



DEC -3 P1 52

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

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>\$300,000Est</u>
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6. Term of Contract: (mm/dd/yyyy) From: <u>Upon CPO Approval</u> To: <u>12 Months</u>	7. Prior Sole Source Ref No. <u>08-040-J</u>
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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.

10. 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.

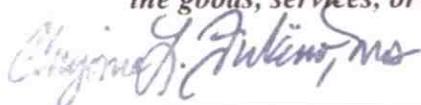
12. Direct any inquiries to:  
 Department: Health  
 Contact Name/Title: Gail Y. Kunimoto/Chief, Medical Microbiology Branch

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.

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

Date

**Reserved for SPO Use Only**

15 Date Notice Posted: 12/4/08

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

## 16. Chief Procurement Officer's comments:

This approval is based on the DOH-State Laboratory's representation that these manufacturer's kits and accessories are essential for their work and available from only this vendor.

Pursuant to HAR 3-122, Subchapter 15, Cost and Pricing Data are required for sole source procurements expected to exceed \$100,000.

17.

APPROVED    DISAPPROVED    NO ACTION REQUIRED

Adam S. Fyler   12/11/08  
Chief Procurement Officer   Date

REQUEST FOR SOLE SOURCE

Analyte Specific Reagents (ASR) and Customer Specified Reagents (CSR)

9/3/2008

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

There is no other company that produces this product. The custom beads are produced by Cepheid's proprietary bead manufacturing technology and intellectual property that has not been licensed to any other company. The *E. coli* O157:H7 CSR allows the laboratory to identify Shiga Toxin producing *E. coli* O157:H7 from stool specimens, environmental samples such as manure and produce. This is an important tool used by increasing number of public health laboratories in investigating gastrointestinal outbreaks.

October 24, 2008

Dear Ms. Rebecca Sciulli,

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

- ASR-FLU1-PRIMER
- ASR-FLU1-PROBE
- ASR-FLU2-PRIMER
- ASR-FLU2-PROBE
- ASR-HV1-PRIMER
- ASR-HV1-PROBE
- ASR-HV2-PRIMER
- ASR-HV2-PROBE
- ASR-BP-PRIMER
- ASR-BP-PROBE
- ASR-PER-PRIMER
- ASR-PER-PROBE
- ASR-NV1-PRIMER
- ASR-NV1-PROBE
- ASR-NV2-PRIMER
- ASR-NV2-PROBE
- ASR-RSVA-PRIMER
- ASR-RSVA-PROBE
- ASR-RSVB-PRIMER
- ASR-RSVB-PROBE
- SMHM-150N-040 and SMHM-100N-200
- OMNI1-100N-050

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.

Cepheid does distribute the SmartCycler reaction tubes, Cooling blocks, tube racks, SmartMix and OmniMix through Fisher Scientific and VWR. However the Analyte Specific Reagents are available only through Cepheid.

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](mailto:kaoru.otaki@cepheid.com).

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

Sincerely,

Kaoru Otaki  
Product Manager  
Cepheid