

STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

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STATE PROCUREMENT OFFICE
STATE OF HAWAII

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)

Table with 2 columns: Vendor/Contractor/Service Provider Name (INBIOS INTERNATIONAL, INC.), Amount of Request (\$20,000.00), Term of contract (CPO APPROVAL to 12 MONTHS), 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 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.
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.

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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.

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).

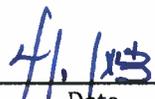
Name	Division/Agency	Phone Number	E-mail Address
Gail Kunimoto	SLD/MMB	453-6700	gail.kunimoto@doh.hawaii.gov

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: 4/4/13

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 04/18/13 to 04/17/14 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 qualitative detection of IgM antibodies to dengue virus recombinant antigens in serum. 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

David. Fuji 4/18/2013
Chief Procurement Officer Signature Date

REQUEST FOR SOLE SOURCE
DENV Detect™ IgM 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 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* IgM Capture ELISA tests for IgM antibodies in human serum to Dengue derived recombinant antigens (DENRA).

In order to get better surveillance data on the incidence of dengue activity in the State, 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 which will greatly increase the department's dengue testing volume being performed here at the SLD annually.