



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

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ADMINISTRATION
STATE PROCUREMENT OFFICE
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TO: Chief Procurement Officer
FROM: Health State Laboratories Division
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.
Cepheid Analyte Specific Reagents (ASRs) kits and accessories for: Flu A and Flu B ASRFLU-150N-040, Enterovirus ASREV-150N-040, HSV Non Typing ASRHVN-150N-040; HSV Typing, ASRHVT-105N-040; Pertussis/Parapertussis ASRPER-150N-040; NoroVirus ASRNV-150N-00; and RSV ASRRSV-105N-040. Cepheid Customer Specified Reagent (CSR) for E.coli STEC: O157 H7 (#901-0004) and OmniMix beads (OMNI1-100N-050).

2. Vendor/Contractor/Service Provider Name: Cepheid, Inc. 904 Caribbean Dr. Sunnyvale, CA 94808-1302	3. Amount of Request: \$15,000 est.
4. Term of contract (shall not exceed 12 months), if applicable: From: 12/29/2014 12/30/14 To: 12/30/2015 12/29/2015	5. Prior SPO-001, Sole Source (SS) No.: 14-032B

6. Describe in detail the following:

a. The unique features, characteristics, or capabilities of the goods, service or construction.
The kits that were described in Section 1 were designed to detect various organisms {e.g., Herpes Simplex Virus (HSV), EnteroHemorrhagic E. coli (EHEC)} from various matrixes. In addition, Texas Red-labeled probes are provided as an internal control to check for sample inhibition in each kit. The primers and probes for the Cepheid ASR kits were designed specifically for the Cepheid Smart Cycler II System only. The primers and probes are provided in a lyophilized format which allows ease of use, increased consistency in setting-up the PCR (Polymerase Chain Reaction) cocktails and the lyophilized form provides greater stability for the enzymes and nucleotides. The Customer Specified Reagent (CSR) 901-0004 and OmniMix beads (OMNI1-100N-050) is a custom product.

b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department
The ASR kits for Enterovirus and HSV (Non Typing and Typing) are part of the CDC-Laboratory Response Network (LRN) testing algorithm for smallpox rule-out and therefore needs a shorter TAT for ruling out suspect smallpox cases. The use of ASRs for the detection of various bacteria and viruses indicated in item # 3 (description of goods,etc.) provides a sensitive method of detecting these bacteria and viruses while reducing the Turn-Around-Time (TAT) for detection from 7-10 days for Influenza, RSV, and Pertussis/Parapertussis. The primers and probes are provided in a lyophilized bead format which allows ease of use, increased consistency in setting-up the PCR (Polymerase Chain Reaction) cocktails and the lyophilized form provides greater stability for the enzymes, primers, probes, dNTPs, and Magnesium Chloride.

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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 CDC-Laboratory Response Network (LRN) has developed standard protocols for the rapid screening of biothreat agents and toxins from clinical specimens, environmental samples and food matrices and is used exclusively by LRN Reference laboratories such as the State Lab Division. To maintain our status as an LRN/NAHLN Reference lab of good standing, depend on our ability to pass Proficiency Testing (PT) challenges that involve testing for unknown biothreat agents and toxins using CDC-LRN and NVSL standard assays. The Customer Specified Reagent (CSR) 901-0004 and OmniMix beads (OMNI1-100N-050) is a custom product that is produced only for and at the request of the customer and is not available as a commercial product. The rest of the Cepheid products can only be used exclusively for the Smart Cycler PCR platform.

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 were no alternative source investigated for reasons indicated on Section 7.

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
Rebecca H. Sciulli	State Lab Division	808-453-5993	rebecca.sciulli@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

9-16-2014

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 9/17/2014

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:

This approval is for the period 12/30/14 – 12/29/15 and is based on the department's representation that these manufacturer's reagents kits and accessories are essential for their work and available from this vendor only. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply and award is required to be posted on the Awards Reporting System. Copies of the HCE certificate and awards posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Bonnie Kahakui at 587-4702, or bonnie.a.kahakui@hawaii.gov.

Approved Disapproved No Action Required

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Chief Procurement Officer Signature Date 9/24/14