



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

RECEIVED
By STATE PROCUREMENT OFFICE at 12:18 pm, Jul 27, 2016

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.

Table with 2 columns: Vendor/Contractor/Service Provider Name, Amount of Request, Term of contract, Prior SPO-001, Sole Source (SS) No.
The Queen's Medical Center, \$47,000.00, From: 9/1/2016 To: 8/31/2017, SS15-059D

6. Describe in detail the following:
a. The unique features, characteristics, or capabilities of the goods, service or construction.
See attached
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 mutation analysis using the mutations most commonly found in the Hawaii nonulation

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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 Hawaii population. The Queen's laboratory is also the only local molecular genetics testing laboratory in Hawaii 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 Hawaii perform DNA mutation analysis for alpha thalassemia.

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

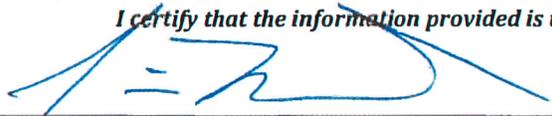
*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	E-mail Address
<i>Gordon Takaki</i>	<i>Family Health</i>	<i>733-8365</i>	<i>Gordon.Takaki@doh.hawaii.gov</i>
	<i>Services Division</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.



GW Department Head Signature

JUL 27 2016

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 07/28/2016

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:

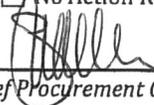
Approval is granted for the period 9/1/2016 to 8/31/2017 and is based on the department's representation that the Queen's Molecular Diagnostic Laboratory is the only CAP accredited molecular genetics laboratory performing alpha thalassemia mutation analysis in the State of Hawaii. This approval is for the solicitation process only. Pursuant to HRS §103D-310(c) and HAR §3-122-112, the procuring officer shall verify compliance (i.e. vendor is required to provide proof of compliance and may use the Hawaii Compliance Express) for all contracts awarded, and the award is required to be posted on the Awards Reporting System. Copies of the compliance and the award posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Stacey Kauleinamoku at 586-0571, or stacey.l.kauleinamoku@hawaii.gov.

Approved

Disapproved

No Action Required



Chief Procurement Officer Signature

8/8/16
Date

6a. The Queen's Molecular Diagnostic Laboratory (QMCDL) is the only College of American Pathologists (CAP) accredited molecular genetics laboratory performing alpha-thalassemia mutation analysis in Hawaii. There are many CAP certified laboratories in Hawaii but QMCDL is the only one that is a molecular laboratory which means that it does DNA analysis. QMCDL is Clinical Laboratory Improvement Amendment (CLIA) certified and licensed by the State of Hawaii to perform high complexity clinical laboratory testing. The QMCDL 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 DNA mutation analysis is performed by polymerase chain reaction (PCR) and gel electrophoresis. QMCDL has worked with the local genetics experts to develop an alpha thalassemia mutation panel that covers the common mutations found in Hawaii's families. Mainland laboratories do not have similar panels so mutation testing would have to be chosen individually which will be much more costly.