

STATE OF MICHIGAN
DEPARTMENT OF TECHNOLOGY MANAGEMENT AND BUDGET
PURCHASING OPERATIONS
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

May 12, 2011

CHANGE NOTICE NO. 7
TO
CONTRACT NO. 071B2001213
between
THE STATE OF MICHIGAN
and

NAME & ADDRESS OF VENDOR Perkin Elmer Health Sciences, Inc. 710 Bridgeport Ave. Shelton, CT 06484 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (330) 242-5312
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 373-3993 Joe Kelly
Contract Compliance Inspector: Tammi Hart Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: June 30, 2011	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

NATURE OF CHANGE (S):

Effective immediately, this contract is hereby **INCREASED** by \$173,750. Please also note that the buyer for this contract is **CHANGED** to Joe Kelly and the Contract Administrator is being changed to Tammi Hart. All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per Agency request, DTMB Purchasing Operations approval and the approval of the State Administrative Board on March 18, 2008.

INCREASE: \$173,750.00

TOTAL REVISED ESTIMATED CONTRACT VALUE: \$2,178,359.00

STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 ACQUISITION SERVICES
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

November 19, 2009

CHANGE NOTICE NO. 6
TO
CONTRACT NO. 071B2001213
between
THE STATE OF MICHIGAN
and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (330) 242-5312
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 241-3215 Steve Motz
Contract Compliance Inspector: Sara Williams (517) 636-0499 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: June 30, 2011	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

NATURE OF CHANGE (S):

Per EO 2009-03, effective immediately, pricing for Future Enhancements is reduced by 10%. All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per Agency request and Vendor approval.

TOTAL ESTIMATED CONTRACT VALUE REMAINS: \$2,005,609.00

STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 ACQUISITION SERVICES
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

April 30, 2008

CHANGE NOTICE NO. 5
 TO
 CONTRACT NO. 071B2001213
 between
 THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (330) 242-5312
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 241-3215 Steve Motz
Contract Compliance Inspector: Sara Williams (517) 636-0499 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: June 30, 2011	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

NATURE OF CHANGE (S):

This contract is hereby EXTENDED to June 30, 2011 and is increased by \$521,250.00 for 3 years of support and enhancements per the attached Statement of Work. In addition, pricing for an option year 4 has been added. All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per agency request and DMB/Purchasing Operations approval. The Administrative Board approved a 3-year extension and an additional \$720,000 of funding on March 18, 2008. \$521,250.00 of this amount is being applied to this change notice, leaving a remaining balance of \$198,750.00.

INCREASE: \$521,250.00

TOTAL REVISED ESTIMATED CONTRACT VALUE: \$2,005,609.00



Specimen Gate® Support Quotation April 15, 2008

Michigan Department of Community Health
3350 N. Martin Luther King Blvd
Newborn Screening Lab
Lansing, MI 48906
(517) 335-9603

Proposal Ref #	Proposal Expires	Sales Representative	Terms
MI.15.04.2008	April 30th, 2008	Janet Perkins	Net 30 Days

Support Services:

Item	Catalog Number	Type	Modules	Price
1	5003-0530	Support (7/1/2008 - 6/30/2009)	Refer to Software Support Agreement	\$133,750
2	5003-0320	Enhancements (7/1/2008 - 6/30/2009)	Requirements to be determined	\$40,000
3	5003-0530	Support (7/1/2009 - 6/30/2010)	Refer to Software Support Agreement	\$133,750
4	5003-0320	Enhancements (7/1/2009 - 6/30/2010)	Requirements to be determined	\$40,000
5	5003-0530	Support (7/1/2010 - 6/30/2011)	Refer to Software Support Agreement	\$133,750
6	5003-0320	Enhancements (7/1/2010 - 6/30/2011)	Requirements to be determined	\$40,000
7	5003-0530	Support (7/1/2011 - 6/30/2012)	Refer to Software Support Agreement	\$133,750
8	5003-0320	Enhancements (7/1/2011 - 6/30/2012)	Requirements to be determined	\$40,000
TOTAL				\$695,000

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Support Services:

Support Services are to be provided from July 1st, 2008, through June 30th, 2011. Refer to the Software Support Agreement below for details.

REVIEWED BY: Mike O'Shea

APPROVED BY: Darren C. Hudach

EXECUTIVE SUMMARY

PerkinElmer will supply the services described in Section 2 below ("Scope of Support") to the Customer with respect to the products described in Section 1 below ("PerkinElmer's Software") for which PerkinElmer has granted a license to the Customer pursuant to a software license agreement by and between PerkinElmer and Customer.

1. PERKINELMER'S SOFTWARE

The software systems supported under this Agreement include:

<i>Product Name</i>	<i>Product Version</i>	<i>Notes</i>
Specimen Gate Laboratory	1.2	
Specimen Gate Office	3.1.8	
Specimen Gate PatientCare	2.0	

The following third party licenses are not provided by PerkinElmer but are required in order for Specimen Gate® to function:

<i>Product Name</i>	<i>Product Version</i>	<i>Notes</i>
SQL Server Enterprise Edition	2000 or later	Need an end-user license for all users of Specimen Gate® (Laboratory, Office, and PatientCare™)
Microsoft Word	2000 or later	Need an end-user license for all users of PatientCare™
Adobe Acrobat Reader	7.0 or later	Need an end-user license for all users of Specimen Gate® (Laboratory, Office, and PatientCare™)
Crystal Reports	8.5	Run-time version is distributed with Office 3.1.8. The full version is only needed if user wants to edit or create new reports
Win2PDF	3.0 or later	Need an end-user license for all users of PatientCare™
TeleForm	8.2	Needed for custom scanning solution. All updated versions must be compatible with 8.2.

2. SCOPE OF SUPPORT

The following are included in the scope of this Agreement (including travel expenses).

- Support services to correct an error which is attributed to PerkinElmer or which affects use of the System
- System recovery services that are required as a result of:
 - User error
 - Network outage or interruption
 - Power outage or interruption
 - Replacement of server or workstation hardware
- Software updates to features previously implemented for the Customer including:

- Those that fix system errors
- Improvements, changes or additions to existing features
- Software configuration changes to:
 - Existing punching protocols *
 - Existing cutoff values *
 - Existing demographic entry forms *
 - Existing result reporting logic *
 - Existing follow-up protocols *
- Integration of additional instruments assuming the instrument has previously been integrated into the Customer's system *

* Changes shall follow the PerkinElmer Software Change Request Process

3. SUPPORT SERVICE TIMES

Support Services will be available from 8AM to 5PM ET, Monday through Friday, except public, bank and other holidays observed by PerkinElmer employees in the United States.

4. SUPPORT SEVERITY LEVELS

PerkinElmer recognizes three (3) severity levels for support issues.

Urgent

A support issue is considered to be Urgent if it meets one of the following conditions:

- System does not allow the Customer to view or enter demographic, result or case data necessary to determine if a sample indicates risk for a disorder
- System produces results that are not equivalent to those expected to be produced as defined in the agreed upon specifications and the results cannot be modified prior to being reported
- System cannot perform a function that is required for results to be reported within the standard lab turn-around time for a single specimen
- System does not allow an action to be performed in patient follow up
- System's positive ID tracking is not accurate
- System presents an error that prevents the completion of an important task and the task cannot be completed by a reasonable workaround or by repeating the task
- System cannot be accessed or used due to:
 - User error
 - Network outage or interruption
 - Power outage or interruption
 - Required replacement of server or workstation hardware

PerkinElmer will acknowledge the receipt of Urgent support issues within four (4) PerkinElmer business hours of receipt of the issue. PerkinElmer business hours are as defined in "Support Service Times" above.

- PerkinElmer will work on Urgent support issues until resolved or as long as useful progress can be made.
- In the event a resolution cannot be provided to an Urgent support issue, PerkinElmer shall work with the Customer to develop a reasonable work around, subject to approval by the Customer.

Moderate

A support issue is considered to be Moderate if it meets one of the following conditions:

- System presents an error. However, results can be reported within the standard lab turn-around time for a single specimen and actions can be performed within the follow up system by using a reasonable workaround.

- System performance is delayed. However, results can be reported within the standard lab turn-around time for a single specimen and actions can still be performed within the follow up system by using a reasonable workaround.
- System does not allow an individual access to a specific module.

PerkinElmer will work on Moderate support issues until resolved or as long as useful progress can be made.

Minor

A support issue is considered to be Minor if it meets the following condition:

- An error in visual presentation, including misspelling or incorrect order or display of columns.

PerkinElmer will provide solutions to Minor support issues as part of a future software update.

5. SOFTWARE UPDATES

PerkinElmer periodically releases product updates which are provided to the Customer as defined in "Scope of Support" above. These updates will be implemented at the Customer site at a mutually agreed upon time.

New products, modules and add-ons are offered by PerkinElmer to the Customer for an additional fee and are not included in this Agreement.

6. CUSTOMER RESPONSIBILITIES

PerkinElmer's obligation to provide support is contingent upon the Customer complying with the following conditions:

- Paying the mutually agreed upon support or reagent rental fees
- Provide PerkinElmer with sufficient information and resources to correct all support issues
- Obtain PerkinElmer's written permission prior to performing or attempting to perform modifications to the System (PerkinElmer shall not be responsible for maintaining Customer modified portions of the System or for maintaining portions of the System affected by Customer modified portions of the System)
- Comply with PerkinElmer's "Software Deployment Terms and Conditions" regarding support services

7. SUPPORT COMMUNICATION

The Customer shall communicate all support issues by phone, e-mail or via PerkinElmer's support software. Phone numbers, e-mail addresses and internet sites are provided to the Customer separate from this Agreement.

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PerkinElmer Life and Analytical
3985 Eastern Road
Norton, OH 44203
Phone: 1-800-321-9632 ext 469
Fax: 501-694-8598
www.perkinelmer.com

memo

Date: April 15, 2008
To: Lena Jedeon
From: Darren C. Hudach
Re: MDCH Maintenance and Support Provisions
cc: Dr. Kevin Cavanagh, Dr. Downes, Linda Myers, Janet Perkins

Lena,

PerkinElmer has responded to your maintenance and support provisions items a, e, f, and g as stated below.

- a. Maintenance programs commence at the end of the warranty period.
The Software Support Agreement defines the parameters of the warranty.
- b. All maintenance must be performed by qualified personnel familiar with the equipment.
- c. The Vendor will have secure remote VPN access to the Perkin Elmer - Specimen Gate software in both test and production environments.
- d. The vendor will be granted database rights needed (i.e. DBO access) to maintain and support the database server.
- e. All development must be performed and tested on the test database.
Development in this case is defined as "schema changes".
- f. All schema changes will be scripted by the vendor and passed to the Department of Information Technology (MDIT) for execution on the production database.
This is subject to the conditions of the "PerkinElmer Hardware Requirements" sent on August 15, 2007.
- g. Scripted data changes will be sent to MDIT for execution.
This is subject to the conditions of the "PerkinElmer Hardware Requirements" sent on August 15, 2007.
- h. The vendor will be granted remote access to the Instrument Workstations and Scheduler (computer used to import results as they are released by instruments).

Thanks,

*Darren C. Hudach
United States Team Leader, Genetic Screening Software Services
PerkinElmer Life and Analytical Sciences
3985 Eastern Road
Norton, OH 44203
Phone: 800.321.9632 / 330.825.4525 ext. 320
Mobile: 330.284.4912*

Software Change Request Process

For the purposes of this Software Change Request Process document, the "Company" refers to PerkinElmer LAS, Inc. and the "Customer" refers to the party receiving the Company's software and/or services.

During the deployment and support of software projects, functionality may be requested that must go through the Software Change Request Process. Functionality requests that must go through this process are those of the following types:

- A request for functionality that has not been previously agreed to by both parties in writing.
- A request to change or remove functionality that has been previously agreed to by both parties in writing.

The following steps should be followed for software change requests:

1. The request is initiated by the Customer or a support request is determined by the Company's software team to be a change request.
2. The Company and Customer define and mutually agree to the requirements of the request.
3. The Company will produce a response within twenty (20) business days upon receipt of the request. This response will either be:
 - a. Acknowledgement that the request is covered as part of a Software Support Agreement.
 - b. Acknowledgement that the request cannot be fulfilled and the reason it cannot be fulfilled.
 - c. Acknowledgement that the request can be fulfilled including the cost and estimated timeline for completion.
4. The request will be scheduled upon receipt of a mutually signed response document or purchase order.
5. Within ten (10) days of the implementation of the requested change, the Customer will validate the change and sign an acceptance document (template to be provided by the Company) stating the request is complete and accepted.



Date: August 15, 2007
To: Lena Jedeon
From: Aniket Parekh
Re: PerkinElmer Hardware Requirements
cc: Dr. Kevin Cavanagh, Dr. Downes, Linda Myers, Darren Hudach

Lena,

As discussed, please find a list of our requirements along with the justification for each. I have also included the impact on the newborn screening program if the requirement is not met.

Item 1: Database Server Permissions

The domain user group named "PerkinElmer Contractor" must be granted Power User access.

Justification: As a result of erroneous situations sometimes necessary services need to be explicitly stopped and re-started. Hence we request ability to start and stop MS SQL sever services.

Impact: SQL server may not function as expected resulting in partial or complete failure of everyday usage of SpecimenGate™ software modules.

Item 2: SQL Server Permissions

All accounts that are part of the domain user group "PerkinElmer Contractor" must be granted administrator / DBO level access for SQL Server. PerkinElmer and DIT agree to the following conditions regarding schema changes and data changes:

- a. Schema Changes
 - i. PerkinElmer agrees to the following:
 1. All schema changes will be scripted by PerkinElmer and passed to the Department of Information Technology (DIT) for execution.
 - ii. DIT agrees to the following:
 1. Schema Changes regarding Level One – Fatal defects will be executed within 15 minutes of receipt 24 hours a day, 7 days a week. A confirmation email will be sent to specimen.gate.support@perkinelmer.com.
 2. Schema Changes regarding Level Two – Critical defects will be executed within 1 hour of receipt 24 hours a day, 7 days a week. A confirmation email will be sent to specimen.gate.support@perkinelmer.com.
 3. Schema Changes regarding Level Three or Four defects will be executed within 16 working hours of receipt during normal

business hours of 8AM to 5PM. A confirmation email will be sent to specimen_gate.support@perkinelmer.com.

iii. *Justification:*

1. **Level One – Fatal** defects have the following conditions:
 - a. System does not allow the Customer to view or enter demographic, result or case data necessary to determine if a sample indicates an infant is at risk for a disorder.
 - b. System produces erroneous results.
 - c. System cannot perform a function that is required for results to be reported for an infant.

Level One defects have the potential to affect laboratory turnaround times, and often need to be fixed within 15 minutes or less.

2. **Level Two – Critical** defects have the following conditions:
 - a. System presents an error that prevents the completion of an important task. The task cannot be completed by a reasonable workaround or by repeating the task.
 - b. System creates delays or failures in reporting. Results can be reported but not within the standard lab turn-around time for a single specimen.

Level Two defects have the potential to affect laboratory turnaround times, and often need to be fixed within 1 hour or less.

3. **Level Three and Four** defects are less serious and do not need to be addressed as quickly.

iv. *Impact:*

1. If **Level One** defects are not addressed within 15 minutes, laboratory turnaround times may be affected. If a specimen at risk for a disorder is reported out late it can have serious health consequences for that patient, along with putting the Michigan Department of Community Health at risk for legal action.
2. If **Level Two** defects are not addressed within 60 minutes, laboratory turnaround times may be affected. If a specimen at risk for a disorder is reported out late it can have serious health consequences for that patient, along with putting the Michigan Department of Community Health at risk for legal action.
3. If **Level Three or Four** defects are not addressed within 16 hours, the laboratory will be forced to operate with workarounds for longer than necessary.

b. **Data Changes**

i. PerkinElmer and DIT agree to the following:

1. When possible data changes will be scripted and sent to DIT for execution. DIT acknowledges that some data changes will be conducted by PerkinElmer directly and without the prior consent of DIT. DIT agrees to the above conditions for turnaround times when data changes are sent to them for execution.

PerkinElmer requires this level of access for the following reasons:

- One of the three primary applications used by the MDCH Newborn Screening program, LifeCycle™, requires DBO permissions.
- Many data changes are completed through configuration applications. These applications do not have scripting capabilities, thus necessitating that some changes will be done on the production server via administrator permissions.
- Many defects require the use of SQL Server Profiler as a troubleshooting step. This requires administrator permissions.

Item 3: Remote Access to the Database Server

PerkinElmer requires always-on high-speed remote access to the Database Server in order to respond to defects as detailed above. This access currently exists in the form of a VPN in combination with Remote Desktop Connection (RDC) into the server. In order to accommodate this level of remote access the domain user group named "PerkinElmer Contractor" must be part of the "Remote Desktop Users" group with the policy pushed to the server all workstations that are running Specimen Gate®, Firewall settings must also be adjusted as appropriate in order to accommodate this access.

Justification: Specimen Gate® is a mission critical application that is utilized by the Michigan Department of Health to send reports to submitters for newborns potentially at risk for life threatening disorders. This type of application requires constant remote access in order to be supported effectively.

Impact: Without consistent access to the Specimen Gate® server, support personnel may not be able to respond to issues within a timely manner, potentially causing life-threatening delays to the children of Michigan.

Item 4: Results Import Setup

PerkinElmer™ requires that a separate computer is used to import results as they are released by instrument, SpecimenGate™ scheduling application, 'Scheduler' should be started when user logs in to that computer and it should be kept running at all times. PerkinElmer™ also requires always-on high-speed remote access to this computer. Preferred way to connect is VPN in combination with Remote Desktop Connection (RDC).

Justification: Using a separate computer to import results will allow the server to host databases only. No PerkinElmer™ applications will then be installed on the server. Importing results is one of the most critical processes in the system and it must happen in timely manner to meet expected turnaround times.

Impact: If 'scheduler' is not running or it fails to import results to SpecimenGate™, scientists will not be able to interpret and review results. Therefore the entire newborn screening processes stops and turnaround times are severely affected.

Item 5: Remote Access to Instrument Workstations

PerkinElmer™ requires remote access to workstations that are connected to PerkinElmer™ instruments. Preferred way to connect is VPN in combination with Remote Desktop Connection (RDC).

Justification: In case of instrument software or hardware failure or changes in configurations, instrument service engineers and software engineers would need to connect directly to the instrument to address the situation.

Impact: If instrument fully or partially fails to process plates, samples from those plates would not be ready and results could not be imported to SpecimenGate™. The turnaround times for these plates would be severely affected.

Item 6: Rebooting Database Server

In addition of MDCH personnel from the lab, SpecimenGate™ support team should be informed in advance when database server would be rebooted.

Item 7: Email Notifications on failed execution of scheduled SQL job

PerkinElmer™ requires that SpecimenGate™ support team is notified via email when a SQL job fails to execute successfully.

Justification: SpecimenGate™ LIMS uses several SQL jobs which are scheduled to execute on intervals from 5 minutes throughout the day to once a week. These jobs are essential to daily operations of the system as well as routine database maintenance.

Impact: If not completed successfully system will fail to create followup cases which will result in a delay informing test results to interested parties. It may also cause delay in treating affected infant.

Item 8: Administrative Permissions on SQL server for certain period of time

PerkinElmer™ request administrative access to database server and SQL server during the time of installation and configuration of SpecimenGate™ databases. Three weeks after the server being in production environment, those permissions could be adjusted as described in **Item 1 and Item 2.**

It was also noted during our meeting that your team would take complete responsibility for the database backups and transaction log backups as suggested in **Backup Recommendations - Aug 15 2007** memo sent earlier today.

I am confident that by working together we can come to a mutually agreeable solution that meets both of our requirements, while providing the highest level of service and support to the Michigan Newborn Screening Team.

Thank you,

Aniket Parekh
Sr. Software Integration Engineer,
Genetic Screening Software Services
aniket.parekh@perkinelmer.com

STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 ACQUISITION SERVICES
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

August 28, 2007

CHANGE NOTICE NO. 4
 TO
 CONTRACT NO. 071B2001213
 between
 THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (330) 242-5312
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 241-3215 Steve Motz
Contract Compliance Inspector: Sara Williams (517) 636-0499 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: June 30, 2008	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

NATURE OF CHANGE (S):

This contract is hereby EXTENDED to June 30, 2008 and is increased by \$170,000 per the attached Statement of Work. All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per agency request and DMB/Purchasing Operations approval. Ad Board approved on August 21, 2008.

INCREASE: \$170,000.00

TOTAL REVISED ESTIMATED CONTRACT VALUE: \$1,484,359.00



Specimen Gate® Support Quotation August 9, 2007

Michigan Department of Community Health
3350 N. Martin Luther King Blvd
Newborn Screening Lab
Lansing, MI 48906
(517) 335-9603

Proposal Ref #	Proposal Expires	Sales Representative	Terms
MI.09.08.2007	August 31, 2007	Janet Perkins	Net 30 Days

Support Services:

Item	Catalog Number	Type	Modules	Price
1	5003-0530	Maintenance and Support (12 months)	Refer to Software Support Agreement	\$125,000.00
TOTAL				\$125,000.00

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Support Services:

Support Services are to be provided from July 1st, 2007, through June 30th, 2008. Refer to the Software Support Agreement (below) for details.

REVIEWED BY: Mike O'Shea

APPROVED BY: Darren C. Hudach

EXECUTIVE SUMMARY

PerkinElmer will supply the services described in Section 2 below ("Scope of Support") to the Customer with respect to the products described in Section 1 below ("PerkinElmer's Software") for which PerkinElmer has granted a license to the Customer pursuant to a software license agreement by and between PerkinElmer and Customer.

1. PERKINELMER'S SOFTWARE

The software systems supported under this Agreement include:

Product Name	Product Version	Notes
Specimen Gate Laboratory	1.2	
Specimen Gate Office	3.1.8	
Specimen Gate PatientCare	2.0	

2. SCOPE OF SUPPORT

The following are included in the scope of this Agreement (including travel expenses).

- Support services to correct an error which is attributed to PerkinElmer or which affects use of the System
- System recovery services that are required as a result of:
 - User error
 - Network outage or interruption
 - Power outage or interruption
 - Replacement of server or workstation hardware
- Software updates to features previously implemented for the Customer including:
 - Those that fix system errors
 - Improvements, changes or additions to existing features
- Software configuration changes to:
 - Existing punching protocols *
 - Existing cutoff values *
 - Existing demographic entry forms *
 - Existing result reporting logic *
 - Existing follow-up protocols *
- Integration of additional instruments assuming the instrument has previously been integrated into the Customer's system *

* Changes shall follow the PerkinElmer Software Change Request Process

3. SUPPORT SERVICE TIMES

Support Services will be available from 8AM to 5PM ET, Monday through Friday, except public, bank and other holidays observed by PerkinElmer employees in the United States.

4. SUPPORT SEVERITY LEVELS

PerkinElmer recognizes three (3) severity levels for support issues.

Urgent

A support issue is considered to be Urgent if it meets one of the following conditions:

- System does not allow the Customer to view or enter demographic, result or case data necessary to determine if a sample indicates risk for a disorder
- System produces results that are not equivalent to those expected to be produced as defined in the agreed upon specifications and the results cannot be modified prior to being reported
- System cannot perform a function that is required for results to be reported within the standard lab turn-around time for a single specimen
- System does not allow an action to be performed in patient follow up
- System's positive ID tracking is not accurate
- System presents an error that prevents the completion of an important task and the task cannot be completed by a reasonable workaround or by repeating the task
- System cannot be accessed or used due to:
 - User error
 - Network outage or interruption
 - Power outage or interruption
 - Required replacement of server or workstation hardware

PerkinElmer will acknowledge the receipt of Urgent support issues within four (4) PerkinElmer business hours of receipt of the issue. PerkinElmer business hours are as defined in "Support Service Times" above.

- PerkinElmer will work on Urgent support issues until resolved or as long as useful progress can be made.
- In the event a resolution cannot be provided to an Urgent support issue, PerkinElmer shall work with the Customer to develop a reasonable work around, subject to approval by the Customer.

Moderate

A support issue is considered to be Moderate if it meets one of the following conditions:

- System presents an error. However, results can be reported within the standard lab turn-around time for a single specimen and actions can be performed within the follow up system by using a reasonable workaround.
- System performance is delayed. However, results can be reported within the standard lab turn-around time for a single specimen and actions can still be performed within the follow up system by using a reasonable workaround.
- System does not allow an individual access to a specific module.

PerkinElmer will work on Moderate support issues until resolved or as long as useful progress can be made.

Minor

A support issue is considered to be Minor if it meets the following condition:

- An error in visual presentation, including misspelling or incorrect order or display of columns.

PerkinElmer will provide solutions to Minor support issues as part of a future software update.

5. SOFTWARE UPDATES

PerkinElmer periodically releases product updates which are provided to the Customer as defined in "Scope of Support" above. These updates will be implemented at the Customer site at a mutually agreed upon time.

New products, modules and add-ons are offered by PerkinElmer to the Customer for an additional fee and are not included in this Agreement.

6. CUSTOMER RESPONSIBILITIES

PerkinElmer's obligation to provide support is contingent upon the Customer complying with the following conditions:

- Paying the mutually agreed upon support or reagent rental fees
- Provide PerkinElmer with sufficient information and resources to correct all support issues
- Obtain PerkinElmer's written permission prior to performing or attempting to perform modifications to the System (PerkinElmer shall not be responsible for maintaining Customer modified portions of the System or for maintaining portions of the System affected by Customer modified portions of the System)
- Comply with PerkinElmer's "Software Deployment Terms and Conditions" regarding support services

7. SUPPORT COMMUNICATION

The Customer shall communicate all support issues by phone, e-mail or via PerkinElmer's support software. Phone numbers, e-mail addresses and internet sites are provided to the Customer separate from this Agreement.

Specimen Gate® is a registered trademark of PerkinElmer, Inc. LifeCycle™ and PatientCare™ are trademarks of PerkinElmer. All other trademarks are property of their respective owners.

All information contained herein is confidential and proprietary to PerkinElmer Life and Analytical Sciences.

The information contained in this document is intended solely for the use of the recipient and contains information that is confidential and may be legally privileged. Access to this document by anyone else is unauthorized. Reproduction, republication, disclosure, dissemination, transfer or other conveyance of this document is strictly prohibited without the prior written consent of an authorized representative of PerkinElmer.



Specimen Gate® Quotation

8/3/2006

Michigan Department of Community Health
 3350 N. Martin Luther King Blvd
 Newborn Screening Lab
 Lansing, MI 48906
 (517) 335-9603

Quote Ref #	Quote Expires	FOB	Sales Representative	Terms
MI.SG.2006.08.01.01	November 1 st , 2006		Janet Perkins	Net 30 Days

Item	Catalog Number	Module	Qty Per Year	Price (\$USD)	Extended Price (\$USD)
1	5003-0320	Neonatal software configuration service	NA	\$45,000.00	\$45,000.00

Definitions:

Company: PerkinElmer Life and Analytical Sciences
 Customer: Michigan Department of Community Health

Scope of Contract:

- This quote serves as an initial scope of contract. Project scope will be elaborated during the creation of a Component Configuration Document (CCD), which will be used to configure the product. Customer sign-off of the CCD is required.
- The following services are provided as part of this quote:
 - The Company will configure Specimen Gate® Laboratory, LifeCycle™, and PatientCare™ modules as described in the Project Deployment section below.
 - The Company will perform internal validation of the software configuration. The Customer is expected to perform final, comprehensive validation of the Specimen Gate® configuration prior to using the software in a live production environment.
 - The Customer will receive one hands-on training class prior to using the software in a live production environment, followed by continued support throughout the 3-5 day site visit while the system is being fully utilized by the Customer.
 - Only new features will be trained.
 - Customer IT is responsible for setting up a room with a projector and functioning Specimen Gate® clients.
- Features that are not available within the Specimen Gate® software will not be custom developed as part of the scope of this contract.

Project Deployment

- The Specimen Gate® Product Description serves as a baseline definition of the Specimen Gate® product features. Additional features, or features that require clarification, are described below.
- Specimen Gate® Laboratory
 - This quote assumes that the Cystic Fibrosis (CF) testing will use IRT as the screening test with DNA as the confirmation test.
 - IRT screening results will be imported into Specimen Gate®.
 - Results import will match the configuration of current AutoDelfia tests.
 - A test will be configured in Specimen Gate® for IRT.
 - DNA confirmation results will be entered manually in Result Viewer.
 - A test will be configured for DNA.
 - A drop down list will be available for selecting the appropriate mutation.
 - Up to thirty mutations may be configured in the drop down list.
 - None, one, or two mutations may be selected per result.
 - The combination of mutations selected per result must be interpreted into a final result for purposes of the mailer, PatientCare™, etc.
 - LifeCycle™
 - Result Editor configured for IRT and the final DNA result.
 - If multiple mutations are selected per result they can not be edited, only the final result used for the mailer and PatientCare™ may be edited in Result Editor.
 - Mailer (i.e. Laboratory Result Report) will be modified for CF per the line items below.
 - One mailer group for CF will be created.

PerkinElmer Life and Analytical Sciences
 3985 Eastern Road
 Norton, Ohio 44203, USA
[Technical Support for Genetic Screening products](#)
 Telephone 800-321-9632 (USA only)
 Fax 330-825-8520



Specimen Gate® Quotation

- One mailer comment can be associated with the above mailer group.
- The final abnormal result will be displayed on the mailer.
- Queries and reports
 - Up to 10 existing queries and reports will be modified to accommodate CF testing
 - Up to 2 new queries and reports may be created as part of this quotation
- PatientCare™
 - PatientCare™ Workflow
 - Allow creating up to two unique workflows for CF.
 - PatientCare™ Worksheet
 - Allow creating up to two worksheet folders; one per workflow.
 - CF disorder will be added to existing searches and applicable worksheet views.
 - PatientCare™ Letters.
 - Allow for up to 3 unique letters per workflow.
 - For reporting results to the responsible party a copy of the mailer will be used.

Project Assumptions:

- The Customer and Company agree to the contents of the following for the duration of the project:
 - Specimen Gate® Deployment Terms and Conditions.
 - Specimen Gate® Change Request Process.
- The Company will provide specifications for any additional hardware and 3rd party software. The customer is expected to acquire these items.
- Commencement of this project is dependent on completion of the following tasks:
 - The customer has assigned a dedicated Laboratory Subject Matter Expert as indicated in the Deployment Terms and Conditions.
 - The customer has the capabilities and capacity to run specimens through the instrumentation.
 - The customer has provided external high speed remote connectivity to the Specimen Gate® hardware.
- The Specimen Gate® software configuration activities will be conducted primarily off-site.
- The addition of CF to Specimen Gate® may result in an increase in support fees at next renewal.

Project Signoff:

Customer signoff verifies the delivery of the software configurations as defined in this document. This signoff verifies the customer has accepted all deliverables and acknowledges the project is complete.

If customer signoff has not been received 15 business days after the go-live date (go-live is defined as the customer reporting Cystic Fibrosis results), then all system anomalies are to be submitted in writing to PerkinElmer with an impact statement and issue description within 5 additional business days (no later than 20 business days from the go-live date). PerkinElmer will respond in writing to each system anomaly within ten Business days or a mutually agreed upon timeline and conduct a conference call to discuss the issue(s). Disputed items will be referred to the United States Team Leader of Genetic Screening Software Services at PerkinElmer, and to the Laboratory Directory at MDCH.

Invoicing:

An invoice will be generated and sent to the Customer 10 days after the go-live date (go-live is defined as the customer reporting Cystic Fibrosis results). Any outstanding issues per the above project signoff will be addressed as part of the support agreement.

REVIEW BY: Darren C. Hudach

APPROVED BY:

PerkinElmer Life and Analytical Sciences
3985 Eastern Road
Norton, Ohio 44203, USA
[Technical Support for Genetic Screening products](#)
Telephone 800-321-9632 (USA only)
Fax 330-825-8520

STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 ACQUISITION SERVICES
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

December 11, 2006

CHANGE NOTICE NO. 3
TO
CONTRACT NO. 071B2001213
between
THE STATE OF MICHIGAN
and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (330) 242-5312
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 241-3215 Steve Motz
Contract Compliance Inspector: Sara Williams (517) 636-0499 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: June 30, 2007	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

NATURE OF CHANGE (S):

This contract is hereby EXTENDED to June 30, 2007 and is increased by \$62,500.00. All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per agency request and DMB/Acquisition Services approval.

INCREASE: \$62,500.00

TOTAL REVISED ESTIMATED CONTRACT VALUE: \$1,314,359.00

STATE OF MICHIGAN
DEPARTMENT OF MANAGEMENT AND BUDGET
ACQUISITION SERVICES
P.O. BOX 30026, LANSING, MI 48909
OR
530 W. ALLEGAN, LANSING, MI 48933

October 10, 2005

CHANGE NOTICE NO. 2
TO
CONTRACT NO. 071B2001213
between
THE STATE OF MICHIGAN
and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (330) 242-5312
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 241-3215 Steve Motz
Contract Compliance Inspector: Sara Williams (517) 636-0499 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: January 1, 2007	
TERMS N/A	SHIPMENT N/A
F.O.B. N/A	SHIPPED FROM N/A
MINIMUM DELIVERY REQUIREMENTS N/A	

NATURE OF CHANGE (S):

PLEASE NOTE: The vendor telephone number has been changed to (330) 242-5312.

All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per agency request and DMB/Acquisition Services approval.

TOTAL ESTIMATED CONTRACT VALUE REMAINS: \$1,251,859.00

STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 ACQUISITION SERVICES
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

July 27, 2005

CHANGE NOTICE NO. 1
TO
CONTRACT NO. 071B2001213
between
THE STATE OF MICHIGAN
and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203	TELEPHONE Janet Perkins (800) 391-9632 ext. 257
	VENDOR NUMBER/MAIL CODE
	BUYER/CA (517) 241-3215 Steve Motz
Contract Compliance Inspector: Sara Williams (517) 636-0499 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: January 1, 2007	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

NATURE OF CHANGE (S):

Effective immediately, this contract is hereby **EXTENDED** for one (1) year. The new contract end date is January 1, 2007. Also, this contract is hereby **INCREASED** by \$375,000.00 to provide 2 years of maintenance support at \$125,000.00 per year and the addition of another lab for \$125,000.00. (See attached statement of work)

PLEASE NOTE: The buyer has been **CHANGED** to Steve Motz.
 The Contract Compliance Inspector has been **CHANGED** to Sara Williams.

All other terms, conditions, specifications and pricing remain unchanged.

AUTHORITY/REASON:

Per agency and vendor concurrence dated 7/11/2005 and DMB/Acquisition Services approval.

INCREASE: \$375,000.00

TOTAL REVISED ESTIMATED CONTRACT VALUE: \$1,251,859.00

**Contract #071B2001213
Between
The State of Michigan
And
Perkin Elmer Life Sciences, Inc.
Statement of Work Addendum
For the period 8/01/05 to 4/30/06**

Pursuant to Section I-AA Modification of Service – page 15 “The Director of Purchasing reserves the right to modify this service during the course of this contract. Such modification may include adding or deleting tasks that this service shall encompass and/or other modifications deemed necessary, in accordance with the process as detailed within this Section of the Agreement...”

DIT/DCH requests the below addendum to Section II – Work Statement.

Pursuant to Section II-A A. Problem Statement – page 27 “The Division of Chemistry and Toxicology, within the Michigan Department of Community Health’s bureau of Laboratories, has a Perkin Elmer Laboratory Information System (LIS) that needs to be extended to the Analytical Chemistry section to accommodate reporting chemical terrorism and other hazardous agents in clinical specimens. This Laboratory Information System (Perkin Elmer Labworks) is required to electronically track the status of specimens and related requests, be compatible with current software, hardware and equipment, and enable on-line status inquiry and reporting requirements. The Trace Metals LIS section and Newborn Screening LIS section are currently operational and this modification of service will extend this LIS to Analytical Chemistry. Upgrades to meet PHIN requirements will be incorporated

Pursuant to the above Problem statement, the following item is being added:

- **Establish a Laboratory Information System for Analytical Chemistry Lab**

The Division of Chemistry and Toxicology, within the Michigan Department of Community Health’s Bureau of Laboratories, does not have a Laboratory Information System for the Analytical Chemistry Lab. A system is required to electronically track specimens from point of receipt through reporting of results. The LabWorks system, which has these capabilities, has been implemented in the Trace Metals Lab. Implementation of the LabWorks system will meet the requirements of the Analytical Chemistry Lab.

- **Enhancements to Newborn Screening Software**

The Newborn Screening Section of the Chemistry and Toxicology, within the Michigan Department of Community Health’s Bureau of Laboratories uses PerkinElmer software, (Specimen Gate, Lifecycle and Patient Care modules) to meet the needs of its high volume laboratory workload. To continue to meet Newborn Screening laboratory workload demands and for test expansion as mandated by new Federal guidelines, application modifications to the PerkinElmer software will be delivered based on development schedules, work plans, specification documents agreed by Newborn Screening Section and available budget.

Pursuant to Section II-A – page 29 add the following section for Analytical Chemistry Request:

H. Project: Implementation of Labworks in the Analytical Chemistry Lab

The contractor will provide software licenses, software maintenance, installation, business rules consulting, required software modification, reporting formats, and service maintenance, configuration and integration assistance for implementation of the LabWorks software in the Analytical Chemistry Lab.

This software must provide for the following:

- Access for 15 additional laboratory staff with security based on their duties – 10 existing Labworks licenses will be used for these staff. There may be a need to purchase additional licenses in the future – please include license structure and cost in the quote.
- Interface with the following equipment:

Name Vendor/version

1. Varian 3400 CX
2. Varian 3800 CX
3. Agilent 6890
4. Agilent 6890
5. ABI 4000
6. Thermo Finnegan Trace 2000

- Ability to add additional instruments

All hardware will be supplied by MDIT/MDCH. The housing and operation of the hardware and the interface with the State's network is the responsibility of MDIT. Delineation of the hardware specifications is the responsibility of the vendor and must be given to MDIT 90 days prior to the date of its first use

Pursuant to Section II-B System Requirements – page 41 after II “Virology Equipment and the EPIC Database.”

JJ. Analytical Chemistry System Requirements

- A. Automation of processing specimens from request to results.

This includes:

Scanning of requests

Complete tracking of specimens including bar coding of specimens, with date, time, by whom, unique identifier for aliquots, and fractions of samples prepared in the lab.

Method and data Quality control, including mean, SD, charting of data with warning & rejection limits, qc outlier reports, trend analysis, trouble shooting, maintenance logs & reminders, exporting of data.

- B. Meet following reporting requirements:

Lab reports for total PCBs and individual congeners, (tissue, adipose tissue, breast milk, serum, urine) pesticides (multiple specimen types), total PBBs and individual congeners (serum), chemical terrorism (blood - cyanide, urine- 5 nerve agents and sulfur mustard), total PDBEs and individual congeners, environmental specimens (liquid, solid, powder) for both qualitative and quantitative analysis.

Reports can be reported as received, pending, preliminary, partial or final

Additional tests as required by CDC, re: chemical terrorism

Meet PHIN compliance and have the ability to send and receive HL7 transactions

Ability to key-in test results including free text comments

Auto fax to public health labs, hospitals and other healthcare providers with audit trail using SMTP.

Report printing available in batch mode or individual reports

Ability to generate ad-hoc reports

- C. Management reports as described below:

Billing and invoicing

Test counts and workload

Work lists

Supervisor Review
Incomplete Work List
Tracking of Specimen Status (received, in-process, preliminary, partial or final)
Turnaround time reports
Amended reports
Must provide capability to Sort data by analyte within a report

D. Must provide for import and export of data.

Import of data into CDC (excel), DNR (access) databases

HL7 format

Test database to allow for testing of new versions of software of database before implementation, training of staff or testing of interfaces for new equipment.

Provide technical support to develop a “downtime” plan and any necessary software revisions associated with the implementation of the plan

E. System Documentation.

Must provide system documentation and manuals.

Pursuant to Section II-C TASKS – page 43 after C Phase III “Maintenance and Support” section

D. Analytical Chemistry TASKS

The following is a preliminary analysis of the major tasks involved for developing the end product of this project. The Contractor is not, however, constrained from supplementing this listing with additional steps, sub tasks or elements deemed necessary to permit the development of alternative approaches or the application of proprietary analytical techniques.

An overall plan must be developed as a basis for executing subsequent steps as the project progresses. Contractor staff assigned to this project must be on-site in Lansing during appropriate stages of development, as detailed in the overall plan.

1. Analysis and Design: Completion within 60 calendar days.

Task 1. The contractor will perform an analysis of the Analytical Chemistry lab data flow, functions, user requirements, and information processing/reporting and unique needs.

Task 2. Determine equipment and/or configuration needs for interfacing instruments.

Task 3. Based on above analysis, provide a system specification document that includes tasks, deliverables, performance standards and detail of the system customization, installation, and testing. This project plan will include scheduling, anticipated MDCH staff contact hours and descriptions of the relationship and interdependencies among tasks. This may include phased installation of functional units.

2. Development and Implementation: Completion within 210 calendar days. Based upon the design developed in Part 1, the system will be customized, tested, documented according to MDCH/MDIT standards and implemented.

Task 1. The vendor shall customize and install all software on site. If the vendor wishes to install the software via a remote line, the proposed method must be approved by and implemented in conjunction with MDIT. Hardware and software provided by the vendor must be installed and maintained by the vendor: Ownership depends on the hardware. If it is part of reagent rental laboratory equipment, then the vendor owns it. If a modular approach is used for installation, each module will be acceptance tested at that time.

Task 2. The vendor must provide a software training and testing environment apart from the production data without affecting normal laboratory operations or actual patient data.

This should include both practice software that can be run without using laboratory instruments and teaching software where training runs can be performed, prepared, reviewed, and transmitted to the system without the data merging into the clinical test results.

- Task 3. A Performance and Reliability Evaluation (PARE) period of at least 30 working days is required in order to determine the impact of cycles, workload peaks, testing patterns, reporting requirements and other laboratory operation requirements and needs. This is the time when MDCH evaluates the total performance of the package and efficiency of the total system. Refer to section I-SS Performance and Reliability Evaluation page 23 in original contract for the PARE requirements. Final systems acceptance will follow this test period.
- Task 4. Post-Implementation Review: Information and data is gathered through interviews, observation and discussion on operating data, volumes, error rates, problem areas, effectiveness of controls, and security, usefulness of outputs and display, processing problems, etc. This information and data analyzed, compared to original objectives and corrective action or enhancements must be made for any shortcomings, deficiencies, and problem areas. Recommended additional enhancements/improvement that will be needed in second or additional phases of this project shall also be made. A written report comparing actual performance to system objectives, performance parameters and user needs must be prepared by the vendor, with assistance by MDCH staff, listing corrective actions taken and recommendations for future changes and enhancements.
- Task 5. Documentation/Manuals. The documentation and manuals will include a detailed step-by-step procedure for the operation of the system and must be provided to MDCH in electronic, camera-ready version before final acceptance of the system. The documentation must follow MDCH/MDIT standards.
3. Maintenance and Support:
- a. Warranty/Support: The vendor must guarantee that the lab information system will perform according to the mutually agreed upon performance standards for one year following the final acceptance of the system. If the system does not perform according to the standards and there have been no substantive functional or operational changes, the vendor must correct the situation at its own expense.
 - b. System Maintenance: The vendor will include a two-year service contract for support in the subsequent years as part of the total cost. This will also include hourly rates for software upgrades and enhancements to the system. Hardware provided by the laboratory information systems vendor that cannot support their software revisions will be upgraded at the vendor's expense.
 - c. Helpdesk Support. The vendor must respond to both support phone calls and emails during regular business hours (Monday through Friday 7:00 am – 6:00 PM EST).
 - d. Pricing for new software releases that encompass increased functions and features, add a test/certification or training subsystem, or extend other system services will be negotiated separately and in advance of any system changes. The vendor should be prepared to add new instruments and expand the testing system within the period of this contract

Pursuant to Section II-I PRICING – PAGE 48

II-J TECHNICAL WORK PLAN/CONTRACT PAYMENT

Enclosed is a table identifying the Analytical Chemistry Labwork Phases and tasks.

Phase 1 – Analysis and Design

Task	Cost
Research of requirements	
Documentation of requirements specification	
Develop Project Plan	
Signoff of the above	
Database, Application architecture, Interface for 4 types of instruction design	
Documentation of the above	
Signoff of the above	
Total	\$8,000.00

Phase 2 – Development and Implementation

Task	Cost
Customization and Implementation of software on site	
Creation of Reports including: <ul style="list-style-type: none"> 1. For PCBs for tissue, adipose tissue, breast milk, and urine 2. PBBs for serum 3. Chemical terrorism # blood-cyanide, urine 5 nerve agent and sulfur mustard, other chemical terrorism agents as designated by the CDC 4. Environmental specimens # liquid, solid, powder 5. Management reports # billing and invoicing, test counts and workload, work lists, supervisor review, turnaround time reports, amended reports, incomplete work lists and tracking of specimen status 	
Unit testing of software on Site	
Documentation of the above	
PARE (30 Days)	\$50,000.00 for PARE and above tasks
Signoff of the above	
Total	\$50,000.00

Phase 3 Maintenance and Support

Task	Duration	Cost
Warranty/Support	1 (one) year	
System Maintenance	2 year service contract	
Help Desk Support	2 year service contract	
New Software Releases		
Total		\$5,250.00

Phase 4 – Miscellaneous Items

Task	Cost
Newborn Screening Enhancements	\$52,250.00
Travel Expenses	\$9,500.00

Total	\$61,750.00

Grand Total

Task	Cost
Phase I – Analysis and Design	\$8,000.00
Phase 2 – Development and Implementation	\$50,000.00
Phase 3 – Maintenance and Support	\$5,250.00
Phase 4 – Miscellaneous Items	\$61,750.00
Grand Total	\$125,000.00

Optional Item

Task	Cost
Additional Users to Current System Licenses - Optional	\$5,000.00 per license X 7 users = \$35,000.00
Total	\$35,000.00

STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 OFFICE OF PURCHASING
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

January 3, 2002

NOTICE
 TO
 CONTRACT NO. 071B2001213
 between
 THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203 janet.perkins@perkinelmer.com	TELEPHONE Janet Perkins (800) 391-9632 ext. 257
	VENDOR NUMBER/MAIL CODE
	BUYER (517) 373-8622 Maritza Garcia-Strong
Contract Administrator: Ron Nelson (517) 373-1435 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories	
CONTRACT PERIOD: From: January 2, 2002 To: January 1, 2006	
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>	

The terms and conditions of this Contract are those of **ITB #07111000211**, this Contract Agreement and the vendor's quote dated **6-21-01**. In the event of any conflicts between the specifications, terms and conditions indicated by the State and those indicated by the vendor, those of the State take precedence.

Estimated Contract Value: **\$876,859.00**

**STATE OF MICHIGAN
 DEPARTMENT OF MANAGEMENT AND BUDGET
 OFFICE OF PURCHASING
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933**

**CONTRACT NO. 071B2001213
 between
 THE STATE OF MICHIGAN
 and**

NAME & ADDRESS OF VENDOR Perkin Elmer Life Sciences Inc. 398 Eastern Rd. Norton, OH 44203		TELEPHONE Mike O'Shea (800) 391-9632 ext. 257 VENDOR NUMBER/MAIL CODE BUYER (517) 373-8622 Maritza Garcia-Strong
Contract Administrator: Ron Nelson (517) 373-1435 Laboratory Information System / Newborn Screening -- Department of Community Health Bureau of Laboratories		
CONTRACT PERIOD: From: January 2, 2002 To: January 1, 2006		
TERMS <p style="text-align: center;">N/A</p>	SHIPMENT <p style="text-align: center;">N/A</p>	
F.O.B. <p style="text-align: center;">N/A</p>	SHIPPED FROM <p style="text-align: center;">N/A</p>	
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">N/A</p>		
MISCELLANEOUS INFORMATION: The terms and conditions of this Contract are those of ITB #07111000211, this Contract Agreement and the vendor's quote dated 6-21-01. In the event of any conflicts between the specifications, terms and conditions indicated by the State and those indicated by the vendor, those of the State take precedence. Estimated Contract Value: \$876,859.00		

THIS IS NOT AN ORDER: This Contract Agreement is awarded on the basis of our inquiry bearing the [ITB No. 07111000211](#). A Purchase Order Form will be issued only as the requirements of the State Departments are submitted to the Office of Purchasing. Orders for delivery may be issued directly by the State Departments through the issuance of a Purchase Order Form.

All terms and conditions of the invitation to bid are made a part hereof.

FOR THE VENDOR: <p style="text-align: center;">Perkin Elmer Life Sciences Inc.</p> <hr/> <p style="text-align: center;">Firm Name</p> <hr/> <p style="text-align: center;">Authorized Agent Signature</p> <hr/> <p style="text-align: center;">Authorized Agent (Print or Type)</p> <hr/> <p style="text-align: center;">Date</p>	FOR THE STATE: <hr/> <p style="text-align: center;">Signature Maritza Garcia-Strong, Buyer</p> <hr/> <p style="text-align: center;">Name Technology & Professional Services Division</p> <hr/> <p style="text-align: center;">Title</p> <hr/> <p style="text-align: center;">Date</p>
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OFFICE OF PURCHASING

**SECTION I
CONTRACTUAL SERVICES TERMS AND CONDITIONS**

I-A PURPOSE

The purpose of this Contract is to obtain services to implement a Newborn Screening Information System for the Department of Community Health, Bureau of Laboratories. The project will be conducted in three phases. Phase I is final system design. Phase II is system development and testing. Phase III is post-implementation support. The State reserves the right to procure services elsewhere for the performance of Phases II and III if the final specifications design resulting from Phase I is not acceptable. It is expected that Phase I activities will be completed within 4 months of Contract execution. After the State of Michigan accepts and approves specifications of Phase I, Phase II will be completed 12 months thereafter. The total of the three phases will extend for four years. This contract is a lump sum/fixed price contract.

I-B TERM OF CONTRACT

The State of Michigan is not liable for any cost incurred by any bidder prior to signing of a Contract by all parties. The activities in the proposed Contract cover the period **January 2, 2002** through **January 1, 2006**. The State fiscal year is October 1st through September 30th. The prospective Contractor should realize that payments in any given fiscal year are contingent upon enactment of legislative appropriations.

I-C ISSUING OFFICE

This contract is issued by the State of Michigan, Department of Management and Budget (DMB), Office of Purchasing, hereafter known as the Office of Purchasing, for the State of Michigan, Department of Community Health. Where actions are a combination of those of the Office of Purchasing and **Community Health**, the authority will be known as the State.

The Office of Purchasing is the sole point of contact in the State with regard to all procurement and contractual matters relating to the services described herein. The Office of Purchasing is the only office authorized to change, modify, amend, alter, clarify, etc., the prices, specifications, terms, and conditions of this Contract. All communications concerning this procurement must be addressed to:

Maritza Garcia-Strong, CPPB
 Technology and Professional Services Division
 DMB, Office of Purchasing
 2nd Floor, Mason Building
 P.O. Box 30026
 Lansing, MI 48909
 Email: garcia-strongm@state.mi.us
 Phone: 517-373-8622

I-D CONTRACT ADMINISTRATOR

Upon receipt at the Office of Purchasing of the properly executed Contract Agreement, it is anticipated that the Director of Purchasing will direct that the person named below or any other person so designated be authorized to administer the Contract on a day-to-day basis during the term of the Contract. However, administration of this Contract implies no authority to change, modify, clarify, amend, or otherwise alter the prices, terms, conditions, and specifications of such Contract. That authority is retained by the Office of Purchasing. The Contract Administrator for this project is:

Ron Nelson, Director
 Bureau of Management Information Systems
 Michigan Department of Community Health



300 E. Michigan Avenue, Chandler Plaza
Lansing, Michigan 48933
Email: nelson@state.mi.us
Phone: 517-373-1435

I-E COST LIABILITY

The State of Michigan assumes no responsibility or liability for costs incurred by the Contractor prior to the signing of this Contract. Total liability of the State is limited to the terms and conditions of this Contract.

I-F CONTRACTOR RESPONSIBILITIES

The Contractor will be required to assume responsibility for all contractual activities offered in this Contract whether or not that Contractor performs them. Further, the State will consider the Contractor to be the sole point of contact with regard to contractual matters, including but not limited to payment of any and all costs resulting from the anticipated Contract. If any part of the work is to be subcontracted, the contractor must notify the state and identify the subcontractor(s), including firm name and address, contact person, complete description of work to be subcontracted, and descriptive information concerning subcontractor's organizational abilities. The State reserves the right to approve subcontractors for this project and to require the Contractor to replace subcontractors found to be unacceptable, consent not to be withheld unreasonably. If the State does not object to said subcontractors within ten (10) days of their start date or notification thereof, such right of approval or replacement shall be deemed waived. The Contractor is totally responsible for adherence by the subcontractor to all provisions of the Contract.

I-G NEWS RELEASES

News releases pertaining to this document or the services, study, data, or project to which it relates will not be made without prior written State approval, and then only in accordance with the explicit written instructions from the State. No results of the program are to be released without prior approval of the State and then only to persons designated.

I-H DISCLOSURE

All information in this Contract is subject to the provisions of the Freedom of Information Act, 1976 Public Act No. 442, as amended, MCL 15.231, *et seq.*

I-I ACCOUNTING RECORDS

The Contractor will be required to maintain all pertinent financial and accounting records and evidence pertaining to the Contract in accordance with generally accepted principles of accounting and other procedures specified by the State of Michigan. Financial and accounting records shall be made available, upon request, to the State of Michigan, its designees, or the Michigan Department of Auditor General at any time during the Contract period and any extension thereof, and for three (3) years from the expiration date and final payment on the Contract or extension thereof.

I-J INDEMNIFICATION

A. General Indemnification

Upon receipt of written notice, as required herein, the CONTRACTOR shall indemnify, defend and hold harmless the State, its departments, divisions, agencies, sections, commissions, officers, employees and agents from and against all losses, liabilities, penalties, fines, damages and claims (including taxes), and all related costs and expenses (including reasonable attorneys' fees and disbursements and costs of investigation, litigation, settlement, judgments, interest and penalties), arising from or in connection with any of the following:

- (1) any claim, demand, action, citation or legal proceeding against the State, its departments, divisions, agencies, sections, commissions, officers, employees and agents for any



negligence or wrongful acts arising out of or resulting from (1) the services and products provided or (2) performance of the work, duties, responsibilities, actions or omissions of the CONTRACTOR or any of its subcontractors under this CONTRACT; provided, however that this indemnification shall not apply to the extent, if any, that such negligence or wrongful acts is caused by the negligence or reckless or intentional wrongful conduct of the State;

- (2) any claim, demand, action, citation or legal proceeding against the State, its departments, divisions, agencies, sections, commissions, officers, employees and agents arising out of or resulting from a material breach by the CONTRACTOR of any representation or warranty made by the CONTRACTOR in the CONTRACT;
- (3) any claim, demand, action, citation or legal proceeding against the State, its departments, divisions, agencies, sections, commissions, officers, employees and agents arising out of or related to occurrences that the CONTRACTOR is required to insure against as provided for in this CONTRACT;
- (4) any claim, demand, action, citation or legal proceeding against the State, its departments divisions, agencies, sections, commissions, officers, employees and agents arising out of or resulting from the death or bodily injury of any person, or the damage, loss or destruction of any real or tangible personal property, in connection with the performance of services by the CONTRACTOR, by any of its subcontractors, by anyone directly or indirectly employed by any of them, or by anyone for whose acts any of them may be liable; provided, however, that this indemnification obligation shall not apply to the extent, if any, that such death, bodily injury or property damage is caused by the negligence or reckless or intentional wrongful conduct of the State;
- (5) any claim, demand, action, citation or legal proceeding against the State, its departments, divisions, agencies, sections, commissions, officers, employees and agents which results from an act or omission of the CONTRACTOR or any of its subcontractors in its or their capacity as an employer of a person.

B. Patent/Copyright Infringement Indemnification

The CONTRACTOR shall indemnify, defend and hold harmless the State, its departments, divisions, agencies, sections, commissions, officers, employees and agents from and against all losses, liabilities, penalties, fines, damages (including taxes), and all related costs and expenses (including reasonable attorneys' fees and disbursements and costs of investigation, litigation, settlement, judgments, interest and penalties) incurred in connection with any action or proceeding threatened or brought against the State by a third party to the extent that such action or proceeding is based on a claim that any piece of equipment, software, commodity or service supplied by the CONTRACTOR or its subcontractors, or the operation of such equipment, software, commodity or service, infringes any United States or foreign patent, copyright, trade secret or other proprietary right of any person or entity, which right is enforceable under the laws of the United States. In addition, should the equipment, software, commodity, or service, or the operation thereof, become or in the Contractor's opinion be likely to become the subject of a claim of infringement, the CONTRACTOR shall at the Contractor's sole expense (i) procure for the State the right to continue using the equipment, software, commodity or service or, if such option is not reasonably available to the CONTRACTOR, (ii) replace or modify the same with equipment, software, commodity or service of equivalent function and performance so that it becomes non-infringing, or, if such option is not reasonably available to CONTRACTOR, (iii) accept its return by the State with appropriate credits to the State against the Contractor's charges and reimburse the State for any losses or costs incurred as a consequence of the State ceasing its use and returning it, such reimbursements not to exceed the compensation to Contractor under this Agreement .

C. Indemnification Obligation Not Limited



In any and all claims against the State of Michigan, its departments, divisions, agencies, sections, commissions, officers, employees and agents, by any employee of the CONTRACTOR or any of its subcontractors, the indemnification obligation under the CONTRACT shall not be limited in any way by the amount or type of damages, compensation or benefits payable by or for the CONTRACTOR or any of its subcontractors under worker's disability compensation acts, disability benefit acts or other employee benefit acts. This indemnification clause is intended to be comprehensive. Any overlap in subclauses, or the fact that greater specificity is provided as to some categories of risk, is not intended to limit the scope of indemnification under any other subclauses.

D. Continuation of Indemnification Obligation

The duty to indemnify will continue in full force and effect notwithstanding the expiration or early termination of the contract with respect to any claims based on facts or conditions, which occurred prior to termination.

I-K LIMITATION OF LIABILITY

Except as set forth herein, neither the Contractor nor the State shall be liable to the other party for indirect or consequential damages, even if such party has been advised of the possibility of such damages. Such limitation as to indirect or consequential damages shall not be applicable for claims arising out of gross negligence, willful misconduct, or Contractor's indemnification responsibilities to the State as set forth in Section I-J with respect to third party claims, action and proceeding brought against the State.

I-L NON INFRINGEMENT/COMPLIANCE WITH LAWS

The Contractor warrants that in performing the services called for by this Contract it will not violate any applicable law, rule, or regulation, any contracts with third parties, following or any intellectual rights of any third party, including but not limited to, any United States patent, trademark, copyright, or trade secret, known to the Contractor as of the effective date of this Agreement.

I-M WARRANTIES AND REPRESENTATIONS

The Contract will contain customary representations and warranties by the Contractor, including, without limitation, the following:

1. The Contractor will perform all services in accordance with high professional standards in the industry;
2. The Contractor will use adequate numbers of qualified individuals with suitable training, education, experience and skill to perform the services;
3. The Contractor will use its best efforts to use efficiently any resources or services necessary to provide the services that are separately chargeable to the State;
4. The Contractor will use its best efforts to perform the services in the most cost effective manner consistent with the required level of quality and performance;
5. The Contractor will perform the services in a manner that does not infringe the proprietary rights of any third party, known to the Contractor as of the effective date of this Agreement;
6. The Contractor will perform the services in a manner that complies with all applicable laws and regulations;
7. The Contractor has duly authorized the execution, delivery and performance of the Contract;
8. The Contractor has not provided any gifts, payments or other inducements to any officer, employee or agent of the State;



9. The Contractor will maintain all equipment and software for which it has maintenance responsibilities in good operating condition and will undertake all repairs and preventive maintenance in accordance with applicable manufacturer's recommendations;
10. The Contractor will use its best efforts to ensure that no viruses or similar items are coded or introduced into the systems used to provide the services;
11. The Contractor will not insert or activate any disabling code into the systems used to provide the services without the State's prior written approval;
12. A ninety (90) day warranty on all purchased and developed software, data conversion programs, and data and customization to the product performed by the contractor.

I-N TIME IS OF THE ESSENCE

The Contractor agrees that time is of the essence in the performance of the Contractor's obligations under this Contract.

I-O STAFFING OBLIGATIONS

The Contractor agrees to notify the State should it become necessary to the Contractor to reassign any of the individuals designated as Key Personnel to this project.

The State has the right to comment on the Contractor's assignment of Key Personnel to this project, and to recommend reassignment of personnel deemed unsatisfactory by the State.

The Contractor shall not remove or reassign, without notifying the State, any of the Key Personnel until such time as the Key Personnel have completed all of their planned and assigned responsibilities in connection with performance of the Contractor's obligations under this Contract. The Contractor agrees that the continuity of Key Personnel is critical and agrees to the continuity of Key Personnel.

The State and the Contractor agree that the following personnel are Key Personnel for purposes of this contract:

- Name: *Mike O'Shea, Account Manager*
- Name: *Scott Palubiak, Contract Administrator*
- Name: *Keith Rosenbaum, Project Manager*
- Name: *James Bailey, System Architect*

I-P WORK PRODUCT AND OWNERSHIP

1. Work Products shall be considered works made by the Contractor for hire by the State and shall belong exclusively to the State and its designees, unless specifically provided otherwise by mutual agreement of the Contractor and the State. If by operation of law any of the Work Product, including all related intellectual property rights, is not owned in its entirety by the State automatically upon creation thereof, the Contractor agrees to assign, and hereby assigns to the State and its designees the ownership of such Work Product, including all related intellectual property rights. The Contractor agrees to provide, at no additional charge, any assistance and to execute any action reasonably required for the State to perfect its intellectual property rights with respect to the aforementioned Work Product.
2. Notwithstanding any provision of this Contract to the contrary, any preexisting work or materials including, but not limited to, any routines, libraries, tools, methodologies, processes or technologies (collectively, the "Development Tools") created, adapted or used by the Contractor in its business generally, including any all associated intellectual property rights, shall be and remain the sole property of the Contractor, and the State shall have no interest in or claim to such preexisting work, materials or Development Tools, except as necessary to exercise its rights in the Work Product. Such rights belonging to the State shall include, but not be limited



to, the right to use, execute, reproduce, display, perform and distribute copies of and prepare derivative works based upon the Work Product, and the right to authorize its agents, but not third parties to do any of the foregoing, irrespective of the existence therein of preexisting work, materials and Development Tools, except as specifically limited herein.

3. The Contractor and its subcontractors shall be free to use and employ their general skills, knowledge and expertise, and to use, disclose, and employ any generalized ideas, concepts, knowledge, methods, techniques or skills gained or learned during the course of performing the services under this Contract, so long as the Contractor or its subcontractors acquire and apply such information without disclosure of any confidential or proprietary information of the State, and without any unauthorized use or disclosure of any Work Product resulting from this Contract.

I-Q CONFIDENTIALITY OF DATA AND INFORMATION

1. All financial, statistical, personnel, technical and other data and information relating to the State's operation which are designated confidential by the State and made available to the Contractor in order to carry out this Contract, or which become available to the Contractor in carrying out this Contract, shall be protected by the Contractor from unauthorized use and disclosure through the observance of the same or more effective procedural requirements as are applicable to the State. The identification of all such confidential data and information as well as the State's procedural requirements for protection of such data and information from unauthorized use and disclosure shall be provided by the State in writing to the Contractor. If the methods and procedures employed by the Contractor for the protection of the Contractor's data and information are deemed by the State to be adequate for the protection of the State's confidential information, such methods and procedures may be used, with the written consent of the State, to carry out the intent of this section.
2. The Contractor shall not be required under the provisions of this section to keep confidential, (1) information generally available to the public, (2) information released by the State generally, or to the Contractor without restriction, (3) information independently developed or acquired by the Contractor or its personnel without reliance in any way on otherwise protected information of the State. Notwithstanding the foregoing restrictions, the Contractor and its personnel may use and disclose any information which it is otherwise required by law to disclose, but in each case only after the State has been so notified, and has had the opportunity, if possible, to obtain reasonable protection for such information in connection with such disclosure.

I-R REMEDIES FOR BREACH OF CONFIDENTIALITY

The Contractor acknowledges that a breach of its confidentiality obligations as set forth in section I-Q of this Contract, shall be considered a material breach of the Contract. Furthermore the Contractor acknowledges that in the event of such a breach the State shall be irreparably harmed. Accordingly, if a court should find that the Contractor has breached or attempted to breach any such obligations, the Contractor will not oppose the entry of an appropriate order restraining it from any further breaches or attempted or threatened breaches. This remedy shall be in addition to and not in limitation of any other remedy or damages provided by law.

I-S CONTRACTOR'S LIABILITY INSURANCE

The Contractor shall purchase and maintain such insurance as will protect him/her from claims set forth below which may arise out of or result from the Contractor's operations under the Contract (Purchase Order), whether such operations be by himself/herself or by any subcontractor or by anyone directly or indirectly employed by any of them, or by anyone for whose acts any of them may be liable:



- (1) Claims under workers' disability compensation, disability benefit and other similar employee benefit act. A non-resident Contractor shall have insurance for benefits payable under Michigan's Workers' Disability Compensation Law for any employee resident of and hired in Michigan; and as respects any other employee protected by workers' disability compensation laws of any other State the Contractor shall have insurance or participate in a mandatory State fund to cover the benefits payable to any such employee.
- (2) Claims for damages because of bodily injury, occupational sickness or disease, or death of his/her employees.
- (3) Claims for damages because of bodily injury, sickness or disease, or death of any person other than his/her employees, subject to limits of liability of not less than \$300,000.00 each occurrence and, when applicable \$1,000,000.00 annual aggregate, for non-automobile hazards and as required by law for automobile hazards.
- (4) Claims for damages because of injury to or destruction of tangible property, including loss of use resulting therefrom, subject to a limit of liability of not less than \$50,000.00 each occurrence for non-automobile hazards and as required by law for automobile hazards.
- (5) Insurance for Subparagraphs (3) and (4) non-automobile hazards on a combined single limit of liability basis shall not be less than \$300,000.00 each occurrence and when applicable, \$1,000,000.00 annual aggregate.

The insurance shall be written for not less than any limits of liability herein specified or required by law, whichever is greater, and shall include contractual liability insurance as applicable to the Contractor's obligations under the Indemnification clause of the Contract (Purchase Order).

UPON CONTRACT EXECUTION, THE CONTRACTOR'S INSURANCE AGENCY MUST FURNISH TO THE DIRECTOR OF THE OFFICE OF PURCHASING, ORIGINAL CERTIFICATE (S) OF INSURANCE VERIFYING LIABILITY COVERAGE. THE CONTRACT OR PURCHASE ORDER NO. MUST BE SHOWN ON THE CERTIFICATE OF INSURANCE TO ASSURE CORRECT FILING.

These Certificates shall contain a provision that coverage's afforded under the policies will not be canceled until at least fifteen days prior written notice bearing the Contract Number or Purchase Order Number has been given to the Director of Purchasing.

I-T NOTICE AND RIGHT TO CURE

In the event of a curable breach by the Contractor, the State shall provide the Contractor written notice of the breach and a sixty (60) day time period to cure said breach described in the notice. This section requiring notice and an opportunity to cure shall not be applicable in the event of successive or repeated breaches of the same nature within a twelve (12) month period or if the State reasonably determines that the breach poses a serious and imminent threat to the health or safety of any person or the imminent loss, damage or destruction of any real or tangible personal property.

I-U CANCELLATION

The State may cancel this Contract without further liability or penalty to the State, its departments, divisions, agencies, offices, commissions, officers, agents and employees for any of the following reasons:

- 1. Material Breach by the Contractor. In the event that the Contractor breaches any of its material duties or obligations under the Contract, which are either not capable of or subject to being cured, or are not cured within the time period specified in the written notice of breach provided by the State, or pose a serious and imminent threat to the health and safety of any person, or



the imminent loss, damage or destruction of any real or tangible personal property, the State may, having provided written notice of cancellation to the Contractor, cancel this Contract in whole or in part, for cause, as of the date specified in the notice of cancellation.

In the event that this Contract is cancelled for cause, in addition to any legal remedies otherwise available to the State by law or equity, the Contractor shall be responsible for all costs incurred by the State in canceling the Contract, including but not limited to, State administrative costs, attorneys fees and court costs, and any additional costs the State may incur to procure the services required by this Contract from other sources. All excess procurement costs and damages shall not be considered by the parties to be consequential, indirect or incidental, and shall not be excluded by any other terms otherwise included in the Contract. Such costs payable by the Contractor shall not exceed ten thousand (\$10,000 USD) dollars.

In the event the State chooses to partially cancel this Contract for cause charges payable under this Contract will be equitably adjusted to reflect those services that are cancelled. Such costs payable by the Contractor shall not exceed ten thousand (\$10,000 USD) dollars.

In the event this Contract is cancelled for cause pursuant to this section, and it is therefore determined, for any reason, that the Contractor was not in breach of contract pursuant to the provisions of this section, that cancellation for cause shall be deemed to have been a cancellation for convenience, effective as of the same date, and the rights and obligations of the parties shall be limited to that otherwise provided in the Contract for a cancellation for convenience.

2. Cancellation For Convenience By the State. The State may cancel this Contract for its convenience, in whole or part, if the State determines that such a cancellation is in the State's best interest. Reasons for such cancellation shall be left to the sole discretion of the State and may include, but not necessarily be limited to (a) the State no longer needs the services or products specified in the Contract, (b) relocation of office, program changes, changes in laws, rules, or regulations make implementation of the Contract services no longer practical or feasible, and (c) unacceptable prices for additional services requested by the State. The State may cancel the Contract for its convenience, in whole or in part, by giving the Contractor written notice 30 days prior to the date of cancellation. If the State chooses to cancel this Contract in part, the charges payable under this Contract shall be equitably adjusted to reflect those services that are cancelled.

3. Non-Appropriation. In the event that funds to enable the State to effect continued payment under this Contract are not appropriated or otherwise made available. The Contractor acknowledges that, if this Contract extends for several fiscal years, continuation of this Contract is subject to appropriation or availability of funds for this project. If funds are not appropriated or otherwise made available, the State shall have the right to cancel this Contract at the end of the last period for which funds have been appropriated or otherwise made available by giving written notice of cancellation to the Contractor. The State shall give the Contractor written notice of such non-appropriation or unavailability within 30 days after it receives notice of such non-appropriation or unavailability.

4. Criminal Conviction. In the event the Contractor, an officer of the Contractor, or an owner of a 25% or greater share of the Contractor, is convicted of a criminal offense incident to the application for or performance of a State, public or private Contract or subcontract; or convicted of a criminal offense including but not limited to any of the following: embezzlement, theft, forgery, bribery, falsification or destruction of records, receiving stolen property, attempting to influence a public employee to breach the ethical conduct standards for State of Michigan employees; convicted under State or federal antitrust statutes; or convicted of any other criminal offense which in the sole discretion of the State, reflects upon the Contractor's business integrity.



5. Approval(s) Rescinded. In the event any final administrative or judicial decision or adjudication disapproves a previously approved request for purchase of personal services pursuant to Constitution 1963, Article 11, section 5, and Civil Service Rule 4-6. Cancellation may be in whole or in part and may be immediate as of the date of the written notice to the Contractor or may be effective as of the date stated in such written notice.

I-V RIGHTS AND OBLIGATIONS UPON CANCELLATION

1. If the Contract is canceled by the State for any reason, the Contractor shall, (a) stop all work as specified in the notice of cancellation, (b) take any action that may be necessary, or that the State may direct, for preservation and protection of Work Product or other property derived or resulting from the Contract that may be in the Contractor's possession, (c) return all materials and property provided directly or indirectly to the Contractor by any entity, agent or employee of the State, (d) transfer title and deliver to the State, unless otherwise directed by the Contract Administrator or his or her designee, all Work Product resulting from the Contract, and (e) take any action to mitigate and limit any potential damages, or requests for Contractor adjustment or cancellation settlement costs, to the maximum practical extent, including, but not limited to, canceling or limiting as otherwise applicable, those subcontracts, and outstanding orders for material and supplies resulting from the canceled Contract.
2. In the event the State cancels this Contract prior to its expiration for its own convenience, the State shall pay the Contractor for all charges due for services provided prior to the date of cancellation and if applicable as a separate item of payment pursuant to the Contract, for partially completed Work Product, on a percentage of completion basis. In the event of a cancellation for cause, or any other reason under the Contract, the State will pay, if applicable, as a separate item of payment pursuant to the Contract, for all partially completed Work Products, to the extent that the State requires the Contractor to submit to the State any such deliverables, and for all charges due under the Contract for any cancelled services provided by the Contractor prior to the cancellation date. All completed or partially completed Work Product prepared by the Contractor pursuant to this Contract shall, at the option of the State, become the State's property, and the Contractor shall be entitled to receive just and fair compensation for such Work Product. Regardless of the basis for the cancellation, the State shall not be obligated to pay, or otherwise compensate, the Contractor for any lost expected future profits, costs or expenses incurred with respect to Services not actually performed for the State.
3. If any such cancellation by the State is for cause, the State shall have the right to set-off against any amounts due the Contractor, the amount of any damages for which the Contractor is liable to the State under this Contract or pursuant to law and equity.
4. Upon a good faith cancellation, the State shall have the right to assume, at its option, any and all subcontracts and agreements for services and materials provided under this Contract, and may further pursue completion of the Work Product under this Contract by replacement contract or otherwise as the State may in its sole judgment deem expedient.

I-W EXCUSABLE FAILURE

1. Neither party shall be liable for any default or delay in the performance of its obligations under the Contract, except for payments if and to the extent such default or delay is caused, directly or indirectly, by: fire, flood, earthquake, act(s) of terrorism, elements of nature or acts of God; riots, civil disorders, rebellions or revolutions in any country; the failure of the other party to perform its material responsibilities under the Contract (either itself or through another contractor); injunctions (provided the injunction was not issued as a result of any fault or negligence of the party seeking to have its default or delay excused); or any other cause beyond the reasonable control of such party; provided the non-performing party and its subcontractors are without fault



in causing such default or delay, and such default or delay could not have been prevented by reasonable precautions and cannot reasonably be circumvented by the non-performing party through the use of alternate sources, workaround plans or other means, including disaster recovery plans. In such event, the non-performing party will be excused from any further performance or observance of the obligation(s) so affected for as long as such circumstances prevail and such party continues to use its best efforts to recommence performance or observance whenever and to whatever extent possible without delay provided such party promptly notifies the other party in writing of the inception of the excusable failure occurrence, and also of its abatement or cessation.

2. If any of the above enumerated circumstances substantially prevent, hinder, or delay performance of the services necessary for the performance of the State's functions for more than 14 consecutive days, and the State determines that performance is not likely to be resumed within a period of time that is satisfactory to the State in its reasonable discretion, then at the State's option: (a) the State may procure the affected services from an alternate source, and the State shall not be liable for payments for the unperformed services under the Contract for so long as the delay in performance shall continue; (b) the State may cancel any portions of the Contract so affected and the charges payable thereunder shall be equitably adjusted to reflect those services canceled; or (c) the Contract will be canceled without liability of the State to the Contractor as of the date specified by the State in a written notice of cancellation to the Contractor. The Contractor will not have the right to any additional payments from the State as a result of any excusable failure occurrence or to payments for services not rendered as a result of the excusable failure condition. Defaults or delays in performance by the Contractor which are caused by acts or omissions of its subcontractors will not relieve the Contractor of its obligations under the Contract except to the extent that a subcontractor is itself subject to any excusable failure condition described above and the Contractor cannot reasonably circumvent the effect of the subcontractor's default or delay in performance through the use of alternate sources, workaround plans or other means.

I-X ASSIGNMENT

The Contractor shall not have the right to assign this Contract or to assign or delegate any of its duties or obligations under this Contract to any other party, without the prior written consent of the State, except that the Contractor may assign this Agreement to any successor by merger or sale of substantially all of its business or assets to which this Agreement pertains, without any such consent.. Any purported assignment in violation of this section shall be null and void. Further, the Contractor may not assign the right to receive money due under the Contract without the prior written consent of the State Purchasing Director.

I-Y DELEGATION

The Contractor shall not delegate any duties or obligations under this Contract to a subcontractor other than a subcontractor named in the bid unless the State Purchasing Director has given written consent, consent not to be withheld unreasonably. If the State does not object to said subcontractor within ten (10) days of their start date or notification thereof, such right of consent shall be deemed waived.

I-Z NON-DISCRIMINATION CLAUSE

In the performance of any Contract or purchase order resulting herefrom, the bidder agrees not to discriminate against any employee or applicant for employment, with respect to their hire, tenure, terms, conditions or privileges of employment, or any matter directly or indirectly related to employment, because of race, color, religion, national origin, ancestry, age, sex, height, weight, marital status, physical or mental disability unrelated to the individual's ability to perform the duties of the particular job or position. The bidder further agrees that every subcontract entered into for the performance of any Contract or purchase order resulting herefrom will contain a provision requiring non-discrimination in employment, as herein specified, binding upon each subcontractor. This covenant is required pursuant



to the Elliot Larsen Civil Rights Act, 1976 Public Act 453, as amended, MCL 37.2101, *et seq*, and the Persons with Disabilities Civil Rights Act, 1976 Public Act 220, as amended, MCL 37.1101, *et seq*, and any breach thereof may be regarded as a material breach of the Contract or purchase order.

I-AA MODIFICATION OF SERVICE

The Director of Purchasing reserves the right to modify this service during the course of this Contract. Such modification may include adding or deleting tasks that this service shall encompass and/or any other modifications deemed necessary, in accordance with the process as detailed within this Section of the Agreement.

This Contract may not be revised, modified, amended, extended, or augmented, except by a writing executed by the parties hereto, and any breach or default by a party shall not be waived or released other than in writing signed by the other party.

The State reserves the right to request from time to time, any changes to the requirements and specifications of the Contract and the work to be performed by the Contractor under the Contract. The Contractor shall provide a change order process and all requisite forms. The State reserves the right to negotiate the process during contract negotiation. At a minimum, the State would like the Contractor to provide a detailed outline of all work to be done, including tasks necessary to accomplish the deliverables, timeframes, listing of key personnel assigned, estimated hours for each individual per task, and a complete and detailed cost justification.

1. Within five (5) business days of receipt of a request by the State for any such change, or such other period of time as to which the parties may agree mutually in writing, the Contractor shall submit to the State a proposal describing any changes in products, services, timing of delivery, assignment of personnel, and the like, and any associated price adjustment. The price adjustment shall be based on a good faith determination and calculation by the Contractor of the additional cost to the Contractor in implementing the change request less any savings realized by the Contractor as a result of implementing the change request. The Contractor's proposal shall describe in reasonable detail the basis for the Contractor's proposed price adjustment, including the estimated number of hours by task by labor category required to implement the change request.
2. If the State accepts the Contractor's proposal, it will issue a change notice and the Contractor will implement the change request described therein. The Contractor will not implement any change request until a change notice has been issued validly. The Contractor shall not be entitled to any compensation for implementing any change request or change notice except as provided explicitly in an approved change notice.
3. If the State does not accept the Contractor's proposal, the State may:
 - a) withdraw its change request; or
 - b) modify its change request, in which case the procedures set forth above will apply to the modified change request.

If the State requests or directs the Contractor to perform any activities that are outside the scope of the Contractor's responsibilities under the Contract ("New Work"), the Contractor must notify the State promptly, and before commencing performance of the requested activities, that it believes the requested activities are New Work. If the Contractor fails to so notify the State prior to commencing performance of the requested activities, any such activities performed before notice is given by the Contractor shall be conclusively considered to be In-scope Services, not New Work.

If the State requests or directs the Contractor to perform any services or functions that are consistent with and similar to the services being provided by the Contractor under the Contract, but which the Contractor reasonably and in good faith believes are not included within the scope of the Contractor's responsibilities and charges as set forth in the Contract, then prior to performing such services or



function, the Contractor shall promptly notify the State in writing that it considers the services or function to be an "Additional Service" for which the Contractor should receive additional compensation. If the Contractor does not so notify the State, the Contractor shall have no right to claim thereafter that it is entitled to additional compensation for performing such services or functions. If the Contractor does so notify the State, then such a service or function shall be governed by the change request procedure set forth in the preceding paragraph.

IN THE EVENT PRICES ARE NOT ACCEPTABLE TO THE STATE, THE CONTRACT SHALL BE SUBJECT TO COMPETITIVE BIDDING BASED UPON THE NEW SPECIFICATIONS.

I-BB NOTICES

Any notice given to a party under this Contract must be written and shall be deemed effective, if addressed to such party as addressed below upon (i) delivery, if hand delivered; (ii) receipt of a confirmed transmission by facsimile if a copy of the notice is sent by another means specified in this section; (iii) the third (3rd) Business Day after being sent by U.S. mail, postage pre-paid, return receipt requested; or (iv) the next Business Day after being sent by a nationally recognized overnight express courier with a reliable tracking system.

For the Contractor: **General Manager
PerkinElmer Life Sciences, Inc.
3985 Eastern Road
Norton, OH 44203**

With a copy to: **General Counsel
PerkinElmer Life Sciences, Inc.
549 Albany Street
Boston, MA 02118**

For the State: **Maritza Garcia-Strong, CPPB
DMB, Office of Purchasing
Technology & Professional Services Division
530 W. Allegan Street
Lansing, MI 48912**

Either party may change its address where notices are to be sent giving written notice in accordance with this section.

I-CC ENTIRE AGREEMENT

The contents of this document and the vendor's proposal will become contractual obligations, if a Contract ensues. Failure of the successful bidder to accept these obligations may result in cancellation of the award.

This Contract shall represent the entire agreement between the parties and supersedes all proposals or other prior agreements, oral or written, and all other communications between the parties relating to this subject.

I-DD NO WAIVER OF DEFAULT

The failure of a party to insist upon strict adherence to any term of this Contract shall not be considered a waiver or deprive the party of the right thereafter to insist upon strict adherence to that term, or any other term, of the Contract.

I-EE SEVERABILITY



Each provision of the Contract shall be deemed to be severable from all other provisions of the Contract and, if one or more of the provisions of the Contract shall be declared invalid, the remaining provisions of the Contract shall remain in full force and effect.

I-FF HEADINGS

Captions and headings used in the Contract are for information and organization purposes. Captions and headings, including inaccurate references, do not, in any way, define or limit the requirements or terms and conditions of this Contract.

I-GG RELATIONSHIP OF THE PARTIES

The relationship between the State and the Contractor is that of client and independent Contractor. No agent, employee, or servant of the Contractor or any of its subcontractors shall be or shall be deemed to be an employee, agent, or servant of the State for any reason. The Contractor will be solely and entirely responsible for its acts and the acts of its agents, employees, servants and subcontractors during the performance of this Contract.

I-HH UNFAIR LABOR PRACTICES

Pursuant to 1980 Public Act 278, as amended, MCL 423.231, et seq, the State shall not award a Contract or subcontract to an employer whose name appears in the current register of employers failing to correct an unfair labor practice compiled pursuant to section 2 of the Act. This information is compiled by the United States National Labor Relations Board.

A Contractor of the State, in relation to the Contract, shall not enter into a Contract with a subcontractor, manufacturer, or supplier whose name appears in this register. Pursuant to section 4 of 1980 Public Act 278, MCL 423.324, the State may void any Contract if, subsequent to award of the Contract, the name of the Contractor as an employer, or the name of the subcontractor, manufacturer or supplier of the Contractor appears in the register.

I-II SURVIVOR

Any provisions of the Contract that impose continuing obligations on the parties including, but not limited to the Contractor's indemnity and other obligations shall survive the expiration or cancellation of this Contract for any reason.

I-JJ GOVERNING LAW

This Contract shall in all respects be governed by, and construed in accordance with, the laws of the State of Michigan. Any dispute arising herein shall be resolved in the State of Michigan.

I-KK YEAR 2000 SOFTWARE COMPLIANCE

The vendor warrants that all software for which the vendor either sells or licenses to the State of Michigan and used by the State prior to, during or after the calendar year 2000, includes or shall include, at no added cost to the State, design and performance so the State shall not experience software abnormality and/or the generation of incorrect results from the software, due to date oriented processing, in the operation of the business of the State of Michigan.

The software design, to insure year 2000 compatibility, shall include, but is not limited to: data structures (databases, data files, etc.) that provide 4-digit date century; stored data that contain date century recognition, including, but not limited to, data stored in databases and hardware device internal system dates; calculations and program logic (e.g., sort algorithms, calendar generation, event recognition, and all processing actions that use or produce date values) that accommodates same century and multi-century formulas and date values; interfaces that supply data to and receive data from other systems or organizations that prevent non-compliant dates and data from entering any State system; user interfaces (i.e., screens, reports, etc.) that accurately show 4 digit years; and assurance that the year 2000 shall be correctly treated as a leap year within all calculation and calendar logic.



The Contractor warrants that services provided under this Contract including but not limited to the production of all Work Products, shall be provided in an accurate and timely manner without interruption, failure or error due the inaccuracy of Contractor's business operations in processing date/time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including leap year calculations. The Contractor shall be responsible for damages resulting from any delays, errors or untimely performance resulting therefrom.

I-LL CONTRACT DISTRIBUTION

The Office of Purchasing shall retain the sole right of Contract distribution to All State agencies and local units of government unless other arrangements are authorized by the Office of Purchasing.

I-MM STATEWIDE CONTRACTS

If the contract is for the use of more than one agency and if the goods or services provided under the contract do not meet the form, function and utility required by an agency, that agency may, subject to state purchasing policies, procure the goods or services from another source.

I-NN ADHERANCE TO PM METHODOLOGY STANDARD

The State has adopted a standard, documented Project Management Methodology (PMM) for use on all Information Technology (IT) based projects. This policy is referenced in the document titled "Project Management Methodology" – DMB Administrative Guide Procedure 1380.02 issued June 2000. Vendors may obtain a copy of this procedure by contacting the DMB Office of Information Technology Solutions. The State of Michigan Project Management Methodology can be obtained from the DMB Office of Project Management's website at <http://www.state.mi.us/cio/opm>.

The contractor shall use the State's PMM to manage State of Michigan Information Technology (IT) based projects. The requesting agency will provide the applicable documentation and internal agency processes for the methodology. If the vendor requires training on the methodology, those costs shall be the responsibility of the vendor, unless otherwise stated.

I-OO ADHERANCE TO PM TOOL STANDARD

The State has adopted NIKU's Results Management Suite as its project management tool. This policy is referenced in the document titled "Project Management Tool Standard" – DMB Administrative Guide Procedure 1380.01 issued January 2000. Vendors may obtain a copy of this procedure by contacting the DMB Office of Information Technology Solutions.

For agencies that have implemented the State's project management tool standard, the vendor must use the NIKU tool suite to manage Information Technology (IT) based efforts for that agency. The contractor may, at the discretion of the requesting agency, incorporate Microsoft Project (version 98 or higher) as a replacement for NIKU Workbench within the standard product suite.

The agency may provide the requisite software licenses and access to this tool suite, but only if stated explicitly in the State of Work section of this Contract. If the vendor requires training on the NIKU tool suite, those costs shall be the responsibility of the vendor, unless otherwise stated.

Under special circumstances vendors that are compelled to use an alternate Project Management tool must submit an exception request to the Office of Project Management and Michigan Department of Community Health, MISB for evaluation and approval of the alternate tool prior to proposal evaluation by the State. The vendor will be requested to demonstrate seamless integration into the NIKU Data Repository, at the vendor's expense, prior to approval of an exception request.

PerkinElmer will use Microsoft Project as the Project Management tool for this project.



I-PP TRANSITION ASSISTANCE

If this Contract is not renewed at the end of this term, or is canceled prior to its expiration, for any reason, the Contractor must provide for up to **4 months** after the expiration or cancellation of this Contract, all reasonable transition assistance requested by the State, to allow for the expired or canceled portion of the Services to continue without interruption or adverse effect, and to facilitate the orderly transfer of such services to the State or its designees. Such transition assistance will be deemed by the parties to be governed by the terms and conditions of this Contract, (notwithstanding this expiration or cancellation) except for those Contract terms or conditions that do not reasonably apply to such transition assistance. The State shall pay the Contractor for any resources utilized in performing such transition assistance at the most current rates provided by the Contract for Contract performance. If the State cancels this Contract for cause, then the State will be entitled to off set the cost of paying the Contractor for the additional resources the Contractor utilized in providing transition assistance with any damages the State may have otherwise accrued as a result of said cancellation.

I-QQ DISCLOSURE OF LITIGATION

1. The Contractor shall notify the State in its bid proposal, if it, or any of its subcontractors, or their officers, directors, or key personnel under this Contract, have ever been convicted of a felony, or any crime involving moral turpitude, including, but not limited to fraud, misappropriation or deception. Contractor shall promptly notify the State of any criminal litigation, investigations or proceeding which may have arisen or may arise involving the Contractor or any of the Contractor's subcontractor, or any of the foregoing entities' then current officers or directors during the term of this Contract and three years thereafter.
2. The Contractor shall notify the State in its bid proposal, and promptly thereafter as otherwise applicable, of any civil litigation, arbitration, proceeding, or judgments that may have arisen against it or its subcontractors during the five years proceeding its bid proposal, or which may occur during the term of this Contract or three years thereafter, which involve (1) products or services similar to those provided to the State under this Contract and which either involve a claim in excess of **\$250,000** or which otherwise may affect the viability or financial stability of the Contractor , or (2) a claim or written allegation of fraud by the Contractor or any subcontractor hereunder, arising out of their business activities, or (3) a claim or written allegation that the Contractor or any subcontractor hereunder violated any federal, state or local statute, regulation or ordinance. Multiple lawsuits and or judgments against the Contractor or subcontractor, in any an amount less than **\$250,000** shall be disclosed to the State to the extent they affect the financial solvency and integrity of the Contractor or subcontractor.
3. All notices under subsection 1 and 2 herein shall be provided in writing to the State within fifteen business days after the Contractor learns about any such criminal or civil investigations and within fifteen days after the commencement of any proceeding, litigation, or arbitration, as otherwise applicable. Details of settlements which are prevented from disclosure by the terms of the settlement shall be annotated as such. Semi-annually, during the term of the Contract, and thereafter for three years, Contractor shall certify that it is in compliance with this Section. Contractor may rely on similar good faith certifications of its subcontractors, which certifications shall be available for inspection at the option of the State.
4. Assurances - In the event that such investigation, litigation, arbitration or other proceedings disclosed to the State pursuant to this Section, or of which the State otherwise becomes aware, during the term of this Contract, causes the State to be reasonably concerned about:
 - a) the ability of the Contractor or its subcontractor to continue to perform this Contract in accordance with its terms and conditions, or



- b) whether the Contractor or its subcontractor in performing services is engaged in conduct which is similar in nature to conduct alleged in such investigation, litigation, arbitration or other proceedings, which conduct would constitute a breach of this Contract or violation of Michigan or Federal law, regulation or public policy, then

the Contractor shall be required to provide the State all reasonable assurances requested by the State to demonstrate that: (a) the Contractor or its subcontractors hereunder will be able to continue to perform this Contract in accordance with its terms and conditions, (b) the Contractor or its subcontractors will not engage in conduct in performing services under this Contract which is similar in nature to the conduct alleged in any such litigation, arbitration or other proceedings.

- 5. The Contractor's failure to fully and timely comply with the terms of this section, including providing reasonable assurances satisfactory to the State, may constitute a material breach of this Contract.

I-RR STOP WORK

- 1. The State may, at any time for cause, by written stop work order to the Contractor, require that the Contractor stop all, or any part, of the work called for by this Contract for a period of up to 90 days after the stop work order is delivered to the Contractor, and for any further period to which the parties may agree. The stop work order must be preceded by a written notice to the Contractor. This notice must be delivered, in writing, to the designated representative of the Contractor no less than ten (10) business days before the scheduled stop work order takes effect. The notice shall document the cause to the stop work, and provide a detailed list of expected action items and deliverables the contractor must meet to avoid the stop work order. If the Contractor is able to meet said expectations, the stop work order will not be sent. The stop work order shall be specifically identified as such and shall indicate that it is issued under this section. Upon receipt of the stop work order, the Contractor shall within five (5) business days comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the stop work order during the period of work stoppage. Within the period of the stop work order, the State shall either:
 - a) Cancel the stop work order; or
 - b) Cancel the work covered by the stop work order as provided in the cancellation section of this Contract.
- 2. If a stop work order issued under this section is canceled or the period of the stop work order or any extension thereof expires, the Contractor shall resume work within five (5) business days from reaching an agreement over necessary adjustments. The State & PerkinElmer shall make an equitable adjustment in the delivery schedule, the contract price, or both, and the Contract shall be modified, in writing, accordingly, if:
 - a) The stop work order results in an increase in the time required for, or in the Contractor's costs properly allocable to the performance of any part of this Contract; and
 - b) The Contractor asserts its right to an equitable adjustment within 30 days after the end of the period of work stoppage; provided, that if the State decides the facts justify the action, the State may receive and act upon a proposal submitted at any time before final payment under this Contract.
- 3. If the stop work order is not canceled and the work covered by the stop work order is canceled for reasons other than material breach, the State shall allow reasonable costs resulting from the stop work order in arriving at the cancellation settlement.



- 4. If a stop work order is not canceled and the work covered by the stop work order is canceled for material breach, the State shall not allow, by equitable adjustment or otherwise, reasonable costs resulting from the stop work order.
- 5. An appropriate equitable adjustment may be made in any related contract of the Contractor that provides for adjustment and is affected by any stop work order under this section. The State shall not be liable to the Contractor for loss of profits because of a stop work order issued under this section.

I-SS PERFORMANCE AND RELIABILITY EVALUATION (PARE)

When the State requires that a performance and reliability evaluation (PARE) is to be performed, the standard of performance for the PARE will be closely monitored during the acceptance period.

In the event that the PARE is for components only, all references to systems (processors) should be changed to components.

The Performance and Reliability Evaluation will consist of two phases.

- A. PHASE I
The first phase shall be comprised of a specification compliance review of the software design and/or equipment specifications listed on the ordering documents. Such equipment shall be checked for total compliance with all required specifications of the Contract and work statement. In the event that the State determines that any component or feature of the delivered equipment or software design, developed software or intergrated products do not comply with the mandatory specifications of the Contract, the State shall so notify the Contractor, allowing 14 calendar days for rectification by the Contractor. Should the Contractor be unable to rectify the deficiency, the State reserves the right to cancel the ordering document. Should the equipment and software pass the specification conformance review, the software and /or equipment shall enter Phase II of the PARE.
- B. PHASE II
 - (1) Determination of System Readiness
 - a. Prior to the PARE, a committee of three persons will be formed to evaluate the system's performance on a daily basis. The committee will consist of one Contractor representative and two State personnel.
 - b. The PARE will begin on the installation dates when the Contractor certifies that the software design and/or equipment is ready for use by the State.
 - (2) During the PARE:
All rerun times resulting from software design and/or equipment failure and preventive maintenance shall be excluded from the performance hours.
 - a. All reconfiguration and reload time shall be excluded from the performance hours.
 - b. If files are destroyed as a result of a problem with Contractor software and/or equipment and must be rebuilt, the time required to rebuild the files will be considered "down-time" for the system.



- c. If the Contractor requests access to failed equipment and the State refuses, then such maintenance will be deferred to a mutually agreeable time and the intervening time will not count against the PARE.
- d. A functional benchmark demonstration will be run for the PARE Committee to confirm that the installed system is capable of performing the same functions that were demonstrated. This run must be completed to the satisfaction of the PARE Committee.

C. STANDARD OF PERFORMANCE

- a. The performance period (a period of thirty consecutive calendar days) shall commence on the installation date, at which time the operational control becomes the responsibility of the State. It is not required that one thirty day period expire in order for another performance period to begin.
- b. If each component operates at an average level of effectiveness of 95 percent or more for a period of 30 consecutive days from the commencement date of the performance period, it shall be deemed to have met the State's standard of performance period. The State shall notify the Contractor in writing of the successful completion of the performance period. The average effectiveness level is a percentage figure determined by dividing the total operational use time by the total operational use time plus associated down-time. In addition, the software design and/or equipment shall operate in substantial conformance with the Contractor's published specifications applicable to such software and/or equipment on the date of this Agreement. Software and/or equipment added by amendment to this contract shall operate in conformance with the Contractor's published specifications applicable to such software and/or equipment at the time of such amendment.
- c. During the successful performance period, all rerun time resulting from software and/or equipment failure and preventive maintenance time shall be excluded from the performance period hours. All reconfigurations and reload time shall be excluded from the performance hours. Software and/or equipment failure down-time shall be measured by those intervals during the performance period between the time that the Contractor is notified of software and/or equipment failure and the time that the software and /or equipment is returned to the State in operating condition.
- d. During the successful performance period, a minimum of 80 hours of operational use time on each component will be required as a basis for computation of the average effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum stated above.
- e. No more than one hour will accrue to the performance hours during any one wall clock hour.
- f. Software and/or equipment shall not be accepted by the State and no charges will be paid by the State until the standard of performance is met.
- g. When a system involves on-line machines, which are remote to the basic installation, the required effectiveness level shall apply separately to each component in the system.
- h. Promptly upon successful completion of the performance period, the State shall notify the Contractor in writing of acceptance of the software and/or equipment and



authorize the monthly payments to begin on the first day of the successful performance period.

- i. After all components have been installed and accepted by Perkin Elmer & the State a final system test on the entire system will be conducted.
- j. If successful completion of the performance test is not attained within 90 days of Perkin Elmer deliverable to the State, the State shall have the option of terminating the Contract, or continuing the performance tests. The State's option to terminate the contract shall remain in effect until such time as a successful completion of the performance period is attained. The Contractor shall be liable for all outbound preparation and shipping costs for contracted items returned under this clause.
- h. The PARE will be complete when the software and/or equipment has met the required effectiveness level for the prescribed time period.
- i. The State agrees to assign resources to perform the PARE as mutually agreed necessary. In case the planned resources are unavailable, and the State is unable to assign other resources to perform necessary PARE work, the Contractor shall not be held accountable for any related delays, and the State cannot exercise the option to cancel the contract for this reason.



SECTION II
WORK STATEMENT

II-A BACKGROUND/PROBLEM STATEMENT

A. Problem Statement

The Division of Chemistry and Toxicology, within the Michigan Department of Community Health's Bureau of Laboratories, has a Laboratory Information System (LIS) that is inadequate to meet the needs of its high volume laboratory workload. A new Laboratory Information System is required to electronically track specimens, assays, patients, compatibility of software and equipment, and enable on-line status inquiry and reporting requirements. The Lead Screening System will be implemented in parallel to the Newborn Screening system.

B. Setting and Organization

The Chemistry and Toxicology Division consists of two sections: Newborn Screening Section, and the Lead Section. Both sections use highly complex laboratories for testing of specimens received from hospitals and all submitters. Submitters to the laboratories include, but are not limited to: physicians, hospitals, clinics, midwives, other laboratories, and local health departments.

The Newborn Screening Section performs ten different assays (tests) for seven different disorders on approximately 130,000 babies born in Michigan (145,000 specimens) each year. The disorders are: phenylketonuria, hypothyroidism, congenital adrenal hyperplasia, galactosemia, biotinidase deficiency, hemoglobinopathies (sickle cell disease), and maple syrup urine diseases.

The Newborn Hearing Screening Program receives and tracks hearing tests for Michigan newborns. The hearing screening result slip is separated out from the Newborn screening sample requisition form and sent to the newborn hearing coordinator. Both the hearing results and blood screening slips share the same bar code number. Since it is not mandatory for newborns to receive hearing tests, currently only 70% of newborn babies obtain the hearing tests. The number of hearing tests performed each year could potentially equal the birthrate number of approximately 130,000. Using a bar code identifier, hearing test results are linked to the patient's demographics from the Newborn Screening Unit. The hearing-screening database will be fully integrated into the newborn database.

The Lead Section performs tests on analysis of environmental (Paint chips, dust wipes, soil) and blood lead specimens. The Lead Section is separate from the Newborn blood screening section. It has its own equipment and reporting criteria, etc. Approximately 45,000 lead tests a year are performed.

The users of the division laboratories include:

- Bureau of Laboratories, Newborn Screening Laboratory, Quality Assurance Office and Virology Section
- Newborn Screening staff in the Community Living, Children and Families Administration (CLCFA)
- Lead Program staff in the CLCFA
- Lead Hazard Remediation staff
- Medical Management Centers
- Newborn Hearing Screening staff



C. Laboratory Workload

Because each laboratory specimen is tested for multiple analytes, over 5,000 assays per day are performed in the Division, with receipt of approximately 600 samples. This is approximately 1.4 million assays per year.

The new system will require an additional 130,000 (number of newborn babies per year) hearing test results to be entered into the database.

D. Description of Existing Laboratory Operation

The current system for the Newborn Screening Section is a relational FoxPro DOS database stationed in-house. This system allows for the manual entry of specimens, results, transfer of results to follow-up/medical management centers, and back-up requirements.

The current system has manual input of data on hearing tests; links to the Bureau of Laboratories Virology Section; and allows for manual input from medical management and follow-up staff.

E. Database Users

- 44 connections required for 25-28 Division laboratory staff located at the MDCH north complex in Building 29, with varying security levels. (This includes the Bureau of Laboratories Virology Section and Quality Assurance Office in Building 44);
- All program follow-up and accounting staff located on the MDCH network system;
- Medical management staff located at the University of Michigan and in Detroit. These users will access the system either over the MDCH network, or via dial-in or equivalent electronic method, as provided by MDCH and discussed below in section II-B.D.
- Laboratory submitters with security codes and with limited patient record access via dial-in or equivalent electronic method.

F. Laboratory Equipment

The list below may be modified by the time of purchase and the vendor should be prepared to interface any types of laboratory equipment. Current equipment for database that must be interfaced:

- PE Wallac systems for PKU, MSUD and Galactosemia
- Bio-Rad for Sickle Cell, to be interfaced via the BioRad Variant Access database
- Isoelectric Focusing – Manual Method – Sickle Cell
- AutoDelfia Systems – PE Wallac for CAH, T4/TSH
- Colorimetric Assay – In-house Method for Biotinidase
- GFAAS – Varian & Perkin Elmer for blood lead
- FAAS – Perkin Elmer for environmental lead
- Cold Vapor Mercury Analyzer – Leeman Labs
- Sato Bar Coder Printers – PE Wallac
- DBS Puncher – PE Wallac
- DBS Barcode readers – PE Wallac
- Multipunch – PE Wallac
- Document Scanning Systems – PE Wallac



G. MDCH Hardware and Software Environment

All hardware (except the direct interfaces with the lab equipment) will be supplied by MDCH/MISB. The housing and operation of the hardware and the interface with the State's network is the responsibility of MDCH/MISB. Delineation of the hardware specifications is the responsibility of the vendor and must be given to MDCH/MISB 90 days prior to the date of its first use.

II-B SYSTEM REQUIREMENTS

The following is a list of system requirements/specifications:

- A. Automation of processing specimen requisition forms: The laboratory receives 700-1,000 forms daily that are manually entered into the database. This requires a staff of four data encoders. The Newborn Screening laboratories currently have scanning equipment for use in the new Laboratory Information System. Data encoding operators would be required for the scanning of the requisition forms. Further, since the requisition forms are handwritten, data encoding operators will be required to follow-up on any data the system cannot read. The sensitivity for each scanned field will have predefined edit criteria with the most critical edit having a higher sensitivity. Any fields that do not pass the edits will be flagged for close scrutiny by the data encoder. *Example:* The system has flagged the birth date field. The data encoders' screen would show the problem field (potentially appearing as a different color) with a copy of the actual image of the scanned form next to the problem field. The data encoder will make a determination of what the data is by comparing other fields on the form to determine handwriting, etc.)
- B. Positive tracking of specimens throughout the laboratory: The laboratory performs 5,000 – 7,000 assays tests) per day. Currently these assays are manually tracked through the laboratory and manually followed up. The new system would be required to electronically track the specimen from its arrival to the lab (either by mail or by courier), track the disorders, the tests, and the result notification. The tracking of the specimen will indicate the specimen analysis for each disorder and which part of the analysis has been completed. Specimen tracking requirements would allow, but not be limited to:
- The date and by whom the specimen was entered into the system;
 - Disorders the specimen is being tested for;
 - The date and by whom the specimen was labeled, i.e. bar-coded
 - The date and by whom the specimen was punched
 - The date, and by whom the specimen was analyzed;
 - The date, and by whom the test results of each disorder;
 - The date, and by whom the final report was printed;
 - The date the results were sent (when done electronically);
 - The date and Medical Management Consultant assigned;
 - Medical Management follow-up tracking of: date treatment initiated, d diagnosis code, results of clinical evaluation, date of closure on the case;
 - Comment fields in each tracking area.
- C. Automated Equipment Interfaces: Currently, a laboratory scientist processes the specimens and manually enters all positive or unsatisfactory results into the database. The specimen bar code is used to track the specimen throughout the system. The new system would require the machines reading the assay results in the micro titer plates to create electronic files of the results for input into the database. The new system would allow for analysis of the test results. Any positive results would be flagged for prompt attention by the scientists.



- D. Remote Inquiry Access for Users of the Laboratory: Currently, staff answer phone inquiries on laboratory results. The new system will be required to allow remote access inquiry to physicians, medical management staff, newborn screening follow-up office and other designated individuals by newborn screening for checking the status/results of tests. Security issues for remote access are discussed under Security in this document.
1. We have found that the implementation of distributed follow-up can be arranged without developing a thin, Internet Browser based, client software. The alternatives to consider include a direct LAN/WAN connection between Lansing and the other locations, using commercially available means to run client server software over the Internet, such as Citrix Metaframe. Citrix licenses will cost the State approximately \$300 per user workstation. Note that this approach can also be used to provide hospitals and doctors with on-line access to the infant screening database. Implementation of this requirement will be included in the revised pricing proposal.
 2. For Remote Access to the laboratory database, we propose using Citrix (as mentioned above). The cost of implementing this will be absorbed into the price of Specimen Gate Product Suite.
 3. If the State would like PerkinElmer Life Sciences to implement a thin client approach to provide hospitals and doctors with on-line access to the infant screening database, the quotation for these components will remain as presented in the original price proposal.
 4. Hardware; while it in theory is possible to run the Citrix service on the main newborn screening database server, PerkinElmer highly recommends a separate server to be dedicated to host this service. The specification for the server would need to be determined by examining the estimated load at different user volumes. The procurement, installation and maintenance of this hardware and Citrix software licenses, will be the responsibility of the MDCH. PerkinElmer will be responsible for installing the Citrix service. The installation of Citrix must be done in conjunction with MISB.
- E. Add Additional Data from Other Identified Sources to a Baby's Demographic Information: The new system's database structure must include storage of additional information that is not on the original requisition form. The additional data could come from Vital Records, phone call information, fax, email, etc. A possible tickler field to indicate that additional data was entered. The additional information fields must allow for a date and time the additional information was entered.
- F. Automatic Reporting of Test Results: Currently results are manually entered on requisition forms. This process delays reporting of results by days. The new system will require test results to be automatically reported via mail, fax or electronically sent.
- G. Print Test Results for Direct Mailing: The new system must print test results in a report format with the address of the submitter printed on the report in a location for direct mailing if indicated. This will eliminate labels to be printed and attached. The test result report can be manually mailed, manually faxed or electronically if capabilities are there. The printing of the reports will be in zip code order. For mailing requirements, the report will be folded to show the address and mailed by one of the following acceptable methods: (1) insertion into a transparent window envelope with the address showing through; or (2) mailing without insertion into an envelope with the report sealed in a manner that is approved by the United States Post Office. (The mailing office for Newborn Screening currently has an older machine that folds mailers.) Laboratory test result report should appear in the following format; the test result report will resemble the image of the scanned requisition form. Since the test result report is



identical to the scanned requisition form, the test results will be indicated on this report in the same location as was on the requisition form. The benefits of this report being identical to the requisition form allow the submitter to have an identical copy of what was requested on the requisition form.

H. Automated Follow-up on Infants: The DCH Newborn Screening Follow-up Office is the liaison between the public, the customers, and the entire Laboratory Information Program. The Newborn Screening Laboratory manually faxes or delivers to the Follow-up Office all strong positive, borderline positive and unsatisfactory test results as well as all previously positive results, which are identified as repeat positive, repeat borderline or negative results. The new system is required to track date of receipt of test results from the labs. The Follow-up Unit will require both inquiry and write access into the system. The Follow-up Unit will require both inquiry and write access into the system. The Follow-up unit has roughly 32 canned letters that are faxed to doctors, etc. to report test results. Each fax letter describes a different test result with follow-up requirements. A copy of the initial Newborn Screening card (Follow-up unit received from labs) is attached to the bottom of a specific test result letter, copied, and electronically or manually faxed to the doctor, midwife, clinic or NICU. The new system would be required to merge the correct fax letter (based on the value from the results field which was input into the database from the NBS laboratory) and the doctor's midwives, clinics and NICU's address/phone information from the doctor's directory for insertion into the letter. The Follow-up Unit has in WordPerfect, a fax directory database with doctors' names and fax numbers that is separate from the labs. The Follow-up Unit would require the new system to include doctor's midwives, clinics and NICU's directory containing the doctor's name, address, telephone and fax number. The Follow-up unit must have the ability to add and modify the directory. The follow-up unit requires that every 6 months all doctors that have been inactive be deleted from the doctor's directory. The new system will be required to track Follow-up requirements:

- Date retest card was received in follow-up unit
- Date and by whom a retest letter was faxed to a doctor, etc.
- Date retest card is due (can be calked field 2 weeks date sent)
- Date and doctor performed retest
- Date and by whom case referred to Medical Management
- Medical Management individual assigned to case
- Date treatment started and by whom
- Diagnostic Code
- Comment field for Medical
- Comment field for Follow-up Unit

Additional tracking required:

- Quality Control Hospital follow-up value. How complete the Newborn Screening cards were filled out (blank, not legible fields, etc.) This could well be determined and input into the system by the Follow-up Unit. Note: Follow-up unit requested ability to automatic fax requesting information when any of the following field are left blank: Original specimens – birth weight, birth date, specimen date, transfusion date, doctor's fax number, mother's first and last name, and submitter. Retest specimens – birth weight, specimen date, birth date, transfusion date, mother's first and last name. Fax should be generated and sent to the nurse manager/submitter as soon as the specimens have been cleared through the data entry process.
- Turn-around time. (How long does it take the hospitals to get the cards from birth date to punch date. Unsatisfactory specimens received from hospitals.):
 1. Unsatisfactory specimens received from hospitals



2. Transfused specimens by hospitals
3. Ability to calculate % of late specimens
4. Ability to calculate difference between punch date and birth date
5. Ability to calculate state and per hospital averages.

Note: The ability to calculate state and per hospital averages is for specimen turn-around time. Need to be able to determine #/% of late specimens. This is the #/% that arrive on the 6th day of life or later.

The Follow-up Unit would like the NIC/Sp. Care Nursery field flagged or highlighted. If a specimen is from the Newborn Intensive Care Unit, babies from MICU are looked at differently than if they were from a regular nursery. (This could be a training issue). The Follow-up Unit needs to have the capabilities to select standard reports and to perform ad hoc reporting on selected fields for analysis reporting.

- I. Medical Management to Access the Laboratory Results: Currently, patient data with positive test results is manually sent to staff and medical management groups to activate a follow-up action. In the new system, the Medical Management group will require access into the Newborn system for inquiry and updating children with positive test results. Medical Management units will have a direct access to the database over the MDCH network. Medical Management groups are contracted through the State of Michigan to insure those children with positive test results get expert medical treatment. There are 3 different Medical Management groups the State currently contracts with. They are (Sickle Cell Center/Detroit, Metabolic/Ann Arbor, and Endocrine/Ann Arbor). The laboratory system can consider the case closed when a diagnosis code from the Medical Management group is returned indicating, i.e., Negative, In treatment, Lost to Follow-Up, etc. If a follow-up sample was sent in with positive results, the Medical Management group would continue the follow-up process until a negative sample is received or they would continue to monitor the infant's treatment and medical care for the disorder. (On every new sample that comes in, the patient's history is located by performing a match on the current and history data bases (history data bases currently date back to January 1, 1995) on the babies name, birth date, mother's first name, mother's last name, birth hospital, medical record number, mother's social security number, multiple birth indication, sex, and mother's address. If a match is found and the patient had a previous positive test, the new specimen is tested and tracked for a negative test. Newborn Screening tests all specimens for all disorders if there is an adequate sample.

Two options for the inquiry/write process would be:

- WEB. Each Medical Management participant would need an Internet connection with ability to support current versions of Internet Explorer and Netscape or other Internet access determinations. Security measures would have to be evaluated on WEB access allowing strict confidentiality of the data. Research, implementation and maintenance of all LAN, WAN and Internet issues, including but limited to security, shall remain the responsibility of MDCH.
- Direct Access. For direct access into the system, each participant would need the necessary software and hardware requirements. Communication issues with Stat of Michigan firewalls and the State's network Operations Center would need to be reviewed and addressed. Research, implementation and maintenance of all communication issues, including but not limited to firewalls and the State's network Operation Center shall remain the responsibility of MDCH.

In either scenario mentioned above, it is agreed all underlying security, communication and other pertinent issues must resolved, and necessary implementation actions will be



completed by MDCH by the time it is necessary to install the software. PerkinElmer software will be expected to operate either on a standard LAN client server configuration, or utilizing the Citrix service described above.

Considering the nature of this highly confidential data, security requirements and departmental standards would have to be determined for the accessibility and updating of the database by non-state employee's.

- J. Allow Entry of Additional Tests, Methods, Cut-off Values and Screening Criteria to the Existing Data Base: The new system will require the ability for additional tests to be entered into the system. All system modifications necessary to incorporate the addition, deletion, editing of new tests would be evaluated and coded by the vendor.
- K. Add New Diseases to the Newborn Screening Program: The system is limited to the diseases currently being screened by the program. There are increasing demands to review new diseases for their screening potential. The new system would require the ability to add or discontinue diseases to be screened as well as a possible increase in the number of tests done in the program. The ability to add specimens from other sources or programs would be required. Vendor involvement will be necessary to modify the system for adding additional diseases into the system. This may include adding additional edit criteria for the disease. Hardware considerations may be needed if tests are conducted on the additional diseases added to the system.

Specimen Gate is flexible by design and facilitates the ability to add or discontinue diseases to be screened as well as the number of tests done in the program. Adding, modifying or deleting of assays, tests or testing equipment is subject to a separate pricing proposal determined on a case by case basis, or alternatively can be included in the software maintenance contract as a per test fee predicated by the characteristics and the methodology of the assay.

- L. Efficiently and Confidentially Track Location of Specimens for Retrieval Purposes: Currently, a manual retrieval of specimen information or the specimen itself occurs. The new system would allow the tracking of specimen demographics and location of the specimen. A unique sequential bar code identifier will be assigned to each specimen received. This unique identifier will be applied on the physical specimen itself for retrieval purposes and is also place on the requisition form for tracking purposes. Specimens are kept in storage for two years for laboratory needs, 21.5 years for research and legal reasons.

Specimen Gate includes a Specimen Bank application, which has been included as a part of this response, and the pricing proposal. PerkinElmer Life Sciences reserves the right to amend the pricing proposal to allow for advanced customization work that may need to be done to the Specimen Bank application in order to meet specific specimen storage and retrieval requirements of the State.

- M. Report and Document Requirements: Currently, reports are manually written. The new system will require standard reports and documents to be printed on a periodic basis or on-demand. Ad hoc reporting software should be available for creation of reports and documents on an ad hoc basis. Training for Newborn staff will be required for ad hoc reporting.
- N. Allow for Printing Requirements: The new system will allow for all print jobs to be sent to a file, screen or printer. The new system will allow for screens to be printed.
- O. Identifying and Tracking Incoming Specimens, Tests, Etc.: The vendor will provide software to electronically print a bar code with the date and time for identification of the requisition form,



blood screening tests, hearing tests, lead tests, and all related paper work for the patient. Barcode generation will be supplied as a stand-alone module. The bar code must have a check digit algorithm. Two identical bar code labels are printed. One label is assigned to the requisition form and the other label is assigned to the specimen. The requisition form will have two numbers, a preprinted number and the sequential bar code number that matches the specimen number. By use of the bar code, the system will be able to positively track the specimen and all tests, etc., related to the patient. The system must be able to test quality control and proficiency samples that may be numbered differently than the newborn samples. The results from these samples must be able to be viewed through quality control software with statistical tables and graphs. The system should be able to generate a fax to the submitter if a critical data field needs to be completed. This fax should contain an image of the card with the incomplete data field identified and a request for the information. These requests should be able to be sent by personnel with a touch of a key when needed. Similarly, there should be an option to make this process automatic for multiple specific fields if desired.

- P. Patient's Demographics: The system will require the vendor to provide software to scan and edit MDCH handwritten requisition forms using an (OMR) Optical Mark Reading Scanner for use in reading mark sense forms. Additionally, the vendor, using an (ICR) Image Character Reader Scanner, will provide software to scan in a copy of the actual image of the requisition form and to be saved into the patients' record for 21.5 years. The sensitivity for each scanned field will have pre-defined edit criteria with the most critical edit having a higher sensitivity. Data encoding operators will scan the requisition forms. The requisition forms are handwritten; thus, data encoding operators would be required to follow-up on any data the system cannot read, i.e., The system has flagged the birth date field. The data encoder would see on the screen the characters the software cannot identify in the problem field (potentially appearing as a different color) with a copy of the actual image of the scanned form next to the problem field. The encoder will make a determination of what the character is by comparing other fields on the form to determine handwriting, etc. This tracking process includes: the date, comment field, who scanned the form into the system, Supervisor review and comment field. The Parties acknowledge that form design is a key ingredient to the success and performance of the OCR/ICR technology and that the layout of the State's present forms does not adhere to the industry standards established for OCR compatible form design, which may reduce the accuracy of the optical recognition of the handwriting. Optical Recognition is dependent on use of drop out inks, boxing of letters, letters per inch, use of optical marks and cornerstones. In addition, informing the birthing staff that an optical recognition form has been deployed, is critical to a successful deployment. These factors including realistic expectations all are factors for a successful optical recognition program. Therefore, the Parties agree that alternative methods, including but not limited to, "Key From Image" methodology can be deployed as an alternative to the full blown OCR/ICR technology. During the 120 day discovery period, the State and the Contractor will agree on the schedule and milestones the State's form design and implementation process needs to meet. Should the implementation of any of the forms be delayed for more than fifteen (15) business days from the scheduled date, the Contractor can exercise the option of deploying the "Key From Image" methodology, which will at that point become the final deliverable for the form in question. Demographics of every sample in the Newborn Screening laboratory is checked again the existing database to determine if it is a retest. The link to a previous sample is made by performing a match on one or many of the following fields: babies name, birth date, mother's first name, mother's last name, birth hospital, medical record number, mother's social security number, babies social security number, multiple birth indication, sex, and mother's address. If a match is found and the patient had a previous positive test, the new specimen is tracked for a negative test. Newborn Screening will test all specimens received for all disorders if there is an adequate sample. For those patients that had a previous positive test and were retested with a negative test, a tickler (comment) field



should be considered to notify the Medical Management group a patient that was positive was retested and is now negative. A report could be created indicating the test results for mailing to the Medical Management Group to advise of negative test. MDCH staff requires the ability to perform matching analysis on any or all of the demographic fields. If the patient cannot be matched by a pre-defined, matching criteria, MDCH staff will manually match by using the additional demographic criteria. The system is required to scan individual hearing requisition forms that were not submitted with the Newborn screening requisition forms. This unit should allow for a senior supervisor or scientist to review and release the work once it is approved. The data operator performing the work will be documented. Data will be available to perform tests, see images and view demographics while in the review stage. Demographic release will automatically enter into the system the demographic influences for specific assays and create the MDCH-defined reports. Some demographic information such as age and birth weight may be necessary to decide a test result; also, results may not be ready until the demographics have been released.

- Q. Bar Code Scanning Requirements: The system will require the bar code to be scanned and interface with the system at each punching/processing station whether this is an automated or manual punching procedure for blood screening tests and lead tests. Inputting the results of hearing tests will also require the ability for bar code interface with the system. The system will be required to allow bar code interface, at a minimum, on 3 types of NBS specimens for test results to be entered into the system: initial, repeat and unsatisfactory.

- R. Out of Sequence Tests: During the testing procedure, the system would be required to alert staff for tests that have become out-of-sequence 1) the staff can get the samples back in sequence before proceeding, 2) system will keep track of specimen numbers before proceeding. The system would require the ability to input test sequence numbers for each test to ensure that each step of the test is in the correct sequence. Tracking requirements: status of all the testing at any point in time. Retests and original tests with supervisor override can allow out-of-sequence punching/processing to take place. The system will allow bar code interface, at a minimum, on three types of NBS specimens for test results to be entered into the system: initial, repeat and unsatisfactory. The system will allow retrieval by bar code with hearing screening tests for test results to be entered into the system. The retrieval will also include access to the demographics on the patient as well as allow query access for review of the specimen tracking results on the patient. The types of specimens from Newborn Screening, Lead and Hearing will generate different actions in the demographic, follow-up and testing procedures depending on the specific requirements of each unit.

- S. Interface with Laboratory Equipment: The system must upload work lists and download results from all automated laboratory equipment within practical limitations of the equipment. The system will allow for manual entry of results for all non-automated assays. The system will also allow for easy addition or deletion of equipment for methodology changes. The vendor must not limit the system to only their kits or instruments. It must have an open architecture for adding new technology or competitor's products. The system will not be accepted until all interfaces are complete and validated.

- T. Assay Parameters/Protocol Management: Programming software for each assay test will include edit criteria as defined by MDCH. Edits will include; but, not limited to, cut-offs, placement of controls on plates/tray/carousels, patient sample quantity (1X, 2X), and reflex testing (automatic ordering of repeat assays) protocols. Programming software will include edits on acceptable test results, worksheets and templates as defined by MDCH. Programming software for repeat assays (reflex testing) will include edit criteria as defined by MDCH.



- U. Test Result Edits and System Requirements: System tests edits will determine if test results are: released, held or retested. Normal test results will be considered and released and automatically flagged for report and mailing purposes. All results that are not normal as defined by MDCH editing criteria, are considered as held within the tracking process. These tests will need to be flagged for retesting and for review by the laboratory scientist who requested the test. The system should have a tickler screen for review of all flagged results by the laboratory scientist who created the test. The system must have a method for senior worker or scientist review of the calibration results, quality control results, reference samples, spikes, blind samples, proficiency test results and patient results including means, standard deviations and coefficients of variation. The system is required to incorporate an audit trail for each action taken on an assay, tray or individual result; date and by whom results were reviewed, date and by whom action was taken, and comment field. At such time the results have been retested, the system should indicate the results as retested with the status results of the retested specimen. If retested results are not normal further determination will take place with reflex testing and scientist decision of actions to take. The system must allow for the creation of new assay protocols for new reagent lots and test methods. Vendor involvement for adding new test methods will be required since edits and reporting requirements will be necessary. The system must allow for adding additional proficiency programs as necessary. Vendor involvement for adding additional proficiency programs will be necessary if editing requirements are involved.

- V. Tracking and Linking of Data: The system is required to generate a cumulative tracking history for each unique patient and for each test specimen. The system is required to track each follow-up sample and link this action to the patient's specimen tracking history. The system will be required to track repeat assays. Repeat assays will require a new repeat work list which may require the addition or deletion of specimens by the staff person authorized to perform the particular task. Tracking is required on the proficiency programs in which the laboratory is currently enrolled (CDC, CAP, AIHA). The system will grade proficiency results as acceptable or unacceptable according to MDCH preset edit parameters. Edits will determine whether or not the assay results meet additional Westgard rules for trend and drift.

- W. Retrieval of Data: The system should allow the laboratory staff to retrieve data by preset parameters such as, but not limited to: test date, signal/concentration, operator, instrument, assay type, analytes.

- X. Quality Assurance of Data: A quality assurance/quality control software tool will be required in the new system. This tool will allow automatic sorting of assay data, scrolling of unlimited data points, lot-to-lot monitoring, target level changes by the week, month or year.

- Y. Creating Reports and Using Report Writer: A report writer will be required for standard and ad hoc reporting needs. Standard reports will be prototyped by the Vendor for approval. Reports can be generated on a periodic basis (daily, weekly, monthly, yearly, etc.) as set by MDCH. Examples of some standard reports used by the laboratories are: quality control, recall/retest specimens received for ordering of tests, status of feeding, open/closed cases, hepatitis report, hearing screening results, antibiotic treatment, steroid treatment, transfusion report, unsatisfactory specimens, initial tests, recall tests, capillary, venous, environmental specimens. Ad Hoc reports will be performed by the users. Ad Hoc report training will need to be determined by the user for their staff. Ad Hoc reports must be able to capture all data fields, including scanned and calculated. All reports must have output capabilities to be viewed, printed, faxed electronically and manually, and ability to be saved in word processing formats. (Reporting on Medical Managements results will be available after input of the medical management data into the database.)



Specimen Gate's reporting model is based on Seagate Crystal Reports where the customized Specimen Gate solution is delivered with a set of predefined reports as described in detailed System Specifications. All reports can subsequently be altered, deleted or added to by authorized laboratory staff. Seagate Crystal Reports training is available commercially and is therefore excluded from PerkinElmer Life Sciences' pricing proposal.

- Z. Access Requirements: The system will be required to allow authorized laboratory employees and authorized Medical Management groups query access to view a patient's record for all actions taken on the case, view or print the image of the original requisition form, write to the follow-up patient action list, do a search on the data and write reports. Authorized MDCH staff will need access to quality control parameters, assay limits, reagent lot numbers, acceptable range for the median of the run, number of positives per plate or assay. Authorized MDCH staff will need access to input data in the follow-up record when they receive calls from submitters.
- AA. Print Test Results for Direct Mailing: Employees assigned report access can print, fax electronically or manually, save to a file or send per e-mail with the file attached. The employees that need security access for querying and writing to the files and creating reports will be determined by MDCH.
- BB. On-Line Search/Lookup of Patient Records: The system will be required to allow authorized employees and Medical Management group on-line search for patient records using a pre-determined list of demographic fields to chose from as well as the use of wildcard characters in a search. Medical management groups must have the ability to work on abnormal test results by searching on name, analyte concentration, date, or by batch, etc. for ease of tracking and closing cases.
- CC. Follow-up of Patient Test Results: The system will be required to merge and correlate testing results for review on the screen. Test results can be printed in either a standard or ad hoc report format. The system will be required to electronically generate letters, fax using GroupWise, send mail using GroupWise, phone lists, create reports electronically with specific test results and analyte.
- DD. Quality Assurance Reporting by Hospital: This unit must be able to evaluate the demographic database fields as to the quality of the data (level of correctness to which they are filled out) so submitters can be notified of problems.
- EE. Data Export: The system must have an export capability that facilitates the transfer of data to other files and formats, such as ASCII. For all results; including, but not limited to, the SOLAR system for lead results.
- FF. Archiving: The vendor will provide an archiving capability, which maintains an active database for a time period set by MDCH. Active files will automatically be moved to the archives after that period. The archival system must be interactive using optical disks or a similar system that allows data to be requested and restored within a short period of time. It will be further determined how and by whom files will be automatically restore.
- GG. Backups of System Software Data: The contractor shall provide a method for recovering from a system crash by Disaster Recovery or the standard backup procedures with the entire data restored. The development of this requirement must be given to MDCH/MISB for implementation. If system is down, a backup plan would be required to allow for each of the different lab processes to be reviewed for manual operation. Manually print bar codes, demographics, etc.



- HH. Maintenance Follow-up: This unit shall allow staff to monitor how the maintenance of the laboratory instruments is performed in the laboratory, the due date, date performed and which staff members completed this task.
- II. Virology Equipment and the EPIC Database: HIV Testing of Dried Blood Spots for HIV demographics. Upon notification, HIV testing is done periodically and this unit should only function as needed by MDCH. Solar Database: This system must transfer automatically overnight (from 5 p.m. to 7:30 a.m. or as determined by NBS) all release Blood Lead results to the SOLAR database that resides on the MDCH network.

II-C TASKS

The following is a preliminary analysis of the major tasks involved for developing the end product of this project. The Contractor is not, however, constrained from supplementing this listing with additional steps, sub tasks or elements deemed necessary to permit the development of alternative approaches or the application of proprietary analytical techniques.

An overall plan must be developed as a basis for executing subsequent steps as the project progresses. Essential to the process of this task is the preparation of a sound approach to attaining the objectives of the project. Contractor staff assigned to this project must be on-site in Lansing during appropriate stages of development, as detailed in the overall plan.

- A. Phase I – Newborn Screening/Lead Lab System
 - 1. Analysis and Design: Completion within 120 calendar days
 - Task 1. The contractor will perform an analysis of the laboratories data flow, laboratory functions, follow-up/medical-management functions, user requirements, information processing/reporting and unique needs of each laboratory unit including implementation of automated vs. manual systems.
 - Task 2. Determine equipment and/or configuration needs for interfacing instruments.
 - Task 3. Based on the above analysis, provide a system specification document that includes tasks, deliverables, performance standards and detail of the system customization, installation, testing and training. This project plan will include scheduling, anticipated MDCH staff contact hours and descriptions of the relationships and interdependencies among tasks. This may include phased installation of functional units, i.e., Newborn Screening, Lead, HIV, SOLAR, etc.
 - Task 4. On a properly configured modern network, where the load on the system is reasonable, the system will return a record by accession number or kit number in about 1-2 seconds.
- B. Phase II - Development and Implementation: Completion within 365 calendar Days. Based upon the design developed in Phase I, the system will be customized, tested, documented according to MDCH/MIS standards, and implemented.
 - Task 1. The vendor shall customize and install all software on site. If the vendor wishes to install the software via a remote link, the proposed method must be approved by and implemented in conjunction with MDCH/MISB. Hardware and software provided by the vendor must be installed and maintained by the vendor: Ownership depends on the hardware. If it is



part of reagent rental laboratory equipment, then the vendor owns it. If a modular approach is used for installation, each module (unit) will be acceptance tested at that time.

- Task 2. The vendor must provide a software training and testing environment apart from the productional data without affecting normal laboratory operations or actual patient data. This should include both practice software that can be run without using laboratory instruments and teaching software where training runs can be performed, prepared, reviewed, and transmitted to the system without the data merging into the clinical test results.
- Task 3. Staff training must be on a rotational basis so that all staff currently employed (27) will receive training in small groups (1-3). There can be allowances for short (1 hour) common functional training sessions for larger groups of staff. The system must supply an offline training mode.
- Task 4. A performance and reliability evaluation (PARE) period of at least 30 working days is required in order to determine the impact of cycles, workload peaks, testing patterns, reporting requirements and other laboratory operating requirements and needs. This is the time when MDCH evaluates the total performance of the package and efficacy of the total system. Final system acceptance will follow this test period.
- Task 5. Post-Implementation Review: Information and data is gathered through interviews, observation and discussion on operating data, volumes, error rates, problem areas, effectiveness of controls, and security, usefulness of outputs and displays, processing problems, etc. This information and data analyzed, compared to original objectives, and corrective action or enhancements must be made for any shortcomings, deficiencies, and problem areas. Recommended additional enhancements and improvement that will be needed in second or additional phases of this project shall also be made. A written report comparing actual performance to system objectives, performance parameters and user needs must be prepared by the vendor, with assistance by MDCH staff, listing corrective actions taken and recommendations for future changes and enhancements.
- Task 6. Documentation/Manuals. The documentation and manuals will include a detailed step-by-step procedure for the operation of the system and must be provided to MDCH in electronic, camera-ready version before final acceptance of the system. The documentation must follow MDCH/MIS Standards.

C. Phase III. Maintenance and Support:

- 1. Warranty/Support: The vendor must guarantee that the laboratory information system will perform according to the mutually agreed upon performance standards for one year following the final acceptance of the system. If the system does not perform according to the standards and there have been no substantive functional or operational changes, the vendor must correct the situation at its own expense.
- 2. System Maintenance: The vendor will include a two-year service contract for support in the subsequent years as part of the total cost. This will also include hourly rates for software upgrades and enhancements to the system.



Hardware provided by the laboratory information systems vendor that cannot support their software revisions will be upgraded at the vendor's expense.

3. Pricing for new software releases that encompass increased functions and features, add a test/certification or training subsystem, or extend other system services will be negotiated separately and in advance of any system changes. The vendor should be prepared to add new instruments and expand the testing systems within the period of this contract.

II-D PROJECT CONTROL AND REPORTS

I. Project Control

- a. The Contractor will carry out this project under the direction and control of the Michigan Department of Community Health.
- b. Although there will be continuous liaison with the Contractor team, the client agency's project director will meet biweekly as a minimum, with the Contractor's project manager for the purpose of reviewing progress and providing necessary guidance to the Contractor in solving problems which arise. Meetings will be held in person, by phone or video and agreed to by both parties.
- c. The Contractor will submit written biweekly progress reports which outline the work accomplished during the reporting period; work to be accomplished during the subsequent reporting period; problems, real or anticipated, which should be brought to the attention of the client agency's project director; and notification of any deviation from previously agreed-upon work plans.
- d. Within five (5) working days of the award of the Contract, the Contractor will submit to the Department of Community Health project director for final approval of a work plan covering Phase I, part 1 (Analysis and Planning – 120 Calendar days). This plan must be in agreement with section IV-C subsection 2 as proposed by the bidder and accepted by the State for Contract, and must include the following:
 - (1) The Contractor's project organizational structure.
 - (2) The Contractor's staffing table with names and title of personnel assigned to the project. This must be in agreement with staffing of accepted proposal. Necessary substitutions due to change of employment status and other unforeseen circumstances may only be made with prior approval of the State.
 - (3) The project breakdown showing sub-projects, activities and tasks, and resources required and allocated to each.
 - (4) The time-phased plan in the form of a graphic display, showing each event, task, and decision point in your work plan.

II-E PRICE PROPOSAL

All prices in this Contract will be firm for the duration of the Contract. No price changes will be permitted.

II-F CONTRACT PAYMENT

All invoices should reflect actual work done.

PAYMENT SCHEDULE

Deliverable

Payable



Requirement Analysis Delivery	\$75,000
System Design Delivery	\$75,000

MDCH will either:

- Set a maximum period of time PerkinElmer must wait before PerkinElmer will be notified as to whether to proceed to Phase II or whether the contract has been terminated.
- Notify PerkinElmer in writing as when to expect approval to proceed.

Milestones based on MDCH acceptance of PARE

- | | |
|--|-----------|
| 1. Newborn Screening – Laboratory Process Automation | \$300,000 |
| <ul style="list-style-type: none"> • Specimen Gate Puncher Interfaces • Specimen Gate Analyzer Interfaces • Specimen Gate Laboratory Database • Specimen Gate QC Management • Specimen Gate Calibration Curve Management • Specimen Gate Result Viewer | |
| 2. Newborn Screening – Office Data Management | \$250,000 |
| <ul style="list-style-type: none"> • Specimen Gate Office – Demographics • Specimen Gate Office – Reporting • Specimen Gate Office – Patient Care Follow Up Automation | |
| 3. Additional Features for Newborn Screening, and Lead screening | \$130,495 |
| <ul style="list-style-type: none"> • Specimen Gate Office – Faxing & Emailing • Specimen Gate Office – OCR • Remote Access to external contract clinics • Specimen Bank • Hearing Screening • Lead Lab | |

II-H TECHNICAL WORK PLAN

Enclosed is a table identifying the Phases and respective project personnel PerkinElmer Life Sciences is presently planning to assign to the project at different stages. Based on the quantity and quality of the information carried by the RFP, PerkinElmer Life Sciences determined this to be the best approach to document the Work Plan until further research of requirements has been conducted.

Phase 1 – Requirement Analysis

Task	Personnel	Duration (total 60 days)
Research of requirements	Project mgr	20 calendar days
	Account Representative	
	System Architect	
	One software engineer	
	State representative(s)	
Documentation of requirements specification	System Architect	30 calendar days
	One to two software engineers	
	Technical writer	
Signoff of the above	Project mgr	10 calendar days
	Account Representative	



	System Architect	
	State representative(s)	
	Technical writer	

Phase 2 – System Design

Task	Personnel	Duration (total 60 days)
Database and Application architecture design	Project mgr	20 calendar days
	System Architect	
	One to two software engineers	
Documentation of the above	System Architect	30 calendar days
	One to two software engineers	
	Technical writer	
Signoff of the above	Project mgr	10 calendar days
	System Architect	
	State representative(s)	
	Technical writer	

Phase 3 – System Development

Task	Personnel	Duration (total 270 days)
Implementation of new software modules, and customization of existing ones	Project mgr	170 calendar days
	System Architect	
	Two to three software engineers	
Documentation of the above	System Architect	40 calendar days
	One to two software engineers	
	One technical writer	
Off site testing of the above	System Architect	60 calendar days
	Account Representative	
	Two QA engineers	

Phase 4 – System Deployment

Task	Personnel	Duration (total 90 days)
Installation, and on site testing of the system	Project mgr	40 calendar days
	System Architect	
	Account Representative	
	Two software engineers	
	QA engineer	
PARE analysis	Project mgr	40 calendar days
	System Architect	
	Account Representative	
	State representative(s)	
Signoff of the above	Project mgr	10 calendar days
	System Architect	
	Account Representative	



	State representative(s)	
	Technical writer	



II-I PRICING

1. Proprietary Software

	<u>Qty</u>	<u>\$ Each</u>	<u>Price</u>
Advanced Specimen Gate Product Suite including Laboratory Process Automation, Demographic and Reporting, and Follow-up modules for the estimated 145,000 specimen laboratory volume, including customization, data migration, installation, training, Lead Screening and GroupWise Integration	1	\$1,100,295	\$1,100,295
Reduction due to efficiencies identified during technical review			\$275,000
			<u>\$825,295</u>

2. Additional Features Requested by Michigan

(The following items are included in the proprietary software, #1 above)

Assisted Data Entry for Hearing Screening	1	\$0	\$0
BioRad Variant Instrument Interface	1	\$0	\$0
Remote Access	1	\$0	\$0
Implementation of distributed Follow-Up	1	\$0	\$0
			<u>\$0</u>

3. Hardware

HP surestore 9100mx 9 GB Optical Drive	1	\$3,900	\$3,900
OnStream Internal SCSI 50/25 GB tape drive	1	\$1,300	\$1,300
			<u>\$5,200</u>

4. 3rd Party Software Licenses

The items below have been eliminated from this revised bid. It is PerkinElmer Life Sciences understanding State of Michigan wishes to acquire necessary 3rd software licenses separately

Windows NT/2000 Server	1	\$0	\$0
Windows NT/2000 Client Access Licenses	44	\$0	\$0
Microsoft SQL Server Enterprise Edition	1	\$0	\$0
Microsoft Access Client Licenses	30	\$0	\$0
Crystal Reports Developer Edition	2	\$0	\$0
Veritas Backup Exec NT Server Edition	1	\$0	\$0
			<u>\$0</u>

Total Software and Hardware			\$830,495
Extended Warranty for Year Three			\$125,000
Extended Warranty for Year Four			\$125,000



	Qty	\$ Each	Price
<u>5. Additional Features not included in Software Package</u>			
Hearing Screening result management	1	\$15,164	\$15,164
Virology, and other data export features	1	\$31,200	\$31,200
Total additional features			\$46,364

PerkinElmer Life Sciences' Consulting Fee used to estimate the cost of including additional features to Specimen Gate is \$800 per person per day, plus expenses. This cost base will also be used when estimating the cost involved in adding features that were not discovered, and agreed upon during System Specification and Contract Writing Phases.



Scope of the Michigan Trace Metals\Lead Screening Laboratory

1. **Purpose:** The purpose of the laboratory is to quantify trace amounts of lead found in both biological and environmental samples. The laboratory needs to follow practices and protocol in order to be accredited by regulatory agencies. The laboratory needs to generate reports back to the submitters in a timely fashion. All blood lead screen information needs to be transferred to the CDC SLOAR database. In addition the laboratory will need the ability to produce statistical reports to be determined during the 120 day discovery period. Additional test types must be easily added to the system as needed in the future.
2. **Type of samples:** the Trace Metals\Lead Laboratory currently receives two general categories of samples. Biological samples could be, but not limited to blood, serum, or urine, with two current blood lead test types, venous and capillary. Environmental samples could be, but are not limited to, paint chips, soil, dust wipes, or miscellaneous. Mercury samples are currently urine and blood.
3. **Receiving samples in the lab:** when the lab receives samples, a form must accompany the samples. Multiple samples can be covered by one submission. When an area is being screened for environmental lead contamination, multiple samples are collected from the site. The environmental form allows for 8 samples to be submitted with each form. Biological (blood lead) form allows for 3 samples to be submitted with each form. The Environmental samples arrive in various containers. Blood samples usually arrive in approved hazardous material type shipping vessels. The form has a location to allow for barcode to be attached to the form. The same barcode would be attached to tube for positive ID. Each blood and environmental sample will need it's own unique number.
4. **Entering Demographics into Database:** Trace Metals Lab performs testing on samples as requested by the submitter. The demographic requirement for blood and environmental are nearly same, but will require two different data entry screens due to the field layout. See attached efax file. Business rules concerning data are to be defined during the 120 day discovery.
5. **Worklist Generation:** The system will need to produce an electronic worklist for the equipment now in the lead lab. GFAAS – Varian & Perkin Elmer for blood lead, FAAS – Perkin Elmer for environmental lead and Cold Vapor Mercury Analyzer – Leeman Labs, and ICP-MS for Perkin Elmer. The system will need to produce unique worklists based on the type of sample received. The worklists should be able to be generated prior to demographic entry. The worklists need to be delivered to the AA furnaces\flames in an electronic format compatible with the AA software. If manufacturers of AA equipment cannot provide information on data file structure, system must be able to produce worklist on paper so that the information can be entered into the AA systems.
6. **Data acquisition:** The proprietary software that controls each of the instruments mentioned in paragraph 5 will collect the data from the samples. It is the responsibility of the manufacturer's software systems to gather and compile data into an ASCII or ODBC format. The system then will read these ASCII or ODBC data structures into their system.
7. **Quality Control:** The system must be able to sort control, standard and sample information. The AA units must clearly label each of these samples. This data must be presented to the operator for approval and release.
8. **Determinations:** The system must be able to accept laboratory rules concerning sample quality, and cutoff. If laboratory rules are violated, the sample must be brought to the attention of the operator for approval or repeat. If results are accepted, then the sample is to be released for reporting. If the operator rejects the result, the sample is to be rescheduled for testing. The system must keep all results on all samples.
9. **Reporting:** The system must produce a distinct report for each sample type submitted.