



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

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.
DENGUE IGM ANTIBODY TEST (DENV Detect IgM CAPTURE ELISA)

2. Vendor/Contractor/Service Provider Name: INBIOS INTERNATIONAL, INC.	3. Amount of Request: \$150,000.00
4. Term of contract (shall not exceed 12 months), if applicable: From: 4/18/2016 To: 4/17/2017	5. Prior SPO-001, Sole Source (SS) No.: 15-052SKa1

6. Describe in detail the following:

a. The unique features, characteristics, or capabilities of the goods, service or construction.
The DENV Detect IgM Capture ELISA is for the qualitative detection of IgM antibodies to DENV (Dengue Virus) recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. The assay is intended for use only in patients with clinical symptoms consistent with either dengue fever or dengue hemorrhagic fever. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current CDC guidelines for diagnosis of this disease.
The DENV Detect IgM CAPTURE ELISA manufactured by Inbios International, Inc. is the only US FDA approved test for the qualitative detection of IgM antibodies to dengue virus recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. (see attached sheet)

b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department
Dengue is an acute viral disease that is most commonly transmitted by Aedes aegypti mosquitoes and far less so other mosquito strains. Dengue is usually characterized clinically by biphasic fever, rash, hematopoietic depression, and by symptoms such as malaise, arthralgia, myalgia and headache. Infrequently, more severe disease is seen, manifested by hemorrhagic fever (DHF) which may progress to lethal shock. Dengue fever is endemic in the tropics and subtropics, worldwide, where an estimated 50-100 million cases occur annually. Dengue outbreaks have been reported in Hawaii. Anti-dengue virus IgM antibody is produced transiently during primary and secondary infection. In patients with primary dengue virus infection, IgM antibodies develop rapidly and are detectable by days 3 to 5 of illness in half of hospitalized patients. Anti-dengue virus IgM levels peak at about 2 weeks post infection and then decline to undetectable levels over 2 to 3 months. In patients with secondary dengue virus infection, while the kinetics of IgM production are similar to those observed in patients with primary infections, IgM levels are significantly lower. Anti-dengue virus (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.

The DENV Detect IgM CAPTURE ELISA manufactured by Inbios International, Inc. is the only US FDA approved test for the qualitative detection of IgM antibodies to dengue virus recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection.

B. 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	SLD/MMB	453-6700	<i>gail.kunimoto@doh.hawaiiig.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.*



Department Head Signature

JAN 21 2016

Date

For Chief Procurement Officer Use Only

1/28/2016

Date Notice Posted:

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 from 4/18/2016 to 4/17/2017 and is based on the department's representation that Inbios International, Inc. is the manufacturer of the DENV Detect IgM CAPTURE ELISA which is the only US FDA approved test for the qualitative detection of IgM antibodies to dengue virus recombinant antigens in serum. This approval is for the solicitation process only. Pursuant to HRS section 103D-310(c) and HAR section 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 compliance and awards posting are required to be documented in the procurement/contract file.

Department is also reminded that sole source contracts in excess of \$100,000 require certified cost or pricing data and analysis of such data pursuant to HAR chapter 3-122, subchapter 15. Certified cost and pricing data and analysis are required to be maintained in the procurement/contract file.

If there are any questions, please contact Kevin Takaesu at 586-0568 or kevin.s.takaesu@hawaii.gov.

Approved

Disapproved

No Action Required


Chief Procurement Officer Signature

2/10/16

Date

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DENV Detect™ 1gM CAPTURE ELISA
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6. Describe in detail the following:

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

Assay performance characteristics have not been established for testing cord blood, for testing neonates, for prenatal screening, or for general population screening. This assay is not FDA cleared or approved for testing blood or plasma donors.

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

IgM antibodies also peak at about 2 weeks post infection, then begin to wane and are still detectable in about 30% of the patients 2 months after onset of symptoms. In contrast to primary infection, secondary infection with dengue virus results in the earlier appearance of high titers of cross-reactive IgG antibodies before or simultaneously with the IgM response.

The State of Hawaii is currently experiencing a dengue outbreak on the Big Island which does not appear to be decreasing in its activity. The SLD is continuing daily testing for dengue in addition to performing the molecular based PCR testing for the viral antigen to identify the cases of suspected dengue.

The disease control program needs to rapidly identify these cases of suspected dengue fever for implementation of appropriate treatment and intervention control measures. The DENV Detect 1gM Capture ELISA tests for 1gM antibodies in human serum to Dengue derived recombinant antigens (DENRA).

Once the dengue outbreak response is completed, the SLD and the disease control program will be encouraging specimen submissions from its community laboratory partners for routine dengue viral serology requests submitted to their laboratories be sent to SLD for testing instead of referring to out of state reference laboratories in order to get better surveillance data on the incidence of dengue activity in the State. This is expected to greatly increase the department's annual dengue testing volume being performed here at the SLD.