



**STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE**

13 APR -2 A7:52

STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health/FHSD/Children with Special Health Needs 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.

DNA testing for alpha thalassemia mutations for newborns and families detected through the state mandated Newborn Metabolic Screening Program: 1) --(a)3.7 single gene deletion; 2) --(a)4.2 single gene deletion; 3) --(a)20.5 double gene deletion; 4) --(a)MED double gene deletion; 5) -- (a) FIL double gene deletion; 6) --(a) THAI double gene deletion; 7) --(a) SEA double gene deletion; 8) HbCS (Constant Springs point mutation) performed upon request at no charge. The testing fee is \$200 per newborn and \$100 for each parent. Each family needs the newborn, mother, and father to be tested. Up to 75 families per year may be tested based on our current screening and follow-up rate.

<p>2. Vendor/Contractor/Service Provider Name:</p> <p>The Queen's Medical Center 1301 Punchbowl Street, Kinau 405, Honolulu, HI 96813</p>	<p>3. Amount of Request:</p> <p><u>\$47,000.00</u></p>
<p>4. Term of contract (shall not exceed 12 months), if applicable:</p> <p>From: <u>9/1/2013</u> To: <u>8/31/2014</u></p>	<p>5. Prior SPO-001, Sole Source (SS) No.:</p> <p><u>13-003K</u></p>

6. Describe in detail the following:

a. The unique features, characteristics, or capabilities of the goods, service or construction.

The Queen's Molecular Diagnostic Laboratory (formerly known as the Queen's Medical Center Genetics Laboratory) is the only CAP accredited molecular genetics laboratory performing alpha-thalassemia mutation analysis in the State of Hawaii. Peter Bryant-Greenwood, M.D. is the laboratory's medical director. The laboratory is Clinical Laboratory Improvement Amendment (CLIA) certified, College of American Pathologists (CAP) accredited and licensed by the State of Hawaii to perform high complexity clinical laboratory testing. The Queen's Molecular Diagnostic Laboratory works in conjunction with the pathologists of Hawaii Pathologists' Laboratory (HPL), which has the expertise to provide quality interpretations of test results. Results and interpretations will be available within 10 days of receipt of specimen in the laboratory. Alpha-thalassemia mutation analysis is performed by polymerase chain reaction (PCR) and gel electrophoresis.

b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department

Approximately 30 newborns per month are identified by the state mandated Newborn Metabolic Screening Program to be at risk for thalassemia trait or disease. In order to provide appropriate follow-up to the identified newborns and their families, DNA mutation analysis must be offered. The information gained from DNA analysis is essential to providing management to newborns with a significant thalassemia condition and to avoid a possible fatal thalassemia condition in future pregnancies. Medicaid and Quest do not provide payment for alpha thalassemia DNA testing, and families covered by these entities are not able to afford to pay for the DNA testing. Therefore, they can not receive the information necessary to accurately diagnose the severity and risks of this trait

The Queens Molecular Diagnostic Laboratory is uniquely equipped to provide the DNA muation analysis using the muations most commonly found in the Hawai'i population.

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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.
 Many of the mutations that are being tested for by the Queen's laboratory were developed using the local Hawai'i population. The Queen's laboratory is also the only local molecular genetics testing laboratory in Hawai'i providing thalassemia testing. The Department of Health genetics program monitors genetics providers in the state so we know that there are no other laboratories doing genetic testing locally.

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.
 The state laboratory does not perform DNA mutation analysis for alpha thalassemia. No other private laboratories in Hawai'i perform DNA mutation analysis for alpha thalassemia.

9. Identify the primary individual(s) who is knowledgeable about this request, who will conduct and manage this process, and has 1) appropriate written delegated procurement authority; 2) completed mandatory training; and 3) who SPO may contact for follow up inquiry, if any.
 (Type over "example" and delete cells not used.)

Name of Department Personnel	Division/Agency	Phone Number	E-mail Address
Gordon Takaki	Family Health Div.	733-8365	Gordon.Takaki@doh.hawaii.gov

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.



 Department Head Signature



 Date

For Chief Procurement Officer Use Only

Date Notice Posted: 4/3/13

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 09/01/13 to 08/31/14 and is based on the department's representation that Queen's Molecular Diagnostic Laboratory is the only CAP accredited molecular genetics laboratory performing alpha-thalassemia mutation analysis in Hawaii. 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.

If there are any questions, please contact Wendy Ebisui at 586-0563, or wendy.mo.ebisui@hawaii.gov.

Approved

Disapproved

No Action Required

Alana J. J...
Chief Procurement Officer Signature

4/18/2013
Date