

STATE OF DELAWARE



DELAWARE HEALTH
AND SOCIAL SERVICES

Division of Management Services
1901 N. DuPont Highway
New Castle, DE 19720

State of Delaware

NEWBORN SCREENING CHEMISTRY TESTING SYSTEMS

For Biotinidase, Total Galactose, GALT, TSH, T4, 17-OHP, IRT

Request for Proposal HSS 16 030

For

Division of Public Health,

November 2, 2016

- *Deadline to Respond* -

December 15, 2016

11:00 AM (Local Time)

STATE OF DELAWARE
Delaware Health and Social Services, Division of Public Health

**REQUEST FOR PROPOSALS
FOR
NEWBORN SCREENING CHEMISTRY TESTING SYSTEMS
ISSUED BY DELAWARE HEALTH AND SOCIAL SERVICES,
DIVISION OF PUBLIC HEALTH,**

HSS 16 030

ALL VENDORS:

The enclosed packet contains a "REQUEST FOR PROPOSAL" for Newborn Screening Chemistry Testing Systems. The proposal consists of the following:

- I. Introduction
- II. Scope of Work
- III. Format For Proposal
- IV. Proposal Evaluation Procedures
- V. No Pre-Bid Meeting
- VI. Definitions and General Provisions
- VII. Proposal Reply Section
 - a. Attachment 1 – No Proposal Reply Form
 - b. Attachment 2 – Non-Collusion Statement
 - c. Attachment 3 – Exceptions
 - d. Attachment 4 – Company Profile and Capabilities
 - e. Attachment 5 – Confidentiality and Proprietary Information
 - f. Attachment 6 – Business References
 - g. Attachment 7 – Subcontractor Information Form
 - h. Attachment 8 – Monthly Usage Report
 - i. Attachment 9 – Subcontracting (2nd tier spend) Report
 - j. Attachment 10 – Office of Supplier Diversity Certification Application
 - k. Attachment 11 – Proposal Reply Requirements
 - l. Appendix A – Scope of Work details
 - m. Appendix B – Pricing Form(s) and Instructions (if applicable)

In order for your proposal to be considered, the Proposal Reply Section shall be executed completely and correctly and returned in a sealed envelope **clearly displaying the Request for Proposal number HSS 16 030 and vendor name** by **December 15, 2016 at 11:00 AM** (Local Time) to be considered.

Proposals must be mailed to:

**Kieran Mohammed
Department of Health and Social Services
Procurement Branch
Main Admin Bldg., Sullivan Street
2nd floor –room #257
1901 N. DuPont Hwy
Herman Holloway Campus
New Castle, DE 19720**

Please review and follow the information and instructions contained in the General Provisions and this Request for Proposal (RFP). Should you need additional information, please call Kieran Mohammed at 302-255-9291 or email Kieran.Mohammed@state.de.us.

I. INTRODUCTION

A. PURPOSE

The purpose of this Request for Proposal is to obtain sealed proposals for multiple chemistry testing methods on Delaware newborn using dried blood spots (DBS) as the sample. The disorders we will be identifying are Biotinidase Deficiency, Galactosemia (Classical Galactosemia, Galactokinase Deficiency & Epimerase Deficiency), Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, and Cystic fibrosis.

Delaware Public Health Laboratory (DPHL) is seeking a vendor or vendors to supply the necessary reagent test kits, equipment, supplies, etc. to provide all, or a portion of this testing for the State of Delaware.

It is the goal of this Request for Proposal to identify one or more vendor and execute contract(s) to provide this testing in a manner that most closely meets the requirements of the Delaware Public Health Laboratory as described herein.

1. COMPETITIVE SEALED PROPOSAL

It has been determined by the Division of Public Health, pursuant to **Delaware Code Title 29, Chapter 6924 (a)** that this solicitation be offered as a request for competitive sealed proposals because the use of competitive sealed bidding is not practical and/or not in the best interest of the State. The use of competitive sealed proposals is necessary to:

- Use a contract other than a fixed-price type; or
- Conduct oral or written discussions with vendors concerning technical and price aspects of their proposals; or
- Afford vendors an opportunity to revise their proposals through best and final offers; or
- Compare the different price, quality and contractual factors of the proposals submitted; or
- Award a contract in which price is not the determining factor.

2. CONTRACT REQUIREMENTS

This contract will be issued to vendors who can provide the screening tests, described in Appendix A, for the purposes of screening newborn babies for metabolic disorders.

3. AGENCY USE CONTRACT

Pursuant to 29 Del. C. [§6904](#)(e) respectively, if no state contract exists for a certain good or service, covered agencies may procure that certain good or service under another agency's contract so long as the arrangement is agreeable to all parties. Agencies, other than covered agencies, may also procure such goods or services under another agency's contract when the arrangement is agreeable to all parties.

4. MULTIPLE SOURCE AWARD

The Agency reserves the right to award this contract to more than one vendor pursuant to 29 Del.C. [§6926](#). The basis for such selection shall be because of the complexity and variety of these tests requested, there may not be one vendor able to supply every test.

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5. POTENTIAL CONTRACT OVERLAP

Vendors shall be advised that the State, at its sole discretion, shall retain the right to solicit for goods and/or services as required by its agencies and as it serves the best interest of the State. As needs are identified, there may exist instances where contract deliverables, and/or goods or services to be solicited and subsequently awarded, overlap previous awards. The State reserves the right to reject any or all bids in whole or in part, to make partial awards, to award to multiple vendors during the same period, to award by types, on a zone-by-zone basis or on an item-by-item or lump sum basis item by item, or lump sum total, whichever may be most advantageous to the State of Delaware.

6. CONTRACT PERIOD

Each Vendor's contract shall be valid for a two (2) year period. Each contract may be renewed for three (3) one (1) year periods through negotiation between the Vendor and Division of Public Health. Negotiation may be initiated no later than ninety (90) days prior to the termination of the current agreement.

The State reserves the right to extend this contract on a month-to-month basis for a period of up to three months after the term of the full contract has been completed.

B. KEY RFP DATES/MILESTONES

The following dates and milestones apply to this RFP and subsequent contract award. Vendors are advised that these dates and milestones are not absolute and may change due to unplanned events during the bid proposal and award process.

Activity	Due Date
RFP Availability to Vendors	November 2, 2016
Pre-bid Meeting	No pre-bid meeting
Written Questions Due No Later Than (NLT)	November 15, 2016
Written Answers Due/Posted to Website NLT	November 23, 2016
Proposals Due NLT	December 15, 2016 11:00am
Proposal Evaluation completed	January 6, 2017
Vendor Best & Final Discussions, as required	January 20, 2017
Contract Award	Will occur within 90 days of bid opening.
Project Start Date (Estimated contract start date)	March 1, 2017

C. INQUIRIES & QUESTIONS

We welcome your interest in working with us, and we will be pleased to answer any questions you may have in formulating your response to this Request for Proposal.

All questions with regard to the interpretation of this solicitation, drawings, or specifications, or any other aspect of this RFP must be received in writing by November 15, 2016. All questions will be answered in writing by November 23, 2016 and posted on <http://bids.delaware.gov/> website. All questions must make specific reference to the section(s) and page numbers from this RFP where applicable. Oral explanations or instructions will not be binding.

D. RFP DESIGNATED CONTACT

All requests, questions, or other communications about this RFP shall be made in writing to the State of Delaware. Address all communications to the person listed below; communications made to other State of Delaware personnel or attempting to ask questions by phone or in person will not be allowed or recognized as valid and may disqualify the vendor. Vendors should rely only on written statements issued by the RFP designated contact.

Patricia Scott
NBS Laboratory Manager
Delaware Public Health Laboratory
30 Sunnyside Road
Smyrna, DE 19977
302-223-1520 phone
302-223-1527 fax
Pat.Scott@state.de.us

To ensure that written requests are received and answered in a timely manner, electronic mail (e-mail) correspondence is acceptable, but other forms of delivery, such as postal and courier services can also be used.

E. CONTACT WITH STATE EMPLOYEE

Direct contact with State of Delaware employees other than the State of Delaware Designated Contact regarding this RFP is expressly prohibited without prior consent. Vendors directly contacting State of Delaware employees risk elimination of their proposal from further consideration. Exceptions exist only for organizations currently doing business in the State who require contact in the normal course of doing that business.

II. SCOPE OF WORK

A. OVERVIEW

The Vendor(s) shall provide all equipment, materials and labor to supplement the State of Delaware's need for the seven (7) test described herein. The contract(s) will require the Vendor(s) to cooperate with the ordering agency to insure the State receives the most current state-of-the-art material and/or services.

B. BACKGROUND

Delaware Public Health Laboratory has been performing newborn screening for the State of Delaware since July 1999, when they brought testing back into the state from the contract laboratory (Northeast Regional @ Oregon). Over those 17 years, the panel has grown to meet the needs and recommendations of the Delaware Newborn Screening Advisory Committee and the Director of Public Health. For all of those years, Delaware has been a 'two specimen state', meaning that we routinely request and receive two specimens from each baby.

The list of disorders on a state's Newborn Screening (NBS) panel is influenced by the Recommended Universal Screening Panel (RUSP), which comes from the U.S. Secretary of Health & Human Services based on the recommendations of the Secretary's Advisory Committee on Heritable Disorders in

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Newborns and Children (SACHDNC). That list only continues to grow. As pressure continues to be placed on laboratories to perform more disorders, it is important for us to be able to streamline the workflow at Delaware Public Health Laboratory, allowing for more work product with less staff.

Timeliness has also been in the national spotlight recently. Not only will we need to do more with less, we will need to do it faster. Methods with flexibility, walk-away functionality, and overnight testing options are therefore desirable.

C. STATEMENT OF NEEDS

The Delaware Public Health Laboratory requires multiple chemistry testing methods on Delaware newborn using dried blood spots (DBS) as the sample. Contracts for Biotinidase, Total Galactose, Galactose-1-Phosphate Uridyltransferase (GALT), Thyroid Stimulating Hormone (TSH), Thyroxin (T4), 17- α -Hydroxyprogesterone (17OHP) and Immunoreactive Trypsin (IRT) neonatal test kits are needed at this time.

D. DETAILED REQUIREMENTS

The technical requirements of this RFP for **Newborn Screening Chemistry Testing System(s) for (A) Biotinidase, (B) Total Galactose, (C) GALT, (D) TSH, (E) T4, (F) 17-OHP & (G) IRT** are stated in Appendix A.

Listed in Appendix A 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 contract with selected vendor(s) to supply the necessary reagent test kits, equipment, supplies, etc. to provide all, or a portion of this testing for the State of Delaware.

Vendors must provide pricing for the items listed in the Pricing Form, Appendix B.

III. FORMAT FOR PROPOSAL

A. INTRODUCTION

This section prescribes the mandatory format for the presentation of a proposal in response to this RFP. Each Vendor must provide every component listed in the order shown in this RFP, using the format prescribed for each component. A proposal may be rejected if it is incomplete or conditional.

B. PROPOSAL RESPONSE

The Request for Proposal may contain pre-printed forms for use by the vendor in submitting its proposal. The forms required by this solicitation shall be considered mandatory, prevailing documents.

When preprinted forms are used, 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, as applicable.

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The Vendor's proposal shall be written in ink or typewritten on the form provided, and any corrections or erasures MUST be initialed by vendor's representative completing the bid submission.

If items are listed with a zero quantity, Vendor 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.

Vendors' proposal must respond to each and every requirement outlined in the RFP criteria in order to be considered responsive. Proposals must be clear and concise.

C. NON-CONFORMING PROPOSALS

Non-conforming proposals will not be considered. Non-conforming proposals are defined as those that do not meet the requirements of this RFP. The determination of whether an RFP requirement is substantive or a mere formality shall reside solely within the State of Delaware.

D. CONCISE PROPOSALS

The State of Delaware discourages overly lengthy and costly proposals. It is the desire that proposals be prepared in a straightforward and concise manner. Unnecessarily elaborate brochures or other promotional materials beyond those sufficient to present a complete and effective proposal are not desired. The State of Delaware's interest is in the quality and responsiveness of the proposal.

E. COVER LETTER

Each proposal will have a cover letter on the letterhead of the company or organization submitting the proposal. The cover letter must briefly summarize the Vendor's ability to provide the services specified in the RFP. The cover letter shall be signed by a representative who has the legal capacity to enter the organization into a formal contract with Division of Public Health.

F. TABLE OF CONTENTS

Each proposal must include a Table of Contents with page numbers for each of the required components of the proposal.

G. DESCRIPTION OF SERVICES AND QUALIFICATIONS

Each proposal must contain a detailed description of how the Vendor will provide the goods and services outlined in this RFP. This part of the proposal may also include descriptions of any enhancements or additional services or qualifications the Vendor will provide that are not mentioned in this RFP.

H. DISCOUNT

Vendors are invited to offer in their proposal value added discounts (i.e. speed to pay discounts for specific payment terms). Cash or separate discounts should be computed and incorporated into unit bid price(s).

I. SAMPLES OR BROCHURES

Samples or brochures may be required 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.

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J. ACKNOWLEDGEMENT OF UNDERSTANDING OF TERMS

By submitting a bid, each Vendor shall be deemed to acknowledge that it has carefully read all sections of this RFP, including all forms, schedules and exhibits hereto, and has fully informed itself as to all existing conditions and limitations.

K. BID BOND REQUIREMENT

The Bid Bond requirement has been waived.

L. PERFORMANCE BOND REQUIREMENT

The Performance Bond requirement has been waived.

M. NUMBER OF COPIES WITH MAILING OF PROPOSAL

To be considered, all proposals must be submitted in writing and respond to the items outlined in this RFP. The State reserves the right to reject any non-responsive or non-conforming proposals. Each proposal must be submitted with two (2) paper copies and five (5) electronic copies on CD or DVD media disk, or USB memory stick. One of the copies shall be marked "Master Copy" and will contain original signatures in all locations requiring a vendor signature. The remaining copies do not require original signatures. CD or DVD media disk, or USB memory stick must also contain the completed Appendix B Pricing Form.

All properly sealed and marked proposals are to be sent to the State of Delaware and received **no later than 11:00 AM (Local Time) on December 15, 2016**. The Proposals may be delivered by Express Delivery (e.g., FedEx, UPS, etc.), US Mail, or by hand to:

**Kieran Mohammed
Department of Health and Social Services
Procurement Branch
Main Admin Bldg., Sullivan Street
2nd floor –room #257
1901 N. DuPont Hwy
Herman Holloway Campus
New Castle, DE 19720**

Vendors are directed to clearly **print "BID ENCLOSED" and the RFP number "HSS 16 030"** on the outside of the bid submission package.

Any proposal submitted by US Mail shall be sent by either certified or registered mail. Any proposal received after the date and time deadline referenced above shall not be considered and shall be returned unopened. The proposing vendor bears the risk of delays in delivery. The contents of any proposal shall not be disclosed as to be made available to competing entities during the negotiation process.

Upon receipt of vendor proposals, each vendor shall be presumed to be thoroughly familiar with all specifications and requirements of this RFP. The failure or omission to examine any form, instrument or document shall in no way relieve vendors from any obligation in respect to this RFP.

The State reserves the right to award the proposed contract to multiple Vendors if the Head of the Agency determines that such an award is in the best interest of the State.

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N. PROPOSAL EXPIRATION DATE

Prices quoted in the proposal shall remain fixed and binding on the bidder at least through December 14, 2017. Delaware reserves the right to ask for an extension of time if needed.

O. WITHDRAWAL OF PROPOSALS

A Vendor 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.

P. PROPOSAL MODIFICATIONS

Any changes, amendments or modifications to a submitted proposal requires that the original proposal be withdrawn, **prior** to the time set for the submission of the proposal, and a new proposal submitted **prior** to the deadline for submission of proposals.

Changes, amendments or modifications to proposals shall not be accepted or considered after the hour and date specified as the deadline for submission of proposals.

Q. LATE PROPOSALS

Proposals received after the specified date and time will not be accepted or considered. To guard against premature opening, sealed proposals shall be submitted, plainly marked with the proposal title, vendor name, and time and date of the proposal opening. Evaluation of the proposals is expected to begin shortly after the proposal due date. To document compliance with the deadline, the proposal will be date and time stamped upon receipt.

R. ADDENDA TO THE REQUEST FOR PROPOSAL (RFP)

If it becomes necessary to revise any part of this RFP, revisions will be posted at <http://bids.delaware.gov/> . By submitting an offer to the State, vendors have acknowledged receipt, understanding and commitment to comply with all materials, revisions, and addenda related to the Request for Proposal.

S. INCURRED EXPENSES

The State will not be responsible for any expenses incurred by the vendor in preparing and submitting a proposal.

T. ECONOMY OF PREPARATION

Proposals should be prepared simply and economically, providing a straight-forward, concise description of the Vendor's offer to meet the requirements of the RFP.

U. DISCREPANCIES AND OMISSIONS

Vendor is fully responsible for the completeness and accuracy of their proposal, and for examining this RFP and all addenda. Failure to do so will be at the sole risk of vendor. Should vendor find discrepancies, omissions, unclear or ambiguous intent or meaning, or should any questions arise concerning this RFP, vendor shall notify the State of Delaware's Designated Contact, in writing, of such findings at least ten (10) days before the proposal opening. This will allow issuance of any necessary

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addenda. It will also help prevent the opening of a defective proposal and exposure of vendor's proposal upon which award could not be made. All unresolved issues should be addressed in the proposal.

Protests based on any omission or error, or on the content of the solicitation, will be disallowed if these faults have not been brought to the attention of the Designated Contact, in writing, no later than ten (10) calendar days prior to the time set for opening of the proposals.

V. EXCEPTIONS

Bidders may elect to take **minor exception** to the terms and conditions of this RFP by completing Attachment 3. The State shall evaluate each exception according to the intent of the terms and conditions contained herein, but the State 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.

Exceptions must be submitted utilizing Attachment 3 to be considered. Exceptions listed elsewhere in the Vendor's proposal will not be considered. The State maintains sole discretion to reject any vendor exceptions that are submitted.

W. BUSINESS REFERENCES

Business references are to be provided via Attachment 6.

X. DOCUMENT(S) EXECUTION

All vendors must complete and submit with its proposal the non-collusion statement that is enclosed with this Request for Proposal labeled as Attachment 2. The awarded vendor(s) will be presented with the contract form for signature and seal, if appropriate. Both of these documents shall be executed by a representative who has the legal capacity to enter the organization into a formal contract with Division of Public Health.

The State of Delaware requires completion of the [Delaware Substitute Form W-9](#) to make payments to vendors. Successful completion of this form enables the creation of a State of Delaware vendor record. The Taxpayer ID (SSN or EIN) and Applicant (vendor) name are submitted to the Internal Revenue Service for "matching." If the Taxpayer ID and name do not match, the vendor record cannot be approved.

It is the applicant's responsibility to select the appropriate 1099 Withholding Type and Class. If incorporated, a business is not subject to 1099 reporting unless the business is providing legal or medical services.

Any questions about completing this form or specific comments about a form that you have submitted, please contact vendor services by phone at 302-672-5000.

Y. SUBCONTRACTS

Subcontracting is not permitted under this RFP and contract.

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Z. CONFIDENTIALITY

Subject to applicable law or the order of a court of competent jurisdiction to the contrary, all documents submitted as part of the vendor's proposal will be treated as confidential during the evaluation process. As such, vendor proposals will not be available for review by anyone other than the State of Delaware/Proposal Evaluation Team or its designated agents. There shall be no disclosure of any vendor's information to a competing vendor prior to award of the contract unless such disclosure is required by law or by order of a court of competent jurisdiction.

The State of Delaware and its constituent agencies are required to comply with the State of Delaware Freedom of Information Act, [29 Del. C. § 10001, et seq.](#) ("FOIA"). FOIA requires that the State of Delaware's records are public records (unless otherwise declared by FOIA or other law to be exempt from disclosure) and are subject to inspection and copying by any person upon a written request. Once a proposal is received by the State of Delaware and a decision on contract award is made, the content of selected and non-selected vendor proposals will likely become subject to FOIA's public disclosure obligations.

The State of Delaware wishes to create a business-friendly environment and procurement process. As such, the State respects the vendor community's desire to protect its intellectual property, trade secrets, and confidential business information (collectively referred to herein as "confidential business information"). Proposals must contain sufficient information to be evaluated. If a vendor feels that they cannot submit their proposal without including confidential business information, they must adhere to the following procedure or their proposal may be deemed unresponsive, may not be recommended for selection, and any applicable protection for the vendor's confidential business information may be lost.

In order to allow the State to assess its ability to protect a vendor's confidential business information, vendors will be permitted to designate appropriate portions of their proposal as confidential business information.

Vendor(s) may submit portions of a proposal considered to be confidential business information in a separate, sealed envelope labeled "Confidential Business Information" and include the specific RFP number. The envelope must contain a letter from the Vendor's legal counsel describing the documents in the envelope, representing in good faith that the information in each document is not "public record" as defined by 29 Del. C. § 10002, and briefly stating the reasons that each document meets the said definitions.

Upon receipt of a proposal accompanied by such a separate, sealed envelope, the State of Delaware will open the envelope to determine whether the procedure described above has been followed. A vendor's allegation as to its confidential business information shall not be binding on the State. The State shall independently determine the validity of any vendor designation as set forth in this section. Any vendor submitting a proposal or using the procedures discussed herein expressly accepts the State's absolute right and duty to independently assess the legal and factual validity of any information designated as confidential business information. Accordingly, Vendor(s) assume the risk that confidential business information included within a proposal may enter the public domain.

AA. PRICE NOT CONFIDENTIAL

Vendors shall be advised that as a publically bid contract, no Vendor shall retain the right to declare their pricing confidential.

BB. ATTACHMENTS

- Attachment 1 – No Proposal Reply Form
- Attachment 2 – Non-Collusion Statement
- Attachment 3 – Exceptions
- Attachment 4 – Confidentiality and Proprietary Information
- Attachment 5 – Business References
- Attachment 6 – Subcontractor Information Form
- Attachment 7 – Monthly Usage Report
- Attachment 8 – Subcontracting (2nd Tier Spend) Report
- Attachment 9 – Office of Supplier Diversity Certification Application
- Attachment 10 – Proposal Reply Requirements
- Appendix A – Scope of Work details
- Appendix B – Pricing Form(s) and Instructions (if applicable)

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IV. PROPOSAL EVALUATION PROCEDURES

A. GENERAL ADMINISTRATION

1. STATE'S RIGHT TO REJECT PROPOSALS

Division of Public Health reserves the right to reject any or all proposals in whole or in part, to make multiple awards, partial awards, award by types, item by item, or lump sum total, whichever is determined to be the most advantageous to the State of Delaware. Vendors submitting proposals may be afforded an opportunity for discussion. Vendors may be requested to provide a best and final offer during the negotiation process. Negotiations may be conducted with responsible Vendors who submit proposals found to be reasonably likely to be selected for award. The contents of any proposal shall not be disclosed so as to be available to competing vendors during the negotiation process.

2. STATE'S RIGHT TO CANCEL SOLICITATION

The State of Delaware reserves the right to cancel this solicitation at any time during the procurement process, for any reason or for no reason. The State of Delaware makes no commitments expressed or implied, that this process will result in a business transaction with any vendor.

This RFP does not constitute an offer by the State of Delaware. Vendor's participation in this process may result in the State of Delaware selecting your organization to engage in further discussions and negotiations toward execution of a contract. The commencement of such negotiations does not, however, signify a commitment by the State of Delaware to execute a contract nor to continue negotiations. The State of Delaware may terminate negotiations at any time and for any reason, or for no reason.

3. FORMAL CONTRACT AND/OR PURCHASE ORDER

No employee of the Contractor(s) is to begin any work prior to receipt of a State of Delaware Purchase Order signed by authorized representatives of the agency requesting service, properly processed through the State of Delaware Accounting Office. A purchase order, telephone call, email, fax, or State credit card shall serve as the authorization to proceed with work in accordance with the bid specifications and the special instructions, once it is received by the Contractor(s).

4. DELIVERY OF PROPOSALS

Proposals shall be delivered in sealed envelopes, and shall bear on the outside the name and address of the Vendor as well as the designation of the RFP. Proposals forwarded by U.S. Mail shall be sent first class to the address stated in this RFP. Proposals forwarded by delivery service other than the U.S. Mail or hand delivered must be delivered to the applicable addresses also stated in this RFP. All bids must clearly display the bid number **HSS 16 030** on the envelope.

**Kieran Mohammed
Department of Health and Social Services
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All proposals will be accepted at the time and place set in the RFP. Vendor bears the risk of delays in delivery. Proposals received after the time set for public opening will be returned unopened.

5. DISQUALIFICATION OF VENDORS

Any one or more of the following causes may be considered as sufficient for the disqualification of a vendor and the rejection of its proposal or proposals:

- a. More than one proposal for the same contract from an individual, firm, or corporation under the same or different names.
- b. Evidence of collusion among vendors.
- c. Unsatisfactory performance record as evidenced by past experience with the State of Delaware or on a State of Delaware central contract.
- d. Any suspension or debarment of the parent company, subsidiary or individual involved with the vendor by federal, any state or any local governments within the last five (5) years.
- e. If the unit prices are obviously unbalanced either in excess or below reasonable cost analysis values.
- f. 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.
- g. Non-attendance of mandatory pre-bid meetings shall be cause of disqualification.

6. 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.

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.

B. RESPONSIVENESS AND RESPONSIBILITY OF VENDOR

Division of Public Health shall award this contract to the most responsible and responsive vendor who best meets the terms and conditions of the proposal.

1. Rejection of individual proposals. -- A proposal may be rejected for 1 or more of the following reasons:
 - a. The person responding to the solicitation is determined to be nonresponsive or non-responsible;
 - b. It is unacceptable;

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- c. The proposed price is unreasonable; or
 - d. It is otherwise not advantageous to the State.
2. Vendors whose proposals are rejected as non-responsive shall be notified in writing about the rejection.
3. Responsibility of vendors. -- It shall be determined whether a vendor is responsible before awarding a contract. Factors to be considered in determining if a vendor is responsible include:
 - a. The vendor's financial, physical, personnel or other resources, including subcontracts;
 - b. The vendor's record of performance and integrity;
 - c. Any record regarding any suspension or debarment;
 - d. Whether the vendor is qualified legally to contract with the State;
 - e. Whether the vendor supplied all necessary information concerning its responsibility.
4. If a vendor is determined to be non-responsive, the vendor shall be informed in writing.
5. The State reserves the right to waive minor irregularities, or request additional information before determining the responsiveness of the Vendor. All Vendors will be afforded the same or similar opportunities, as necessary, and will be treated with equal regard before such determinations are finalized.

C. PROPOSAL EVALUATION COMMITTEE

The Proposal Evaluation Committee ("Committee") is comprised of representatives of the State of Delaware.

The Committee reserves the right to:

- Select for contract or for negotiations a proposal other than that with lowest costs.
- Reject any and all proposals or portions of proposals received in response to this RFP or to make no award or issue a new RFP.
- Waive or modify any information, irregularity, or inconsistency in proposals received.
- Request modification to proposals from any or all vendors during the contract review and negotiation.
- Negotiate any aspect of the proposal with any vendor and negotiate with more than one vendor at the same time.
- Select more than one vendor pursuant to 29 Del. C. §6926.

Division of Public Health 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.

D. REQUIREMENTS OF THE VENDOR

The purpose of this section is to assist the Proposal Evaluation Committee to determine the ability of the organization to provide the materials and services described in the application. The proposal response should contain at a minimum the following information:

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- Responses by the vendor should INDIVIDUALLY and SPECIFICALLY address each specification listed in the bid for each testing system bids are submitted for. Vendors should include information on 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 options within the bid, i.e. options, 1, 2, 3.
- Bidders are asked to price out each of the specifications A through G individually. If equipment is to be shared with other testing methods, then cost benefits of multiple tests should be indicated separately.
- Bidders are asked to 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. Please include a listing of any additional materials/supplies/reagents/equipment required to perform the assay, but not included in the bid response.
- The specifications listed in Appendix A are the desired requirements based on the needs of the Division of Public Health. If the proposed system is unable to meet an item described in the specification, note “Unable to Meet Specification” and include the reason why. Incomplete or omitted responses for any item (1-28) within the specifications may be considered grounds for rejection of a bid.
- Division of Public Health reserves the right to choose separate vendors for each area of SPECIFICATION A through G, or combine vendors to best meet the needs of the Newborn Screening program.

E. CRITERIA AND SCORING

EVALUATION CRITERIA		PERCENTAGE	POINTS
1.	Qualifications of Vendor a) Past experience in successful implementation of method(s) in a newborn screening laboratory b) Resource/Support availability (supply line, sales reps, service techs) c) Quality of manufacturing / product d) Results of reference checks	20	20
2.	Methodology Proposed a) If partial bid, how well the proposed methods fit with other bids b) How proposed methods fit with limited staff and space @ Division of Public Health Laboratory c) Flexibility in method to allow for variable work flow(s) d) Adequacy of work plan & timeline schedules	20	20

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3.	Responses to Scope of Work are thorough and meet needs of laboratory a) Biotinidase Deficiency (Biot) b) Total Galactose (T.Gal) c) Galactose-1-phospate uridyl transferase (GALT) d) Thyroid Stimulating Hormone (TSH) e) Thyroxin (T4) f) 7 α -hydroxyprogesterone (17OHP) g) Immunoreactive Trypsin (IRT)	40	40
4.	Cost of proposed methods (cost/test)	20	20
TOTAL SCORE		100%	100
1)	Does the bidder have a Supplier Diversity plan currently in place?	Yes/No	
2)	Does the bidder have any diverse sub- contractors as outlined in Attachment 8 Tier II Sub-contractors?	Yes/No	
Answers to these two criteria are mandatory and does not affect the weighted evaluation of this proposal.			

Procurement Evaluation Committee members will assign up to the maximum number of points listed for each of the criteria listed above. For items having quantitative answers, points will be proportionate to each proposal's response. Items with qualitative answers will receive the average of points assigned by Proposal Evaluation Committee members.

F. BEST AND FINAL OFFERS

Once the proposals have been evaluated and negotiations have been held with the vendor(s) determined to be likely to receive an award, the Procurement Evaluation Committee may issue a request for Best and Final Offers from the vendor(s).

G. REFERENCES

The Committee may contact any customer of the vendor, whether or not included in the vendor's reference list, and use such information in the evaluation process. Additionally, the State of Delaware may choose to visit existing installations of comparable systems, which may or may not include vendor personnel. If the vendor is involved in such site visits, the State of Delaware will pay travel costs only for State of Delaware personnel for these visits.

H. ORAL PRESENTATIONS

Selected vendors may be invited to make oral presentations to the Committee. The vendor representative(s) attending the oral presentation shall be technically qualified to respond to questions related to the proposed system and its components.

All of the vendor's costs associated with participation in oral discussions and system demonstrations conducted for the State of Delaware are the vendor's responsibility.

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V. PREBID MEETING

There will be no pre-bid meeting for this Request for Proposal.

VI. DEFINITIONS AND GENERAL PROVISIONS

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

A. 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.

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

BOND: The approved form of security furnished by the Vendors and its surety as a guaranty of good faith on the part of the Vendor to execute the work in accordance with the terms of the contract.

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

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

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.

LOCAL TIME: Eastern Standard Time/Eastern Daylight Time

OPPORTUNITY BUY: A special offer from a supplier that is usually associated with a limited time to respond.

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

RFP: Request for Proposal.

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.

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

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

VENDOR'S DEPOSIT: The security designated in the proposal to be furnished by the Vendor 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 it.

B. GENERAL PROVISIONS

1. INTERPRETATION OF ESTIMATES/QUANTITIES

- a. Unless stated otherwise, the quantities given in the RFP 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. Bidders shall recognize there are no guaranteed minimum contract quantities or values associated with this solicitation.
- b. An increase or decrease in the quantity for any item is not sufficient ground for an increase or decrease in the unit price.
- c. Vendor usage reports for previous awards may be found at <http://contracts.delaware.gov/> . Past usage shall not be considered a guaranteed future volume.

2. 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.

3. EXAMINATION OF SPECIFICATIONS AND PROVISIONS

The Vendor shall examine carefully the proposal and the contract forms for the material contemplated. The Vendor 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 any Special Provisions in the RFP and the contract. The submission of a proposal shall be conclusive evidence that the Vendor has made examination of the aforementioned conditions.

4. PRICES QUOTED

The prices quoted are those for which the material will be furnished F.O.B. Ordering Agency and include all charges that may be imposed during the period of the contract. **All prices quoted must be in U.S. Dollars.**

All vendors that maintain a core list of products under this contract shall maintain the appropriate negotiated prices on their core list. Vendors shall routinely offer to add to the core list material that has

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been identified as necessary. The Vendors are expected to routinely update any changes to the core list with the appropriate discounts listed.

Any adjustments to a core list must receive prior written approval from the State before a core list can be changed by the Vendor. Changes include but are not limited to the migration of items on and off the core list as well as any price adjustments from the original agreed upon pricing.

5. PUBLIC INSPECTION OF PROPOSALS

All documents submitted as part of the vendor's proposal will be deemed confidential during the evaluation process. Vendor proposals will not be available for review by anyone other than the State of Delaware/Proposal Evaluation Committee or its designated agents. There shall be no disclosure of any vendor's information to a competing vendor prior to award of the contract.

The State of Delaware is a public agency as defined by state law, and as such, it is subject to the Delaware Freedom of Information Act, 29 Del. C. Ch. 100. Under the law, all the State of Delaware's records are public records (unless otherwise declared by law to be confidential) and are subject to inspection and copying by any person. Vendor(s) are advised that once a proposal is received by the State of Delaware and a decision on contract award is made, its contents will become public record and nothing contained in the proposal will be deemed to be confidential except proprietary information.

Vendor(s) shall not include any information in their proposal that is proprietary in nature or that they would not want to be released to the public. Proposals must contain sufficient information to be evaluated and a contract written without reference to any proprietary information. If a vendor feels that they cannot submit their proposal without including proprietary information, they must adhere to the following procedure or their proposal may be deemed unresponsive and will not be recommended for selection. Vendor(s) must submit such information in a separate, sealed envelope labeled "Proprietary Information" with the RFP number. The envelope must contain a letter from the Vendor's legal counsel describing the documents in the envelope, representing in good faith that the information in each document is not "public record" as defined by 29 Del. C. § 10002(d), and briefly stating the reasons that each document meets the said definitions.

Upon receipt of a proposal accompanied by such a separate, sealed envelope, the State of Delaware will open the envelope to determine whether the procedure described above has been followed.

6. LAWS TO BE OBSERVED

The vendor is presumed to know and shall strictly comply with all Federal, State, or County laws, and City or Town ordinances and regulations in any manner affecting the conduct of the work. The Vendor 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, by its employees, or by its subcontractor (s).

7. APPLICABLE LAW AND JURISDICTION

This bid, any resulting contract, and any and all litigation or other disputes arising therefrom, in connection with, or related hereto shall be governed by the applicable laws, regulations and rules of evidence of the State of Delaware. Bidder submits to personal jurisdiction in the State of Delaware. Any and all litigation or other disputes arising out of, in connection with, or relating to this bid, and any

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resulting contract, shall be brought exclusively in a court in the State of Delaware or the United States District Court of the District of Delaware as applicable.

8. SEVERABILITY

If any term or provision of this Agreement is found by a court of competent jurisdiction to be invalid, illegal or otherwise unenforceable, the same shall not affect the other terms or provisions hereof or the whole of this Agreement, but such term or provision shall be deemed modified to the extent necessary in the court's opinion to render such term or provision enforceable, and the rights and obligations of the parties shall be construed and enforced accordingly, preserving to the fullest permissible extent the intent and agreements of the parties herein set forth.

9. PERMITS AND LICENSES

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

10. PATENTED DEVICES, MATERIAL AND PROCESSES

- a. The Vendor 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 Vendor 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.

11. 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 Vendor 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.

12. 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.
- 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 Vendor. Each Vendor shall take its exemption into account in calculating its bid for its work.

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13. INVOICING

After the awards are made, the agencies participating in the bid may forward their purchase orders ("P.O.") to the successful Vendor(s) in accordance with State Purchasing Procedures. The State will generate a payment voucher upon receipt of an acceptable invoice from the vendor.

14. EQUALITY OF EMPLOYMENT OPPORTUNITY ON PUBLIC WORKS

During the performance of any contract for public works financed in whole or in part by appropriation of the State of Delaware, the contractor agrees as follows:

- a. The contractor, as set forth in Title 19 Delaware Code Chapter 7 section 711, will not discriminate against any employee or applicant for employment with respect to compensation, terms, conditions or privileges of employment because of such individual's race, marital status, genetic information, color, age, religion, sex, sexual orientation, gender identity, or national origin. The contractor will take affirmative action to ensure that applicants are employed and that employees are treated equally during employment without regard to their race, marital status, genetic information, color, age, religion, sex, sexual orientation, gender identity, or national origin. Such action shall include, but not be limited to the following: advertising, lay-off or termination, rates of pay or other forms of compensation, and selection for training including apprenticeships. The contractor agrees to post in conspicuous places, notices to be provided by the contracting agency setting forth the provisions of this non-discrimination clause.
- b. During the performance of this contract, the contractor agrees as follows:
 1. The contractor, as set forth in Title 19 Delaware Code Chapter 7 section 711, will not discriminate against any individual with respect to compensation, terms, conditions or privileges of employment because of such individual's race, marital status, genetic information, color, age, religion, sex, sexual orientation, gender identity, or national origin. The contractor will take positive steps to ensure that applicants are employed and that employees are treated during employment without regard to their race, marital status, genetic information, color, age, religion, sex, sexual orientation, gender identity, or national origin. Such action shall include, but not be limited to, the following: employment, upgrading, demotion or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places available to employees and applicants for employment notices to be provided by the contracting agency setting forth this nondiscrimination clause.
 2. The contractor will, in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive consideration for employment without regard to race, marital status, genetic information, color, age, religion, sex, sexual orientation, gender identity, or national origin."
- c. The term "contractor for public works" means construction, reconstruction, demolition, alteration, and/or repair work, maintenance work, and paid for in whole or in part out of the funds of a public body except work performed under a vocational rehabilitation program. The manufacture or furnishing of materials, articles, supplies or equipment is not a public work within the meaning of this subsection unless conducted in connection with and at the site of the public work.

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15. PRICES

Prices and/or rates shall remain firm for the initial one year term of the contract, unless further negotiations are deemed necessary by the State.

The pricing policy that you choose to submit must address the following concerns:

- a. The structure must be clear, accountable and auditable.
- b. It must cover the full spectrum of services required.
- c. Costs and compensation must be consistent with the rates established or negotiated as a result of this RFP or P.O. issued based on this contract.

16. COOPERATIVES

Vendors, who have been awarded similar contracts through a competitive bidding process with a cooperative, are welcome to submit the cooperative pricing for this solicitation.

17. PRICE ADJUSTMENT

The Vendor is not prohibited from offering a price reduction on its services or materiel offered under the contract. The State is not prohibited from requesting a price reduction on those services or materiel during the initial term or any subsequent options that the State may agree to exercise.

If agreement is reached to extend this contract beyond the initial period, Division of Public Health shall have the option of offering a determined price adjustment that shall not exceed the current Philadelphia All Urban Consumers Price Index (CPI-U), U.S. City Average. If the CPI-U is used, any increase/decrease shall reflect the change during the previous published twelve (12) month period at the time of renegotiation.

18. SHIPPING TERMS

FOB Destination, freight prepaid.

19. ELECTRONIC CATALOG

At the discretion of Division of Public Health, the successful vendor(s) may be required to submit their items list in an electronic format designated by the State.

By example, but not limited to, the following items may be required:

- Electronic catalogs,
- Electronic catalogs converted to a CSV format with contract specific pricing,
- Items designated by commodity/classification code: United Nations Standard Products and Services Code (UNSPSC), and/or
- A unique item ID for all items in your system and/or our award.

20. INDEPENDENT CONTRACTORS

The parties to any contract from this solicitation shall be independent contractors to one another, and nothing herein shall be deemed to cause the agreement to create an agency, partnership, joint venture or employment relationship between parties. Each party shall be responsible for compliance with all

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applicable workers compensation, unemployment, disability insurance, social security withholding and all other similar matters. Neither party shall be liable for any debts, accounts, obligations or other liability whatsoever of the other party or any other obligation of the other party to pay on the behalf of its employees or to withhold from any compensation paid to such employees any social benefits, workers compensation insurance premiums or any income or other similar taxes.

21. TEMPORARY PERSONNEL ARE NOT STATE EMPLOYEES UNLESS AND UNTIL THEY ARE DIRECTLY HIRED

Vendor agrees that any individual or group of temporary staff person(s) provided to the State of Delaware pursuant to this Solicitation shall remain the employee(s) of Vendor for all purposes including any required compliance with the Affordable Care Act by the Vendor. Vendor agrees that it shall not allege, argue, or take any position that individual temporary staff person(s) provided to the State pursuant to this Solicitation must be provided any benefits, including any healthcare benefits by the State of Delaware and Vendor agrees to assume the total and complete responsibility for the provision of any healthcare benefits required by the Affordable Care Act to aforesaid individual temporary staff person(s). In the event that the Internal Revenue Service, or any other third party governmental entity determines that the State of Delaware is a dual employer or the sole employer of any individual temporary staff person(s) provided to the State of Delaware pursuant to this Solicitation, Vendor agrees to hold harmless, indemnify, and defend the State to the maximum extent of any liability to the State arising out of such determinations.

Notwithstanding the content of the preceding paragraph, should the State of Delaware subsequently directly hire any individual temporary staff employee(s) provided pursuant to this Solicitation, the aforementioned obligations to hold harmless, indemnify, and defend the State of Delaware shall cease and terminate for the period following the date of hire. Nothing herein shall be deemed to terminate the Vendor's obligation to hold harmless, indemnify, and defend the State of Delaware for any liability that arises out of compliance with the ACA prior to the date of hire by the State of Delaware. Vendor will waive any separation fee provided an employee works for both the vendor and hiring agency, continuously, for a three (3) month period and is provided thirty (30) days written notice of intent to hire from the agency. Notice can be issued at second month if it is the State's intention to hire.

22. ACA SAFE HARBOR

The State and its utilizing agencies are not the employer of temporary or contracted staff. However, the State is concerned that it could be determined to be a Common-law Employer as defined by the Affordable Care Act ("ACA"). Therefore, the State seeks to utilize the "Common-law Employer Safe Harbor Exception" under the ACA to transfer health benefit insurance requirements to the staffing company. The Common-law Employer Safe Harbor Exception can be attained when the State and/or its agencies are charged and pay for an "Additional Fee" with respect to the employees electing to obtain health coverage from the Vendor.

The Common-law Employer Safe Harbor Exception under the ACA requires that an Additional Fee must be charged to those employees who obtain health coverage from the Vendor, but does not state the required amount of the fee. The State requires that all Vendors shall identify the Additional Fee to obtain health coverage from the Vendor and delineate the Additional Fee from all other charges and fees. The Vendor shall identify both the Additional Fee to be charged and the basis of how the fee is applied (i.e. per employee, per invoice, etc.). The State will consider the Additional Fee and prior to award reserves the right to negotiate any fees offered by the Vendor. Further, the Additional Fee shall be separately scored in the proposal to ensure that neither prices charged nor the Additional Fee charged will have a detrimental effect when selecting vendor(s) for award.

23. FUNDING OUT or NON-APPROPRIATION

In the event the General Assembly fails to appropriate the specific funds necessary to enter into or continue the contractual agreement, in whole or part, the agreement shall be terminated as to any obligation of the State requiring the expenditure of money for which no specific appropriation is available at the end of the last fiscal year for which no appropriation is available or upon the exhaustion of funds.

24. MANDATORY INSURANCE REQUIREMENTS

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 the following coverage depending on the type of service or product being delivered.

- a. Commercial General Liability - \$1,000,000 per occurrence/\$3,000,000 aggregate,
and
- b. Medical/Professional Liability - \$1,000,000 per occurrence/\$3,000,000 aggregate,
or
- c. Miscellaneous Errors and Omissions - \$1,000,000 per occurrence/\$3,000,000 aggregate,
or
- d. Product Liability - \$1,000,000 per occurrence/\$3,000,000 aggregate,
and
- e. 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 other,
and
- f. The vendor shall maintain such insurance as will protect against claims under Worker's Compensation Act and from any other claims for damages for personal injury, including death, which may arise from operations under this contract. The vendor is an independent contractor and is not an employee of the State of Delaware.

All contractors must carry (a), (e), and (f), and at least one of (b), (c), or (d), depending on the type of service or product being delivered.

Before any work is done with the State, a Certificate of Insurance referencing the name and contract number stated herein, shall be filed with the State. The certificate holder is as follows:

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**State of Delaware
Division of Public Health
417 Federal Street
Dover, DE 19901**

Note: The State of Delaware shall not be named as an additional insured.

Should any of the above described policies be cancelled before the expiration date thereof, notice will be delivered in accordance with the policy provisions.

25. STATE OF DELAWARE BUSINESS LICENSE

Prior to receiving an award, the successful Vendor shall either furnish the Agency 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: 302-577-8778.

<http://revenue.delaware.gov/services/BusServices.shtml>

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.

26. INDEMNIFICATION

a. General Indemnification

By submitting a proposal, the proposing vendor agrees that in the event it is awarded a contract, it will indemnify and otherwise hold harmless the State of Delaware, its agents and employees from any and all liability, suits, actions, or claims, together with all costs, expenses for attorney's fees, arising out of the vendor's its agents and employees' performance work or services in connection with the contract.

b. Proprietary Rights Indemnification

Vendor shall warrant that all elements of its solution, including all equipment, software, documentation, services and deliverables, do not and will not infringe upon or violate any patent, copyright, trade secret or other proprietary rights of any third party. In the event of any claim, suit or action by any third party against the State of Delaware, the State of Delaware shall promptly notify the vendor in writing and vendor shall defend such claim, suit or action at vendor's expense, and vendor shall indemnify the State of Delaware against any loss, cost, damage, expense or liability arising out of such claim, suit or action (including, without limitation, litigation costs, lost employee time, and counsel fees) whether or not such claim, suit or action is successful.

If any equipment, software, services (including methods) products or other intellectual property used or furnished by the vendor (collectively "Products") is or in vendor's reasonable judgment is likely to be, held to constitute an infringing product, vendor shall at its expense and option either:

1. Procure the right for the State of Delaware to continue using the Product(s);
2. Replace the product with a non-infringing equivalent that satisfies all the requirements of the contract; or

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3. Modify the Product(s) to make it or them non-infringing, provided that the modification does not materially alter the functionality or efficacy of the product or cause the Product(s) or any part of the work to fail to conform to the requirements of the Contract, or only alters the Product(s) to a degree that the State of Delaware agrees to and accepts in writing.

27. NON-PERFORMANCE

In the event the Vendor does not fulfill its obligations under the terms and conditions of this contract, in addition to proceeding with termination of the contract, the ordering agency may terminate any individual orders in accordance with General Provisions, Item titled as "TERMINATION OF INDIVIDUAL PURCHASE ORDERS" below and purchase equivalent product on the open market. Regarding any such open market purchase, payment for any difference in cost or expense in excess of the contract prices for reasonably equivalent products or services herein shall be the responsibility of the Vendor and shall be submitted to the State no later than 30 days following the delivery of the State's invoice detailing the open market purchase. 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.

28. 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.

29. VENDOR NON-ENTITLEMENT

State of Delaware Vendors for Materiel and for Services shall not have legal entitlement to utilize any Central Contract held by the State of Delaware. The Vendors may not seek business from another Vendors' Central Contract for the purpose of preparing a bid or proposal to the State of Delaware. Additionally, they shall not utilize other Central Contracts to fulfill the requirements of their respective contract unless they are considered a "Covered Agency" as defined by Title 29 Chapter 69 of the State Procurement Code or otherwise permitted by law.

This is not a prohibition from any Vendor choosing to work with another Vendor who holds a State Central Contract for private business.

30. OPPORTUNITY BUYS

The Director for the Division of Public Health can waive use of a contract pursuant to 29 Del. C. §6911(d). A process has been developed to permit any vendor the opportunity to submit an Opportunity Buy offer to the State for goods and/or services for consideration despite the existence of a contract. See [Opportunity Buy Flowchart](#). The Director will afford any vendor on an existing contract an opportunity to match or to beat the Opportunity Buy offer made by a non-contracted vendor prior to a waiver being granted.

31. REQUIRED REPORTING

One of the primary goals in administering this contract is to keep accurate records regarding its actual value/usage. This information is essential in order to update the contents of the contract and to

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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 parties.

A complete and accurate Usage Report (Attachment 8) shall be furnished in an Excel format and submitted electronically, no later than the 15th (or next business day after the 15th day) of each month, detailing the purchasing of all items on this contract. The reports shall be submitted and sent as an attachment to Patricia Scott at Pat.Scott@state.de.us. Submitted reports shall contain accurate descriptions of the products, goods or services procured, purchasing agency information, including the six-digit department and organization code, quantities procured and prices paid. Any exception to this mandatory requirement or failure to submit complete reports, or in the format required, may result in corrective action, up to and including the possible cancellation of the award. Failure to provide the report with the minimum required information may also negate any contract extension clauses. Additionally, Vendors 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.

In accordance with Executive Order 44, the State of Delaware is committed to supporting its diverse business industry and population. The successful Vendor will be required to accurately report on the participation by Diversity Suppliers which includes: minority (MBE), woman (WBE), veteran owned business (VOBE), or service disabled veteran owned business (SDVOBE) under this awarded contract. The reported data elements shall include but not be limited to; name of state contract/project, the name of the Diversity Supplier, Diversity Supplier contact information (phone, email), type of product or service provided by the Diversity Supplier and any minority, women, veteran, or service disabled veteran certifications for the subcontractor (State OSD certification, Minority Supplier Development Council, Women's Business Enterprise Council, VetBiz.gov). The format used for Subcontracting 2nd Tier reporting is shown as Attachment 9.

Accurate 2nd Tier reports shall be submitted to the contracting Agency's Office of Supplier Diversity at vendorausage@state.de.us on the 15th (or next business day) of the month following each quarterly period. For consistency quarters shall be considered to end the last day of March, June, September and December of each calendar year. Contract spend during the covered periods shall result in a report even if the contract has expired by the report due date.

32. ORDERING PROCEDURE

Successful vendors 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. Depending on the nature and scope of the event, each State agency or other governmental entity shall be responsible for contacting the awarded vendor directly for all required resources. All consumables delivered by the Vendor and received by a State agency or other governmental entity, become the property of that State agency or entity. Orders may be accomplished by written purchase order, telephone, email, fax or computer on-line systems.

33. PURCHASE ORDERS

Agencies that are part of the First State Financial (FSF) system are required to identify the Request for Proposal number HSS 16 030 on all Purchase Orders (P.O.) and shall complete the same when entering P.O. information in the state's financial reporting system.

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34. BILLING

The 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.

Agencies will make every effort to achieve available discount opportunities under this contract. Vendors shall be required to report semi-annually opportunities to enhance the discounts achieved.

35. METHOD OF PAYMENT

- a. For each P.O. issued as part of this Request for Proposal, the State will pay Vendor monthly, within thirty (30) days of receipt of the Vendor's billing, the amount which is legitimately earned by the Vendor, and supported by payroll data and an itemized accounting of reasonable reimbursable direct non-salary costs. A current progress report of the work shall accompany each billing.

Final settlement for total payment to the Vendor will be made within thirty (30) days from the date of final written State acceptance of the work and services as agreed to in the P.O.

- b. No premium time for overtime will be paid without prior written State authorization. Indirect overhead cost shall not be applied to the premium portion of the overtime.
- c. The agencies or school districts using this award will authorize and process for payment each invoice within thirty (30) days after the date of receipt of a correct invoice. The State of Delaware intends to maximize the use of the P-Card for payment for goods and services provided under contract. Vendors shall not charge additional fees for acceptance of this payment method and shall incorporate any costs into their proposals. Additionally there shall be no minimum or maximum limits on any P-Card transaction under the contract. While it is the State's intention to utilize the P-card payment method the State reserves, at its discretion, the right to pay by ACH/ ACI or check. Should a Vendor wish to provide a financial incentive to not process payment by P-Card in their proposal, they are to prepare their proposals to clearly outline any incentives for alternative payment methods the Vendor is willing to accept.

36. PRODUCT SUBSTITUTION

All items or services delivered during the life of the contract shall be of the same type and manufacture as specified or accepted as part of the proposal unless specific approval is given by the Agency to do otherwise. 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 all cases, the state may require the submission of written specifications and/or product samples for evaluation prior to any approvals being granted.

If a substitution is granted by the state, the Vendor must update its core list and maintain said list in a timely manner.

37. SCHEDULE FOR PERFORMANCE OF WORK

All work described in these specifications shall be completed with reasonable promptness. As used in this Section, the State of Delaware shall be the sole judge of the term "reasonable". If the Vendor does not begin the work in a reasonable amount of time, they will be notified that if they fail to initiate the

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work promptly, the contract may be terminated and the State will forthwith proceed to collect for nonperformance of work.

38. VENDOR RESPONSIBILITY

The State will enter into a contract with the successful Vendor(s). The successful Vendor(s) shall be responsible for all products and services as required by this RFP whether or not the Vendor or its subcontractor provided final fulfillment of the order. Subcontractors, if any, shall be clearly identified in the Vendor's proposal by completing Attachment 7, and are subject the approval and acceptance of Division of Public Health.

39. VENDOR- OWNED RENTAL EQUIPMENT AND SUPPLIES REMOVAL

The awarded Vendor shall remove all rental equipment and supplies from the event location (s) no later than an agreed to date once all contract obligations by the Vendor have been met.

40. ENVIRONMENTAL PROCUREMENT REQUIREMENTS

Energy Star - If applicable, the Vendor must provide products that earn the ENERGY STAR rating and meet the ENERGY STAR specifications for energy efficiency in order to keep overall event costs to a minimum. The Vendor is encouraged to visit www.energystar.gov for complete product specifications and updated lists of qualifying products.

Green Products – third party certification of green products accepted from GSS w/approved green certification shall be offered wherever available in addition to or as a substitute for non-green products.

Vendors shall report all green items procured during the monthly reporting period using the Usage Report that will be provided to the awarded Vendor(s).

Environmental Procurement Policies of the State shall determine acceptable consideration and credit for environmentally preferred products and services in the performance of this award. The State Environmental Procurement Policies may be found: [Environmentally Preferred Purchasing Policy](#)

41. PERSONNEL, EQUIPMENT AND SERVICES

- a. The Vendor represents that it has, or will secure at its own expense, all personnel required to perform the services required under this contract.
- b. All of the equipment and services required hereunder shall be provided by or performed by the Vendor 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 equipment and/or services covered by this contract shall be subcontracted without the prior written approval of the State. Only those subcontractors identified in Attachment 7 are considered approved upon award. Changes to those subcontractor(s) listed in Attachment 7 must be approved in writing by the State.

42. FAIR BACKGROUND CHECK PRACTICES

Pursuant to 29 Del. C. [§6909B](#), the State does not consider the criminal record, criminal history, credit history or credit score of an applicant for state employment during the initial application process unless

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otherwise required by state and/or federal law. Vendors doing business with the State are encouraged to adopt fair background check practices. Vendors can refer to 19 Del. C. [§711\(g\)](#) for applicable established provisions.

43. VENDOR BACKGROUND CHECK REQUIREMENTS

Vendor(s) selected for an award that access state property or come in contact with vulnerable populations, including children and youth, shall be required to complete background checks on employees serving the State's on premises contracts. Unless otherwise directed, at a minimum, this shall include a check of the following registry:

- Delaware Sex Offender Central Registry at:
<https://sexoffender.dsp.delaware.gov/>

Individuals that are listed in the registry shall be prevented from direct contact in the service of an awarded state contract, but may provide support or off-site premises service for contract vendors. Should an individual be identified and the Vendor(s) believes their employee's service does not represent a conflict with this requirement, may apply for a waiver to the primary agency listed in the solicitation. The Agency's decision to allow or deny access to any individual identified on a registry database is final and at the Agency's sole discretion.

By Agency request, the Vendor(s) shall provide a list of all employees serving an awarded contract, and certify adherence to the background check requirement. Individual(s) found in the central registry in violation of the terms stated, shall be immediately prevented from a return to state property in service of a contract award. A violation of this condition represents a violation of the contract terms and conditions, and may subject the Vendor to penalty, including contract cancellation for cause.

Individual contracts may require additional background checks and/or security clearance(s), depending on the nature of the services to be provided or locations accessed, but any other requirements shall be stated in the contract scope of work or be a matter of common law. The Vendor(s) shall be responsible for the background check requirements of any authorized Subcontractor providing service to the Agency's contract.

44. DRUG TESTING REQUIREMENTS FOR LARGE PUBLIC WORKS

Pursuant to 29 Del.C. [§6908\(a\)\(6\)](#), effective as of January 1, 2016, OMB has established regulations that require Contractors and Subcontractors to implement a program of mandatory drug testing for Employees who work on Large Public Works Contracts funded all or in part with public funds. The regulations establish the mechanism, standards and requirements of a Mandatory Drug Testing Program that will be incorporated by reference into all Large Public Works Contracts awarded pursuant to 29 Del.C. [§6962](#).

Final publication of the identified regulations can be found at the following:
[4104 Regulations for the Drug Testing of Contractor and Subcontractor Employees Working on Large Public Works Projects](#)

45. MINIMUM WAGE RATES

Work performed under this solicitation may fall under the [State of Delaware Minimum Wage Rates](#) or the Delaware Prevailing Wage rates. Prior to issuing a purchase order, the ordering agencies must obtain from the Department of Labor a determination if prevailing wage applies to the project and, if appropriate, what the applicable prevailing wage rates would be for the work to be performed. No work

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shall proceed without a determination by the Department of Labor. Request for prevailing wage certification can be found at: <http://dia.delawareworks.com/labor-law/prevailing-wage.php> .

46. PREVAILING WAGE

The prevailing wage law, 29 Del.C. §6960, is enforced by the Department of Labor and states that the specifications for every contract or aggregate of contracts relating to a public works project in excess of \$500,000 for new construction (including painting and decorating) or \$45,000 for alteration, repair, renovation, rehabilitation, demolition or reconstruction (including painting and decorating of building or works) to which this State or any subdivision thereof is a party and for which the State appropriated any part of the funds and which requires or involves the employment of mechanics and/or laborers shall contain a provision stating the minimum wages to be paid various classes of laborers and mechanics which shall be based upon the wages that will be determined by the Delaware Department of Labor, Division of Industrial Affairs, to be prevailing in the county in which the work is to be performed.

47. DISPUTE RESOLUTION

At the option of, and in the manner prescribed by the Office of Management and Budget (OMB), the parties shall attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between executives who have authority to settle the controversy and who are at a higher level of management than the persons with direct responsibility for administration of this Agreement. All offers, promises, conduct and statements, whether oral or written, made in the course of the negotiation by any of the parties, their agents, employees, experts and attorneys are confidential, privileged and inadmissible for any purpose, including impeachment, in arbitration or other proceeding involving the parties, provided evidence that is otherwise admissible or discoverable shall not be rendered inadmissible.

If the matter is not resolved by negotiation, as outlined above, or, alternatively, OMB elects to proceed directly to mediation, then the matter will proceed to mediation as set forth below. Any disputes, claims or controversies arising out of or relating to this Agreement shall be submitted to mediation by a mediator selected by OMB, and if the matter is not resolved through mediation, then it shall be submitted, in the sole discretion of OMB, to the Office of Management and Budget, Government Support Services Director, for final and binding arbitration. OMB reserves the right to proceed directly to arbitration or litigation without negotiation or mediation. Any such proceedings held pursuant to this provision shall be governed by Delaware law and venue shall be in Delaware. The parties shall maintain the confidential nature of the arbitration proceeding and the Award, including the Hearing, except as may be necessary to prepare for or conduct the arbitration hearing on the merits. Each party shall bear its own costs of mediation, arbitration or litigation, including attorneys' fees.

48. TERMINATION OF INDIVIDUAL ORDERS OR PURCHASE ORDERS

The individual orders may be terminated as follows:

- a. Termination for Cause:** If, for any reasons, or through any cause, the Vendor fails to fulfill in timely and proper manner his obligations, or if the Vendor violates any of the covenants, agreements, or stipulations of this contract, the Agency shall have the right to terminate the P.O. by giving written notice to the Vendor of such termination and specifying the effective date thereof, at least five (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

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or other material prepared by the Vendor in the performance of the P.O. shall, at the option of the Agency, become its property, and the Vendor 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 Agency.

- b. Termination for Convenience:** The Agency may terminate the P.O. 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 such termination. In that event, all finished or unfinished documents, data, studies, surveys, drawings, models, photographs, reports, supplies, and other materials shall, at the option of the department, become its property and the Vendor shall be entitled to receive compensation for any satisfactory work completed on such documents and other materials which are usable to the Agency.
- c. Termination for Non-Appropriations:** In the event the General Assembly fails to appropriate the specific funds necessary to enter into or continue the contractual agreement, in whole or part, the agreement shall be terminated as to any obligation of the State requiring the expenditure of money for which no specific appropriation is available at the end of the last fiscal year for which no appropriation is available or upon the exhaustion of funds. This is not a termination for convenience and will not be converted to such.

49. TERMINATION OF CONTRACT

The contract awarded as a result of this RFP may be terminated as follows by Division of Public Health.

- a. Termination for Cause:** If, for any reasons, or through any cause, the Vendor fails to fulfill in timely and proper manner its obligations under this Contract, or if the Vendor 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 Vendor of such termination and specifying the effective date thereof, at least thirty (30) 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 Vendor under this Contract shall, at the option of the State, become its property, and the Vendor 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.

On receipt of the contract cancellation notice from the State, the Vendor shall have not less than five (5) days to provide a written response and may identify a method(s) to resolve the violation(s). A vendor response shall not effect or prevent the contract cancellation unless the State provides a written acceptance of the vendor response. If the State does accept the Vendor's method and/or action plan to correct the identified deficiencies, the State will define the time by which the Vendor must fulfill its corrective obligations. Final retraction of the State's termination for cause will only occur after the Vendor successfully rectifies the original violation(s). At its discretion the State may reject in writing the Vendor's proposed action plan and proceed with the original contract cancellation timeline.

- b. Termination for Convenience:** The State may terminate this 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 such termination. In that event, all finished or unfinished documents, data, studies, surveys, drawings, models, photographs, reports, supplies, and other materials shall, at the option of the State, become its property and the Vendor shall be entitled to receive

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compensation for any satisfactory work completed on such documents and other materials, and which is usable to the State.

- c. Termination for Non-Appropriations:** In the event the General Assembly fails to appropriate the specific funds necessary to enter into or continue the contractual agreement, in whole or part, the agreement shall be terminated as to any obligation of the State requiring the expenditure of money for which no specific appropriation is available at the end of the last fiscal year for which no appropriation is available or upon the exhaustion of funds. This is not a termination for convenience and will not be converted to such.

50. CHANGES

Both parties may, from time to time, require changes in the services to be provided by the Vendor under the Scope of Work. Such changes, including any increase or decrease in the amount of the Vendor's compensation, which are mutually agreed upon by and between the Agency and the Vendor shall be incorporated in written amendments to the Purchase Order or contract.

51. INTEREST OF VENDOR

The vendor covenants that it presently has no interest and shall not acquire any interest, direct or indirect, which would conflict in any manner or degree in providing products or performing services required under this contract. The vendor further covenants, that in the performance of this contract, no person having any such interest shall be employed.

52. PUBLICATION, REPRODUCTION AND USE OF MATERIAL

No material produced in whole or part under this contract shall be subject to copyright in the United States or in any other country. The State shall have unrestricted authority to publish, disclose, distribute and otherwise use, in whole or in part, any reports, data, or other materials prepared under this contract; provided, however, that the State agrees not to use any design or engineering plans prepared by the vendor for anything other than their intended purpose under this Contract. The Vendor shall have the right to publish any and all scientific findings. Appropriate acknowledgment and credit for the State's support shall be given in the publication.

53. RIGHTS AND OBLIGATIONS

The rights and obligations of each party to this agreement shall not be effective, and no party shall be bound by the terms of this agreement, unless and until a valid executed purchase order has been approved by the Secretary of Finance, and all procedures of the Department of Finance have been complied with. A separate purchase order shall be issued for every project or order.

54. ASSIGNMENT OF ANTITRUST CLAIMS

As consideration for the award and execution of this contract by the State, the Vendor hereby grants, conveys, sells, assigns, and transfers to the State of Delaware all of its right, title and interest in and to all known or unknown causes of action it presently has or may now or hereafter acquire under the antitrust laws of the United States and the State of Delaware, regarding the specific goods or services purchased or acquired for the State pursuant to this contract. Upon either the State's or the Vendor notice of the filing of or reasonable likelihood of filing of an action under the antitrust laws of the United States or the State of Delaware, the State and Vendor shall meet and confer about coordination of representation in such action.

55. TESTING AND INSPECTION

The State of Delaware reserves the right to conduct any test or inspection it may deem necessary to insure equipment, materials and services conform to contract requirements.

56. COVENANT AGAINST CONTINGENT FEES

The Vendor warrants that no person or selling agency has been employed or retained to solicit or secure this contract upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees. For breach or violation of this warranty, the State shall have the right to annul this contract without liability or in its discretion to deduct from the contract price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fees.

57. GRATUITIES

- a. If it is found, after notice and hearing, by the State that gratuities (in the form of entertainment, gifts, or otherwise) were offered or given by the Vendor or any agent of the State with a view toward securing a contract, or securing favorable treatment with respect to the awarding, amending, or the making of any determinations with respect to the performance of this contract, the State may, by written notice to the Vendor, terminate the right of the Vendor to proceed under this contract and/or may pursue such other rights and remedies provided by law or under this agreement; provided that the existence of the facts upon which the State makes such findings shall be in issue and may be reviewed in proceedings pursuant to the Remedies clause of this contract; and
- b. In the event this contract is terminated pursuant to subparagraph "a", the State shall be entitled (i) to pursue the same remedies against the Vendor, and (ii) to exemplary damages, as a penalty in addition to any other damages to which it may be entitled by law, in an amount which shall be not less than three, nor more than ten, times the costs incurred by the Vendor in providing any such gratuities to any such officer or employee. The amount of such exemplary damages shall be in the sole discretion of the State.

58. AFFIRMATION

The Vendor must affirm that within the past five (5) years the firm or any officer, controlling stockholder, partner, principal, or other person substantially involved in the contracting activities of the business is not currently suspended or debarred and is not a successor, subsidiary, or affiliate of a suspended or debarred business.

59. AUDIT ACCESS TO RECORDS

The Vendor shall maintain books, records, documents, and other evidence pertaining to this Contract to the extent and in such detail as shall adequately reflect performance hereunder. The Vendor agrees to preserve and make available to the State, upon request, such records for a period of five (5) years from the date services were rendered by the Vendor. Records involving matters in litigation shall be retained for one (1) year following the termination of such litigation. The Vendor agrees to make such records available for inspection, audit, or reproduction to any official State representative in the performance of their duties under the Contract. Upon notice given to the Vendor, representatives of the State or other duly authorized State or Federal agency may inspect, monitor, and/or evaluate the cost and billing records or other material relative to this Contract. The cost of any Contract audit disallowances resulting from the examination of the Vendor's financial records will be borne by the

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Vendor. Reimbursement to the State for disallowances shall be drawn from the Vendor's own resources and not charged to Contract cost or cost pools indirectly charging Contract costs.

60. REMEDIES

Except as otherwise provided in this contract, all claims, counterclaims, disputes, and other matters in question between the State and the Vendor arising out of, or relating to, this contract, or a breach of it may be decided by arbitration if the parties mutually agree, or in a court of competent jurisdiction within the State of Delaware.

61. SUBCONTRACTS

Subcontracting is not permitted under this RFP and contract.

62. AGENCY'S RESPONSIBILITIES

The Agency shall:

- a. Examine and review in detail all letters, reports, drawings and other documents presented by the Vendor to the Agency and render to the Vendor in writing, findings and decisions pertaining thereto within a reasonable time so as not to delay the services of Vendor.
- b. Give prompt written notice to the Contractor whenever the Agency observes or otherwise becomes aware of any development that affects the scope or timing of the Contractor's services.
- c. When an ordering agency first experiences a relatively minor problem or difficulty with a vendor, the agency will contact the vendor directly and attempt to informally resolve the problem. This includes failure to perform by the date specified and any unacceptable difference(s) between the purchase order and the merchandise received. Ordering agencies should stress to vendors that they should expedite correction of the differences because failure to reply may result in an unfavorable rating in the execution of the awarded contract.
- d. The state has several remedies available to resolve non-performance issues with the contractor. The Agency should refer to the Contract Terms and Conditions to view these remedies. When a default occurs, the Agency should first review the contract to confirm that the issue is a part of the contract. If the issue is not covered by the contract, the state cannot expect the contractor to perform outside the agreement. If the issue is a part of the contract, the Agency or GSS - Contracting must then contact the contractor, discuss the reasons surrounding the default and establish a date when the contractor will resolve the non-performance issue.
- e. If there is a performance deficiency, a Corrective Action Report (CAR) may be used. Complete this form to report concerns with vendors or commodities. Be sure to furnish as much detail as possible. [Corrective Action Report](#)

63. CONTRACT DOCUMENTS

The Definitions and General Provisions and any Special Instructions, Specifications, Request for Proposal, Proposal, Purchase Order, and Contract shall be a part of and constitute the entire Agreement entered into by the State of Delaware and any Vendor. In the event there is any discrepancy between any of these contract documents, the following order of documents governs so

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that the former prevails over the latter:

- Contract
- Request for Proposal
- Specifications or Scope of Work
- Definitions & General Provisions
- Proposal
- Purchase Order
- Special Instruction

64. ASSIGNMENT

This contract shall not be assigned except by express prior written consent from the Agency.

65. NOTICE

Any notice to the State of Delaware required under the Request for Proposal shall be sent by registered mail to:

**Kieran Mohammed
Department of Health and Social Services
Procurement Branch
Main Admin Bldg., Sullivan Street
2nd floor –room #257
1901 N. DuPont Hwy
Herman Holloway Campus
New Castle, DE 19720**

66. 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 where there is a critical need for commodities or services when the Governor of the State of Delaware declares a state of emergency under the Delaware Emergency Operations Plan or in the event of a local emergency or disaster where a state governmental entity requires the services of the vendor. Failure to provide this information could render the proposal as non-responsive.

In the event of a serious emergency, pandemic or disaster outside the control of the State, the State may negotiate, as may be authorized by law, emergency performance from the Contractor to address the immediate needs of the State, even if not contemplated under the original Contract or procurement. Payments are subject to appropriation and other payment terms.

67. NO PRESS RELEASES OR PUBLIC DISCLOSURE

The State of Delaware reserves the right to pre-approve any news or broadcast advertising releases concerning this solicitation, the resulting contract, the work performed, or any reference to the State of Delaware with regard to any project or contract performance. Any such news or advertising releases pertaining to this solicitation or resulting contract shall require the prior express written permission of the State of Delaware.

The State will not prohibit or otherwise prevent the awarded vendor(s) from direct marketing to the State of Delaware agencies, departments, municipalities, and/or any other political subdivisions,

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however, the Vendor shall not use the State's seal or imply preference for the solution or goods provided.

C. AWARD AND EXECUTION OF CONTRACT

1. CONSIDERATION OF PROPOSALS

The right is reserved to waive technicalities, to reject any or all bids, or any portion thereof, to seek new proposals, 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 Vendor 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. AWARD OF CONTRACT

Within ninety (90) days from the date of opening proposals, the contract will be awarded or the proposals rejected.

4. EXECUTION OF CONTRACT

The Vendor (s) to whom the award is made shall execute a formal contract within twenty (20) days after date of official notice of the award of the contract.

5. WARRANTY

The successful Vendor(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.

6. THE CONTRACT(S)

The contract(s) with the successful Vendor(s) will be executed with Division of Public Health acting for all participating governmental entities.

7. INFORMATION REQUIREMENT

The successful vendor's shall be required to advise and provide Division of Public Health of the gross costs associated with this contract.

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VII. PROPOSAL REPLY SECTION for REQUEST FOR PROPOSAL NO. HSS 16 030

Newborn Screening Chemistry Testing Systems

Please fill out the attached forms fully and completely and return with your proposal in a sealed envelope clearly displaying the contract number to the State of Delaware, Division of Public Health by **December 15, 2016 11:00am** (Local Time) at which time bids will be opened.

NO PRE-BID MEETING

Proposals must be mailed to:

**Kieran Mohammed
Department of Health and Social Services
Procurement Branch
Main Admin Bldg., Sullivan Street
2nd floor –room #257
1901 N. DuPont Hwy
Herman Holloway Campus
New Castle, DE 19720**

Remainder of page intentionally left blank

NO PROPOSAL REPLY FORM

Contract No.: **HSS 16 030** Contract Title: **Newborn Screening Chemistry Testing Systems**

To assist us in obtaining good competition on our Request for Proposals, we ask that each firm that has received a proposal, 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 Vendor's List by so indicating below, or do not return this form or bona fide proposal.

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

- _____ 1. We do not wish to participate in the proposal process.
- _____ 2. We do not wish to bid under the terms and conditions of the Request for Proposal document. Our objections are:

- _____ 3. We do not feel we can be competitive.
- _____ 4. We cannot submit a Proposal 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 Proposals are requested.
- _____ 7. Other: _____

_____ FIRM NAME

_____ SIGNATURE

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

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

PLEASE FORWARD NO PROPOSAL REPLY FORM TO THE CONTRACT OFFICER IDENTIFIED.

CONTRACT NO.: HSS 16 030

TITLE: Newborn Screening Chemistry Testing Systems

DEADLINE TO RESPOND: December 15, 2016 at 11:00 AM (local time)

NON-COLLUSION STATEMENT

This is to certify that the undersigned Vendor 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 proposal, **and further certifies that it is not a sub-contractor to another Vendor who also submitted a proposal as a primary Vendor in response to this solicitation** submitted this date to the State of Delaware, Division of Public Health.

It is agreed by the undersigned Vendor that the signed delivery of this bid represents, subject to any express exceptions set forth at Attachment 3, the Vendor's acceptance of the terms and conditions of this solicitation 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, Division of Public Health.

	Corporation
	Partnership
	Individual

COMPANY NAME _____ (Check one)

NAME OF AUTHORIZED REPRESENTATIVE _____

SIGNATURE _____ TITLE _____

COMPANY ADDRESS _____

PHONE NUMBER _____ FAX NUMBER _____

EMAIL ADDRESS _____

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

COMPANY CLASSIFICATIONS: CERT. NO.: _____	Certification type(s)	Circle all that apply
	Minority Business Enterprise (MBE)	Yes No
	Woman Business Enterprise (WBE)	Yes No
	Disadvantaged Business Enterprise (DBE)	Yes No
	Veteran Owned Business Enterprise (VOBE)	Yes No
	Service Disabled Veteran Owned Business Enterprise (SDVOBE)	Yes No

[The above table is for informational 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 _____

Contract No.: **HSS 16 030**
Contract Title: **Newborn Screening Chemistry Testing Systems**

BUSINESS REFERENCES FORM

List a minimum of three business references, including the following information:

- Business Name and Mailing address
- Contact Name and phone number
- Number of years doing business with
- Type of work performed

Please do not list any State Employee as a business reference. If you have held a State contract within the last 5 years, please provide a separate list the contract(s).

1.	Contact Name & Title:	
	Business Name:	
	Address:	
	Email:	
	Phone # / Fax #:	
	Current Vendor (YES or NO):	
	Years Associated & Type of Work Performed:	

2.	Contact Name & Title:	
	Business Name:	
	Address:	
	Email:	
	Phone # / Fax #:	
	Current Vendor (YES or NO):	
	Years Associated & Type of Work Performed:	

3.	Contact Name & Title:	
	Business Name:	
	Address:	
	Email:	
	Phone # / Fax #:	
	Current Vendor (YES or NO):	
	Years Associated & Type of Work Performed:	

STATE OF DELAWARE PERSONNEL MAY NOT BE USED AS REFERENCES.

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Attachment 6

SUBCONTRACTOR INFORMATION FORM

PART I – STATEMENT BY PROPOSING VENDOR		
1. CONTRACT NO. HSS 16 030	2. Proposing Vendor Name:	3. Mailing Address
4. SUBCONTRACTOR		
a. NAME	4c. Company OSD Classification: Certification Number: _____	
b. Mailing Address:	4d. Women Business Enterprise <input type="checkbox"/> Yes <input type="checkbox"/> No 4e. Minority Business Enterprise <input type="checkbox"/> Yes <input type="checkbox"/> No 4f. Disadvantaged Business Enterprise <input type="checkbox"/> Yes <input type="checkbox"/> No 4g. Veteran Owned Business Enterprise <input type="checkbox"/> Yes <input type="checkbox"/> No 4h. Service Disabled Veteran Owned Business Enterprise <input type="checkbox"/> Yes <input type="checkbox"/> No	
5. DESCRIPTION OF WORK BY SUBCONTRACTOR		
6a. NAME OF PERSON SIGNING	7. BY (<i>Signature</i>)	8. DATE SIGNED
6b. TITLE OF PERSON SIGNING		
PART II – ACKNOWLEDGEMENT BY SUBCONTRACTOR		
9a. NAME OF PERSON SIGNING	10. BY (<i>Signature</i>)	11. DATE SIGNED
9b. TITLE OF PERSON SIGNING		

Use a separate form for each subcontractor

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Attachment 8

SAMPLE REPORT – FOR ILLUSTRATION PURPOSES ONLY

State of Delaware																			
Subcontracting (2nd tier) Quarterly Report																			
Prime Name:							Report Start Date:												
Contract Name/Number							Report End Date:												
Contact Name:							Today's Date:												
Contact Phone:							*Minimum Required			Requested detail									
Vend or Name *	Vend or TaxID *	Contra ct Name/ Numbe r*	Vendo r Conta ct Name*	Vendo r Conta ct Phone *	Repo rt Start Date*	Repo rt End Date*	Amount Paid to Subcontract or*	Work Performed by Subcontrac tor UNSPSC	M/WBE Certifyi ng Agency	Veteran/Serv ice Disabled Veteran Certifying Agency	2nd tier Suppli er Name	2nd tier Suppli er Addre ss	2nd tier Suppli er Phone Numbe r	2nd tier Suppli er email	Descripti on of Work Performe d	2nd tier Suppli er Tax Id	Dat e Pai d		

Note: A copy of the Usage Report will be sent by electronic mail to the Awarded Vendor

Completed reports shall be saved in an Excel format, and submitted to the following email address: Office of Supplier Diversity at vendorusage@state.de.us

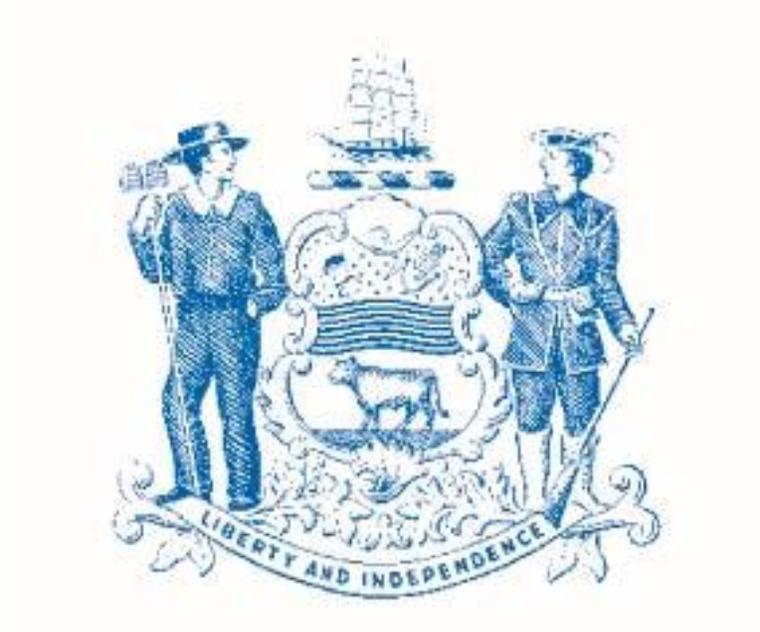
State of Delaware
Office of Supplier Diversity
Certification Application

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

<http://gss.omb.delaware.gov/osd/certify.shtml>

Submission of a completed Office of Supplier Diversity (OSD) application is optional and does not influence the outcome of any award decision.

The minimum criteria for certification require the entity must be at least 51% owned and actively managed by a person or persons who are eligible: minorities, women, veterans, and/or service disabled veterans. Any one or all of these categories may apply to a 51% owner.



Complete application and mail, email or fax to:

Office of Supplier Diversity (OSD)

100 Enterprise Place, Suite 4

Dover, DE 19904-8202

Telephone: (302) 857-4554 Fax: (302) 677-7086

Email: osd@state.de.us

Web site: <http://gss.omb.delaware.gov/osd/index.shtml>

THE OSD ADDRESS IS FOR OSD APPLICATIONS ONLY.
THE OSD WILL NOT ACCEPT ANY VENDOR BID RESPONSE PACKAGES.

PROPOSAL REPLY REQUIREMENTS

The response should contain the following minimum information:

1. A brief Cover Letter including an Applicant's experience, if any, providing similar services.
2. Vendor shall provide a detailed description of services to be provided, and shall respond to the Scope of Work identified, in Appendix A. Failure to adequately describe the extent of their abilities may affect how the state evaluates and scores the vendor proposal.
3. Pricing Form, identified in Appendix B, must also be included.

Vendors are encouraged to review the Evaluation criteria to see how the proposals will be scored and verify that the response has sufficient documentation to support each scoring criteria identified.

4. One (1) complete, signed and notarized copy of the Non-Collusion Agreement (Attachment 2). **MUST HAVE ORIGINAL SIGNATURES AND NOTARY MARK** – Form must be included.
5. One (1) completed RFP Exception Form (Attachment 3) – please check box if no information – Form must be included.
6. One (1) completed Profile and Capabilities Form (Attachment 4)
7. One (1) completed Confidentiality Form (Attachment 5) – please check if no information is deemed confidential – Form must be included.
8. One (1) completed Business Reference Form (Attachment 6) – please provide references other than State of Delaware contacts – Form must be included.
9. One (1) complete and signed copy of the Subcontractor Information Form (Attachment 7) for each subcontractor – only provide if applicable.
10. One (1) complete OSD Application (see link on Attachment 10) – optional, only provide if applicable

The items listed above provide the basis for evaluating each vendor's proposal. **Failure to provide all appropriate information may deem the submitting vendor as "non-responsive" and exclude the vendor from further consideration.** If an item listed above is not applicable to your company or proposal, please make note in your submission package.

Vendors shall compile all documentation noted above, and all other documents as required in the Scope of Work, Appendix A, and shall provide in the following format(s):

1. **Two (2)** paper copies of the vendor proposal paperwork.
2. **Five (5)** electronic copy of the vendor proposal saved to CD or DVD media disk, or USB memory stick. Any copies of electronic price files shall be included on the same electronic media, but shall be saved separately from.

**APPENDIX A
SCOPE OF WORK**

**Newborn Screening Chemistry Testing System(s) for
(A) Biotinidase, (B) Total Galactose, (C) GALT, (D) TSH, (E) T4, (F) 17-OHP & (G) 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 contract with selected vendor(s) to supply the necessary reagent test kits, equipment, supplies, 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 G, 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 G, then indicate No Proposal Submitted.

Responses by the vendor should INDIVIDUALLY and SPECIFICALLY address each specification listed in the bid for each test bids are submitted for. Vendors should include information on 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 options within the bid, i.e. options, 1, 2, 3.

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

Bidders are asked to 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. Please list any additional materials/supplies/reagents/equipment required to perform the assay, but not included in the bid response.

The specifications listed below are the desired requirements based on the needs of the DPHL. If the proposed system is unable to meet an item described in the specification, note "Unable to Meet Specification" and include the reason why. Incomplete or omitted responses for any item (1-28) within the specifications may be considered grounds for rejection of a bid.

DPHL reserves the right to choose separate vendors for each area of SPECIFICATION A through G, 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 be collected between 7-28 days of age. In 2015, approximately 22,900 dried blood spot specimens (11,700

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initial and 11,200 repeat) were received on newborns born in Delaware. Not every test is run on both specimens. See descriptions in sections for volumes and testing protocols.

All data resulting from the methods described in this RFP 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 should be detailed and may require additional agreements with the State of Delaware.

DEFINITIONS:

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

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

SPECIFICATIONS:

A. **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/initial specimens and only those second specimens with previously flagged results will be screened. The 2015 testing volume for patient testing, retests, controls, standards and surveys was 15,552 on 162 runs/plates.

Proposal Submitted, No Proposal Submitted

1. Fully automated testing method capable of running 150 patient samples per day with minimal sample and reagent preparation. Describe preparations needed.
2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred.
4. Vendor agrees, if manufactured outside of the continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
5. 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.
6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" Punch size preferred).
7. Quantitative method with ability to accurately identify Biotinidase levels in low and normal clinical ranges. Indicate reportable range, expected accuracy and source.
8. Method free from interfering substances. Indicate statistically significant interfering factors.
9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV levels at or below 10% for all ranges of analyte is preferred.
10. Method that is FDA approved and/or cleared.

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11. Method that uses 96-well microtiter plates.
12. 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.
13. If applicable, indicate type pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably the same matrix as a dried blood spot. Describe the standard material(s).
18. 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).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked Printer
21. A comprehensive software package with these capabilities:
 - a. User interface using _____specify 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. Include a sample report.
 - 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.

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- 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**
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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
 - c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. 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 within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
27. Delivery and Installation
- a. Delivery of all necessary equipment must be guaranteed to occur no later than 30 days after

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

B. 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/initial and second/repeat specimens from the Delaware newborn population will be screened. The 2015 testing volume for patient testing, retests, controls, standards and surveys was 30,800 on 321 plates/runs

Proposal Submitted, No Proposal Submitted

- 1. Fully automated testing method capable of running 250 patient samples per day with minimal sample and reagent preparation. Describe preparations needed.
- 2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
- 3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred.
- 4. Vendor agrees, if manufactured outside of the continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
- 5. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
- 6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
- 7. Quantitative method with ability to accurately identify Total Galactose levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
- 8. Method free from interfering substances. Indicate statistically significant interfering factors.
- 9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV levels at or below 10% for all ranges of analyte is preferred.

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10. Method is FDA approved and/or cleared.
11. Method that uses 96-well microtiter plates.
12. 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.
13. If applicable, indicate type pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably a dried blood spot matrix. Standard levels to range from 0.0 to 50.0 mg/dL. Describe the standard material(s).
18. Multiple levels of Controls made from human whole blood and hemoglobin adjusted to that of an average newborn, and spotted onto FDA-regulated filter paper provided with the kit. 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. Describe the control material(s).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked printer
21. A comprehensive software package with these capabilities:
 - a. User interface using _____ 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. Include a sample report.
 - 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:

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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,**
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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 problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. 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 within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

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27. 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 repeatable 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.

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

C. **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/initial specimens and a selected set of second/repeat specimens from the Delaware newborn population will be screened. The 2015 testing volume for patient testing, retests, controls, standards and surveys was 30,800 or 315 plates/runs. With the reduced volume by eliminating most testing on repeat samples, we expect the volume to be closer to 20,000 tests/year.

Proposal Submitted, No Proposal Submitted

1. Fully automated testing method capable of running 150 patient samples per day with minimal sample and reagent preparation. Describe preparations needed.
2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred.
4. Vendor agrees, if manufactured outside of the continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
5. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
7. Quantitative method with ability to accurately identify GALT levels in low and high clinical ranges. Indicate reportable range, accuracy and source.

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8. Method free from interfering substances. Indicate statistically significant interfering factors.
9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV levels at or below 10% for all ranges of analyte is preferred.
10. Method is FDA approved and/or cleared.
11. Method uses 96-well microtiter plates.
12. 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.
13. If applicable, indicate type pipettors to be used and whether pipettes and tips are included in the bid. Cost out individually for comparison purposes.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably in a dried blood spot matrix. Describe the standard material(s).
18. 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. Describe the control material(s).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked printer
21. A comprehensive software package with these capabilities:
 - a. User interface using _____ 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. Include a sample report.
 - f. On-board reagent tracking features to include bar code entry of kit lot information

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- 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,**
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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
 - c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. 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

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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 within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

27. 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 repeatable 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.

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

D. 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/initial and second/repeat specimens from the Delaware newborn population will be screened. The 2015 testing volume for patient testing, retests, controls, standards and surveys was 29,700 on 310 runs/plates.

Proposal Submitted, No Proposal Submitted

- 1. Fully automated testing method capable of running 250 patient samples per day with minimal sample and reagent preparation. Describe preparations needed.
- 2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
- 3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred.
- 4. Vendor agrees, if manufactured outside of continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
- 5. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.
- 6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
- 7. Quantitative method with ability to accurately identify **TSH** levels in low and high clinical ranges.

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Indicate reportable range, accuracy and source.

8. Method free from interfering substances. Indicate statistically significant interfering factors.
9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV levels at or below 10% for all ranges of analyte is preferred.
10. Method is FDA approved and/or cleared.
11. Method uses 96-well microtiter plates.
12. 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.
13. 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.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably in a dried blood spot matrix. Describe the standard material(s).
18. Multiple 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. Describe the control material(s).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked printer.
21. A comprehensive software package with these capabilities:
 - a. User interface using _____ 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. Include a sample report.

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- 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,**
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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
 - c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. 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

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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 within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

27. 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 repeatable 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.

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

E. **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 (in triplicate). The 2015 testing volume for initial, retests, controls, standards and surveys was 1000 on 29 runs/plates.

Proposal Submitted, No Proposal Submitted

- 1. Fully automated testing method capable of running 250 patient samples per day with minimal sample and reagent preparation, even though actual test volume is extremely low. Describe preparations needed.
- 2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
- 3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred. Explain packaging & reagent stability and plan to cover extremely low test volume.
- 4. Vendor agrees, if manufactured outside the continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
- 5. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.

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6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
7. Quantitative method with ability to accurately identify **T4** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
8. Method free from interfering substances. Indicate statistically significant interfering factors.
9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV levels at or below 10% for all ranges of analyte is preferred.
10. Method is FDA approved and/or cleared.
11. Method uses 96-well microtiter plates.
12. 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.
13. 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.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably in a dried blood spot matrix. Describe the standard material(s).
18. Multiple levels of control material made from human whole blood, with 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. Describe the control material(s).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked printer.
21. A comprehensive software package with these capabilities:
 - a. User interface using _____ 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

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- e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics. Include a sample report.
 - 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**.
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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 problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. 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

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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 within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

27. 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 repeatable 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.

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

F. 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/initial and second/repeat specimens from the Delaware newborn population will be screened. The 2015 testing volume for patient testing, retests, controls, standards and surveys was 30,300, on 316 runs/plates.

Proposal Submitted, No Proposal Submitted

- 1. Fully automated testing method capable of running 250 patient samples per day with minimal sample and reagent preparation. Describe preparations needed.
- 2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
- 3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred.
- 4. Vendor agrees, if manufactured outside continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
- 5. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred. Indicate total processing time and configurations.

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6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
7. Quantitative method with ability to accurately identify **17- α Hydroxyprogesterone** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
8. Method free from interfering substances. Indicate statistically significant interfering factors.
9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV at or below 10% for all levels of analyte is preferred.
10. Method is FDA approved and/or cleared.
11. Method uses 96-well microtiter plates.
12. 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.
13. 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.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably in a dried blood spot matrix. Describe the standard material(s).
18. Multiple levels of control material 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. Describe control material(s).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked printer.
21. A comprehensive software package with these capabilities:
 - a. User interface using _____ 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

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- e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics. Include example of sample report.
 - 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,**
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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 problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. 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

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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 two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

27. 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 repeatable 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.

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

G. IMMUNOREACTIVE TRYPSINOGEN (IRT) - For use as a screening test to aid in the identification of Cystic fibrosis in a newborn screening population. All first/initial specimens and only those second/repeat specimens with previous flagged results from the Delaware newborn population will be screened. The 2015 testing volume for patient testing, retests, controls, standards and surveys was 17,660 on 184 runs/plates.

Proposal Submitted, No Proposal Submitted

- 1. Fully automated testing method capable of running 150 patient samples per day with minimal sample and reagent preparation. Describe preparations needed.
- 2. Capacity to run method by one (1) full-time Technician, responsible for all testing described in this bid. Indicate specific processing steps that will be required with proposed method and hands-on time estimates.
- 3. 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. On board closed environment for reagents with controlled temperature and humidity is preferred.
- 4. Vendor agrees, if manufacturing occurs outside of the continental United States, to forward-stock three (3) months' supply of reagent kits in an alternate location.
- 5. Method that can be completed in one 7.5 hour work day. Methods with flexibility in timing preferred.

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Indicate total processing time and configurations.

6. Neonatal method that utilizes a dried blood spot punched from filter paper as the sample. Indicate punch size required (1/8" punch size preferred).
7. Quantitative method with ability to accurately identify **Immunoreactive Trypsin** levels in low and high clinical ranges. Indicate reportable range, accuracy and source.
8. Method free from interfering substances. Indicate statistically significant interfering factors.
9. Able to consistently reproduce results. Indicate expected Intra-assay, Inter-assay, and Total Variation statistics. Percent CV at or below 10% for all ranges of analyte is preferred.
10. Method is FDA approved and/or cleared.
11. Method uses 96-well microtiter plates.
12. 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.
13. 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.
14. A redundant method allowing work to continue uninterrupted in event of equipment failure. Describe redundancy.
15. 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.
16. Capacity to perform double the number of tests in one 7.5 hour shift.
17. Four or more levels of standards included and in sufficient quantity to run 2 replicates of each per plate, preferably in a dried blood spot matrix. Describe the standard material(s).
18. Multiple levels of control material 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. Describe the control material(s).
19. Computer and/or lap tops needed to process runs and generate reports.
20. Local or networked printer.
21. A comprehensive software package with these capabilities:
 - a. User interface using _____ technology.
 - b. Ability to interface with an automated punch. Describe requirements.
 - c. Ability to generate a sample list and/or plate map.

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- d. Standard curve fitting functionality
 - e. Produces run reports that include all standards, QC values, patient results, outliers, and other relevant statistics. Include example of report.
 - 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,**
22. 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.
23. 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.
24. Equipment UL approved and instrument manufactured in accordance with quality system requirements that comply with ISO 9001:2000 standards.
25. Warrantee for the entire system (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
 - c. If problem unsolvable by telephone, then on-site Technical Service available to correct the problem with a factory-trained engineer providing the service within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST
26. Maintenance agreement for the term of the contract to include:

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- 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 within two (2) working days, Monday – Friday 8:00 am – 5:00 pm EST

27. 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 repeatable 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.

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

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**APPENDIX B
Pricing Form**

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 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.	BIOTINIDASE					
B.	TOTAL GALACTOSE					
C.	GALT					
D.	TSH					
E.	T4					
F.	17-OHP					
G.	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.	BIOTINIDASE					
B.	TOTAL GALACTOSE					
C.	GALT					
D.	TSH					

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E.	T4					
F.	17-OHP					
G.	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.