

STATE OF DELAWARE



DELAWARE HEALTH AND SOCIAL SERVICES
DIVISION OF MANAGEMENT SERVICES

“DMS - Serving Those Who Serve Delaware”

SPECIFICATIONS AND CONTRACT DOCUMENTS NO. HSS 09-050

FOR

**Buy Equipment, Test Kits and Reagents for
CYSTIC FIBROSIS MUTATION ANALYSIS**

(Contract Period: 2/15/10 – 09/30/11)

Required for Use By

**Division of Public Health
DELAWARE PUBLIC HEALTH LABORATORY**

Deposit	WAIVED
Performance Bond	WAIVED
Date Due:	January 26, 2010 11:00 A.M. Local Time

Questions may be submitted to sylvia.adams@state.de.us until January 5, 2010.

Delaware Health and Social Services
Main Administration Building – Sullivan Street
DMS - Procurement Branch
1901 N. DuPont Highway
New Castle, Delaware 19720

INVITATION TO BID # HSS 09-050

Sealed bids for *Equipment, Test Kits and Reagents for Cystic Fibrosis Mutation Analysis* are requested by the Division of Public Health, Office, **Delaware Public Health Laboratory**.

Questions may be submitted to sylvia.adams@state.de.us until January 5, 2010. Q&A will be posted at <http://www.dhss.delaware.gov/dhss/rfp/dhssrfp.htm> no later than January 15, 2010.

Sealed bids must be received at:

Delaware Health & Social Services
Main Administration Building – Sullivan Street
Division of Management Services
Procurement - Room # 262
1901 N. DuPont Highway
New Castle, Delaware 19720

until **11:00 A.M. local time on January 26, 2010** at which time they will be opened and recorded.

Please review the General Rules and Conditions and the General Requirements, which appear on the DHSS website.

NOTE: The following paragraphs from the General Requirements hereby become part of the General Terms and Conditions of this bid.

1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 16, 18, 19, 20a, 23, 24 and 25

Applicable forms to this bid:

- 1.) Bidder Signature Form
- 2.) Vendor Certification Sheet (Commodities only)
- 3.) Office of Minority and Women Business Enterprise Form

All of the above documents and any addenda associated with this bid can be accessed on the DHSS website:

<http://www.dhss.delaware.gov/dhss/rfp/dhssrfp.htm>

NOTE TO VENDORS

- Only one bid will be accepted from a bidder. Remember to check the DHSS website for any Addenda before sending your bid.
- Your bid **must be signed** and all information on the Bidders Signature Form and Vendor Certification Sheet completed.
- Include a detailed response to the specifications.
- Bid total must include delivery, installation, warranty, service agreement, training, and/or upgrades or **your bid will not be accepted.**
- Agency will review all bid proposals and evaluate same.
- This contract will be valid from 2/15/2010 through 09/30/11 and may be renewed for up to one (1) year if both parties agree, and grant is continued. Extension may be initiated no later than ninety (90) days prior to the termination of the current agreement.

DELIVERY INSTRUCTIONS

- Your bid must have on the outside envelope the HSS contract number. **IF THIS IS OMITTED YOUR BID WILL IMMEDIATELY BE REJECTED.**
- Under no circumstances will a bid be accepted that is late, delivered to the wrong building, signed for by a person other than a member of the procurement staff. To ensure that your bid is in the procurement office on the date and time specified, there are three (3) recommended methods of delivering bid proposals:
 - Hand Deliver
 - Federal Express
 - UPS

FOR FURTHER BID INFORMATION PLEASE CONTACT:

Buyer: Sylvia T. Adams
Delaware Health and Social Services
Main Administration Building – Sullivan Street
DMS - Procurement – Room 262
1901 N. DuPont Highway
New Castle, DE 19720
(302) 577-8778
sylvia.adams@state.de.us

SPECIAL TERMS AND CONDITIONS/REQUIREMENTS

The following supersedes the General Requirements where applicable

- 1.) Ordering Procedure: Successful contractors are required to have either a local telephone number within the (302) area code, a toll free (800) number, or agree to accept collect calls. Each Agency is responsible for placing their orders. This may be accomplished by written purchase order, telephone, fax or computer on-line systems.
- 2.) Billing: The successful vendor is required to “Bill as Shipped” to the respective ordering agency(s). Ordering agencies shall provide at a minimum the contract number, ship to and bill to address, contract name and phone number.
- 3.) Payment: The agencies or school districts involved will authorize and process for payment each invoice within thirty (30) days after the date of receipt. The contractor or vendor must accept full payment by procurement (credit) card and/or conventional check and/or other electronic means at the State’s option, without imposing any additional fees, costs or conditions.
- 4.) Product Substitution: All items delivered during the life of the contract shall be of the same type and manufacture as specified unless specific approval is given by DHSS-DMS-Procurement to do otherwise. Substitutions may require the submission of written specifications and product evaluation prior to any approvals being granted.
- 5.) Hold Harmless: The contractor agrees that it shall indemnify and hold the State of Delaware and all its agencies harmless from and against all claims for injury, loss of life or damage to or loss of use of property cause or alleged to be caused by acts or omissions of the contractor, its employees and invitees on or about the premises and which arise out of the contractor’s performance or failure to perform as specified in the Agreement.
- 6.) Force Majeure: Neither the contractor nor the ordering Agency shall be held liable for non-performance under the terms and conditions of this contract due, but not limited to, government restriction, strike, flood, fire or unforeseen catastrophe beyond either party’s control. Each party shall notify the other in writing of any situation that may prevent performance under the terms and conditions of this contract.
- 7.) Business License: The successful vendor must submit a current copy of their Delaware business license with their bid or show proof of initiating the process of application. To apply for a Delaware business license, call 302-577-8778 or apply online at www.revenue.delaware.gov.
- 8.) UNSPS Code: The State of Delaware is in the process of implementing a new financials system. The successful vendor must supply the United Nations Standard Products and Services Code (UNSPSC) for each item in their bid proposal. The UNSPSC can be accessed at www.top500.de/lexikon/unspsc.php. Failure to include the UNSPSC may be grounds for rejection of bid.

9.) Vendor Emergency Response Point of Contact: The awarded vendor shall provide the contact person's name, address, telephone number and/or cell phone number of those individual(s) who can be contacted twenty-four (24) hours a day, seven (7) days a week where there is a critical need for commodities or services when the Governor of the State of Delaware declares a State of Emergency under the Delaware Emergency Operations Plan of April 2005. Failure to provide this information could render the bid as non-responsive.

Contact Person: _____

Address: _____

Phone Number: _____

Cell Phone Number: _____

A. INTRODUCTION:

Delaware Public Health Laboratory has received a CDC grant (RFA EH-09-003) for a two-year project period (10/01/09 – 09/30/11) to set up a regional laboratory for testing CFTR mutations. It is estimated that a minimum of 850 tests, including controls and validations, will be tested during the first year with an increase to more than 1200 in the second year, although the exact figures may vary depending on the level of participation with other states.

The testing population will consist of newborns from the NYMAC (New York, Mid Atlantic Consortium) region, specifically Delaware, Maryland, New Jersey, and Virginia who have expressed an interest in this service.

We are looking for a complete testing system (molecular assay, equipment, reagents, maintenance, training and support) that is easy to use, fits into the work operations of the laboratory and provides a large number of CFTR mutations in a single test.

B. SPECIFICATIONS:

Please address how your system meets / exceeds / does not meet EACH of these optimum specifications in your bid response. Failure to respond will indicate you are unable to meet this specification in any manner.

EXTRACTION

1. Method can run successfully from extracted DBS (dried blood spot) specimens. Include preferred extraction method in your response.
2. Method can run successfully from extractions produced from a variety of extraction methods including Roche MagNAPure Compact system. Please list all methods.

MUTATIONS

3. Provides comprehensive mutation coverage for a varied genetic population, as found in the New York Mid-Atlantic region (Maryland, Delaware, New Jersey, and Virginia).
4. Includes the 23 CFTR gene mutations recommended by the ACMG.
5. Screens for additional mutations and variants, price out all options.
6. Good coverage >95% for Hispanic population CFTR mutations, as described in Elaine A. Sugarman, et.al., article, *CFTR mutation distribution among U.S. Hispanic and African American individuals: Evaluation in cystic fibrosis patient and carrier screening populations*, Genetics IN Medicine, Sept/Oct 2004, pg 392-399.
7. Good coverage >95% for African-American population CFTR mutations, as described in Elaine A. Sugarman, et.al., article, *CFTR mutation distribution among U.S. Hispanic and African American individuals: Evaluation in cystic fibrosis patient and carrier screening populations*, Genetics IN Medicine, Sept/Oct 2004, pg 392-399.
8. Integrated Poly T analysis, describe process.

9. Flexibility in choosing mutations to screen for, describe.

METHODOLOGY

10. Approved for use in the United States
11. Has FDA clearance for all or most of the mutations, detail which mutations are FDA cleared.
12. Uses microtiter plate technology.
13. Minimal hands-on time, include SOP in response.
14. Turnaround time of 4 hours or less for the expanded panel, after extraction.

QUALITY

15. Low repeat rate (<1.0%), include source of data
16. Superior accuracy compared to DNA sequencing, describe
17. Excellent Precision (>99.5%), include source of data
18. Excellent Reproducibility (>99.5%), include source of data
19. Supply of Quality control materials, sufficient to include on each run. Describe source.

INSTRUMENTATION

20. Instrumentation and other associated laboratory equipment (i.e., centrifuges, thermocyclers, power conditions, heat blocks, printers, computers, barcode readers, plate sealers, etc.) necessary to make a final identification to be provided to use without additional expense to the laboratory. Include individual costs as separate line items in the bid.
21. Maintenance contract included with all methodology-specific equipment for the length of the contract, include cost as separate line items in bid.

CONNECTIVITY / REPORTING

22. Reporting software included that will be able to produce individual reports for each sample and customizable to allow individual reporting options for any state submitting samples. Each report should include sufficient demographic information in order to meet CLIA requirements as a stand-alone report.
23. Interface to existing laboratory information system (Natus MSDS) in order to send and receive input and output files.

C. DELIVERY AND INSTALLATION

1. Delivery of all necessary equipment must occur no later than 30 days after submission of the purchase order or earlier by specific arrangement. Installation must occur no later than 10 working days by the vendor after notification of site readiness.

2. All ancillary pneumatic and electrical cables, cords, gauges, filters, lines, etc. must be supplied so that the instrument is operational upon installation.
3. Installation must include the entire instrument set-up and a demonstration to ensure that the system is in complete operational condition. On-site introductory training of up to four DPH Laboratory staff members must be provided to assure that staff can operate and maintain the system satisfactorily.

D. TRAINING

1. On-site training upon installation
2. Technical training must be included for one laboratory staff member to attend manufacturer's comprehensive course to learn operation, maintenance, and basic repair and trouble shooting of the instrument. If travel is required, all costs for travel, lodging and meals are to be covered by the vendor.
3. Training shall commence within a period of 60 days after installation at no additional cost to the Division.

E. SERVICE AND SUPPORT

1. The service period shall coincide with the dates of the contract and shall include all services necessary to maintain the instrument for this period. This includes all parts, labor, travel, lodging and software updates.
2. In order to facilitate repairs, systems shall be modular in order to ensure that repairs can be performed by modular replacement of major systems (i.e., critical components, power supplies, pumps, PC boards, etc.) rather than by multiple component troubleshooting and repair.
3. Application support must be provided in a timely manner with a telephone response time of 8 working hours by a service technician after initial contact is made by DPHL staff. On-site response must be no greater than 72 hours including delivery of necessary repair/upgrade parts.
4. Service must be provided by a factory trained engineer.
5. During the specified period of coverage, the offeror is expected to provide upgrades and/or replacements as they become available, as well as any corresponding training associated with such.

F. SPECIAL CRITERIA:

1. References for up to three states already using your product for the identification of Cystic Fibrosis CFTR mutations on a newborn screening population.
2. No payment will be processed until the Delaware Public Health Laboratory personnel are satisfied that the testing reagents and instrumentation is functioning according to declared specifications. Final acceptance shall occur upon delivery of undamaged goods meeting the manufacturer's published specifications; in the event that the delivered goods are

defective, damaged, or incomplete, the State of Delaware shall have fifteen (15) days from delivery of the goods to inspect them and notify vendor in writing of their defective, damaged or incomplete condition and reject the goods. In the event that vendor fails to promptly repair or replace such goods, vendor shall refund to the State the full amount paid for the goods.

3. PLEASE ADDRESS THE EXTENT YOUR SYSTEM MEETS EACH OF THE ABOVE SPECIFICATIONS LISTED IN THIS INVITATION TO BID.

Bid # **HSS 09-050**

Vendor Name: _____

TOTAL COST PAGE

(Must be all inclusive – product cost, delivery, installation,
training, upgrades, warranty, service agreement)

Total Cost: \$ _____

In addition to the Total Cost, break down individual costs for equipment, reagents, kits, maintenance contracts, etc. Include cost of all options as separate line items, including mutation panels, controls samples, equipment maintenance contract options, etc. If volume discounts are available at certain purchasing levels, include that information also.

All Bidders:

Please include 2 Originals and 4 Copies of your bid. This should include any pamphlets or additional materials bidder wants to be taken for consideration.

**REMARK: PLEASE ADHERE TO THE ABOVE SPECIFICATIONS AS LISTED
IN THIS INVITATION TO BID. DEVIATIONS FROM THESE
SPECIFICATIONS WILL NOT BE ACCEPTED.**