



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

14 MAR 25 P2:59
14 MAR 21 A8:36

STATE PROCUREMENT OFFICE
STATE OF HAWAII
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TO: Chief Procurement Officer
FROM: Health/State Laboratories/Medical Microbiology Branch
Name of Requesting Department

Pursuant to HRS §103D-306 and HAR chapter 3-122, Subchapter 9, the Department requests sole source approval to purchase the following:

1. Describe the goods, services, or construction to be procured.
Quantiferon -TB Gold In-Tube (IT) Test Kits and Accessories for detection of latent Mycobacterium tuberculosis infection in heparinized whole blood.

Table with 2 columns: Vendor/Contractor/Service Provider Name, Amount of Request, Term of contract, Prior SPO-001, Sole Source (SS) No.

6. Describe in detail the following:
a. The unique features, characteristics, or capabilities of the goods, service or construction.
The Quantiferon-TB Gold In-Tube (IT) Test is manufactured by Cellestis, Inc. which was acquired by Qiagen, Inc. in August 2011. The Quantiferon-TB Gold In-Tube Test is the only US FDA approved blood test for latent TB infection in the market that does not require microscopy (labor intensive) and is automated.
The Quantiferon-TB Gold IT software is proprietary to Qiagen and cannot be used with any other manufacturer's product. The Quantiferon-TB Gold IT test is an enzyme-linked immunosorbent assay (ELISA) that detects the release of interferon-gamma (IFN-G) in fresh heparinized whole blood from sensitized persons when it is incubated with synthetic peptides simulating two proteins present in M. tuberculosis. Because these proteins are absent from Bacille Calmette-Guerin (BCG) vaccine strains and from commonly encountered nontuberculosis mycobacteria (NTM) (see attached sheet)
b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department
Testing capabilities for Quantiferon TB-Gold IT will significantly improve our laboratory's ability for the Department's Tuberculosis Control Program to identify and treat patients with latent tuberculosis infections so they do not spread their disease to the public.
Quantiferon-TB Gold IT can be used in all circumstances in which TST is used, including contact investigations, evaluation of recent immigrants who have BCG vaccination, and TB screening of healthcare workers and others undergoing serial evaluation for M. tuberculosis infection. Quantiferon-TB Gold IT usually can be used in place of TSTs. The TB Control Program can use Quantiferon-TB Gold IT for investigating contacts of persons with potentially infectious TB disease. Because Quantiferon-TB Gold IT does not require a second visit to complete, test results will probably be available from a greater percentage of contacts than would be available using TST. Because of its greater specificity, Quantiferon-TB Gold IT is expected to include a smaller portion of contacts as infected that the TST would indicate. (see attached sheet)

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7. Describe the efforts and results in determining that this is the only vendor/contractor/service provider who can provide the goods, services or construction.

See the attached letter from Qiagen, Inc. that confirms that they are the manufacturer and sole distributor of the Quantiferon-TB Gold In-Tube Test.

8. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.

There are none.

9. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required.)

*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	E-mail Address
Gail Kunimoto	Health/SLD	453-6700	<i>gail.kunimoto@doh.hawaii.gov</i>

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR chapter 3-122, Subchapter 15, Cost or Pricing Data if required.

**All requirements/approvals and internal controls for this expenditure is the responsibility of the department.
I certify that the information provided is to the best of my knowledge, true and correct.**

Linda Brown RMP

Department Head Signature

3-25-2014

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 3/27/2014

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is granted for the period 4/18/2014 to 4/17/2015. This approval is based on Quantiferon TB Gold In-Tube Test is the only US FDA approved for diagnosis of tuberculosis infection. Qiagen, Inc. has been assigned the rights of sole source supplier of the Quantiferon TB Gold In-Tube test and other products to commercial customers in the United States effective 12/1/2012. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System. Copies of the HCE certificate and awards posting are required to be documented in the procurement/contract file. If there are any questions, please contact Stanton Mato at 586-0566, or Stanton.d.mato@hawaii.gov.

Approved

Disapproved

No Action Required

Acting  _____ Date 4/17/14

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Test Kits and Accessories to Detect Latent *Mycobacterium tuberculosis* in Heparinized Whole Blood

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6. Describe in detail the following:

- a. The unique features, characteristics, or capabilities of the goods, services, or construction.(continued)

except for a few species, the Quantiferon-TB Gold IT is expected to be more specific for *M. tuberculosis* than tests that use tuberculin protein derivative (PPD) as the antigen.

Tuberculosis is a communicable disease which typically spreads to new hosts via airborne droplet nuclei from patients with respiratory tuberculosis disease. A newly infected individual can become ill from tuberculosis within weeks to months, but most infected individuals remain well. Latent tuberculosis infection (LTBI), a non-communicable asymptomatic condition, persists in some individuals who may develop tuberculosis disease months or years later. The main purpose for diagnosing LTBI is to consider medical treatment for preventing tuberculosis disease. Until recently, the tuberculin skin test (TST) was the only available method for diagnosing LTBI. LTBI must be distinguished from tuberculosis disease which usually involves the lungs and lower respiratory tract, although other organ systems may also be affected. Tuberculosis disease is diagnosed from historical, physical, radiological, histological, and mycobacterial findings.

QFT-G has been approved by the USFDA since 2005 as an aid for diagnosing both latent tuberculosis (LTBI) and TB disease. The tuberculin skin test (TST) was the only test available for detecting LTBI prior to the Quantiferon-TB Gold IT results can be available <24 hours after testing without the need for a second visit, whereas a TST requires a second encounter to read the result 24-72 hours after administration of the test. As a laboratory-based assay, the Quantiferon-TB Gold IT assay is not subject to the biases and errors of TST placement and reading.

TST and Quantiferon-TB Gold IT rely on a different immune response and differs in its relative measures of sensitivity and specificity. The TST assesses in vivo delayed-type sensitivity (Type IV) whereas Quantiferon-TB Gold IT measure in-vitro release of IFN- γ . The TST measures response to PPD, a polyvalent antigenic mixture, whereas Quantiferon-TB Gold IT measures a response mixture of synthetic peptides simulating two specific antigenic proteins that are present in PPD. Quantiferon-TB Gold IT is not affected by prior BCG vaccination and is expected to be less influenced by previous infection with non-tuberculosis mycobacteria. TSTs are variably affected by these factors. Quantiferon-TB Gold IT does not trigger an anamnestic response (i.e. boosting) because it does not expose persons to antigen. Injection of PPD for TST can boost subsequent TST responses, primarily in persons who have been infected with NTM or

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vaccinated with BCG. Compared with the TST, Quantiferon-TB Gold IT might be less affected by boosting from a previous TST.

- b. How the unique features, characteristics, or capabilities of the goods, services or construction are essential for the department (continued)

Public health resources that were previously devoted to completion of testing can be concentrated on full evaluation and complete treatment of contacts who have positive Quantiferon-TB Gold IT results. In contrast to the TST, initial Quantiferon-TB Gold IT testing of contacts will not boost subsequent test results, which avoids uncertainty without interpreting follow-up results.

Quantiferon-TB Gold IT might represent a cost-effective alternative to TST in testing programs which are part of the TB Infection Control Program in institutions such as health care settings, correctional facilities, or homeless shelters. In these settings, false-positive reactions to TST pose a problem compounded in settings with BCG-vaccinated persons in countries where TB is prevalent. Disadvantages of TST testing include the need for follow-up visits for reading the TST. The advantages of Quantiferon-TB Gold IT includes greater specificity and the requirement for only one visit.