



11 OCT 25 P 1:51

STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE
STATE OF HAWAII

1. TO: Chief Procurement Officer
2. FROM: Health/State Laboratories Division
Department/Division/Agency

Pursuant to §103D-306, HRS, and Subchapter 9, Chapter 3-122, HAR, the Department requests sole source approval to purchase the following:

3. Description of goods, services, or construction:
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).

4. Vendor Name: Cepheid, Inc. Address: 904 Caribbean Drive Sunnyvale, CA 94809-1302	5. Price: \$ <u>100,000</u> Est
6. Term of Contract: (mm/dd/yyyy) From: <u>12/30/2011</u> <u>Upon CPO Approval</u> To: <u>12 Months</u> <u>12/29/2012</u> <i>for 10/20/11</i>	7. Prior Sole Source Ref No. <u>11-028-D</u>

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: Analyte Specific Reagent (ASR) kits containing primers, FAM and Alexa-labeled probes were designed to detect various organisms such as Flu A and B, Enterovirus, Pertussis and Bordetella parapertussis, Herpes Simplex Virus (HSV), NoroVirus, Respiratory Syncytial Virus (RSV), and 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 that is produced only for and at the request of the customer and is not available as a commercial product.

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: 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.

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 ASR kits for Enterovirus and HSV (Non Typing and Typing) are part of the testing algorithm for smallpox rule-out and therefore needs a shorter TAT for ruling out suspect smallpox cases. The use of NoroVirus (NV) ASRs will likewise shorten the TAT from 3-5 days to 2 days. This is critical because NV infections are likely to occur in cruise ships, nursing homes, hospital facilities and even schools, (See Attached Sheet)

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: There are no alternate sources.

12. Direct any inquiries to:
 Department: Health
 Contact Name/Title: Gail Y. Kunimoto/Chief, Medical Microbiology Branch

13 Phone Number:
453-6700
 Fax Number:
453-6716

Expenditure may be processed with a purchase order: Yes No If no, a contract must be executed and funds certified.
See 12/11

Agency shall ensure adherence to applicable administrative and statutory requirements.

14. *I certify that the information provided above is to the best of my knowledge, true, correct and that the goods, services, or construction are available through only one source.*


 Department Head

10/24/11
 Date

Reserved for SPO Use Only

15 Date Notice Posted: 10/26/2011

Submit written objections to this intent to issue a sole source contract within seven calendar days or as otherwise allowed from the above posted date to: Chief Procurement Officer
 State Procurement Office
 P.O. Box 119
 Honolulu, Hawaii 96810-0119



WEB WWW.CEPHEID.COM
MAIN 1.888.336.2743
FAX 1.408.734.1260

October 11, 2011

Dear Sir or Madam:

This letter is to confirm that Cepheid is the sole manufacturer and distributor of the following products:

ASR-BP-Primer	ASR-FLU1-Primer	ASR-RSVA-Primer	QC-DNA-CIC
ASR-BP-Probe	ASR-FLU1-Probe	ASR-RSVA-Probe	QC-DNA-SSC
ASR-PER-Primer	ASR-FLU2-Primer	ASR-RSVB-Primer	QC-RNA-Low
ASR-PER-Probe	ASR-FLU2-Probe	ASR-RSVB-Probe	QC-RNA-Med
ASR-HV1-Primer	ASR-NVG1-Primer		QC-RNA-High
ASR-HV1-Probe	ASR-NVG1-Probe		QC-RNA-SPC
ASR-HV2-Primer	ASR-NVG2-Primer		
ASR-HV2-Probe	ASR-NVG2-Probe		

All the products listed above are manufactured under cGMP for maximum product consistency and quality. The freeze-dried bead format provides lot to lot consistency of testing results, ease of use and greater stability when compared to wet reagents. The internal controls are available for purchase to check for sample inhibition and quality control.

Please let me know if you have any questions or need any additional information. I can be reached at 408-400-8379 or email address kaoru.otaki@cepheid.com.

Thank you for your interest in Cepheid's molecular diagnostic products.

Sincerely,

Kaoru Otaki
Sr. Product Manager
Cepheid