



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

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ADMINISTRATION
STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health/State Laboratories Division
Name of Requesting Department

Pursuant to HRS §103D-306 and HAR chapter 3-122, Subchapter 9, the Department requests sole source approval to purchase the following:

1. Describe the goods, services, or construction to be procured.
Roche MagNapure Extraction kits and consumables, FASTART DNA Master Hybridization probes, Glycogen, Proteinase K, Rnase inhibitor, and microplates and sealers. Please refer to attachment for Catalog numbers.

Table with 2 columns: Vendor/Contractor/Service Provider Name, Amount of Request, Term of contract, Prior SPO-001, Sole Source (SS) No.
Roche Diagnostics, 9115 Hague Road, Indianapolis, ID 46250
\$50,000 Est.
From: 12/1/2015 To: 11/30/2016
SS15-018B

6. Describe in detail the following:
a. The unique features, characteristics, or capabilities of the goods, service or construction.
The Fastart probes and other PCR assay reagents (glycogen, Proteinase K, Rnase inhibitor) were selected by the CDC and have passed the performance characteristics set by the CDC for the extraction of biothreat agents and toxins. Our laboratory has demonstrated that these PCR reagents and kits have performed well and have demonstrated good sensitivity for detection as expected. MagNapure extraction kits and consumables are used exclusively in the performance of High-Throughput, semi-automated nucleic acid extraction of clinical specimens, tissues, environmental and food specimens using the MagNapure LC system.
b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department
Molecular testing of clinical specimens (human and animal), environmental, food and drinking water samples have been developed by National Reference Laboratories such as the CDC, NVSL and FDA for Public Health Laboratories. These molecular methods, such as the real-time (rti) PCR provide a rapid way to screen for biothreat agents and emerging threats such as Ebola virus, MERS-CoV, West Nile Virus (WNV), Chikungunya and dengue viruses, Human, Avian and swine Flu virus, norovirus, B. pertussis/parapertussis, and a number of emerging pathogens of public health importance. The MagnaPure extraction protocols provide a High-Throughput (HT) extraction which is critical in improving testing capacity by increasing the number of specimens that we can process and consequently, will allow timely completion of test results.

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7. Describe the efforts and results in determining that this is the only vendor/contractor/service provider who can provide the

~~goods, services, or construction~~
This vendor is the sole source of the reagents and kits described in Section 1. The methods that we use in testing for specific biothreat agents and toxins are standardized by the Center for Disease Control (CDC)-Laboratory Response Network (LRN) for member LRN Reference laboratories, such as the Hawaii State Lab Division. Our ability to maintain our status as an LRN Reference lab of good standing, depend on our ability to pass Proficiency Testing (PT) challenges that involve testing for unknown biothreat agents and toxins usong CDC-LRN standard assays using reagents and kits stated in Section1. Passing PTs are essential in obtaining CDC funds for public health preparedness and emergency response.

8. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.

There are no alternate source.

9. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required.)

*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	E-mail Address
Rebecca H. Sciulli	HI State Lab Division	808-453-5993	rebecca.sciulli@doh.hawaii.gov

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR chapter 3-122, Subchapter 15, Cost or Pricing Data if required.

All requirements/approvals and internal controls for this expenditure is the responsibility of the department.

I certify that the information provided is to the best of my knowledge, true and correct.

RC

Department Head Signature

SEP 30 2015

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 10/2/2015

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is granted for the period 12/1/2015 to 11/30/2016 and is based on the department's representation that the supplies and test kits are essential for their work and can only be obtained through Roche Diagnostics.

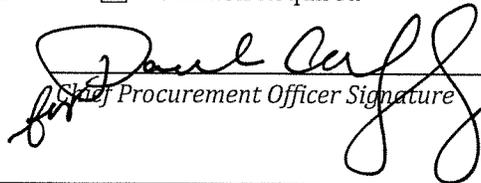
HRS Section 103D-310(c) and HAR section 3-122-112 shall apply (e.g., vendor is required to show proof of compliance and may use the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System. Proof of compliance and awards posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Bonnie Kahakui at 587-4702, or bonnie.a.kahakui@hawaii.gov.

Approved

Disapproved

No Action Required


Chief Procurement Officer Signature Date 10-2-2015



September 22, 2015

Hawaii Dept. of Health/State Lab Division
Bioterrorism Response Lab
2725 Waimano Home Road
Pearl City, HI 96782

RE: Roche as Sole Source for MagNA Pure Products

Dear Elsie B. Cristobal:

Thank you for your interest in our MagNA Pure Product Line! Roche is the sole manufacturer and distributor of MagNA Pure branded products, including MagNA Pure 96 and MagNA Pure LC 2.0 Instruments, Reagents, Consumables, and Accessories.

If you have any questions, or would like any additional information, please contact your local Roche Account Manager.

Thank You!

A handwritten signature in black ink, appearing to read "DLahm".

David Lahm
Roche Diagnostics Corporation
Molecular Diagnostics
Marketing Manager, Instrumentation
Phone 317-521-4210
Cell 317-270-3434
eMail David.Lahm@roche.com

**Roche Diagnostics
Corporation**

9115 Hague Road
Indianapolis, IN 46250-0457
USA

Phone: 800-428-5074

5516-016B

Roche

- MagNa Pure LC RNA Kit, High Performance Cat. # 03-542-394-001
- Fastart DNA Master Hybridization Kit Cat. # 3003248001
- Light Cycler Faststart DNA Master Plus Hybridization Kit Cat. # 03515575001
- Uracil N-glycosylate Cat. # 1775367
- Glycogen Cat. # 901-393
- MagNa Pure LC RNA Isolation Kit III Cat. # 3330591001
- MagNa Lyser Green Beads Cat. # 3358941001
- Proteinase K, Recombinant-PCR Grade Cat. # 03115879001
- Swab Extraction Tube System(SETS) Cat. # 3315568
- MagNa Pure LC Medium 20 Reagent Tubs Cat. # 3004058
- MagNa Pure LC Processing Cartridges Cat. # 3004147
- MagNa Pure LC Reagent Tubs - Large Cat. # 3004040
- MagNa Pure LC Tub Lids - Small/Medium Cat. # 3004082
- MagNa Pure LC Tub Lid Seals Cat. # 3004104
- MagNa Pure LC Reaction Tips Small Cat. # 3004180
- MagNa Pure LC Reaction Tips Large Cat. # 3004171
- MagNa Pure LC Sample Cartridges Cat. # 3004112
- MagNa Pure LC cap Seals Cat. # 3118827
- MagNa Pure LC Reagent Tubs - Small Cat. # 3004066
- MagNa Pure LC Reagent Tubs - Medium 30 Cat. # 3045501
- MagNa Pure LC Tub Lids - large Cat. # 3004074
- MagNa Pure LC Tip Stands Cat. # 3004155
- MagNa Pure LC Waste Bottles Cat. # 3004198

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