



05 JUL -5 P1:19

STATE PROCUREMENT OFFICE NOTICE & REQUEST FOR SOLE SOURCE

- 1. TO: Chief Procurement Officer
- 2. FROM: Health / State Laboratories Division / Administration
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:
Three units of LC 480 Real-Time Polymerase Chain Reaction (PCR) instruments.

The Light Cycler (LC) 480 Real-Time Polymerase Chain Reaction (PCR) System is a real-time Polymerase Chain Reaction (PCR) system that detects and quantitates nucleic acid sequences in a 96-well or 384-well platform. The components of the LC 480 PCR System are as follows: an interchangeable 96-well and a 384-well thermal block cycler module; LC 480 basic software, relative quantification and melting curve analysis and genotyping software, including an integrated bar code reader, Laboratory Information Management System connectivity, reagent starter kit, installation and operator training, and an extended warranty service agreement.

4. Vendor Name: Roche Diagnostics Corporation Address: P.O. Box 50414, 9115 Hague Road Indianapolis, IN 46250	5. Price: <u>\$184,000.00</u>
6. Term of Contract: (mm/dd/yyyy) From: _____ To: _____	7. Prior Sole Source Ref No. _____

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities:
Please see attached.

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

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities:

The LC 480 uses a patented technology called Therma-base to insure homogenous temperature control throughout the block. The Therma-based cycling blocks are designed for an interchangeable 96-well and 384-well modules that needs no further warm-up or re-calibration. The LC 480 is fully automated and is designed to perform real-time PCR, and melting curve analyses in a real-time platform. It is a high throughput instrument capable of analyzing up to 384 samples for 30 cycle runs in less than 40 minutes. The LC 480 system software is the only software available on a block-based system that can perform gene expression analysis for parallel PCR curves and non-parallel/non-linear curves. Reaction volume for detection varies from 3 ul – 20 ul on a 384-well plate and 20 ul – 100 ul on a 96-well plate. The LC 480 System employs a high-intensity Xenon lamp over a broad wavelength (430-620 nm) allowing flexibility in the choice of fluorescent dyes which enhances its detection formats and multiplexing capabilities. Its five excitation filters and six emission filters can be used in any combination and the special arrangement of its optical components ensure uniform signal excitation and uniform data across the plate. The software provides new features that allow easy and time-saving handling of data with proven algorithms for data analysis.

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

- Since the instrument is fully automated, it does not require user intervention for the processing of up to 384-well reaction plates enhancing productivity and efficiency in the laboratory. The ability to use a 96-well or a 384-well sample format, interchangeably allows for flexibility which is very critical when testing for multiple samples during a Pandemic Influenza event.
- Automated loading and unloading of reaction plates further enhance productivity in the laboratory. Further, switching from a 96-well to a 384-well block is easy and requires no further warm-up or re-calibration. This feature is ideal during a pandemic flu situation where over 600 specimens needed to be tested within a 24-hour period.
- Since the LC 480 is a real-time PCR that can offer 30 cycle, 96-well runs in less than one hour or a 384-well runs in less than 40 minutes, testing over 600 specimens will take less than two hours. The reduced detection time is critical for public health intervention during a pandemic flu event.
- The ability of the instrument to provide real-time quantitative melting curve analysis is another key benefit that ensures reliability of results.
- The instrument is designed such that reactions take place in an enclosed system thereby reducing the chance of aerosolization and contamination which is an important biosafety feature.
- The combination of a high-intensity Xenon lamp and flexible combinations of the built-in excitation and emission filters allow the use of multiple dyes enhancing its multiplexing capabilities and detection format for real-time PCR applications. Multiplexing capabilities allow the laboratorian to screen for a number of pathogens in a single specimen, increasing the laboratory's productivity and efficiency.
- The LC 480 instrument's enhanced software capabilities allow its easy integration to the State Laboratories Division's Laboratory Information Management System. This feature allows accurate and timely electronic reporting of results to the Department of Health and to the Centers for Disease Control and Prevention.

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: None. There is no other instrument that has all the features and capabilities that meet our needs in terms of speed, reliability, safety, flexibility, high-throughput and accuracy. In addition to this unique software, the LC 480 uses a Thermo-based and melting curve technology that is patented for this machine. The lab performed test on this Roche machine and a comparable Applied Biosystems, Inc. (ABI) 7500 machine. We achieved 100% correlation of our testing of previously tested specimens and only 50% correlation with the ABI equipment. Also reagents and chemistries needed to run the Roche machine are available; similar ABI materials are not being manufactured as yet.

Finally, during the one week testing, the LC 480 is the only high-throughput real time PCR that has flexibility in the choice of fluorescent dye which is critical for multiplexing analyses (testing one sample for various analytes in one tube). Roche Diagnostics Corp is the only company that sells this specialized piece of equipment.

<p>12. Direct any inquiries to: Department: <u>DOH - State Laboratories</u> Contact Name/Title: <u>Rebecca H. Sciulli, BT Microbiologist & Coord</u></p>	<p>13 Phone Number: <u>(808) 453-5993</u> Fax Number: <u>(808) 453-5995</u></p>
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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.



JUN 30 2006

Department Head

Date

Reserved for SPO Use Only

15 Date Notice Posted: 7/8/06

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's representation that this equipment possesses unique features that are not available on other manufacturer's equipment and is critical to perform tests to detect and quantitate acid sequences in a 96-well or 384-well platform necessary to perform their functions.

17. APPROVED DISAPPROVED


 Chief Procurement Officer 7/19/06
 Date