

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS  
OF SAN BERNARDINO COUNTY  
AND RECORD OF ACTION**

**May 7, 2024**

**FROM**

**JOSHUA DUGAS, Director, Department of Public Health**

**SUBJECT**

Agreements with QIAGEN for Latent Tuberculosis Infection Test Kits and Preventive Maintenance Service for QIAGEN EZ1 Instrument

**RECOMMENDATION(S)**

1. Approve the EZ1 Service **Agreement No. 24-374** with QIAGEN, including non-standard terms, for preventive maintenance service for the QIAGEN EZ1 instrument, in a total amount not-to-exceed \$31,692, effective May 12, 2024 through June 30, 2029.
2. Approve the Master Purchase **Agreement No. 24-375** with QIAGEN, including non-standard terms, for the purchase of QuantiFERON® test kits used to test for latent tuberculosis infection, in a total amount not-to-exceed \$1,250,000, effective March 20, 2024 through February 26, 2029.
3. Authorize the Director of the Department of Public Health or Assistant Director of the Department of Public Health to electronically accept the terms and conditions of the EZ1 Service Agreement with QIAGEN, and any future non-substantive amendments, on behalf of the County, subject to review by County Counsel.
4. Direct the Director of the Department of Public Health to transmit all non-substantive amendments in relation to the EZ1 Service Agreement with QIAGEN to the Clerk of the Board of Supervisors within 30 days of execution.

(Presenter: Joshua Dugas, Director, 387-9146)

**COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES**

**Operate in a Fiscally Responsible and Business-Like Manner.**

**Provide for the Safety, Health and Social Service Needs of County Residents.**

**FINANCIAL IMPACT**

Approval of this item will not result in the use of Discretionary General Funding (Net County Cost). The five-year EZ1 Service Agreement with QIAGEN (Service Agreement), in the amount not-to-exceed \$31,692, will be funded with a Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness grant from the California Department of Public Health in the amount of \$30,799, with the remaining \$893 funded by other Department of Public Health (DPH) sources. Adequate appropriation and revenue are included in the DPH 2023-24 budget and will be included in future recommended budgets.

The DPH laboratory is funded through a variety of sources including Medi-Cal, Medicare, fee-for-service, and 1991 Realignment funding. The cost of the recommended purchase of QuantiFERON® test kits in a total amount not-to-exceed \$1,250,000 will be offset by funds from Medi-Cal, Medicare, 1991 Realignment, or private pay insurance.

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**BACKGROUND INFORMATION**

The QIAGEN EZ1 instrument was purchased in May 2023 to replace obsolete laboratory testing equipment. The manufacturer warranty for this instrument expires on May 11, 2024. Therefore, the Service Agreement will replace the warranty with regular preventative maintenance and repair. Recommendation No. 1 is requesting approval of the Service Agreement for a term of five years totaling \$30,799, plus an additional month and a half to cover the remaining fiscal year, of May 12, 2024 through June 30, 2024, in the amount of \$893.

The Service Agreement provides service and preventive maintenance for the QIAGEN EZ1 instrument over a five-year and one month term. The instrument is used to extract nucleic acid from clinical and environmental samples. Once extracted, the material is tested using other equipment to detect the presence of infectious organisms. The QIAGEN EZ1 instrument is one of the instruments required for standardized testing through the CDC Laboratory Response Network (LRN), of which DPH is registered as a reference laboratory.

Recommendation No. 2 requests approval for a Master Purchase Agreement (Purchase Agreement) with QIAGEN for the purchase of Tuberculosis (TB) test kits to be used throughout the county. TB is a serious and infectious disease mostly affecting the lungs. Every year 10,000,000 people worldwide fall ill, with approximately 1,500,000 dying, despite TB being a preventable and curable disease. Inadequately treated TB can become drug resistant, with treatment costing thousands of dollars and taking 18 to 24 months to cure. Two TB-related conditions exist, Latent TB Infection (Latent TB) and TB Disease. Latent TB is when a person has been infected with the TB bacteria but does not feel sick and has no symptoms. TB Disease includes symptoms which worsen if left untreated. When Latent TB is treated timely, patients are prevented from developing TB Disease.

There are two kinds of tests used to determine if a person has been infected with the TB bacteria, the TB skin test (Skin Test) and TB blood test. QuantiFERON® test kits are used to perform TB blood tests. The CDC has recommended that agencies that commonly perform TB surveillance using the Skin Test should switch to QuantiFERON® TB blood test as this test is more effective by only requiring a single office visit, does not cross-react with Bacillus Calmette-Guérin vaccinated individuals, and can be used with people who have had a positive Skin Test in the past

The DPH laboratory has performed 55,338 QuantiFERON® tests since 2011 to evaluate patients for Latent TB. Additionally, beginning in September 2014, the County Human Resources Department contracted with DPH to use the QuantiFERON® test to evaluate new employees in place of the former Skin Test. Under this Purchase Agreement, the County anticipates purchasing approximately 8,500 QuantiFERON® test kits per year, at an approximate cost of \$29 per test kit.

Latent TB testing has increased from 620 in 2011 to 7,947 in 2023. DPH is expected to continue performing QuantiFERON® testing in increasing numbers for County programs and local hospitals for the next five years. DPH previously had annual contracts created for QIAGEN within the Purchasing Agent's authority, with target amounts of \$200,000. Instead of renewing these contracts or requesting to increase the target amounts at the end of the year, DPH recommends approval of the proposed five-year Purchase Agreement with QIAGEN, including the non-standard terms, to expand Latent TB testing from approximately 8,000 to 8,500 QuantiFERON® tests annually for the retroactive period of March 20, 2024 through February 26, 2029, thereby securing ongoing annual prices.

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This item is retroactive due to extended negotiations. On March 20, 2024 QIAGEN provided the final draft Purchase Agreement listing March 20 as the retroactive begin date. In the event DPH requests an updated term on the contract, further delay will result and may adjust the current pricing quote of the QuantiFERON® tests.

Both the Purchase Agreement and Service Agreement include QIAGEN's standard commercial contract language, which includes terms that differ from the standard County contract and omits certain County standard terms. QIAGEN is unwilling to negotiate these terms.

The non-standard and missing terms include the following:

1. Governing law is the State of Maryland.
  - The County standard contract requires California governing law.
  - Potential Impact: The Purchase Agreement and Service Agreement will be interpreted under Maryland law. Any questions, issues or claims arising under each agreement will require the County to hire outside counsel competent to advise on Maryland law, which may result in fees that exceed the total Agreement amount.
2. The prevailing party is entitled to recover attorneys' fees and costs.
  - The County standard contract requires each party to bear its own costs and attorney fees, regardless of who is the prevailing party.
  - Potential Impact: If either party institutes any legal proceedings related to the Purchase Agreement or Service Agreement, the prevailing party will be entitled to recover reasonable attorneys' fees, which could exceed each total agreement amount.
3. All disputes arising under the Agreement must be settled by binding arbitration.
  - The County standard contract does not require arbitration.
  - Potential Impact: Binding arbitration decisions are not appealable. In addition, disputes that might otherwise be settled in small claims court would incur arbitration costs that could exceed the costs of a small claims action, and the Purchase Agreement and Service Agreement amounts. County Counsel cannot advise on whether and to what extent such arbitration provisions may be enforceable against a government entity under Maryland law.
4. The Purchase Agreement and Service Agreement do not require QIAGEN to indemnify the County, as required by County Policies 11-05 and 11-07.
  - The County standard contract indemnity provision requires the contractor to indemnify, defend, and hold the County harmless from third party claims arising out of the acts, errors or omissions of any person.
  - Potential Impact: QIAGEN is not required to defend, indemnify or hold the County harmless from any claims, including indemnification for claims arising from QIAGEN's negligent or intentional acts and intellectual property infringement, which could exceed the total Purchase Agreement and Service Agreement amounts. County Counsel cannot advise on whether and to what extent Maryland law may allow the County to require QIAGEN to defend or indemnify the County absent an express provision in each agreement.
5. The Purchase Agreement and Service Agreement do not require QIAGEN to meet the County's insurance standards as required pursuant to County Policies 11-05, 11-07 and 11-07SP.

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- County policy requires contractors to carry appropriate insurance at limits and under conditions determined by the County's Risk Management Department and as set forth in County policy and in the County standard contract.
  - Potential Impact: The County has no assurance that QIAGEN will be financially responsible for claims that may arise under the Purchase Agreement and Service Agreement, which could result in expenses to the County that exceed each total agreement amount.
6. QIAGEN's maximum liability to the County is limited to the cost of the defective product or services causing the damage.
- The County standard contract does not include a limitation of liability.
  - Potential Impact: Claims could exceed the liability cap and the Purchase Agreement and Service Agreement amount leaving the County financially liable for the excess. County Counsel cannot advise on, whether and to what extent, Maryland law may limit or expand the exclusion of limits to the extent prohibited by applicable law.
7. Payment terms are Net 30 days with late payment interest of 1.5 percent per month.
- County standard payment terms are Net 60 days with no interest or late payment penalties.
  - Potential Impact: County standard processing time is 60 days or more. Failing to pay timely may result in a material breach of the Purchase Agreement and/or Service Agreement, which could allow QIAGEN to terminate either agreement and seek other legal remedies, including charging the County interest at a rate of 1.5 percent, which could exceed each agreement amount.
8. There is no termination for convenience without penalty.
- The County standard contract gives the County the right to terminate the contract, for any reason, with a 30-day written notice of termination without any obligation other than to pay amounts for services rendered and expenses reasonably incurred prior to the effective date of termination.
  - Potential Impact: Upon any termination by either party regardless of cause, the County is required to pay all purchase commitments under the contract, which could result in payment liability where no funds are available due to lack of allocation or loss of funding.

DPH recommends the approval of the Purchase Agreement and the Service Agreement, including the non-standard terms, as the QIAGEN EZ1 instrument and QuantiFERON® TB testing supplies allow DPH to conduct critical testing activities and immediately respond to public health emergencies.

**PROCUREMENT**

The Purchasing Department supports the non-competitive procurement of the QIAGEN Service Agreement and the Purchase Agreement for the QuantiFERON® test kits based on the functional specifications of the instrument and the testing products.

DPH operates the Qiagen EZ1 instrument for clinical testing purposes. QIAGEN holds proprietary service and preventive maintenance for the QIAGEN EZ1 instrument. As required under the LRN, DPH must maintain preventative maintenance service agreements on standardized testing equipment. Approval of this non-competitive Agreement will provide the QIAGEN EZ1 instrument service, critical preventive maintenance, and support services.

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QIAGEN is the only company offering a Latent TB blood test which can be performed in a local laboratory. The only alternate test available requires shipping the specimen to Tennessee, which would result in additional costs and delays in receiving the test results.

**REVIEW BY OTHERS**

This item has been reviewed by County Counsel (Adam Ebright, Deputy County Counsel, 387-5455) on April 18, 2024; Purchasing (Ariel Gill, Supervising Buyer, 387-2070) on April 18, 2024; Risk Management (Victor Tordesillas, Director, 386-8623) on April 15, 2024; Finance (Carl Lofton, Administrative Analyst, 387-5404) on April 19, 2024; and County Finance and Administration (Robert Saldana, Deputy Executive Officer, 387-5423) on April 22, 2024.

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Record of Action of the Board of Supervisors  
San Bernardino County

**APPROVED (CONSENT CALENDAR)**

Moved: Joe Baca, Jr. Seconded: Curt Hagman  
Ayes: Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.  
Absent: Col. Paul Cook (Ret.)

Lynna Monell, CLERK OF THE BOARD

BY   
DATED: May 7, 2024



cc: PH - Saucedo w/agrees  
Contractor - c/o PH w/agree  
File - w/agree  
CCM 05/13/2024