OF SANT	one COUNTY one FUTURE	BOARD OF SU AGENDA		Agenda Number:	
CALIFOR		Clerk of the Board of Supervisors 105 E. Anapamu Street, Suite 407 Santa Barbara, CA 93101 (805) 568-2240		Submitted on: (COB Stamp)	
				Department	Public Health
				Name:	
				Department No.:	041
				For Agenda Of:	December 3, 2024
				Placement:	Administrative
				Estimated Time:	
				Continued Item:	No
				If Yes, date from:	
				Vote Required:	4/5
TO:	Board of Supe	ervisors			
FROM:	Department I	Director(s):	Mouhanad Hammami, Director		

DM:	Department Director(s):	Mouhanad Hammami, Director	
		Public Health Department	
	Contact Info:	Dr. Henning Ansorg, Health Officer 805-681-5152	

# SUBJECT: Bid Waiver Request for Purchase of Public Health Laboratory Instruments: Whole Genome Sequencer and Panther Fusion for Fiscal Years 2024-25

County Counsel Concurrence	Auditor-Controller Concurrence
As to form: Yes	As to form: Yes

#### **Other Concurrence: CEO Budget**

As to form: Yes

## **Recommended Actions:**

That the Board of Supervisors:

- a) Approve and authorize the County Purchasing Agent, pursuant to County Code section 2-39, to issue a purchase order for a Whole Genome Sequencer from Clear Labs for a total purchase amount not to exceed \$452,300, without being required to conduct a formal competitive bid process;
- b) Approve and authorize the County Purchasing Agent, pursuant to County Code section 2-39, to issue a purchase order for a Panther Fusion, which is an extension system for the Panther Instrument, from Hologic for a total purchase amount not to exceed \$160,000, without being required to conduct a formal competitive bid process;
- c) Approve budget revision BJE Number 0010151 (Attachment C) in the amount of \$612,300 to establish appropriations for unanticipated revenue in the Public Health Laboratory in FY 2024-2025 for the purchase of necessary instrumentation for laboratory testing. Funding is coming

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from the already approved CDPH Epidemiology and Laboratory Capacity Enhancing Detection Expansion grant; and

d) Determine that the proposed actions do not constitute a "Project" within the meaning of California Environmental Quality Act (CEQA) and is exempt pursuant to Section 15378(b)(5) of the CEQA Guidelines, because it is an administrative activity of government that will not result in direct or indirect physical changes in the environment

## Summary:

Pursuant to County Code section 2-39, the Public Health Department (PHD) Laboratory is requesting that the Board of Supervisors waive the requirement for competitive bidding due to "limitation on source or supply" and the "necessary restriction in manufacturers" and is requesting authorization for the County's Purchasing Agent to purchase instrumentation for laboratory testing on Tuberculosis (TB) and Bacteriology for the fiscal year of 2024-25 using Federal Epidemiology and Laboratory Capacity Enhancing Detection Expansion (ELC3) grant funds which have already been approved to purchase by the California Department of Public Health (CDPH).

The recommended actions will allow the Public Health Laboratory to procure the laboratory testing necessary to conduct increased tuberculosis testing and changes to enhance the ongoing improvements needed to work with communicable diseases such as SARS CoV-19.

## Background:

PHD requests that your Board waive the requirement for a competitive bid for the purchase of the necessary Whole Genome Sequencer by Clear Labs as well as the Extension unit for the Panther Instrument by Hologic.

Testing technologies in Microbiology have evolved rapidly over the past five years. In particular Tuberculosis specimens are nowadays tested via Genomic Testing techniques. In order to respond to our local Tuberculosis outbreaks (which are above California's average), our Public Health Lab needs to have appropriate equipment available.

The Panther instrument extension will enable the Public Health Lab to meet increasing demand for timely STI testing, in particular for Gonorrhea and Chlamydia.

In general, laboratory equipment is very sensitive and designed to function properly with specific parameters. Use of alternate instruments in many cases is not possible, may negatively impact readings and test results, and may damage equipment and void warranties. For these situations and reasons, PHD is requesting bid waivers.

Santa Barbara County is experiencing an increase of Tuberculosis (TB) patients resulting in a significant increase of specimens coming to the Public Health Laboratory. In order to rule out if a patient has TB, multiple specimens over a period of time have to be tested. Depending on the results, subsequent, different tests must be conducted. This standard practice demonstrates that one patient requires multiple tests, thus causing the need for increased reagent supplies. Two companies provide the instruments needed to conduct testing on the equipment used.

<u>Clear Labs Inc</u> is the only supplier of specific laboratory instrument used for Tuberculosis (TB), SARS CoV-19, and other Bacteriology testing. Clear Dx System LR-SR manufactured by Clear Labs offers the only fully automated, intelligent library prep and NGS platform for whole genome sequencing of SARS-CoV-19 and Bacterial Isolates (Microbial Surveillance). The Clear Dx<sup>TM</sup> System provides rapid, real-time genomic surveillance, enabling public health officials and epidemiologists to make, actionable

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and timely decisions with a fraction of the labor required. Additionally, CDPH is encouraging local Public Health Laboratories to use this specific system in order to be able to network and collaborate consistently and efficiently.

<u>Hologic</u> is the only FDA-approved vendor with the instruments required for rapid detection and identification of Chlamydia/Gonorrhea in patient specimens that are used in the Public Health Laboratory. The Panther instrument (manufactured by Hologic) is validated for the testing of Chlamydia/Gonorrhea and is currently used by the Public Health Laboratory. The Panther Fusion is an extension of the instrument which will allow for the addition of automated tests for a variety of viruses like HIV, measles, mumps, and rabies PCR.

## Fiscal Analysis:

Authorizing the County of Santa Barbara Purchasing Agent to procure the Whole Genome Sequencer from Clear Labs in the not-to-exceed amount of \$452,300, and the Panther Fusion extension from Hologic in the not-to-exceed amount of \$160,000, without formal bid requirements will allow PHD to:

- Enhance the capability for Mycobacteria (TB), Covid-19, Bacteriology (food outbreaks) and TB Drug susceptibility; and
- Add the capacity to, at a minimum, test for measles, mumps, and rabies PCR.

The attached budget revision in the amount of \$612,300 is necessary to amend the adopted Fiscal Year 2024-25 PHD's capital asset budget. These capital assets are funded by the existing Epidemiology and Laboratory Capacity Enhancing Detection Expansion grant, which ends July 31, 2026.

Funding Source	Current FY Cost	Annualized On-going Cost	Total One-Time Project Cost
General Fund			
State			
Federal	\$612,300.00		\$612,300 .00
Fees			
[Other Source]			
Total	\$612,300.00		\$612,300.00

## **Funding Source Table**

# Special Instructions to Clerk of the Board:

Request the Clerk of the Board to provide a copy of the minute order by email to the Public Health Department Contracts Unit at <u>phdcu@sbcphd.org</u> and one copy to Purchasing. Attn: Phung Loman.

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## Attachments:

Attachment A – Clear Labs Quote for Whole Genome Sequencer Attachment B – Hologic Quote for Panther Fusion Attachment C – BJE 0010151

#### Authored by:

Aisling Morgan, Public Health Laboratory Supervisor Stacy Covarrubias, Public Health Financial Manager