00 to \$4,800,000.00 for a cumulative not-to-exceed contract amount of \$4,800,000.00.

On July 10, 2020, the Procurement Director approved Amendment No. 3, which added COVID-19 testing services at a County-Owned facility to the Scope of Services and provided a one-time increase in the amount of \$30,000,000.00 for a cumulative not-to-exceed contract amount of \$34,800,000.00

PRCUID: 374840

Attachment: Contract Amendment No. 4

***Program Goals/Predicted Outcomes:**

To provide Pima County with COVID-19 test kits and processing, testing services and reporting that meets U. S. Food and Drug Administration performance and product standards.

***Public Benefit:**

To aid in the detection and response of pandemic outbreak COVID-19.

***Metrics Available to Measure Performance:**

Delivery of required goods and services.

***Retroactive:**

Yes, due to emergency need for service.

TD: COB 10-12-20 (1)

Ver: 7

Pgs: 8

Contract / Award Information

Document Type: _____ Department Code: _____ Contract Number (i.e., 15-123): _____
 Commencement Date: _____ Termination Date: _____ Prior Contract Number (Synergen/CMS): _____
☐ Expense Amount: \$* _____ ☐ Revenue Amount: \$ _____

***Funding Source(s) required:**

Funding from General Fund? ☐ Yes ☐ No If Yes \$ _____ % _____

Contract is fully or partially funded with Federal Funds? ☐ Yes ☐ No

If Yes, is the Contract to a vendor or subrecipient?

Were insurance or indemnity clauses modified? ☐ Yes ☐ No

If Yes, attach Risk's approval.

Vendor is using a Social Security Number? ☐ Yes ☐ No

If Yes, attach the required form per Administrative Procedure 22-10.

Amendment / Revised Award Information

Document Type: MA Department Code: PO Contract Number (i.e., 15-123): 20-166
 Amendment No.: 4 AMS Version No.: 7
 Commencement Date: 09/03/2020 New Termination Date: _____
 Prior Contract No. (Synergen/CMS): _____
☒ Expense or ☐ Revenue ☐ Increase ☐ Decrease Amount This Amendment: \$ 0.00

Is there revenue included? ☐ Yes ☒ No If Yes \$ _____

***Funding Source(s) required:** Health Department Operations / Federal Grant Funds

Funding from General Fund? ☐ Yes ☐ No If Yes \$ _____ % _____

Grant/Amendment Information (for grants acceptance and awards) ☐ Award ☐ Amendment

Document Type: _____ Department Code: _____ Grant Number (i.e., 15-123): _____
 Commencement Date: _____ Termination Date: _____ Amendment Number: _____
☐ Match Amount: \$ _____ ☐ Revenue Amount: \$ _____

***All Funding Source(s) required:**

*Match funding from General Fund? ☐ Yes ☐ No If Yes \$ _____ % _____

*Match funding from other sources? ☐ Yes ☐ No If Yes \$ _____ % _____

***Funding Source:** _____

***If Federal funds are received, is funding coming directly from the Federal government or passed through other organization(s)?** _____

Contact: **Keith E. Rogers**
Digitally signed by Keith E. Rogers
 DN: cn=Keith E. Rogers, o, ou,
 email=keith.rogers@pima.gov, c=US
 Date: 2020.10.06 10:34:53 -07'00'

Department: Procurement Mary Jo Furphy Telephone: 724-3542
Digitally signed by Mary Jo Furphy
 DN: cn=Mary Jo Furphy, o=Pima County, ou=Procurement,
 email=maryjo.furphy@pima.gov, c=US
 Date: 2020.10.06 11:08:16 -07'00'

Department Director Signature/Date: _____ 10/06/2020

Deputy County Administrator Signature/Date: _____ 12 Oct 2020

County Administrator Signature/Date: _____ 10/12/2020
 (Required for Board Agenda/Addendum Items)

Pima County Department of Health

Project: COVID-19 Test Kits, Processing and Reporting

Contractor: Paradigm Laboratories, LLC dba P2 Diagnostic, LLC
6117 E. Grant Rd.
Tucson, AZ 85712

Contract No.: MA-PO-20-166

Contract Amendment No.: 04

Orig. Contract Term: 04/07/2020 - 04/06/2021	Orig. Amount: \$1,500,000.00
Termination Date Prior Amendment: N/A	Prior Amendments Amount: \$33,300,000.00
Termination Date This Amendment: 04/06/2021	This Amendment Amount: 0.00
	Revised Total Amount: \$34,800,000.00

CONTRACT AMENDMENT

The parties agree to amend the above-referenced contract as follows:

1. Background and Purpose.

1.1. Background. On April 7, 2020, County and Contractor entered into the above referenced agreement to provide COVID-19 Test Kits, Processing, and Reporting. The agreement has since been amended to include COVID-19 testing at a County-owned site.

1.2. Purpose. County requires comprehensive testing services by a mobile Rapid Response Testing Team to cover the additional need for COVID-19 testing.

2. Compensation and Payment. The parties have agreed to amend the Offer Agreement Article 7 for additional language regarding discounted payment for test results not provided within the specified time frame.

Timeliness of Results Reporting:

CONTRACTOR agreed to a 24-hour result return time for COVID-19 testing. Rapid communication of test results is a vital factor in reducing the spread of COVID-19 by infected individuals. In recognition of this, CONTRACTOR agrees to a 20% reduction in the compensation for any tests with results not published to the portal and available to the tested individual within 24 hours of specimen delivery to CONTRACTOR's lab facility. Specimens collected by CONTRACTOR must arrive at the lab facility within 6 hours of the collection time and have results available within 24 hours of arrival or the compensation reduction applies. For CONTRACTOR specimen collections performed more than 45 miles from CONTRACTOR's Tucson lab facility, the arrival window is extended to 12 hours.

This credit will be applied to future invoices from CONTRACTOR. If there are no future invoices to be paid, CONTRACTOR will issue payment of the credit amount to COUNTY within 30 days of the final testing activity performed under this contract.

3. **Research.** The parties have agreed to add Article 13, **Research**, to the Offer Agreement.

13. RESEARCH: No research activities, including academic, methodological or other, will be performed without the explicit authorization of the Pima County Health Department Director. This includes, among other elements, validation studies of alternative testing methods. Such authorization will only be considered following submission of a detailed research plan.

4. **Policies, Procedures, Orders and Quality Assurance Documents.** The parties have agreed to add Article 14, **Policies, Procedures, Orders and Quality Assurance Documents**, to the Offer Agreement.

14. Policies, Procedures, Orders and Quality Assurance Documents: CONTRACTOR will provide COUNTY with all standard operating procedures, policies and orders or other documents related to the fulfillment of duties identified in this contract. For such items CONTRACTOR claims contain proprietary information, CONTRACTOR will provide COUNTY the opportunity to review those documents in person at COUNTY's convenience rather than transmitting those documents to COUNTY. CONTRACTOR will provide COUNTY with updates to those policies, procedures, orders or other documents in a timely fashion and will not implement those changes until such time as COUNTY has reviewed and provided written or electronic approval. CONTRACTOR will adhere to the quality assurance requirements detailed in Exhibit D – Quality Agreement.

5. **Subcontractors.** The parties have agreed to amend the Pima County Standard Terms And Conditions, Article 40, for additional language regarding the use of subcontractors.

CONTRACTOR will notify COUNTY in advance of subcontractors being engaged for any duties performed under this contract.

6. **Scope of Services.** The parties have agreed to replace in its entirety Exhibit A (1 page) – Scope of services with **Exhibit A Revised Scope of Services Amendment No. 04 (1 page)** for additional language regarding Days of Operation, Testing of Children, Medical/Clinical Oversight, and Results Dissemination.

7. **Unit Prices.** The parties have agreed to replace in its entirety Exhibit B (1 page) Unit Prices with **Exhibit B Revised Unit Prices Amendment No. 04 (1 page)** for the additional Line Item Description and Unit Price of Comprehensive Testing Services by the Rapid Response Testing Team.

8. **Quality Agreement.** The parties have agreed to add the Quality Agreement to the Offer Agreement as **Exhibit D – Quality Agreement (3 pages)**.

9. **Commencement Date.** The commencement date of September 8, 2020 is before the Effective Date of this amendment, the parties will, for all purposes, deem the amendment and all changes to have been in effect as of the commencement date, with the exception of the changes to 2. Compensation and Payment, specifically Timeliness of Results Reporting, which will commence on October 20, 2020.

All other provisions of the Contract not specifically changed by this Amendment remain in effect and are binding upon the parties.

PIMA COUNTY

Chairman, Board of Supervisors

Date

CONTRACTOR



Signature

 PRESIDENT

Name and Title (Please Print)



Date

ATTEST:

Clerk of the Board

APPROVED AS TO FORM:



Deputy County Attorney

Tiffany Tom

Printed Name

Date

Exhibit A –Revised Scope of Services(1 page)

Contractor will provide comprehensive testing process from start to finish and perform all phases of PCR testing services.

The entire testing site, organization, and execution will be supervised by the County's Public Health agency.

Public testing will begin on Monday, July 13, 2020.

Contractor will provide comprehensive services involving a number of activities including the following:

- Pre-registration appointments
- Reception
- Appropriate additional medical screening
- Collection of test samples
- Laboratory testing and processing of the sample
- Development of portals and protocols for notifying individuals of both positive and negative test results
- Regulatory notifications to the Arizona Department of Health Services and Pima County
- Rapid Response Team for mobile testing composed of: 2 specimen collectors and 1 accessioner, including Mobile SOPs

Days of Operation

CONTRACTOR will provide services, including result notification, Sunday through Saturday, in recognition that identification and communication of positive COVID-19 tests is most valuable when rapidly delivered to the individual testing.

Testing of children

CONTRACTOR will not administer COVID-19 tests to individuals under age 10 without prior approval from the Pima County Health Department. This approval will be issued only after review of CONTRACTOR policies, procedures and clinical orders related to testing of children. Once approval is granted, CONTRACTOR will be allowed to administer COVID-19 tests to clients under age 10 so long as those policies, procedures and orders are followed.

Operational and Clinical Oversight

CONTRACTOR agrees that the individuals identified below will serve as the primary Operational and Clinical points of contact for COUNTY regarding this contract:

Steve Kelly, VP of Client Services and Logistics will serve as the operational point of contact and will be responsible for responding to COUNTY on all issues outside the clinical arena.

Dr. Norman Relkin, Chief Medical Officer, will serve as the clinical point of contact and is responsible for responding to COUNTY on all clinical issues and will coordinate with COUNTY medical officers as required. Additionally, this officer must be a licensed provider in the state of Arizona and be empowered to sign off on CONTRACTOR orders, standard operating procedures and clinical regulatory documents..

Results Dissemination

CONTRACTOR will maintain the electronic results portal. Should the portal be inaccessible for a period exceeding 24 hours, CONTRACTOR will, at their own expense, convey results to tested clients via an alternative means (phone, electronic communication, etc) and continue to do so until such time as the portal is again accessible. The means used to disseminate results must be in accordance with HIPAA guidelines, requiring proper consent from the patient prior to leaving messages or using electronic modes of communication.

End of Exhibit A

Exhibit B – Revised - Amendment No. 04 (1 page)
Unit Prices

	Line Item Description	Unit Price
1	Initial Patient Portal Setup and Integration	\$97,550.00
2	Per Test - Comprehensive Testing Services at County-Owned site	\$ 42.00
3	Per Test - Comprehensive Testing Services – Rapid Response Testing Team	\$ 42.00

Offer Agreement Term 7. Compensation and Payment, contains language about timeliness of results reporting and includes reduced payment terms to the above standard unit prices if the Contractor obligation is not met.

1. **Initial Patient Portal Setup and Integration** include:
 - Live agents for test scheduling and re-scheduling
 - Pre-capturing information prior to appointment
 - A HIPAA compliant portal to direct patients to their results and back to the health department for next steps, all pos/neg
 - Multi-lingual support and scheduling
2. **Per Test - Comprehensive Testing Services at County-Owned site** include:
 - clinical medical staff
 - scheduling staff
 - non-medical administrative staff
 - accessioning
 - biomedical waste disposal
 - hot-zone sanitation
 - the procurement of personal protective equipment
 - portal setup for appropriate notifications for positive and negative test results
3. **Per Test - Comprehensive Testing Services – Rapid Response Testing Team** include:
 - Training and staffing of a 3 person mobile team - 2 specimen collectors and 1 accessioner, available Monday through Saturday
 - Mobile SOPs
 - Biomedical waste disposal
 - Personal protective equipment
 - Custom patient results portal creation for University of Arizona
 - Patient portal setup for appropriate notifications for positive and negative test results
 - IT equipment and mobile satellite for Wi-Fi
 - Portable fogging units with daily disinfecting of the medical trailer and all equipment
 - Phone team support for patients

End of Exhibit B

Exhibit D – Quality Agreement (3 pages)

This exhibit comprises the 'Quality Agreement' and defines the roles and responsibilities of the Contractor and County related to analytical testing under this contract by, in accordance with current CLIA, CDC and any other applicable licensing, credentialing or safety requirements.

This Quality Agreement concerns the validation and transfer of test methods and samples, and the testing of samples of the contract data, processes and procedures to this Quality Agreement.

CONTRACTOR will test and handle samples, equipment, data, processes and procedures in compliance with the recognized pharmaceutical, lab, infection control and healthcare rules and relevant legal provisions. If COUNTY further wishes any special regulations or directives followed, that are not generally known and recognized under the above-mentioned regulations, COUNTY shall notify CONTRACTOR and the Parties will discuss in good faith how to proceed.

AUDITS AND INSPECTIONS

COUNTY has the right to inspect the CONTRACTOR facilities and the analyses of data, processes and procedures to ensure that the activities under this Quality Agreement are carried out in accordance with the health regulations.

Quarterly Reports will be sent to COUNTY with the following information (Example below):

Measure Definitions and Variation Studies EXAMPLES	Indicator (% or ratio) Relative to agreed upon defined threshold	Intervention (if outside threshold) Responsible Party Start Date	Post-Intervention Indicator (% or #)	Outcome Satisfactory or Unsatisfactory
Sample Gathering: Labeling Sample Collection Handling				
Processing to Result Time Interval				
Lab Process Errors (with sources)				
Result Validation Disparities				

CONTRACTOR further agrees that PIMA COUNTY HEALTH DEPARTMENT's affiliations, if previously coordinated and consented by PIMA COUNTY HEALTH DEPARTMENT, or competent authorities also have the right to inspect the facilities and the analyses of data, processes and procedures at the vendor's location. CONTRACTOR agrees to inform PIMA COUNTY HEALTH DEPARTMENT in writing and without delay about planned inspections in advance and about problems found at inspections by authorities related to testing of PIMA COUNTY HEALTH DEPARTMENT's data, processes and procedures.

Audits will be performed on dates and times mutually agreed between the Parties, provided, however, that audits for investigational reason ('for cause audits') may be performed at any time during normal business hours.

PROCEDURES AND DOCUMENTS

CONTRACTOR is responsible for maintenance and update of its own SOPs to ensure that the processing and testing of the samples of data, processes and procedures is done in compliance with the FEDERAL, STATE AND/OR LOCAL Regulations. CONTRACTOR will make SOPs and related documents will available on demand by COUNTY.

CHANGE MANAGEMENT

Changes are variations to this Quality Agreement, and to any activity hereunder, relevant to the regulatory status of data, processes and procedures. Any intended major change must be submitted to COUNTY in writing and accepted by both Parties. Change approval by COUNTY is necessary prior to implementation.

TEST SAMPLES, STORAGE

CONTRACTOR will ensure that the samples to be tested are prepared and unambiguously labelled (including the batch number) and that the necessary information (laboratory order per sample or cluster of samples, storage conditions, safety handling requirement/MSDS, etc) is recorded and available. CONTRACTOR is responsible to store samples received at ambient temperature or as specified in the analytical order accompanying the sample.

INSTRUMENT CALIBRATION AND VALIDATION

Quality controls are to be completed in compliance with the Federal, State And/Or Local Regulations, using qualified, calibrated equipment and machines as well as validated testing methods. Data, processes and procedures and specific validation of testing methods is to be provided quarterly by CONTRACTOR to COUNTY by the 15th of the month following each quarter.

REAGENTS, MATERIALS

CONTRACTOR is liable for the regular quality of the reagents/materials used.

PERSONNEL

During the period of this contract, CONTRACTOR ensures that suitable rooms or settings, equipment and qualified personnel are available to carry out the corresponding activities and can provide substantiating documentation upon request. CONTRACTOR shall inform PIMA COUNTY HEALTH DEPARTMENT without delay if essential changes happen in their management or essential operational staff.

REVIEW AND STORAGE OF RAW DATA AND REPORTS

All raw data acquired by CONTRACTOR for COUNTY and the subsequent calculations of results shall be reviewed, dated and initialed by a second analyst at vendor's company and assessed for conformity. The summary reports are to be authorized by CONTRACTOR official prior to quarterly submission to COUNTY. CONTRACTOR shall keep the documentation (including but not limited to raw data, calculations, testing instructions and final reports) for at least 10 years after issue of the final report. In addition, all raw data related to analytical development, including but not limited to any raw data from method validation, will be archived by CONTRACTOR over the life cycle of the concerned data, processes and procedures.

CONTRACTOR must submit a written request for COUNTY authorization prior to the disposal of any raw data related to COUNTY's orders and data, processes and procedures. At COUNTY's sole discretion it will authorize if such raw data shall be disposed of by CONTRACTOR or have to be transferred to COUNTY. In the case of closure of the business by CONTRACTOR or expiry of its authority approval the documentation has to be transferred to COUNTY.

DEVIATIONS FROM TESTING INSTRUCTIONS AND OOS/OOE RESULTS If not otherwise agreed to, Out Of Specification (OOS) and Out of Trend results and/or unplanned deviations shall be handled according to the CONTRACTOR SOP and shall be reported to COUNTY within 3 business days. Prior to effecting any planned deviations from the agreed testing instructions CONTRACTOR will notify COUNTY. Subsequently CONTRACTOR shall complete a deviation report including an explanation of the reasons for the deviation and transmit this report to COUNTY together with the final report for affected sample or data, processes and procedures batch.

FORMAT OF THE FINAL REPORTS

For each lab batch tested, CONTRACTOR will provide COUNTY with an aggregate report detailing the batch testing results in a mutually agreeable manner. In addition, CONTRACTOR will provide Certificates

of Compliance (CoC) with regard to FEDERAL, STATE AND/OR LOCAL bodies and registration compliance for certain labs, processes, procedures equipment and batches tested, if specifically requested by COUNTY.

Additional information (including raw data) may be required by COUNTY and shall be provided by CONTRACTOR upon request; especially for investigations in case of complaints and/or recall.

RESULT TRANSFER

CONTRACTOR will complete the agreed tests without delay (within 24 hours for COVID testing or 2 business days for other testing unless otherwise specified in the contract), and transfer the final report (Aggregate or Analytical Report) by e-mail to the COUNTY and electronically to the State within the expected timeframes as outlined by regulation. COUNTY's due dates for receipt of the final report (Aggregate or Analytical Report) are daily for testing and quarterly for QA/QI/QC. In case of delay, CONTRACTOR immediately shall inform COUNTY about reasons and time line. If no due date determined by agreed upon processing time is expressly specified in the original contract time limits will be determined and the contract amended.

FINAL PROVISIONS

This Quality Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of data, processes and procedures by COUNTY to CONTRACTOR unless the Parties specifically agree in writing an extension of the Quality Agreement.

If individual provisions of this Quality Agreement are rendered void or unenforceable, they shall be replaced by the legally permissible interpretation that most closely approaches the original intent and they shall not be construed to render any other provision of this Quality Agreement either void or unenforceable.