518

SUBMITTAL TO THE BOARD OF SUPERVISORS
COUNTY OF RIVERSIDE, STATE OF CALIFORNIA

SUBMITTAL DATE:
October 4, 2011

FROM: Riverside County Regional Medical Center

SUBJECT: Approve Hologic, Inc. as the Sole Source Vendor

RECOMMENDED MOTION: That the Board of Supervisors:

1. Approve and authorize the sole source procurement of reagents, supplies and equipment used for the detection of Fetal Fibronectin in accordance with Ordinance 459.4, in the amount of 38,000.00 yearly; and
2. Authorize the Purchasing Agent to renew this Agreement annually on behalf of the County for up to three (3) additional years, not to exceed $38,000.00 annually.

(cont. on Page 2)

Douglas D. Bagley, Hospital Director

Purchasing: Mark Seitz, Assistant Director — Recommended for Concurrence

FINANCIAL DATA	**Current F.Y. Total Cost:**	$ 38,000.00	**In Current Year Budget:**	Yes
	Current F.Y. Net County Cost:	$ 0	**Budget Adjustment:**	No
	Annual Net County Cost FY:	$ 0	**For Fiscal Year:**	11/12

SOURCE OF FUNDS: Enterprise Funds

Positions To Be Deleted Per A-30 ☐

Requires 4/5 Vote ☐

C.E.O. RECOMMENDATION: APPROVE

BY: Debra Cournoyer

County Executive Office Signature Debra Cournoyer

Dep't Recomm.: ☐ Consent ☒ Policy

Per Exec. Ofc.: ☐ Consent ☒ Policy

Prev. Agn. Ref.:

District: 5

Agenda Number: 3.24

BACKGROUND:
Riverside County Regional Medical Center's (RCRMC) Clinical Laboratory will provide the Fetal Fibronectin test to assist the Hospital's Ob/Gyn Physicians in the proper diagnosis of premature labor for their patients. This Fetal Fibronectin clinical laboratory test detects the presence of a protein found in pregnant women and is used as an aid in the assessment of the risk of premature birth from 22 to 35 weeks of pregnancy and prevents unnecessary hospital admissions. The results of this Fetal Fibronectin test will enable the physician to monitor their patients on an outpatient basis or immediately admit the patient by knowing whether or not the patient is experiencing premature labor.

PRICE REASONABLENESS:
Hologic, Inc. certifies that the prices offered are the lowest or equal to those offered to any of its customers in California.

DB:rs

Date: September 19, 2011

From: Douglas D. Bagley, Chief Executive Officer, Riverside County Regional Medical Center

To: Riverside County Board of Supervisors

Via: Purchasing Agent

Subject: Sole Source Procurement; Request for Hologic, Inc.

The below information is provided in support of my Department requesting approval for a sole source. Outside of a duly declared emergency, the time to develop a statement of work or specifications is not in itself justification for sole source.

1. **Supply/Service being requested:** Reagents, supplies and equipment used for the detection of Fetal Fibronectin to detect preterm labor in Obstetric patients

2. **Supplier being requested:** Hologic, Inc.

3. **Alternative suppliers that can or might be able to provide supply/service:** None

4. **Extent of market search conducted:** Internet and trade publications

5. **Unique features of the supply/service being requested from this supplier, which no alternative supplier can provide:** Detects a protein found in pregnant women that is used as an aid in the assessment of the risk of premature birth from 22 to 35 weeks of pregnancy.

6. **Reasons why my department requires these unique features and what benefit will accrue to the county:** This test will allow the physicians to monitor their patients on an outpatient basis without the need to unnecessarily admit a patient for observation only. This ability will prevent unnecessary admissions.

7. **Price Reasonableness including purchase price and any ongoing maintenance or ancillary costs from the supplier:** Hologic, Inc certifies that the prices offered are the lowest or equal to those offered to any of its customers in California.

8. **Does moving forward on this product or service further obligate the county to future similar contractual arrangements or any ongoing costs affiliated with this sole source? (Maintenance, support, or upgrades, if so, please explain).** No

9. **Period of Performance:** July 1, 2011 – June 30, 2012

D Bagley 10/6/11

Department Head Signature **Date**

Purchasing Department Comments:

Form-11 Authorizes 3 year Renewals

Approve Approve with Condition/s Disapprove

Not to exceed: $ 38,000.00 per year ☐ One time **X** Annual Amount through June 30, 2015

10-12-11 12-249

Purchasing Agent **Date** **Approval Number**
(Reference on Purchasing Documents)

Form # 116-333 rev 8/10/11

To Whom It May Concern:

I am writing to inform you that Hologic Limited Partnership is the sole proprietary manufacturer and domestic distributor of the Rapid fFN test for the TLi$_{IQ}$ System. The Rapid fFN test is performed using immunodiagnostic products that are solely manufactured by Hologic. There are no other vendors for the Rapid fFN test.

The Rapid fFN test has the following unique benefits:

- The single strongest predictor of preterm birth <32 weeks[1]
- Indicated for use in women with signs and symptoms of preterm labor and in women with risk factors but no symptoms
- Recommended by the American College of Obstetrics and Gynecology[2]

In addition, over 150 clinical studies, including the landmark Preterm Prediction Study by the National Institute of Health, have evaluated the clinical utility of fFN testing in a variety of patient populations.

If you have any questions or need any additional information, please feel free to call 1-888-PRETERM.

Regards,

Michael L. Maus
Vice President and General Manager
Diagnostics Division

[1] Goldenberg RL,k Iams JD, Mercer BM, et al. The preterm prediction study: the value of new vs. standard risk factors in predicting early and all spontaneous preterm births. Am J Public Health. 1998; 88:233-238.
[2] ACOG Practice Bulletin Number 43, 2003 and ACOG Practice Bulletin Number 31, 2001

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