



Board Agenda Item 51

DATE: July 12, 2022

TO: Board of Supervisors

SUBMITTED BY: David Luchini, RN, PHN, Director, Department of Public Health

SUBJECT: Retroactive Agreement with GM Lab Consulting, LLC.

RECOMMENDED ACTION(S):

- 1. Make a finding that it is in the best interest of the County to suspend the competitive bidding process consistent with Administrative Policy No. 34 for unusual or extraordinary circumstances as GM Lab Consulting, LLC., is the only provider with specified qualifications and knowledge of the Department of Public Health's Laboratory; and,**
- 2. Approve and authorize the Chairman to execute a retroactive Agreement with GM Lab Consulting, LLC., for laboratory director services, effective July 1, 2022, not to exceed five consecutive years, which includes a three-year base contract and two optional one-year extensions, total not to exceed \$540,848.**

Approval of the recommended actions will continue laboratory director services for the Department of Public Health's Laboratory (PHL). Approval of the recommended agreement will satisfy the requirement under Clinical Laboratory Improvement Amendments (CLIA), which requires an identified laboratory director. The services will be funded with Health Realignment and grant funds, with no increase in Net County Cost. This item is countywide.

ALTERNATIVE ACTION(S):

There are no viable alternative actions. Should your Board not approve the recommended actions, PHL would not have an identified laboratory director and would therefore be out of CLIA compliance. This would jeopardize the PHL certification and require ceasing clinical laboratory testing, which is necessary for timely response to communicable disease investigation and bioterrorism testing.

SUSPENSION OF COMPETITION/SOLE SOURCE CONTRACT:

The Department's request to suspend the competitive bidding process consistent with Administrative Policy No. 34 due to GM Lab Consulting, LLC. (GM) being the only uniquely qualified vendor that can seamlessly provide lab director consultation and representation. GM has a proven history and expertise in the management of the PHL and for the last five years has been the County's contracted provider. The Internal Services Department - Purchasing Division concurs with the Department's request to suspend the competitive bidding process.

RETROACTIVE AGREEMENT:

Due to preparation for an onsite CLIA visit in mid-April and the deployment of resources to bring critical laboratory testing capability online, the Department was not able to complete processing and finalizing

contract negotiations to bring the agreement before you Board at an earlier date.

FISCAL IMPACT:

There is no increase in Net County Cost associated with the recommended actions. The maximum compensation for the recommended agreement is \$540,848. Yearly compensation includes a 3% growth factor for four years starting with year two. The recommended agreement will be fully offset with Health Realignment and grant funds. Sufficient appropriations and estimated revenues are included in the Department's Org 5620 FY 2022-23 Recommended Budget and will be included in subsequent budget requests for the duration of the term.

DISCUSSION:

Pursuant to Title 42 of the Code of Federal Regulations et seq., CLIA certification is required to conduct clinical laboratory testing in the PHL. To retain CLIA certification, the laboratory must have a designated lab director.

Under the guidance and auspices of GM, the PHL has completed various milestones while being a major contributor to the COVID-19 public health emergency (COVID-19) response. While the PHL has continued its COVID-19 response, steps to bring new testing assays and certifications to broaden its capabilities were initiated. GM's vision for the PHL continues to align with the Department's goals and expectations. GM's progression as the PHL's lab director will allow the PHL to complete the remaining work that includes onboarding all the tests and training needed to respond to departmental needs. The was completely rebuilt after a flood into a state-of-the-art facility, prepared to respond quickly and efficiently to the needs of the residents of the County. In accordance with the duties and responsibilities of the laboratory director, GM provided extensive consultation and oversight during the rebuild to ensure the following:

- Successful certification of the Biosafety Level 3 rooms per Centers for Disease Control and Prevention (CDC) standards;
- Completion of CLIA certification as a PHL;
- Evaluation and revision of clinical protocols to meet CLIA guidelines;
- Recommendations and evaluation of PHL equipment and reagents;
- Leveraging of State resources and relationships to improve lab efficiencies and protocols;
- Evaluation and consultation on security measures to bring them to current and appropriate standards;
- Consultation and assistance to construct a Bioterrorism room to meet current CDC standards;
- Quarterly evaluation of lab standards and adherence to CLIA provisions; and,
- Onboarding of new assays including HIV (human immunodeficiency virus), Tuberculosis, Rabies, Quantiferon, and COVID.

With your Board's approval, the Department will continue to utilize GM as the PHL laboratory director. The compensation clause of the agreement was amended to include advance payment each month, which deviates from the County's standard language regarding payment to vendors due to the operating practice of GM while contracting with other counties for similar services.

REFERENCE MATERIAL:

BAI #45, June 12, 2018

ATTACHMENTS INCLUDED AND/OR ON FILE:

On file with Clerk - Agreement with GM
Suspension of Competition

CAO ANALYST:

Sonia M. De La Rosa