

# STATE OF HAWAII REQUEST FOR SOLE SOURCE

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TO: Chief Procurement Officer

STATE PROCUREMENT OFFICE  
STATE OF HAWAII

FROM: Department of Health/State Laboratories Division/Administration/Bioterrorism Response Laboratory  
(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:

<p><b>Description of goods, services, or construction:</b></p> <p>The MagNA Pure LC instrument is a fully automated walk-away system for the isolation and purification of DNA, RNA, mRNA and viral nucleic acids. The MagNA Pure system consists of the bench-top instrument with a peltier heating component, cooling block sample carousel for automatic filling of samples, a cooling block for reaction tubes and 96-well plates, a cooling block for centrifuge adapters, a reagent reservoir rack, a barcode reader, an ultra-violet (UV) decontamination capability, heating blocks for temperature stability, a software package that supports reagent handling, sample tracking and record keeping. A computer station, operator training, and a service agreement that provides service on parts and labor for two years, including engineering updates, enhancements, and preventive maintenance schedules.</p>
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<p><b>Name of Vendor:</b> Roche Diagnostics Corporation  <b>Address:</b> Roche Applied Science  P.O. Box 50414  9115 Hague Road  Indianapolis, IN 46250</p>	<p><b>Cost:</b></p> <p>\$93,489.88</p> <p><i>lump sum</i></p>
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<p><b>Term of Contract:</b> From: To:</p>	<p><b>Prior Sole Source Reference No.:</b></p> <p>04-3-R</p>
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<p><b>The goods, services, or construction has the following unique features, characteristics, or capabilities:</b></p> <p>The MagNA Pure system is a fully automated nucleic acid isolation and purification system that uses a proven magnetic bead isolation technology in tips. The MagNA Pure system does not employ vacuum or tubing on stage and there is no sample or reagent contact with the instrument during normal operations which minimize the risk of contamination, the peltier cooled sample storage allows for overnight operation of the instrument. The instrument allows for flexibility in sample dispensing range between 5-1,000 ul; sample volume between 20-300 ul; and elution volume range of 25-100 ul. It also features a drop catcher that prevents drop loss during operation, an essential safeguard against contamination. The system uses RNase free disposables and reagents which minimize cross contamination, a critical issue in molecular diagnostic assays. More importantly, the MagNA Pure instrument is a closed system, designed with a UV decontamination capability thus ensuring safety of the microbiologist during operation. Other unique features include software-supported reagent handling, sample tracking, record keeping, and generation of sample information, which enhances efficiency and greater productivity in the laboratory.</p>
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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 enhancing productivity and efficiency in the laboratory.

-The MagNA Pure system utilizes a proven magnetic bead technology for the purification of high quality DNA or RNA or mRNA from various sources such as blood, blood cells, cell cultures, serum, tissues, stool, and environmental samples. This is very important in providing rapid molecular testing for bioterrorism agent detection, and for the detection of pathogens involved in infectious disease outbreak such as Norovirus, West Nile, and Severe Acute Respiratory Syndrome (SARS) virus.

-Since the instrument is a high-speed system, 32 samples can be loaded and processed in an hour allowing for faster turn-around time (TAT) for PCR detection of target nucleic acid. Rapid TAT is critical in public health response to a BT event or during an outbreak disease investigation; early detection means early intervention and treatment.

-Some of the unique features described maximizes sample integrity and reduce the risk of cross and

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The following other possible sources for the goods, services, or construction were investigated but do not meet our needs because:

Qiagen Mdx- \$170,000; did not have the UV decontamination capability that MagNA Pure system offers, a critical biosafety feature.

The MagNA Pure system is currently being used at the BT Rapid Response and Advance Technology Laboratory (BRRAT) of the CDC in Atlanta. Thus, protocols for rapid molecular assays of potential bioagents have been validated at this laboratory (BRRAT) using this MagNA Pure platform.

Direct questions to: Rebecca H. Sciulli

Phone: 808-453-5993 Fax: 808-453-5995

*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.*



OCT - 7 2005

Department Head or Designee

Date

Deputy Director of Health

Title (If other than Department Head)

Chief Procurement Officer's comments:

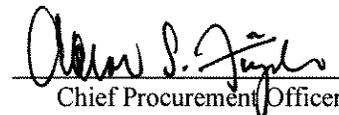
This approval is based on the DOH's representation that this instrument utilizes a unique "enclosed system" and they are not aware of any other manufacturer who offers similar equipment with this technology that has been acceptable to the CDC. Future requests should detail updated effort and research to justify the sole source request.

Please ensure adherence to applicable administrative and statutory requirements.

Expenditure may be processed through a purchase order: Yes  No . If no, a contract must be executed and funds certified.

APPROVED

DISAPPROVED

  
Chief Procurement Officer

10/20/05  
Date

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

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carry-over contamination which is a problem when dealing with sensitive tests.

-The UV decontamination capability is an important biosafety feature when dealing with BT and other highly infectious agents.

-This instrument is being purchased with federal Epidemiology and Laboratory Capacity (ELC) funds.