STATE PROCUREMENT OFFICE

NOTICE & REQUEST FOR SOLE SOURCE

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ADMINISTRATION
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.
GenBio ImmunoDOT Leptospira IgM Test

2. Vendor/Contractor/Service Provider Name:	3. Amount of Request:
Innominata dba GenBio	$20,000.00
4. Term of contract (shall not exceed 12 months), if applicable:	5. Prior SPO-001, Sole Source (SS) No.:
From: 4/19/2015 To: 4/18/2016	14-048S

6. Describe in detail the following:

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

The GenBio IgM ImmunoDOT Leptospira test is a qualitative enzyme immunoassay that specifically detects IgM antibodies to Leptospira biflexa (serovar patoc 1). The test is presumptive for the laboratory diagnosis of leptospirosis. The IgM ImmunoDOT Test may be used to evaluate a single specimen or paired specimens to detect seroconversion. The test in intended for used in serum, plasma, heparinized whole blood or finger stick capillary method.

The GenBio IgM Immunodot Leptospirosis Test utilizes an enzyme linked immunoassay (EIA) dot technique for the detection of IgM antibodies. This assay can be completed within an hour. The SLD test algorithm requires reactive sera to be submitted to the Kauai DHL for the microscopic agglutination test (MAT) which is the current WHO preferred method. The GenBio ImmunoDOT Leptospira IgM Test is the only US FDA approved EIA assay for detection (see attached sheet)

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

The laboratory diagnosis of leptospirosis is based on serological methods. Although culture methods are understood to be of epidemiological importance, the time elapsed are understood to be of epidemiological importance, the time elapsed between the culture and the identification of the infecting organism permits only a retrospective diagnosis. Cultures from blood and cerebrospinal fluid grown on specific media during the first week of illness can be useful to confirm a diagnosis. However, it may take 6-8 weeks for leptospira organisms to grow out. The SLD currently performs culture and culture confirmation of leptospira organisms.

The microscopic agglutination test (MAT) is the preferred method and is the current World Health Organiziation (WHO) standard reference method. The MAT method has high sensitivity and specificity and permits the detection of group-specific antibodies. The performance of the MAT test is limited to the few highly specialized laboratories in the world that are capable of maintaining live stock serovar cultures. The Kauai DHL currently performs the MAT test. (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.

This is the only US FDA approved test for detecting IgM antibodies for leptospirosis using an enzyme-linked immunoassay (EIA) dot technique by dipstick. See attached letter from Innominata dba GenBio.

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. The GenBio ImmunoDOT Leptospira IgM Test is the only US FDA approved test for detecting IgM antibody for leptospirosis by dipstick for use in serum, plasma, heparinized whole blood or finger stick capillary blood.

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.

Virginia Pressler — 2-20-15

Department Head Signature — Date

For Chief Procurement Officer Use Only

Date Notice Posted: 2/24/2015

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 4/19/2015 to 4/18/2016. This approval is based on Innominata dba GenBio is the sole manufacturer of the ImmunoDot Leptospira IgM test and is the only US FDA-approved EIA assay for detection of leptospirosis. 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 provide proof of compliance) and award is required to be posted on the Awards Reporting System. Copies of the compliance 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 email stanton.d.mato@hawaii.gov.

☒ Approved ☐ Disapproved ☐ No Action Required

Chief Procurement Officer Signature *Date* 3/9/15

6. Describe in detail the following:

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

      of IgM antibodies by EIA.

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

      Criteria for the laboratory diagnosis of leptospirosis have been established by the Centers for Disease Control and Prevention (CDC). These criteria are the isolation of leptospira from a clinical specimen, or a four-fold or greater increase in leptospira agglutination titer between acute and convalescent-phase serum specimens obtained greater than or equal to two weeks apart, or the demonstration of leptospira in a clinical specimen by immunofluorescence. A presumptive diagnosis may be made on the basis of a leptospira agglutination titer of greater than or equal to 200 ($\geq$ 200) in specimens from a clinically symptomatic case.

      A number of methods have been described for the detection of IgM antibodies in acute phase sera, using enzyme-linked microplate immunosorbent (ELISA) assays. An IgM ELISA test for leptospirosis and an indirect hemagglutination (IHA) in vitro diagnostic procedure are commercially available and are reported to have sensitivity and specificity comparable to the MAT method. The MAT method is not available commercially. The ImmunoDOT™ Leptospira IgM Test is the only US FDA approved IgM ELISA test for leptospirosis using the dot technique.