



**State of Delaware
Delaware Health & Social Services
Division of Management Services**

Newborn Screening Chemistry Testing Systems

**Invitation to Bid
Contract No. 12002-TEST SYSTEMS**

December 28, 2011

**- *Deadline to Respond* -
January 25, 2012
*11:00 A.M. (EST)***

***Questions regarding the specifications will be accepted until
January 11, 2012 at Noon by sylvia.adams@state.de.us.
Questions and Answers will be posted as an Addendum to
this bid by January 19, 2012.***

STATE OF DELAWARE
Department of Health and Social Services
Division of Management Services

CONTRACT NO. HSS 12002-TEST SYSTEMS

ALL BIDDERS:

The enclosed packet contains an "INVITATION TO BID" for Newborn Screening Chemistry Testing Systems. The invitation consists of the following documents:

INVITATION TO BID - CONTRACT NO. HSS 12002-TEST SYSTEMS

- 1 DEFINITIONS and GENERAL PROVISIONS
- 2 SPECIAL PROVISIONS and SPECIFICATIONS
- 3 BID QUOTATION REPLY SECTION
 - A - QUOTATION SUMMARY
 - B - NO BID REPLY FORM
 - C - NON-COLLUSION STATEMENT AND ACCEPTANCE
 - D - BIDDER'S SIGNATURE FORM
 - E - CERTIFICATION SHEET
 - F - OFFICE OF MINORITY AND WOMEN BUSINESS ENTERPRISE (OMWBE) APPLICATION

In order for your bid to be considered, the bid quotation reply section shall be executed completely and correctly and returned in a sealed envelope clearly displaying the contract number, by January 25, 2012 at 11:00 a.m. (EST).

Bids shall be submitted to:

**STATE OF DELAWARE
DELAWARE HEALTH AND SOCIAL SERVICES
DIVISION OF MANAGEMENT SERVICES
PROCUREMENT BRANCH- MAIN BLDG., ROOM 262
HERMAN M. HOLLOWAY SR. HEALTH AND SOCIAL SERVICES CAMPUS
1901 N. DUPONT HIGHWAY
NEW CASTLE, DELAWARE 19720**

Please review and follow the information and instructions contained in the general and special provisions section of the invitation. Should you need additional information, please call Sylvia Adams at 302-255-9297 or sylvia.adams@state.de.us.

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Department of Health and Social Services
Division of Management Services

DEFINITIONS

The attached Definitions and General Provisions apply to all contracts and are part of each invitation to bid. The requirement to furnish a bid bond and performance bond is applicable unless waived in the Special Provisions. Should the General Provisions conflict with the Special Provisions, the Special Provisions shall prevail. Bidders or their authorized representatives are required to fully acquaint themselves as to State procurement laws and regulations prior to submitting bid.

DEFINITIONS: Whenever the following terms are used, their intent and meaning shall be interpreted as follows:

STATE: The State of Delaware

AGENCY: State Agency as noted on cover sheet.

DESIGNATED OFFICIAL: The agent authorized to act for the Agency.

BID INVITATION: The "bid invitation" or "invitation to bid" is a packet of material sent to vendors and consists of General Provisions, Special Provisions, specifications, and enclosures.

GENERAL PROVISIONS: General Provisions are instructions pertaining to contracts in general. They contain, in summary, requirements of laws of the State, policies of the Agency, and instructions to vendors.

SPECIAL PROVISIONS: Special Provisions are specific conditions or requirements peculiar to the contract under consideration and are supplemental to the General Provisions. Should the Special Provisions conflict with the General Provisions, the Special Provisions shall prevail.

BIDDER OR VENDOR: Any individual, firm, or corporation formally submitting a proposal for the material or work contemplated, acting directly or through a duly authorized representative.

PROPOSAL: The offer of the bidder submitted on the approved form and setting forth the bidder's prices for performing the work or supplying the material or equipment described in the specifications.

SURETY: The corporate body which is bound with and for the contract, or which is liable, and which engages to be responsible for the contractor's payments of all debts pertaining to and for its acceptable performance of the work for which it has contracted.

BIDDER'S DEPOSIT: The security designated in the proposal to be furnished by the bidder as a guaranty of good faith to enter into a contract with the Agency if the work to be performed or the material or equipment to be furnished is awarded to the bidder.

CONTRACT: The written agreement covering the furnishing and delivery of material or work to be performed.

CONTRACTOR: Any individual, firm, or corporation with whom a contract is made by the Agency.

CONTRACT BOND: Approved form of security furnished by the contractors and its surety as a guaranty of good faith on the part of the contractor to execute the work in accordance with the terms of the contract.

SECTION A - GENERAL PROVISIONS

1. **BID INVITATION:**

See "Definitions".

2. **PROPOSAL FORMS:**

The invitation to bid shall contain either pre-printed forms for use by the vendor in submitting its bid or a specification page(s) detailing product(s) requirements. In the case of pre-printed forms, the forms shall contain basic information such as description of the item and the estimated quantities and shall have blank spaces for use by the vendor for entering information such as unit bid price, total bid price, etc.

3. **INTERPRETATION OF ESTIMATES:**

- a. The attention of bidders is called to the fact that, unless stated otherwise, the quantities given in the proposal form are to be considered to be approximate only and are given as a basis for the comparison of bids. The Agency may increase or decrease the amount of any item as may be deemed necessary or expedient, during the period of the contract.
- b. An increase or decrease in the quantity for any item is not sufficient ground for an increase or decrease in the unit price.

4. **SILENCE OF SPECIFICATIONS:**

The apparent silence of the specifications as to any detail, or the apparent omission from it of detailed description concerning any point, shall be regarded as meaning that only the best commercial practice is to prevail and only material and workmanship of the first quality are to be used. Proof of specifications compliance will be the responsibility of the vendor.

5. **EXAMINATION OF SPECIFICATIONS AND PROVISIONS:**

The bidder shall examine carefully the proposal and the contract forms for the material contemplated. The bidder shall investigate and satisfy itself as to the conditions to be encountered, quality and quantities of the material to be furnished, and the requirements of the Special Provisions and the contract. The submission of a bid shall be conclusive evidence that the bidder has made examination of the aforementioned conditions.

6. **PREPARATION OF PROPOSAL:**

- a. The bidder's submission shall be written in ink or typewritten on the form provided unless the inclusion of such form is waived.
- b. If items are listed with a zero quantity, bidder shall state unit price **ONLY** (intended for open end purchases where estimated requirements are not known). The proposal shall show a total bid price for each item bid and the total bid price of the proposal excluding zero quantity items.

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7. **PRICES QUOTED:**

The prices quoted are those for which the material will be furnished F.O.B. Destination and include all charges that may be imposed during the period of the contract.

8. **DISCOUNT:**

No qualifying letter or statements in or attached to the proposal, or separate discounts will be considered in determining the low bid except as may be otherwise herein noted. Cash or separate discounts should be computed and incorporated into unit bid price(s).

9. **SAMPLES OR BROCHURES:**

Samples or brochures may be requested by the agency for evaluation purposes. They shall be such as to permit the Agency to compare and determine if the item offered complies with the intent of the specifications. Requested samples or brochures are to be supplied free of charge.

10. **PROPOSAL GUARANTY; BID BOND:**

- a. Each bidder shall submit with its proposal a guaranty in sum equal to at least 10% of the total value of its bid, according to Delaware Code Title 29, Section 6927(a) unless this requirement is waived under Special Provisions.
- b. This bid bond shall be submitted in the form of good and sufficient bond drawn upon an insurance or bonding company authorized to do business in the State of Delaware, to the State of Delaware for the benefit of the Agency, or a certified check drawn on a reputable banking institution and made payable to the Agency in the requirement amount. If Agency bond form is not utilized, the substituted bond forms must conform to the minimum of conditions specified in the Agency bond form.

11. **DELIVERY OF BIDS:**

Bids shall be delivered in sealed envelopes, and shall bear on the outside the name and address of the bidder as well as the designation of the contract. Bids submitted by other than hand delivery must be sent in a manner requiring a signature on receipt. We recommend an overnight or second day delivery service. Bids must be delivered to the address listed below. All bids must clearly display the bid number on the envelope.

It is the bidder's responsibility to ensure their bid is received on time. All bids will be accepted until the date and time shown on page 2 of this document. Bidder bears the risk of delays in delivery. Proposals received after the time set for public opening will be returned unopened.

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12. **WITHDRAWAL OF PROPOSALS:**

A bidder may withdraw its proposal unopened after it has been deposited, if such a request is made prior to the time set for the opening of the proposal.

13. **PUBLIC OPENING OF PROPOSALS:**

The bids shall be publicly opened at the time and place specified by the Agency. Bidders or their authorized representatives are invited to be present.

14. **PUBLIC INSPECTION OF PROPOSALS:**

If the bidder designates a portion of its bid as confidential, it shall isolate and identify in writing the confidential portions. The bidder shall include with this designation a statement that explains and supports the firm's claim that the bid items identified as confidential contain trade secrets or other proprietary data. Only information not directly affecting the bid can be designated as confidential.

15. **DISQUALIFICATION OF BIDDERS:**

Any one or more of the following causes may be considered as sufficient for the disqualification of a bidder and the rejection of its bid or bids:

- a. More than one bid for the same contract from an individual, firm, or corporation under the same or different names.
- b. Evidence of collusion among bidders.
- c. Unsatisfactory performance record as evidenced by past experience.
- d. If the unit prices are obviously unbalanced either in excess or below reasonable cost analysis values.
- e. If there are any unauthorized additions, interlineations, conditional or alternate bids or irregularities of any kind which may tend to make the proposal incomplete, indefinite, or ambiguous as to its meaning.

16. **BID AND FINAL CONTRACT**

The contents of each bid will be considered binding. The contents of the successful bid will be included by reference in the resulting contract.

SECTION B - AWARD AND EXECUTION OF CONTRACT

1. **CONSIDERATION OF BIDS:**

- a. After the proposals have been opened, the bids will be tabulated. Tabulations of the bids will be based on the correct summation of items at the unit price bid.
- b. The right is reserved to waive technicalities, to reject any or all bids, or any portion thereof, to advertise for new bids, to proceed to do the work otherwise, or to abandon the work, if in the judgment of the Agency or its agent, the best interest of the State will be promoted thereby.

2. **MATERIAL GUARANTY:**

Before any contract is awarded, the successful bidder may be required to furnish a complete statement of the origin, composition and manufacture of any or all of the material to be used in the contract together with such samples as may be requested for the purpose of testing.

3. **CONTRACT AWARD:**

Within thirty days from the date of opening the bids, the bid will be awarded or the bid rejected.

4. **EXECUTION OF CONTRACT:**

- a. The bidder to whom the award is made shall execute a formal contract and bond within twenty days after date of official notice of the award of the contract.
- b. If the successful bidder fails to execute the required contract and bond, as aforesaid, within twenty days after the date of official notice of the award of the contract, its proposal guaranty shall immediately become forfeited as liquidated damages. Award will then be made to the next responsive and responsible bidder of the work or re-advertised, as the Agency may decide.

5. **REQUIREMENT OF CONTRACT / PERFORMANCE BOND:**

- a. Successful bidders shall furnish bond, simultaneously with the execution of the formal contract, to the State of Delaware for the benefit of the Agency with surety in the amount of 100% of the total contract award or as otherwise provided in the Special Provisions. Said bonds shall be conditioned upon the faithful performance of the contract.
- b. The bond forms shall be provided by the Agency and the surety shall be acceptable to the Agency.

6. **WARRANTY:**

The successful bidder(s) shall be required to extend any policy guarantee usually offered to the general public, FEDERAL, STATE, COUNTY, or MUNICIPAL governments, on material in this contract against defective material, workmanship, and performance.

7. **THE CONTRACT(S):**

The contract(s) with the successful bidder(s) will be executed with the Department of Health and Social Services / Division of Management Services acting for all participating agencies.

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8. **RETURN OF BIDDER'S DEPOSIT:**

The deposits shall be returned to the successful bidder upon the execution of the formal contract. The deposits of unsuccessful bidders shall be returned to them immediately upon the awarding of the contract or rejection of their bids.

9. **INFORMATION REQUIREMENT :**

The successful bidder(s) shall be required to advise the Department of Health and Social Services/ Division of Management Services of the gross amount of purchases made as a result of the contract.

10. **CONTRACT EXTENSION:**

The State reserves the right to extend this contract on a month-to-month basis for a period of up to three months.

11. **TERMINATION FOR CONVENIENCE:**

Contracts shall remain in effect for the time period and quantity specified unless the contract is terminated by the State. The State may terminate the contract at any time by giving written notice of such termination and specifying the effective date thereof, at least sixty (60) days before the effective date of termination.

12. **TERMINATION FOR CAUSE:**

If, for any reasons, or through any cause, the Contractor fails to fulfill in timely and proper manner its obligations under this Contract, or if the Contractor violates any of the covenants, agreements, or stipulations of this Contract, the State shall thereupon have the right to terminate this contract by giving written notice to the Contractor of such termination and specifying the effective date thereof, at least 5 days before the effective date of such termination. In that event, all finished or unfinished documents, data, studies, surveys, drawings, maps, models, photographs, and reports or other material prepared by the Contractor under this Contract shall, at the option of the State, become its property, and the Contractor shall be entitled to receive just and equitable compensation for any satisfactory work completed on such documents and other materials which is usable to the State.

SECTION C - GENERAL

1. **AUTHORITY OF AGENCY:**

On all questions concerning the interpretation of specifications, the acceptability and quality of material furnished and/or work performed, the classification of material, the execution of the work, and the determination of payment due or to become due, the decision of the Agency shall be final and binding.

2. **LAWS TO BE OBSERVED:**

The contractor is presumed to know and shall strictly comply with all National, State, or County laws, and City or Town ordinances and regulations in any manner affecting the conduct of the work. The contractor shall indemnify and save harmless the State of Delaware, the Agency, and all Officers, Agency and Servants thereof against any claim or liability arising from or based upon the violation of any such laws, ordinances, regulations, orders, or decrees whether by itself or by its employees.

3. **PERMITS AND LICENSES:**

All necessary permits, licenses, insurance policies, etc. required by local, State or Federal laws, shall be provided by the contractor at its own expense.

4. **PATENTED DEVICES, MATERIAL AND PROCESSES:**

- a. The contractor shall provide for the use of any patented design, device, material, or process to be used or furnished under this contract by suitable legal agreement with the patentee or owner, and shall file a copy of this agreement with the Agency.
- b. The contractor and the surety shall hold and save harmless the State of Delaware, the Agency, the Director, their Officers or Agents from any and all claims because of the use of such patented design, device, material, or process in connection with the work agreed to be performed under this contract.

5. **EMERGENCY TERMINATION OF CONTRACT:**

- a. Due to restrictions which may be established by the United States Government on material, or work, a contract may be terminated by the cancellation of all or portions of the contract.
- b. In the event the contractor is unable to obtain the material required to complete the items of work included in the contract because of restrictions established by the United States Government and if, in the opinion of the Agency, it is impractical to substitute other available material, or the work cannot be completed within a reasonable time, the incomplete portions of the work may be cancelled, or the contract may be terminated.

6. **TAX EXEMPTION:**

- a. Material covered by this proposal is exempt from all FEDERAL and STATE TAXES. Such taxes shall not be included in prices quoted.

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- b. Any material which is to be incorporated in the work or any equipment required for the work contemplated in the proposal may be consigned to the Agency. If the shipping papers show clearly that any such material is so consigned, the shipment will be exempt from the tax on the transportation of property under provisions of Section 3475 (b) of the Internal Revenue Code, as amended by Public Law 180 (78th Congress). All transportation charges shall be paid by the contractor. Each bidder shall take its exemption into account in calculating its bid for its work.

7. **OR EQUAL (PRODUCTS BY NAME):**

Specifications of products by name are intended to be descriptive of quality or workmanship, finish and performance. Desirable characteristics are not intended to be restrictive. Substitutions of products for those named will be considered provided the vendor certifies that the function, characteristics, performance and endurance qualities of the material offered is equal or superior to that specified. When quoting an approved equal product, provide a cross reference to easily identify items for comparison.

8. **BID EVALUATION AND AWARD:**

The Department of Health and Social Services / Division of Management Services will award this contract to the lowest responsible bidder(s) which in their judgment best serves the interest of the State of Delaware in accordance with Delaware Code Title 29, Section 6923(k). Personnel with experience and technical background may be utilized by the Department of Health and Social Services / Division of Management Services in making judgment. In case of error in price extension, the unit price(s) shall prevail.

9. **INVOICING:**

After the contracts are executed, the agencies participating in the bid may forward their purchase orders to the successful bidder(s) in accordance with State Purchasing Procedures. The State will generate a payment voucher upon receipt of an invoice from the vendor.

If partial payments are required, the bidder must submit a proposed payment schedule stating partial payments less 10% of invoice amount as part of their response to the bid. The proposed payment schedule is subject to approval by the State of Delaware. If approved, invoices must be sent to the designated State of Delaware agency within the Department of Health and Social Services. After final inspection and acceptance of all work under the contract, the contractor shall prepare his invoice for final payment. The final payment shall consist of the total cost of the contract less partial payment(s) previously received.

10. **DELIVERY**

Delivery must be made as directed by the Department when not in conflict with the bid or quotation. The decision of the Procurement Administrator as to reasonable compliance with delivery terms shall be final. The burden of proof of delay claimed to be beyond the contractor's control shall rest with the contractor.

11. **DELIVERY EXTENSION OF TIME**

Any extension of time on delivery as specified must be in writing by the Procurement Administrator with such extension applicable only to the particular item or shipment affected.

SECTION D: SPECIAL PROVISIONS

1. **CONTRACT REQUIREMENTS**

This contract will be issued to cover the Newborn Screening Chemistry Testing Systems requirements for Delaware Health and Social Services / Division of Management Services on behalf of the Public Health Laboratory.

2. **CONTRACT PERIOD**

Each vendor's contract shall be valid for two years from **June 1, 2012 through May 31, 2014.** Each contract may be renewed up to three - one year periods through negotiation between the contractor and Department of Health and Social Services / Division of Management Services or their designee. Negotiation must be initiated no later than ninety (90) days prior to the termination of the current agreement.

3. **PRICES**

Prices shall remain firm for the term of the contract.

4. **QUANTITIES**

The attention of bidders is called to the fact that, unless stated otherwise, the quantities given in the proposal are best estimates and are given as a basis for comparison of bids. Quantities ordered may be increased or decreased by any eligible agency as deemed necessary during the period of the contract.

5. **SHIPPING TERMS**

F.O.B. destination; freight pre-paid.

6. **PACKAGING, PACKING AND MARKING**

Packaging – Unless otherwise specified; commercial packaging as applicable is acceptable under these specifications.

Packing – All items shall be delivered in standard commercial containers so constructed as to insure acceptance by common or other carrier for safe transportation, at the lowest rate, to the point of delivery, or blanket wrapped trailer load lots.

Marking – Each shipping package shall be marked with the name of the item, the quantity contained therein, the name of the contractor and the purchase order number.

7. **MOST-FAVORED CUSTOMER**

The contractor shall not offer to others prices lower than those provided in the contract, or if lower prices are offered they must also apply to the subject contract.

8. **FUNDING OUT**

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Division of Management Services

The continuation of this contract is contingent upon funding appropriated by the legislature.

9. **BID BOND REQUIREMENT**

Bid Bond Waived.

10. **PERFORMANCE BOND REQUIREMENT**

Performance Bond Waived

11. **MANDATORY INSURANCE REQUIREMENTS**

A. Certificate of Insurance and/or copies of insurance policies for the following:

1. As a part of the contract requirements, the contractor must obtain at its own cost and expense and keep in force and effect during the term of this contract, including all extensions, the minimum coverage limits specified below with a carrier satisfactory to the State. All contractors must carry Comprehensive General Liability and at least one of the other coverages depending on the type of service or product being delivered.
 - a. Comprehensive General Liability - \$1,000,000.00 per person/\$3,000,000 per occurrence.

and

 - b. Medical/Professional Liability - \$1,000,000.00 per person/\$3,000,000 per occurrence.

or

 - c. Miscellaneous Errors and Omissions - \$1,000,000.00 per person/\$3,000,000 per occurrence.

or

 - d. Product Liability - \$1,000,000.00 per person/\$3,000,000 per occurrence.
2. Automotive Liability Insurance covering all automotive units used in the work with limits of not less than \$100,000 each person and \$300,000 each accident as to bodily injury and \$25,000 as to property damage to others.
3. Forty-five (45) days written notice of cancellation or material change of any policies is required.

STATE OF DELAWARE
Department of Health and Social Services
Division of Management Services
Administrator, Kieran Mohammed
Contract No. HSS 12002-TEST SYSTEMS
Delaware Health and Social Services
Main Admin Bldg., Rm. 257
New Castle, DE 19720

Note: The State of Delaware shall not be named as an additional insured but must be added or named as a Certificate holder.

12. **BASIS OF AWARD**

Department of Health and Social Services / Division of Management Services shall award this contract to the lowest responsible and responsive bidder(s) who best meets the terms and conditions of the bid. Department of Health and Social Services / Division of Management Services reserves the right to reject any or all bids in whole or in part, to make multiple awards, partial awards, award by types, item by item, or lump sum total, whichever may be most advantageous to the State of Delaware.

13. **HOLD HARMLESS**

The successful bidder agrees that it shall indemnify and hold the State of Delaware and all its agencies harmless from and against any and all claims for injury, loss of life, or damage to or loss of use of property caused or alleged to be caused, by acts or omissions of the successful bidder, its employees, and invitees on or about the premises and which arise out of the successful bidder's performance, or failure to perform as specified in the Agreement.

14. **OWNERSHIP OF INTELLECTUAL PROPERTY**

All copyright and patent rights to all papers, reports, forms, materials, creations, or inventions created or developed in the performance of this contract shall become the sole property of the State of Delaware. On request, the contractor shall promptly provide an acknowledgment or assignment in a tangible form satisfactory to the State to evidence the State's sole ownership of specifically identified intellectual property created or developed in the performance of the contract.

15. **NON-PERFORMANCE**

In the event the vendor does not fulfill its obligations under the terms and conditions of this contract, the ordering agency may purchase equivalent product on the open market. Any difference in cost between the contract prices herein and the price of open market product shall be the responsibility of the vendor. Under no circumstances shall monies be due the vendor in the event open market products can be obtained below contract cost. Any monies charged to the vendor may be deducted from an open invoice.

16. **FORCE MAJEURE**

Neither the vendor 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.

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17. **CONTRACTOR NON-ENTITLEMENT**

State of Delaware Contractors for Materiel and for Services shall not have legal entitlement to, nor seek business from another Contractors' Central Contract. Additionally, they shall not utilize other Central Contracts to fulfill the requirements of their respective contract as they are not a "Covered Agency" as defined by Title 29 Chapter 69 of the State Procurement Code.

18. **EXCEPTIONS**

Bidders may elect to take no more than four (4) minor exceptions to the terms and conditions of this ITB. Department of Health and Social Services / Division of Management Services shall evaluate each exception according to the intent of the terms and conditions contained herein, but Department of Health and Social Services / Division of Management Services must reject exceptions that do not conform to State bid law and/or create inequality in the treatment of bidders. Exceptions shall be considered only if they are submitted with the bid or before the date and time of the bid opening.

19. **MANDATORY USAGE REPORT**

One of the primary goals in administering this contract is to keep accurate records regarding its actual value. This information is essential in order to update the contents of the contract and to establish proper bonding levels if they are required. The integrity of future contracts revolves around our ability to convey accurate and realistic information to all interested bidders.

A report shall be furnished by the successful contractor **MONTHLY Electronically in Excel format** detailing the purchasing of all items on this contract. The format to be followed is described herein and shall be filed within fifteen (15) days after the end of each reporting period. Any exception to this mandatory requirement may result in cancellation of the award. Failure to provide the report with the minimum required information may also negate any contract extension clauses. Additionally, contractors who are determined to be in default of this mandatory report requirement may have such conduct considered against them, in assessment of responsibility, in the evaluation of future proposals. Vendors not having activity during a specific month, shall reply with a "no activity" if there is no activity during the reporting period.

The report shall be submitted electronically in EXCEL and sent as an attachment to the Agency Contact (TBA at time of award). It shall contain the six-digit department and organization code.

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20. **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 and may be accomplished by written purchase order, telephone, fax or computer on-line systems. Purchase orders will be issued to the successful bidder within a reasonable time after award of contract has been made. No expense of obligation in connection with fulfillment of the contract agreement should be made until an official State of Delaware purchase order has been received. 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.

21. **BILLING**

The successful vendor is required to "Bill as Shipped" to the respective ordering agency(s). Ordering agencies shall provide contract number, ship to and bill to address, contact name and phone number. The Vendor shall not charge a late fee that exceeds more than one percent (1%) per month, not to exceed twelve percent (12%) per annum.

22. **PAYMENT**

The agencies or school districts involved will authorize and process for payment each invoice within thirty (30) days after the date of receipt of a correct invoice. 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.

23. **PRODUCT SUBSTITUTION**

All items delivered during the life of the contract shall be of the same type and manufacture as specified or accepted as part of the bid unless specific approval is given by Department of Health and Social Services / Division of Management Services to do otherwise. However, awarded vendors are highly encouraged to offer any like substitute product (s); either generic or brand name, at any time during the subsequent contract term, especially if an opportunity for cost savings to the state exists. In such cases, the state may require the submission of written specifications and/or product samples for evaluation prior to any approvals being granted.

24. **LIFE CYCLE COSTING**

If applicable, the specifications contained within this ITB have been developed through Life Cycle Cost Analysis that will allow the State to realize the lowest total cost of ownership and operation over the useful life of the equipment.

25. **TERMINATION FOR CONVENIENCE**

Contracts shall remain in effect for the time period and quantity specified unless the contract is terminated by the State. The State may terminate the contract at any time by giving written notice of such termination and specifying the effective date thereof, at least sixty (60) days before the effective date of termination.

26. **TERMINATION FOR CAUSE:**

If, for any reasons, or through any cause, the Contractor fails to fulfill in timely and proper manner its obligations under this Contract, or if the Contractor violates any of the covenants, agreements, or

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stipulations of this Contract, the State shall thereupon have the right to terminate this contract by giving written notice to the Contractor of such termination and specifying the effective date thereof, at least 5 days before the effective date of such termination. In that event, all finished or unfinished documents, data, studies, surveys, drawings, maps, models, photographs, and reports or other material prepared by the Contractor under this Contract shall, at the option of the State, become its property, and the Contractor shall be entitled to receive just and equitable compensation for any satisfactory work completed on such documents and other materials which is usable to the State.

27. **ENERGY STAR PRODUCTS**

The contractor **must** provide products that earn the ENERGY STAR rating and meet the ENERGY STAR specifications for energy efficiency. The offeror is encouraged to visit www.energystar.gov for complete product specifications and updated lists of qualifying products.

28. **COLORS**

All colors, wood finishes, fabrics or tops which are not specified herein will be selected at a later date.

29. **CONTRACTOR'S SIGNS**

The facility authorities will not permit the use of any signs, billboards or other advertising media on the grounds or buildings.

30. **DISPOSAL OF DEBRIS**

All fill dirt, debris or other material generated in the performance of this contract must be removed from the building leaving all areas neat and clean and all debris dumped in an area designated by the owner.

31. **CORRECTION OF WORK AFTER FINAL PAYMENT**

Neither the final payment nor any provision in the contract documents shall relieve the contractor of responsibility for faulty materials or workmanship and unless otherwise specified, he shall remedy any defects due thereto and pay for any damage to other work resulting there from, which shall appear within a period of one year from date of final payment.

32. **INTERPRETATIONS OR AGENDA**

No oral interpretation will be made to any bidder as to the meaning of the Contract Documents or any part thereof. Every request for such an interpretation shall be made in writing to the Procurement Office. Any inquiry received fourteen (14) or more days prior to the bid closing date will be given consideration. Every interpretation made to a bidder will be in the form of an Addendum to the Contract Documents and when issued will be posted with this solicitation at least five (5) days before bids are opened. It shall be the bidder's responsibility to monitor the website for any Addenda. All such Addenda shall become part of the Contract documents and all bidders shall be bound to such Addenda, whether or not received by the bidders.

33. **EXAMINATION OF SITE**

Due to the nature of the work involved under this contract, bidders may be required to thoroughly examine the site. No claims will be allowed for extra labor, materials or equipment required or for difficulties encountered which could have been foreseen by a thorough examination of the site.

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34. **MEASUREMENTS**

Before ordering any materials or doing any work, the contractor shall verify all measurements at the building and shall be responsible for their correctness. No extra charge or compensation will be allowed because of differences between actual dimensions and measurements indicated on drawings, if provided.

35. **MATERIALS AND APPLICATION**

Manufacturer's specifications in material handling, preparation and installation must be adhered to in all cases. No exceptions will be made without prior, written approval of the Manufacturing Representative or his designee. All materials shall conform to those of good quality as manufactured by reputable companies.

36. **GUARANTEE**

The contractor shall guarantee all materials and workmanship against original defects or against injury from proper and usual wear when used for the purpose intended.

37. **WAGE PROVISIONS/RELEASE OF LIENS IN PUBLIC WORKS**

34a. All successful contractors are required by Section 6960, Chapter 69, Delaware Code, to pay the various classes of laborers and mechanics wages that will be determined by the Department of Labor and Industrial Relations of the State of Delaware to be prevailing for the corresponding labor of classes of laborers and mechanics employed on projects of a character similar to the work in the city, town, village or other subdivision of the State on which the work is to be performed.

34b. Contractor or his subcontractor shall pay all mechanics and laborers employed directly upon the site of the work, unconditionally and not less than once a week, and without subsequent deduction or rebate on any account, the full amounts accrued at time of payment, computed at wage rates not less than those stated in the wage determination decision of the Department of Labor and Industrial Relations schedule contained and made part of this bid contract solicitation.

34c. Along with his application for final payment, the contractor shall submit a satisfactory release of all liens against the premises on the part of all persons or firms who have delivered materials for use in or work done in the performance of this contract.

38. **CONDUCT OF WORKMEN – SAFETY AND SECURITY PRECAUTIONS**

35a. Owing to the nature of the institution the following rules of conduct will be strictly enforced by the facility authorities: No workmen are to loiter around the building and they are not to contact employees of the facility, excepting those employees especially assigned to the work.

35b. Contractor will perform the work using all safety precautions to protect himself, facility personnel and property. All tools and equipment will be stored in a safe manner and at a location designated by the owner. No tools may be left unattended at any time.

35c. Contractor will be responsible for security of all property within the boundaries of this facility during working hours.

39. **BID/CONTRACT EXECUTION**

Both the non-collusion statement that is enclosed with this Invitation to Bid and the contract form delivered to the successful bidder for signature **shall** be executed by a representative who has the legal capacity to enter the organization into a formal contract with the State of Delaware, Department of

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Health and Social Services / Division of Management Services The awarded vendor(s) will be required to complete the new W-9 Form by visiting the Division of Accounting's Website: <http://accounting.delaware.gov>.

40. **STATE OF DELAWARE BUSINESS LICENSE**

Prior to receiving an award, the successful vendor shall either furnish Department of Health and Social Services / Division of Management Services with proof of State of Delaware Business Licensure or initiate the process of application where required. An application may be requested in writing to: Division of Revenue, Carvel State Building, P.O. Box 8750, 820 N. French Street, Wilmington, DE 19899, or by telephone to one of the following numbers: (302) 577-8201 – Public Service, (302) 577-8205 – Licensing Department. A business license can also be obtained online at: <http://onestop.delaware.gov>.

Information regarding the award of this contract will be given to the Division of Revenue. Failure to comply with the State of Delaware licensing requirements may subject your organization to applicable fines and/or interest penalties.

++ *Items after this point require a detailed response in the bid proposal* ++

41. **CONTRACTOR RESPONSIBILITY**

The State will enter into a contract with the successful contractor. The successful contractor shall be responsible for all products and services as required by this ITB. ***Subcontractors, if any, shall be clearly identified in the financial proposal.***

- a. The Contractor represents that they have, or will secure at their own expense, all personnel required to perform the services required under this contract.
- b. All of the services required hereunder shall be performed by the Contractor or under its direct supervision, and all personnel, including subcontractors, engaged in the work shall be fully qualified and shall be authorized under State and local law to perform such services.
- c. None of the work or services covered by this contract shall be subcontracted without the prior written approval of the State.

42. **BUSINESS REFERENCES**

In order to have your bid considered, please supply three (3) business references consisting of current or previous customers with your reply. Please include name, address, telephone number, and a contact person.

43. **VENDOR EMERGENCY RESPONSE POINT OF CONTACT**

The awarded vendor(s) shall provide the name(s), telephone, or cell phone number(s) of those individuals who can be contacted twenty four (24) hours a day, seven (7) days a week to meet a critical need for commodities or services when the Governor of the State of Delaware declares a state of emergency under the current Delaware Emergency Operations Plan. Failure to provide this information could render the bid as non-responsive.

SPECIFICATIONS
**Newborn Screening Chemistry Testing System(s) for
Biotinidase, Total Galactose, GALT, TSH, T4, 17-OHP & IRT**

Listed below are the specifications for multiple chemistry testing methods that will be used in a Newborn Screening application. Dried blood spot specimens (DBS) from all babies born in Delaware will be tested for Biotinidase Deficiency, Galactosemia (Classical Galactosemia, Galactokinase Deficiency & Epimerase Deficiency), Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, and Cystic fibrosis. Delaware Public Health Laboratory (DPHL) wishes to enter into a reagent/equipment rental contract with selected vendor(s) to supply the necessary reagent test kits, equipment, computers, etc. to provide all, or a portion of this testing for the State of Delaware. The contract will be for a period of two (2) years with options for continuation of that contract for three (3) additional one (1) year contracts.

BID RESPONSES

Bidders are encouraged to submit a response for all of the Sections, A through H, listed under SPECIFICATIONS, but are not required to do so. Bidders may submit a response for a portion of the sections. If a bidder chooses not to respond to any of the Specifications A through H, then indicate No Proposal Submitted. All responses should address each item in the Section(s) bid upon and how their system and/or components will meet or exceed the requirements.

Vendors can only submit one bid. However if multiple testing options/configurations are available, then they can be included in the bid as options, 1, 2, etc.

Bidders should price out each of the specifications A through H individually. If equipment is to be shared with other testing methods, then cost benefits of multiple tests should be indicated separately.

Bidders should provide with their proposal a detailed list of reagents and equipment, including but not limited to, kit configurations, instruments, processors, software, uninterrupted power supply (UPS), and miscellaneous hardware. Any materials/supplies/reagents/equipment required to perform the assay, but not included in the bid response, should also be listed.

The specifications listed below are the optimum requirements based on the needs of the DPHL. If the proposed system is unable to meet an item specification, note "Unable to Meet Specification" and include the reason why. Incomplete or omitted items may be considered grounds for rejection of a bid.

DPHL reserves the right to choose separate vendors for each area of SPECIFICATION A through H, or combine vendors to best meet the needs of the Newborn Screening program.

DESCRIPTION OF TESTING

Delaware Public Health Laboratory is responsible for all newborn screening testing performed on newborns living or born in Delaware hospitals. Delaware is a two-specimen state, requiring a second specimen from each baby be collected and submitted for laboratory analysis between 7-28 days of age. In 2010, approximately 23,000 newborn screening dried blood spot specimens (11,900 initial and 11,300 repeat) were received. Not every test method is run on both specimens. See descriptions in sections for volumes and testing protocols.

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All data resulting from the methods described in this ITB will be merged into the existing Natus IV database system located on a secure server via input (merge) files and transferred using a secure file transfer process (SFTP) using WinSCP3. Any software needed to complete the systems in this bid will not be able to reside on the existing state servers.

DEFINITIONS:

System = Refers to the whole package and includes Semi-Automated Punch, Computer, Software, Cables and necessary hardware.

Semi-Automated = The majority of processes are handled automatically, specifically referring to pipetting processes. Minimal hands-on steps in process, i.e., moving plates

Automated = Hands free operation. Punch spots, load, return, retrieve results.

I. SPECIFICATIONS:

A. SEMI-AUTOMATED HOLE PUNCH - Proposal Submitted, No Proposal Submitted

1. Must have ability to simultaneously punch a minimum of four (4) 3.2mm dried blood spot punches into standard and/or deep 96-well or 384-well microtiter plates.
2. Must be fully programmable with the ability to punch multiple spots into one well.
3. Must have auto-trigger, hand and/or foot operation modes.
4. Ability to switch size of punch head is a preferred, but not required. Describe capabilities
5. Must have a light targeting system providing for greater punch accuracy.
6. Must have on-board mechanism to minimize effects of static electricity, i.e. humidifier.
7. Must have barcode reader that can be turned on and off.
8. Must be UL approved. The instrument must be manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
9. A listing of all options included with the instrument proposed in the bid, plus available options and associated costs should be detailed.
10. Training for up to six (6) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, and advanced maintenance.
11. Warrantee for the entire system (instrument, computer, software, reagents) included for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
 - a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
 - b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST

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- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within three (3) working days, Monday – Friday 8:00 am – 5:00 pm EST

12. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within three (3) working days, Monday – Friday 8:00 am – 5:00 pm EST

13. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming for all possible configurations used in the DPHL, and one or more successful runs.

14. Three positive references from current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar birth rate and work flow. Please include name, address, telephone number, and a contact person.

15. Price as a yearly / monthly rental for the term of the contract.

B. BIOTINIDASE – For use as a semi-quantitative / quantitative screening test to identify Biotinidase Deficiency and Partial Biotinidase Deficiency in a newborn screening population. All first specimens and only those second specimens with previously flagged results will be screened. The 2010 testing volume for patient testing, retests, controls, standards and surveys was 14,000.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method capable of running 150 patient samples per day, with repeat testing at the end/beginning of the plate. Capacity to run with minimal hands-on operation by one (1) Technician. Indicate specific manual processing steps that will be required with proposed method and hands-on time estimates.
- 2. Individual reagent stability and/or kit configuration sufficient to use all reagents within their open vial expiration limit, if only one 96-well plate is run per day.

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3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing are preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" Punch size preferred).
6. Quantitative method with ability to accurately identify Biotinidase levels in low and high clinical ranges. Indicate reportable range, expected accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method that is FDA approved / cleared.
10. Method that uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing included in the bid proposal. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate.
17. At least two levels of control material made from human whole blood, hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal and abnormal range of results. Describe control material(s).
18. Computer and/or lap tops needed to process runs and generate reports.
19. Local or networked Printer
20. A comprehensive software package with these capabilities:
 - a. User interface using non-DOS technology.
 - b. Ability to interface with an automated punch. Describe requirements.

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- c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values along with the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - Increment #, 11-digit specimen ID#, Value, i.e., **1,20113650001,0.00**
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
- a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
 - b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
 - c. If problem unsolvable by telephone, then on-site Technical Service available to correct the

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problem with a factory-trained engineer providing the service.

- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three positive references from current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

C. TOTAL GALACTOSE - For use as a screening test to aid in the identification of Galactosemia (Classical Galactosemia, Galactokinase Deficiency & Epimerase Deficiency), in a newborn screening population. All first specimens and second specimens from the Delaware newborn population will be screened. The 2010 testing volume for patient testing, retests, controls, standards and surveys was 31,700.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method capable of running 250 patient samples of each analyte per day, with repeat testing at the end/beginning of the plate. Capacity to run with minimal hands-on processing by one (1) Technician. Indicate specific manual processing steps that will be required with proposed method and hands-on time estimates.
- 2. Individual reagent stability and/or kit configuration sufficient to use all reagents within their open vial expiration limit, if only one 96-well plate is run per day.

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3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
6. Quantitative method with ability to accurately identify Total Galactose levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method is FDA approved / cleared.
10. Method that uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing included in bid. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate. Standard levels to range from 0.0 to 50.0 mg/dL.
17. Three levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal, elevated and intermediate range of results.
18. Computer and/or lap tops needed to process runs and generate reports.
19. Local or networked printer
20. A comprehensive software package with these capabilities:
 - a. User interface using non-DOS technology.
 - b. Ability to interface with an automated punch. Describe requirements.

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- c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values as well as the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - Increment #, Value, Specimen ID#, i.e., **1,6.22,20113650002,**
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
- a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
 - b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
 - c. If problem unsolvable by telephone, then on-site Technical Service available to correct the

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problem with a factory-trained engineer providing the service.

- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three references of current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

D. GALT (Galactose-1-Phosphate Uridyl Transferase) - For use as a screening test to aid in the identification of Galactosemia (Classical, Galactokinase Deficiency & Epimerase Deficiency) in a newborn screening population. All first specimens and second specimens from the Delaware newborn population will be screened. The 2010 testing volume for patient testing, retests, controls, standards and surveys was 25,300.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method capable of running 250 patient samples of each analyte per day, with repeat testing at the end/beginning of the plate. Capacity to run with minimal hands-on processing by one (1) Technician. Indicate specific manual processing steps that will be required with proposed method and hands-on time estimates.
- 2. Individual reagent stability and/or kit configuration sufficient to use all reagents within their open vial

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expiration limit, if only one 96-well plate is run per day.

3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
6. Quantitative method with ability to accurately identify GALT levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method is FDA approved / cleared.
10. Method uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing included in bid. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate.
17. Three levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal, elevated and intermediate range of results.
18. Computer and/or lap tops needed to process runs and generate reports.
19. Local or networked printer
20. A comprehensive software package with these capabilities:
 - a. User interface using non-DOS technology.

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- b. Ability to interface with an automated punch. Describe requirements.
 - c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values along with the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - **Increment #, Value, 11-digit specimen ID#, i.e., 1,6.22,20113650003,**
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
- a. All services necessary to maintain the system for the period of the WARRANTEE. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
 - b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST

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- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three references of current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

E. THYROID STIMULATING HORMONE (TSH) - For use as a screening test to aid in the identification of Congenital and Secondary Hypothyroidism in a newborn screening population. All first specimens and second specimens from the Delaware newborn population will be screened. The 2010 testing volume for patient testing, retests, controls, standards and surveys was 31,600.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method capable of running 250 patient samples of each analyte per day, with repeat testing at the end/beginning of the plate. Capacity to run with minimal hands-on processing by one (1) Technician. Indicate specific manual processing steps that will be required with proposed method and hands-on time estimates.
- 2. Individual reagent stability and/or kit configuration sufficient to use all reagents within their open vial

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expiration limit, if only one 96-well plate is run per day.

3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
6. Quantitative method with ability to accurately identify **TSH** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method is FDA approved / cleared.
10. Method uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing included in bid. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type of pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate.
17. Three levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal, elevated and intermediate range of results.
18. Computer and/or lap tops needed to process runs and generate reports.
19. Local or networked printer.
20. A comprehensive software package with these capabilities:
 - a. User interface using non-DOS technology.

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- b. Ability to interface with an automated punch. Describe requirements.
 - c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values along with the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - Increment #, Value, 11-digit specimen ID#, i.e., **1,6.22,20113650004,**
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
- a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
 - b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST

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- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three references of current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

F. **THYROXIN (T4)** - For use as a screening test to aid in the identification of Congenital and Secondary Hypothyroidism in a newborn screening population. Presently, only specimens with elevated TSH (> 50) are being evaluated for T4. The 2010 testing volume for initial, retests, controls, standards and surveys was 1100.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method that is capable of running 250 patient samples of each analyte per day (even though actual initial volume will be very low), with repeat testing at the end/beginning of the plate, even though actual test volume is extremely low. Capacity to run with minimal hands-on processing by one (1) Technician. Indicate specific manual processing steps that will be required with proposed method and hands-on time estimates.

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2. Individual reagent stability and/or kit configuration sufficient to minimize kit waste and maximize kit use. Explain packaging & reagent stability and plan to cover extremely low test volume.
3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
6. Quantitative method with ability to accurately identify **T4** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method is FDA approved / cleared.
10. Method uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing volume included in bid. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type of pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate.
17. Three levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal, elevated and intermediate range of results.
18. Computer and/or lap tops needed to process runs and generate reports.
19. Local or networked printer.
20. A comprehensive software package with these capabilities:

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- a. User interface using non-DOS technology.
 - b. Ability to interface with an automated punch. Describe requirements.
 - c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values along with the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - Increment #, Value, 11-digit specimen ID#, i.e., **1,6.22,20113650005**.
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
- a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.

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- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three references of current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

G. 17- α HYDROXYPROGESTERONE (17-OHP) - For use as a screening test to aid in the identification of Congenital Adrenal Hyperplasia (CAH) in a newborn screening population. All first specimens and second specimens from the Delaware newborn population will be screened. The 2010 testing volume for patient testing, retests, controls, standards and surveys was 33,500.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method capable of running 250 patient samples of each analyte per day, with repeat testing at the end/beginning of the plate. Capacity to run with minimal hands-on processing by one (1) Technician. Indicate specific manual processing steps that will be required

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with proposed method and hands-on time estimates.

2. Individual reagent stability and/or kit configuration sufficient to use all reagents within their open vial expiration limit, if only one 96-well plate is run per day.
3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
6. Quantitative method with ability to accurately identify **CAH** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method is FDA approved / cleared.
10. Method uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing included in bid. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type of pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate.
17. Three levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal, elevated and intermediate range of results.
18. Computer and/or lap tops needed to process runs and generate reports.
19. Local or networked printer.

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20. A comprehensive software package with these capabilities:
- a. User interface using non-DOS technology.
 - b. Ability to interface with an automated punch. Describe requirements.
 - c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values along with the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - Increment #, Value, 11-digit specimen ID#, i.e., **1,6.22,20113650006,**
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:
- a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software

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updates.

- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three references of current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

H. **IMMUNOREACTIVE TRYPsinOGEN (IRT)** - For use as a screening test to aid in the identification of Cystic fibrosis in a newborn screening population. All first specimens and only those second specimens with previous flagged results from the Delaware newborn population will be screened. The 2010 testing volume for patient testing, retests, controls, standards and surveys was 20,000.

Proposal Submitted, No Proposal Submitted

- 1. Fully/Semi-automated testing method capable of running 200 patient samples of each analyte per

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day, with repeat testing at the end/beginning of the plate. Capacity to run with minimal hands-on processing by one (1) Technician. Indicate specific manual processing steps that will be required with proposed method and hands-on time estimates.

2. Individual reagent stability and/or kit configuration sufficient to use all reagents within their open vial expiration limit, if only one 96-well plate is run per day.
3. Vendor agrees to forward-stock three (3) months supply of reagent kits in an alternate location.
4. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
5. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
6. Quantitative method with ability to accurately identify **IRT** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
7. Method free from interfering substances. Indicate statistically significant interfering factors.
8. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation (%CV's).
9. Method is FDA approved / cleared.
10. Method uses 96-well microtiter plates.
11. All laboratory equipment/instrumentation needed for testing included in bid. If same laboratory equipment is to be used for other tests, please indicate how equipment will be shared.
12. If applicable, indicate type of pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
13. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
14. A product acceptability evaluation by the DPHL NBS laboratory staff may be conducted to determine whether a bidder's product meets the bid specifications. If the results of the evaluation indicate that the bidder's product does not meet the bid specifications, this may be cause for rejection of bid.
15. Capacity to perform double the number of tests in one 7.5 hour shift.
16. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate.
17. Three levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper. Amount of each control sufficient to run 2 replicates of each per plate. Control values to cover the normal, elevated and intermediate range of results.
18. Computer and/or lap tops needed to process runs and generate reports.

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19. Local or networked printer.
20. A comprehensive software package with these capabilities:
 - a. User interface using non-DOS technology.
 - b. Ability to interface with an automated punch. Describe requirements.
 - c. Ability to generate a sample list and/or plate map.
 - d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics.
 - f. On-board reagent tracking features to include bar code entry of kit lot information
 - g. Ability to utilize bar code entry for control ranges and standard values along with the ability to manually set quality control limits for run.
 - h. Ability to store QC results over a one year period and produce customizable statistics including: Levy Jennings graphs detailing mean, +/- 2 SD, and +/- 3 SD.
 - i. Ability to import accession numbers or easily populate run with identifiers. Describe process.
 - j. Ability to store patient results over an extended period (one or more years). Ability to sort and select a range of population data and produce statistical reports, including: Mean, standard deviation and population percentiles.
 - k. Ability to export QC and patient data to an EXCEL file or inter-state program such as the Region4 MS/MS Project.
 - l. Ability to produce a comma-delimited export file compatible with current configuration of the Delaware Natus database, MSDS IV system - Increment #, 11-digit specimen ID#, Value, i.e., **1,20113040102,53.3**,
 - m. Ability to add LOINC codes to export file, to be used in future HL-7 messaging.
21. Introductory training for up to six (6) staff of DPHL, given by field application specialist and conducted at the time of installation. The introductory training must be sufficient to operate and maintain the instrument and include hands-on instruction.
22. Advanced training to be offered for two (2) Public Health Laboratory staff members to cover set-up and programming of the equipment, instrument troubleshooting, statistical calculations and advanced maintenance.
23. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
24. Warrantee for the entire system included, (instrument, computer, software, reagents) for a period of one year from the date of installation (or fifteen months from the date of shipment). The warrantee must include:

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- a. All services necessary to maintain the system for the period of the WARRANTY. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

25. Maintenance agreement for the term of the contract to include:

- a. All services necessary to maintain the system for the period of the CONTRACT. This includes all travel, parts, labor, annual preventative maintenance inspections, hardware and software updates.
- b. Telephone technical support for problem solving with available response time within 3 working hours of initial call, Monday – Friday 8:00 am – 5:00 pm EST
- c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service.
- d. On-site Technical Service response available within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

26. Delivery and Installation

- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 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, programming, and one or more successful runs.
- d. Installation will not be considered complete until the entire system is “ready to go” that is after plates are run with acceptable results, data is generated and reports are printed. This would include optimization of the application, if necessary.

27. Three references of current customers utilizing the same equipment for newborn screening DBS testing, preferably with a similar testing volume. Please include name, address, telephone number, and a contact person.

COST PROPOSAL

When determining costs, indicate each individual component and component part numbers that have been included in the total cost, including software and hardware interfaces, installation, delivery, training, warranty

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and 2-year maintenance contract as described in the Specifications. Summarize costs in following table. If more than one option is being proposed, submit separate cost proposals using tables below as Option 1, 2, etc.

SPECIFICATION Option 1		Rental Cost		Unit	Terms	Annual Cost
		Stand Alone	Multi-Test Bid			
	<i>Example</i>	\$1.50	\$1.25	<i>Per test delivered</i>	<i>Discount if E, F and G awarded</i>	<i>36 kits x 960 tests/kit = \$51,840 Discount = \$43,200</i>
A.	HOLE PUNCH					
B.	BIOTINIDASE					
C.	TOTAL GALACTOSE					
D.	GALT					
E.	TSH					
F.	T4					
G.	17-OHP					
H.	IRT					
	TOTAL COST (1)					

SPECIFICATION Option 2		Rental Cost		Unit	Terms	Annual Cost
		Stand Alone	Multiple Bids			
	<i>Example</i>	\$1.50	\$1.25	<i>Per test delivered</i>	<i>Discount if E, F and G awarded</i>	<i>36 kits x 960 tests/kit = \$51,840 Discount = \$43,200</i>
A.	HOLE PUNCH					
B.	BIOTINIDASE					
C.	TOTAL GALACTOSE					
D.	GALT					
E.	TSH					
F.	T4					
G.	17-OHP					
H.	IRT					
	TOTAL COST (2)					

FINAL ACCEPTANCE BY PUBLIC HEALTH LABORATORY

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.

II. TECHNICAL REQUIREMENTS

A. State Information Technology Requirements

The proposed solution must be fully compatible with the Department of Health and Social Services' technical environment.

The DHSS Information Technology Services for Vendors web page has links to the DHSS and DTI policies and standards.

<http://www.dhss.delaware.gov/dhss/dms/irm/vendorsvcs.html>

The DTI Systems Architecture Standard contains information confidential to the State and is not available from the internet. However, DTI has set up an email address which will automatically send a response with this document attached. The email address is sysarch@lists.state.de.us

All contractor staff working on this project will be subject to a Criminal Background Check (CBC). The contractor will be solely responsible for the cost the CBC. DHSS will review the CBC results. DHSS at their sole discretion may request that a contractor staff member be replaced if their CBC result is unsatisfactory. See Criminal Background Check Instructions below.

Contractor staff will be required to fill out DTI's Acceptable Use Policy, Biggs Data Center User Authorization Form, and the Biggs Data Center Non-Disclosure Agreement for necessary authorizations before starting work. Staff working at a secured State site will be issued a security access card by DHSS as per the State Standard.

All components of the proposed solution, including third party software and hardware, are required to adhere to the policies and standards described above, as modified from time to time during the term of the contract, including any links or documents found at the above referenced web sites.

Vendors that electronically store, transmit or process information on behalf of State are required to comply with State standards to properly secure State data. The specific requirements vary with the type of information being stored. Electronic protected health information has the strictest security requirements. Securing this data is covered generally by HIPPA requirements but State requirements are more restrictive. State technical staff will discuss these standards with the selected vendor. Vendor is instructed to provide a technical contact for this purpose.

The State Architecture Review Board (ARB) reviews proposed system architecture as it relates to State standards. System architecture diagrams are a key component of the proposed solution in terms of meeting State architecture requirements. As part of contract negotiations, the selected vendor will work with IRM to produce a final State approved detailed diagram. For vendor solutions that are not compliant with State standards, State technical staff will assist the division with an alternate approach. The diagram will also be made part of a project business case that must be in "Recommended" status prior to contract signature. The project business case is a State responsibility.

Vendor is required to submit technology costs that the State will be directly or indirectly responsible for as part of this contract. In addition to the Cost Schedule, the vendor will break down technology costs into three categories for implementation and the same three categories for out-year costs:

1. Hardware
2. Software
3. Technical staffing

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For vendor hosted websites, hosting costs can be allocated to the above categories at the discretion of the vendor.

B. Criminal Background Check Instructions

Contractor staff is required to request their own criminal history. For privacy reasons, the SBI and FBI will not mail the results to anyone except the requestor, so the results must be delivered to the DHSS Security Manager at the Biggs Data Center in a sealed envelope. Costs will be borne by the contractor.

1. Visit one of the State Police locations listed on the next page. **Note:** For the New Castle and Sussex locations, appointments may take up to six weeks to schedule.
2. Complete a SBI Personal Criminal History authorization form.
3. Present valid government-issued photo identification, such as a driver's license.
4. The State fee is \$45 and the Federal check fee is \$10, payable by cash or debit/credit card. (No personal checks).
5. The State Police will require you to fill out an FBI fingerprint card, which they will return to you after you have completed the fingerprint process.
6. Complete and sign the FBI Applicant Information Form to request the national record check. The form can be found on-line at <http://www.fbi.gov/about-us/cjis/background-checks/applicant-information-form>
7. Mail the Cover Letter and fingerprint card, along with an \$18 processing fee, payable by money order, certified check, or credit card. The FBI turnaround time is 3-6 weeks.
8. When you receive your reports at your home address, **DO NOT OPEN THE ENVELOPES**. If you break the seal on the envelopes, you will be responsible to go through the process again at your own expense.
9. Either hand-deliver or mail the **SEALED** FBI and SBI envelopes to:

DHSS Security Manager
 1901 N Dupont Highway
 Biggs Data Center
 New Castle, DE 19720

Mark envelopes as **CONFIDENTIAL**.

The results of the criminal background check will be reviewed and kept completely confidential. The total cost is \$73.

New Castle County	Kent County (Primary Facility)	Sussex County
<p style="text-align: center;">State Police Troop 2</p> <p style="text-align: center;">100 LaGrange Ave Newark, DE 19702 (Between Rts. 72 and 896 on Rt. 40)</p> <p style="text-align: center;">** By appointment only To schedule an appointment: Phone: 302-739-2528 or Toll Free 1-800-464-4357</p>	<p style="text-align: center;">State Bureau of Identification</p> <p style="text-align: center;">655 Bay Road Blue Hen Mall and Corporate Center Suite 1B Dover, DE 19903 Customer Service: 302-739-5871</p> <p style="text-align: center;">** Walk-ins accepted Hours of Operation Monday 9AM – 7PM Tuesday – Friday 9AM – 3PM</p>	<p style="text-align: center;">State Police Troop 4</p> <p style="text-align: center;">S DuPont Hwy & Shortly Rd Georgetown, DE 19947 (Across from DelDOT & State Service Center)</p> <p style="text-align: center;">** By appointment only (every other Wednesday) To schedule an appointment: Phone: 302-739-2528 or Toll Free 1-800-464-4357</p>

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BID REPLY SECTION

CONTRACT NO. HSS 12002-TEST SYSTEMS

Newborn Screening Chemistry Testing Systems

Please fill out the attached forms fully and completely and return with your bid in a sealed envelope clearly displaying the **bid number** on the outside envelope and send to Department of Health and Social Services / Division of Management Services by January 25, 2012 at 11:00 a.m. (EST) at which time bids will be opened. **One (1) signed original and five (5) copies of your bid response must be submitted.**

Bids shall be submitted to:

**STATE OF DELAWARE
DELAWARE HEALTH AND SOCIAL SERVICES
DIVISION OF MANAGEMENT SERVICES
PROCUREMENT BRANCH- MAIN BLDG., ROOM 262
HERMAN M. HOLLOWAY SR. HEALTH AND SOCIAL SERVICES CAMPUS
1901 N. DUPONT HIGHWAY
NEW CASTLE, DELAWARE 19720**

PUBLIC BID OPENINGS

The public bid opening insures the citizens of Delaware that contracts are being bid fairly on a competitive basis and comply with Delaware procurement laws. The agency conducting the opening is required by law to publicly open the bids at the time and place specified and the contract shall be awarded within thirty (30) days thereafter. The main purpose of the bid opening is to reveal the name(s) of the bidders(s), not to serve as a forum for determining the apparent low bidders. Only the bidder's names will be read at the bid opening. The disclosure of any additional information will be dependent on a fully executed contract.

NOTE: ONLY THE BIDDER'S NAME WILL BE READ AT THE BID OPENING

STATE OF DELAWARE
Department of Health and Social Services
Division of Management Services

CONTRACT NO.: HSS 12002-TEST SYSTEMS

BID QUOTATION

Insert Bid Quotation

TERMS - _____

CONTRACT TOTAL VALUE \$ _____

(Delivery, installation, training, warranty and 2-year maintenance agreement must be included in total cost)

DELIVERY – F.O.B. Destination

COMPANY

Ship Stock _____ days ARO

Ship Non-Stock _____ days ARO

INSTALLATION

_____ Days to install

DATE _____

STATE OF DELAWARE
Department of Health and Social Services
Division of Management Services

Herman M. Holloway Sr. Health and Social Services Campus
Procurement Branch – Main Bldg., Room 254
1901 N. DuPont Highway
New Castle, Delaware 19720

NO BID REPLY FORM

BID # HSS 12002-TEST SYSTEMS

BID TITLE: NBS Chemistry Testing Systems

To assist us in obtaining good competition on our Request for Bids, we ask that each firm that has received an invitation, but does not wish to bid, state their reason(s) below and return in a clearly marked envelope displaying the contract number. This information will not preclude receipt of future invitations unless you request removal from the Bidder's List by so indicating below, or do not return this form or bona fide bid.

Unfortunately, we must offer a "No Bid" at this time because:

_____ 1. We do not wish to participate in the bid process.

_____ 2. We do not wish to bid under the terms and conditions of the Request for Bid document. Our

_____ 3. We do not feel we can be competitive.

_____ 4. We cannot submit a Bid because of the marketing or franchising policies of the manufacturing company.

_____ 5. We do not wish to sell to the State. Our objections are: _____

_____ 6. We do not sell the items/services on which Bids are requested.

_____ 7. Other: _____

FIRM NAME

SIGNATURE

_____ We wish to remain on the Bidder's List **for these goods or services.**

_____ We wish to be deleted from the Bidder's List **for these goods or services.**

CONTRACT NO.: HSS 12002-TEST SYSTEMS
TITLE: NBS Chemistry Testing Systems
OPENING DATE: January 25, 2012

NON-COLLUSION STATEMENT

This is to certify that the undersigned bidder has neither directly nor indirectly, entered into any agreement, participated in any collusion or otherwise taken any action in restraint of free competitive bidding in connection with this bid submitted this date to Delaware Health and Social Services, Division of Management Services.

It is agreed by the undersigned bidder that the signed delivery of this bid represents the bidder's acceptance of the terms and conditions of this Invitation to Bid including all specifications and special provisions.

NOTE: Signature of the authorized representative **MUST** be of an individual who legally may enter his/her organization into a formal contract with the State of Delaware, Delaware Health and Social Services, Division of Management Services.

COMPANY NAME: _____ Check one)

<input type="checkbox"/>	Corporation
<input type="checkbox"/>	Partnership
<input type="checkbox"/>	Individual

NAME OF AUTHORIZED REPRESENTATIVE _____
(Please type or print)

SIGNATURE _____ TITLE _____

COMPANY ADDRESS _____

PHONE NUMBER _____ FAX NUMBER _____

EMAIL ADDRESS _____

FEDERAL E.I. NUMBER _____ STATE OF DELAWARE LICENSE NUMBER _____

	(circle one)		(circle one)		(circle one)				
COMPANY CLASSIFICATIONS: CERT. NO. _____	Women Business Enterprise (WBE)	Yes	No	Minority Business Enterprise (MBE)	Yes	No	Disadvantaged Business Enterprise (DBE)	Yes	No

[The above table is for information and statistical use only.]

PURCHASE ORDERS SHOULD BE SENT TO: _____
(COMPANY NAME)

ADDRESS _____

CONTACT _____

PHONE NUMBER _____ FAX NUMBER _____

EMAIL ADDRESS _____

AFFIRMATION: Within the past five years, has your firm, any affiliate, any predecessor company or entity, owner, Director, officer, partner or proprietor been the subject of a Federal, State, Local government suspension or debarment?

YES _____ NO _____ if yes, please explain _____

THIS PAGE SHALL BE SIGNED, NOTARIZED AND RETURNED FOR YOUR BID TO BE CONSIDERED

SWORN TO AND SUBSCRIBED BEFORE ME this _____ day of _____, 20 _____

Notary Public _____ My commission expires _____

City of _____ County of _____ State of _____



**DELAWARE HEALTH AND SOCIAL SERVICES
INVITATION TO BID**

BIDDERS SIGNATURE FORM

BID #/NAME: HSS 12002-TEST SYSTEMS / NBS Chemistry Testing Systems

NAME OF BIDDER: _____

SIGNATURE OF AUTHORIZED PERSON: _____

TYPE IN NAME OF AUTHORIZED PERSON: _____

TITLE OF AUTHORIZED PERSON: _____

STREET NAME AND NUMBER: _____

CITY, STATE, & ZIP CODE: _____

CONTACT PERSON: _____

TELEPHONE NUMBER: _____

FAX NUMBER: _____

CONTACT E-MAIL: _____

DATE: _____

BIDDER'S FEDERAL EMPLOYERS IDENTIFICATION NUMBER: _____

THE FOLLOWING MUST BE COMPLETED BY THE VENDOR:

AS CONSIDERATION FOR THE AWARD AND EXECUTION BY THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES OF THIS CONTRACT, THE (COMPANY NAME) _____
HEREBY GRANTS, CONVEYS, SELLS, ASSIGNS, AND TRANSFERS TO THE STATE OF DELAWARE ALL OF ITS RIGHTS, TITLE AND INTEREST IN AND TO ALL KNOWN OR UNKNOWN CAUSES OF ACTION IT PRESENTLY HAS OR MAY NOW HEREAFTER ACQUIRE UNDER THE ANTITRUST LAWS OF THE UNITED STATES AND THE STATE OF DELAWARE, RELATING THE PARTICULAR GOODS OR SERVICES PURCHASED OR ACQUIRED BY THE DELAWARE HEALTH AND SOCIAL SERVICES DEPARTMENT, PURSUANT TO THIS CONTRACT.



VENDOR CERTIFICATION SHEET

As the official representative for the contractor, I certify on behalf of the company that we are and will agree to the following:

- A. We are an approved vendor in the service(s) and/or product(s) being procured.
- B. We agree to fulfill all specified requirements that are awarded to us at the prices we bid on for the duration of the bid. We will be responsible for reviewing our bid prices very carefully to make sure we are in compliance of same.
- C. We agree that we are accurately representing the type of business and affiliations as specified in the bid.
- D. We agree to fulfill all contracted items as specified in our bid and agree not to substitute an item(s) without the permission of Delaware Health and Social Services.
- E. We agree to secure a Delaware business license.

Date

Signature of Bidder (Representative)

Name of Company



State of Delaware

Office of Minority and Women Business Enterprise Certification Application

The most recent application can be downloaded from the following site:

http://gss.omb.delaware.gov/omwbe/docs/certapp_022510.pdf



Complete application and mail, email or fax to:
Office of Minority and Women Business Enterprise (OMWBE)
100 Enterprise Place, Suite 4
Dover, DE 19904-8202
Telephone: (302) 857-4554 Fax: (302) 677-7086
E-mail: deomwbe@state.de.us
Web site: <http://gss.omb.delaware.gov/omwbe/index.shtml>