SANTA BARBARA COUNTY
BOARD AGENDA LETTER

Clerk of the Board of Supervisors
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Santa Barbara, CA 93101
(805) 568-2240

Agenda Number:	
Prepared on:	03/22/2006
Department Name:	Public Health Department
Department No.:	041
Agenda Date:	04/04/2006
Placement:	Administrative
Estimate Time:	10minutes on 05/02/06
Continued Item:	No
If Yes, date from:	

TO:	Board of Supervisors
FROM:	Elliot Schulman, MD, MPH, Director and Health Officer Public Health Department
STAFF CONTACT:	Frank Alvarez, MD, MPH, Deputy Health Officer, 681-5281 Michael Hartley, Public Health Laboratory Supervisor 681-5256
SUBJECT:	Fee Resolution for QuantiFERON®-TB Gold testing by the Public Health Laboratory

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Recommendation(s):
That the Board of Supervisors:

Set a Hearing on May 2, 2006, for 10 minutes to consider a fee for the QuantiFERON®-TB test, as follows:

Adopt a Resolution establishing a fee to medical providers for QuantiFERON®-TB GOLD testing performed in the Public Health Laboratory to be effective thirty days after adoption of this resolution.

Alignment with Board Strategic Plan:
Goal #1: An Efficient Government Able to Respond Effectively to the Needs of the Community.
Goal #2: A Safe and Healthy Community in Which to Live, Work, and Visit.

Executive Summary and Discussion: The Public Health Department is requesting that your board set a hearing to consider establishing a fee for QuantiFERON®-TB Gold (QFT-G) testing service provided by the Public Health Laboratory and adopt a Resolution setting a fee of $50 to medical providers and community healthcare agencies for QuantiFERON®-TB GOLD testing performed in the Public Health Laboratory effective May 25, 2006. It is optional for local providers to utilize this service; the Public Health Laboratory will simply make it available as a local resource.

Current Method: Tuberculin Skin Test and Its Limitations
The Tuberculin Skin Test (TST), has been used for detection of both active and latent tuberculosis infection for more than 70 years. The TST requires intra-dermal injection of tuberculin purified protein derivative (tuberculin PPD) into the skin. The result (if positive) is an area of hardness and redness at the site of injection 48-72 hours later. The area of induration is measured in millimeters, usually on day two or three following the injection.

Although TST is currently the most widely used test for the detection of tuberculosis infection, it has important limitations, which delay the timeliness of a contact investigation which include:

- Test Results (repeat visits required) - the patient must return two days later for medical staff to measure the diameter of the induration and interpret the test result. Patients frequently do not return for test interpretation; thus necessitating a repeat test-thereby delaying the identification and therapy of an infected individual.
- Low Sensitivity (False Negatives)- TST fails to detect infection in approximately 20% of patients with active TB infection. This failure occurs most frequently because the patient is in the early stages of infection but can also be due to a suppressed immune system due to HIV infection or various drug treatments, thereby misdiagnosing and failing to appropriately treat an infected individual.
- Low Specificity (False Positives) - False positive results are mainly due to non-specific reactions caused by exposure to certain environmental bacteria, called non-tuberculosis mycobacteria (NTM), which do not cause tuberculosis. False positive misdiagnosis leads to inappropriate therapy, costs and misallocation of staff resources.
- Technical Errors - Errors that occur due to improper administration of PPD to the patient or inaccuracy in measuring the diameter of induration can lead to false negative or false positive interpretations of the TST.

It is difficult to quantify the resources and costs of false positive TSTs. A "false" positive skin test reading could result in all of the following costs and burden of course of treatment for both the patient and staff: chest x-rays, lab tests (liver function test), and a 9-month course of drug therapy. All patients started on latent TB infection treatment must have monthly medical evaluations with their providers prior to medication refills as a measure of identifying early signs of liver toxicity. Each "false" positive TST is estimated to cost a minimum of $531 (PHD costs and those of other providers will be higher) and the patients could suffer adverse drug effects.

New Method: QuantiFERON®-TB GOLD Test (QFT-G)

In May of 2005, FDA gave final approval for a new blood test for the detection of tuberculosis infection. The new test is called QuantiFERON®-TB Gold (QFT-G). The new test has several advantages over the Tuberculin Skin Test.

- Test Results (one blood draw only) - There is no need for patient follow-up visits to read test results so there are no patient compliance issues.
- Higher Sensitivity (minimizes False Negatives) - Studies show that QF T-G tests detect 91.3% of cultured confirmed TB cases.
- Higher Specificity (minimizes False Positives)- QFT-G greatly reduces false positive outcomes due to BCG (Bacille Calmette-Guerin)vaccination and most non-tuberculosis mycobacteia.
- Technical Errors (standardized lab results-minimizes subjective interpretation) - Although technical errors can occur in the performance of the QFT-G in the laboratory, the reading and interpretation of the test is performed by objective laboratory instruments and software. The subjective errors inherent in reading the TST are eliminated.
- QFT-G is an objective test with results read by an instrument. So there is no need for subjective measurements.

Because of the lower incidence of false positives, PHD staff and medical staff in local hospitals and clinics can focus their resources on patients who are truly positive for exposure to TB.

It is not the intent of the Public Health Department to replace the TST with QFT-G testing. At this point, the test and fee needs to be established and implemented in order to find out what the community demand might

be. Until community demand is evaluated, materials and on-going staffing levels cannot be determined. At a minimum, and at current staffing levels, the new test could begin with County clinics, homeless shelters and partnering entities confirming positive TST results; thus reducing the count of false positives and reducing the cost of treating false positives.

Partnering Entities
Cottage Hospital, Sansum Santa Barbara Medical Foundation Clinic, San Luis Obispo County Public Health Department and Exxon-Mobil Corp. (off-shore platform workers- international TB exposure) have expressed an interest in having QFT-G testing done by the Public Health Laboratory.

Mandates and Service Levels: California Code of Regulations, Title 17, Section 1276 (c) mandates a tuberculosis control program as one of the basic services required of local health jurisdictions. There is no reference to specific tests and how they are conducted.

Fiscal and Facilities Impacts: Adopting the fee for QuantiFERON-TB Gold will not result in additional General Fund Contribution. Although this test is more expensive to conduct than the skin test currently available, it will return considerably fewer false positives, and therefore would eliminate needless treatment costs, which are difficult to quantify.

Usually, medical fees are established at either a Medi-Cal reimbursement rate, prevailing rate by like service providers, or based on historical workload and costs. In the case of QuantiFERON testing, none of these resources apply. California has not established a Medi-Cal rate for this test. Statewide there are only a few providers, and for-profit laboratories charge over $100 while other County Laboratories are charging between $20 to $30. Since there is no workload history, the $50 fee before you represents the estimated cost of material, staff time, and overhead. The fee calculation is further complicated by the shelf-life of the test kit material. There are 40 usable tests per kit so optimally, 'batching' blood tests in 20s will yield the most efficient cost. However, until it is know what entities wish to use this technology and to what level of service, it cannot be determined if the 'optimal' will be the norm.

In the case that optimal batching of tests cannot be met, the department would like to recover the costs of the test kit materials that could expire and would need to be thrown away.

The Auditor's office reviewed this fee for mathematical accuracy, reasonableness of methodology and assumptions, and appropriateness of results. It was determined that the methodology was rational and appeared to generally approximate the cost of providing service. It is the intention of the Department to return to your Board after one year of accumulated history to adjust fees if necessary.

Special Instructions: Publish the attached legal notice in a newspaper of general circulation in Santa Barbara County 10 days prior to the hearing and again 5 days prior to the hearing.

Please return one full executed copy of the resolution along with a copy of the minute order to PHD Contracts Unit, 300 North San Antonio Road, Building 8, Santa Barbara, CA 93110 Attention: Margaret Granger (805) 681-5367.

Concurrence: None required.