

STATE OF DELAWARE



DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MANAGEMENT SERVICES

"DMS - Serving Those Who Serve Delaware"

SPECIFICATIONS AND CONTRACT DOCUMENTS NO. HSS 09-046

FOR

A Real-Time Polymerase Chain Reaction (PCR) System

Required for Use By

**Division of Public Health Laboratory
30 Sunnyside Road
Smyrna, DE 19977**

Deposit	WAIVED
Performance Bond	WAIVED
Date Due:	November 12, 2009
	11:00 A.M. Local Time

Questions may be submitted to sylvia.adams@state.de.us until noon on October 22, 2009. Q&A will be posted at <http://www.dhss.delaware.gov/dhss/rfp/dhssrfp.htm> no later than October 29, 2009.

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

INVITATION TO BID # HSS 09-046

Sealed bids for A Real-Time Polymerase Chain Reaction (PCR) System are requested by the Division of Public Health Laboratory, 30 Sunnyside Road, Smyrna, DE 19977.

Questions may be submitted to sylvia.adams@state.de.us until noon on October 22, 2009. Q&A will be posted at <http://www.dhss.delaware.gov/dhss/rfp/dhssrfp.htm> no later than October 29, 2009.

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 November 12, 2009** 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 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.

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
Division of Management Services
Procurement – Room 262
1901 N. DuPont Highway
New Castle, DE 19720
(302) 255-9297
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 302-744-1085 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

- 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.

ITEM DESCRIPTION: Real-Time PCR System

Listed below are the specifications and special criteria necessary for a Real-time PCR system. Provide a detailed written response for each item in your proposal, including list of equipment needed to run the tests proposed, including but not limited to, instruments, processors, software, and uninterrupted power supply (UPS) hardware needs.

When determining costs, indicate which components are included in the total cost. For each section, cost should be based on the individual components, including training estimates for on-site and vendor site training programs. All bids must include software and hardware interface and a three (3) year service contract for two (2) day or less response. Vendors may only bid on the whole system, that is, the real-time PCR system. Only one (1) written bid including a detailed response to each item per vendor will be accepted.

Responses should be detailed and written and address how the system and/or component will meet or exceed each item in the proposal, including training, service contracts, maintenance agreements and warranty. If the proposed system is unable to meet an item specification, note "Unable to Meet Specification" with the appropriate item number. Incomplete or omitted items will be considered grounds for rejection of a bid. Each item of each section must be addressed including the component number, instrument ability denoted (range, statement, or numeration) to meet the specification requirement, and cost.

1. DESCRIPTION:

A high speed 96-well format thermal cycling block capable of quantitative real-time PCR and end-point analysis system for the Molecular Virology Laboratory in order to enhance and initiate biological preparedness testing service. The instrument proposed shall include the necessary instrumentation, software, hardware, controls, training, maintenance and support to provide a fully functional, semi-automated testing instrumentation for determination of targeted sequences in clinical samples on approximately >5,000 samples per year.

The real-time PCR system must provide fast thermal cycling, real-time PCR applications, fluorescence detection, sequence detection and have an approach combining hardware, advanced component control and data analysis software, performance validation tools and high sensitivity into a single integrated unit for bench top usage. Bids will be accepted for the high speed 96-well format thermal cycling block capable of quantitative real-time PCR and analysis system only. The high speed real-time PCR system should provide the source hardware, software, method development service, maintenance and support our laboratory needs to maintain our laboratory productivity and rapid, accurate assessment and reporting.

The instrument proposed shall include the necessary training, and support to provide a fully functional, semi-automated testing instrumentation. This instrument will utilize standardized methods generated by Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and other related agencies or programs. These methods are not available outside governmental partners without formal, written consent of the governing agency.

2. SPECIFICATIONS:

- A. The instrument must be capable of analyzing 96 samples simultaneously in a 96-well plate format and support volumes less than 30 µl. The instrument must be an integrated system/platform designed to perform both real-time PCR (polymerase chain reaction) and end-point/data analysis. Specialized software must be provided to analyze the fluorescence data for the applications of absolute quantitation, relative quantitation, Single Nucleotide Polymorphism (SNP) detection and plus/minus assays that utilize internal positive controls. The software should incorporate the ability to simultaneously visualize and analyze up to ten 96-well plates of gene expression data.
- B. The instrument must be able to perform quantitative real-time PCR applications in less than 40 minutes in a 96-well format consumable.
- C. The system shall be FDA approved or cleared for use in diagnosis for the presence of influenza nucleic acid using nasopharyngeal swabs or washes.
- D. The instrument must support two homogeneous reaction chemistries, the fluorogenic 5' nuclease assay using TaqMan[®] probes and the SYBR[®] Green I double stranded DNA binding dye chemistry.
- E. The instrument must have individual filters designed for use with a dedicated set of fluorescent dyes, which are available from the vendor as reporter dyes on fluorogenic probes.
- F. The instrument must be capable of supporting three thermal cycling modes; Fast, Standard and 9600 emulation.
- G. A heated lid assembly must heat the top half of the sample plates and their sealing devices so that no refluxing occurs in the sample plates. The heated lid assembly must apply sufficient sealing force to the reaction plate to ensure effective sealing and minimize reaction mixture evaporation.
- H. The instrument must have real-time quantitative PCR installation specifications which demonstrate the ability to distinguish between 5,000

and 10,000 template copies with a 99.7% confidence level.

- I. The system must have the ability to view runs in progress (amplification of the growth curves).
- J. The ability to add extra PCR cycles while runs are in progress.
- K. The ability to analyze and quantitative nucleic acid targets and simultaneously analyze multiple standard curves on a single plate.
- L. The instrument must be supplied with either a dedicated notebook or tower computer platform running the Windows® XP Operating System.
- M. The instrument must be UL approved. The instrument must be manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
- N. The instrument must be provided with a warranty for a period of one year from the date of installation (or fifteen months from the date of shipment). A factory trained service engineer must be available to perform installation and all repairs. Optional service contracts after warranty period must also be offered.
- O. The vendor must be able to supply all the necessary consumables to perform real-time quantitative PCR and SNP genotyping, including PCR reagents designed for use with the fluorogenic 5' nuclease assay, PCR reagents designed for use with SYBR® Green I dye assay chemistry, fluorogenic probes, reaction plates and adhesive plate sealing covers. All PCR reagents should contain a passive internal reference dye to minimize well-to-well variability.
- P. The vendor must provide comprehensive assay design and development guidelines for real-time quantitative PCR and SNP genotyping assays.
- Q. The vendor must be able to offer Telephone Technical Support and Field Applications/Sales/Service Support to help solve instrumentation problems encountered with real-time quantitative PCR and SNP genotyping.

3. SPECIAL CRITERIA:

A. MAINTENANCE AGREEMENT must include:

- a. Telephone technical support for problem solving with availability within three (3) hours Monday – Friday 8:00 am – 6:00 pm EST

- b. If unsolvable by telephone, then on-site Technical Service available to correct the problem(s)
- c. On-site Technical Service response within two (2) working days, Monday – Friday 8:00 am – 6:00 pm EST
- d. Three year maintenance agreement for all components of the system. This laboratory is required to be available 24/7; any downtime severely affects state and national response capabilities.

B. WARRANTY

- a. The warranty must include all services necessary to maintain the instrument for the period of the CONTRACT. This includes all travel, parts, labor, and software updates. Hardware updates will be prorated based on the availability to market versus the application need.
- b. A factory-trained engineer must provide Service. Telephone response time must be within 3 working hours of contact and on-site response must be no greater than 2 working days including delivery of necessary repair parts.

C. SERVICE AND SUPPORT

- a. All hardware must be modular so that repairs can be performed by modular replacement of major components (i.e., power supplies, optics, computer boards) rather than by individual component trouble shooting and repair in order to minimize repair time.
- b. Applications support must be provided in a timely manner with telephone call back within 3 working hours of initial contact.
- c. On-site technical support and repair must be available within two working days of notification.
- d. Instrument must be able to support multiple functional software platform needs (CDC, FDA methods, laboratory LIMS system, etc.)

D. DELIVERY AND INSTALLATION

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 90 days after submission of purchase order or earlier by specific arrangement. Installation must occur no later than 10 working days after notification of site readiness by the vendor.
- b. All extraneous cables, gauges, parts, accessories, including any and/or all accessories must be supplied such that the instrument is immediately operational upon installation.

- c. Installation must include the entire instrument set-up and introductory training of up to four Public Health Laboratory staff members. The introductory training must be sufficient to operate and maintain the instrument.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after standards/validation plates are run with acceptable results, data are generated and reports are printed. This would include optimization of the application (LRN methods).
- e. Onsite installation, including system verification, must be included.

E. TRAINING

- a. The instrument Theory and Training Course must be offered by vendor at vendor’s site, vendor related facility or our lab site for at least two (2) DPHL staff. This is separate from on-site installation and familiarization.
- b. The vendor must provide a course detailing integrated instrument troubleshooting, basic method development, instrument operations, and data analysis and reporting.
- c. There must be availability of a pre-award for hands-on evaluation of instrumentation by DPHL staff.
- d. The quotation price should include hands-on training for a minimum of two (2) staff of DPHL, given by field application specialist of the company without further charge. It should include all extraneous cables, gauges, parts, accessories, including any and/or all accessories, at no charge to get the DPHL started on its first assays including detailed start-up procedures. These course(s) may be held at vendor facilities.

F. FINAL ACCEPTANCE BY PUBLIC HEALTH LABORATORY

- a. No payment for the materials will be processed until the Division of Public Health personnel is satisfied that the complete system is functioning according to these specifications.

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

Bid # **HSS 09-046**

Vendor Name: _____

TOTAL COST PAGE

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

Total Cost: \$ _____

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.