



10 DEC 15 P2:19

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: 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:
\$300,000Est

6. Term of Contract:
(mm/dd/yyyy) From: 12/30/2010 Upon CPO Approval To: 12 Months

7. Prior Sole Source Ref No.
10-018-B

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities:
They are the only products that work with SLD machines to test certain microbial pathogens. CDC and FERN protocols can only use these products and 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: SLD cannot test for certain micobial pathogens such as B. pertussis, norovirus, and we cannot rule-out small pox without these reagents. SLD can only perform fast tests using these reagents on the Cepheid machines. Further, these reagents allow SLD to perform fast and reliable results with the use of these reagents and machines.

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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.

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.*



ACTING DIRECTOR OF HEALTH

Department Head

12/14/10

Date

Reserved for SPO Use Only

15 Date Notice Posted: 12-16-10

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:

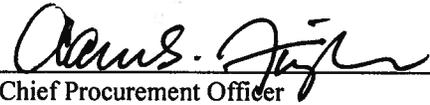
Chief Procurement Officer
 State Procurement Office
 P.O. Box 119
 Honolulu, Hawaii 96810-0119

16. Chief Procurement Officer's comments:

This approval is based on the department's representation that these manufacturer's kits and accessories are essential for their work and available from only this vendor. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply. Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to HAR chapter 3-122, subchapter 15. This award is required to be posted on the Awards Reporting System.

17.

APPROVED DISAPPROVED

 1/27/2011
Chief Procurement Officer Date

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.

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State Procurement Office
P.O. Box 119
Honolulu, Hawaii 96810-0119



November 11, 2010

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-NVGI-Primer | QC-DNA-CIC |
| ASR-BP-Probe | ASR-NVGI-Probe | QC-DNA-SSC |
| ASR-PER-Primer | ASR-NVG2-Primer | QC-RNA-Low |
| ASR-PER-Probe | ASR-NVG2-Probe | QC-RNA-Med |
| ASR-HVI-Primer | ASR-RSVA-Primer | QC-RNA-High |
| ASR-HVI-Probe | ASR-RSVA-Probe | QC-RNA-SPC |
| ASR-HV2-Primer | ASR-RSVB-Primer | Cepheid SmartTube |
| ASR-HV2-Probe | ASR-RSVB-Probe | |
| ASR-FLUI-Primer | GXEV-100N-10 | |
| ASR-FLUI-Probe | GXM RSA-100N-10 | |
| ASR-FLU2-Primer | | |
| ASR-FLU2-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
Product Manager
Cepheid



Senior Sales Specialist
Cepheid, Inc.
904 Caribbean Drive
Sunnyvale, CA 94089
888-838-3222

To whom it may concern,

This letter is to confirm that Cepheid Inc. is the sole manufacturer of the Smart Cycler System®, Smart Cycler® processing Block, Smart Cycler® Reaction Tubes and Smart Cycler® Accessories, and that Fisher Scientific and VWR are the sole distributor of the Smart Cycler® System in the U.S. Life Science Research Market; i.e. the aforementioned Smart Cycler® products cannot be obtained from any other source other than Cepheid or Fisher.

This document also details the unique aspects of the Smart Cycler®. These features are exclusive to the Smart Cycler system:

1. The real-time thermocycler must have 16 individually programmable sample processing sites using either 25 uL and/or 100 uL optically integrated reaction tubes.
2. The real-time thermocycler must utilize unbreakable polypropylene sample reaction tubes, with a high surface to volume ratio; not glass capillary-based (amenable to easy breakage, especially in field use).
3. The real time thermocycler must be expandable to 96 sample reaction sites, and yet maintain the ability to independently program each sample reaction site.
4. Each of the individual reaction sites must have its own independent thermal cycling and optical control system, with the ability to accurately record all thermal and spectral (fluorescent) measurements for each sample reaction site.
5. The thermocycler must have the capability to detect four spectral bands using high-intensity LED emitters and silicon detectors for 4 color real-time, simultaneous, optical excitation and detection; allowing the capability to monitor in true real time up to 4 different targets in one sample.
6. The instrument must be factory calibrated to optimally detect the following 4 fluorescent dyes simultaneously; FAM, Cy3, Texas Red, Cy5 ; FAM, TET, Texas Red, Cy5; or FAM, Alexa532, Texas Red, ALexa647 for Taqman, Beacon, Scorpion, and Amplifluor fluorescent probes. Additionally, the instrument must be capable of melt-curve analysis when intercalating dye chemistries are being employed.
7. The thermocycler software must be capable of performing and illustrating 2nd derivative threshold cycle analysis, for efficient and accurate quantitative analysis.
8. The thermocycler software must be capable of automatically advancing to next stage after Ct crossing.
9. The thermocycler must be capable of rapid, real time PCR experimental analysis; sample amplification and analysis must be able to be performed in as few as 20 to 30 minutes.
10. The thermocycler must have the capability to be easily transported with a ruggedized hardened carrying case.
11. The SmartCycler software is to be run on the computer provided with the SmarCycler System. Computers purchased from other sources will not be supported by Cepheid's technical support.

This versatility is required to handle the variety, workflow and performance needed to design and carry out protocols that will best meet experimental requirements.

Please contact me if you have any questions.

Sincerely,

R. Chris Wilkins, Ph.D.



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WEB WWW.CEPHEID.COM
MAIN 1.888.336.2743
FAX 1.408.734.1260

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| ASR-FLU1-Primer | GXEV-IDON-ID | |
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