



NOV 22 2006

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:
 Flu A/B Analyte Specific Reagent (ASR), Catalog No. ASRFLU-100N-050 kits containing primers and a FAM-labeled probe designed to detect Flu A and an Alexa 532-labeled probe to detect Flu B from respiratory specimens. In addition, primers and a Texas Red-labeled probe as internal controls to check for sample inhibition are included in each kit.

4. Vendor Name: Cepheid, Inc. Address: 904 Caribbean Drive Sunnyvale, CA 94809-1302	5. Price: \$500,000
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6. Term of Contract: (mm/dd/yyyy) From: CPO Approval To: 11/13/2007	7. Prior Sole Source Ref No.
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8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: The primers and probes for the Cepheid ASR for Flu A/B are designed for the Cepheid Smart Cycler II System. 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 and nucleotides. These reagents were designed for use with the Cepheid Smart Cycler II PCR machine only.

See Attached Letter from Cepheid, Inc..

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 the FLU A/B ASRs for screening respiratory specimens by RT-PCR provides a more sensitive method for Flu detection while reducing the Turn-Around-Time (TAT) for detection from 7 days to 2 days using culture and isolation. Based on the previous year's volume the State Laboratories received over 8,000 specimens from October 2005 to may 2006. The high volume of testing during Flu season can easily inundate the State Lab's Virology Section. This improvement in our testing capability using RT-PCR with a shorter TAT increases the testing capacity of the State Lab during the peak of the flu season and will allow the Department's disease control program to recommend appropriate interventions with the use of antivirals.

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: None.

12. Direct any inquiries to:
Department: Health
Contact Name/Title: Rebecca Sciulli, BT Microbiologist & Coord.

13 Phone Number:
453-5993
Fax Number:
453-5995

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 *Christina G. Fulin, MD*

NOV 21 2006
Date

Reserved for SPO Use Only

15 Date Notice Posted: 11/22/07

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:

17.
 APPROVED DISAPPROVED NO ACTION REQUIRED

Clarence S. Fjeller 11/29/06
Chief Procurement Officer Date



October 12th, 2006

State of Hawaii Lab Division
2725 Waimano Home Rd
Pearl City, HI 96782

Attention: Rebecca Sciulli

Dear Rebecca,

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

Influenza Virus A/B Primer and Probe Set Analyte Specific Reagents
Mix: 50 tests per package in a 25 beads format
Catalog #: ASRFLU-100N-050

This product meets or exceeds the following specifications:

Influenza Virus A/B bead contains a FAM-labeled probe designed to detect the Flu A viruses, and ALEXA 532-labeled probe designed to detect the Flu B viruses. Additionally, the bead contains a Texas Red-labeled probe and DNA template for an internal control sequence.

There are enough reagents in each bead for two 25 l reactions.

Included in the ASR reagent package are sample processing control (SPC) bead templates. Each bead is intended to serve as a procedural control to insure the highest quality RNA results.

The freeze-dried test format, the length/sequence of primers/probes, fluorescent dyes (FAM, ALEXA 532, and Texas Red) and internal/sample processing controls are proprietary to the Cepheid ASR reagents.

Influenza Virus A/B Analyte Specific Reagent is 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 and SmartCycler reaction tubes through Fisher Scientific, however the Influenza Virus A/B Analyte Specific Reagents are available only through Cepheid.