

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

June 25, 2009

**CHANGE NOTICE NO. 5**  
**TO**  
**CONTRACT NO. 071B5200120**  
**between**  
**THE STATE OF MICHIGAN**  
**and**

NAME & ADDRESS OF VENDOR		TELEPHONE (284) 471-4111 <b>Richard Zakaria</b>
<b>Detroit Bio-Medical Laboratories, Inc.</b> <b>23955 Freeway Park Drive</b> <b>Farmington Hills, MI 48335</b>  detroitbio@aol.com		BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Dr. Ruby Roc (734) 367-8512 rocr@michigan.gov <b>Clinical Laboratory Services – Department of Community Health - WRPH</b>		
CONTRACT PERIOD: From: <b>January 3, 2005</b> To: <b>December 31, 2009</b>		
TERMS	<b>Net 30</b>	SHIPMENT <b>Contractor</b>
F.O.B.	<b>Delivered</b>	SHIPPED FROM <b>N/A</b>
MINIMUM DELIVERY REQUIREMENTS <b>N/A</b>		

**NATURE OF CHANGE (S):**

Effective immediately, this Contract is hereby **INCREASED** by \$100,000.00. All other terms, conditions, specifications, and pricing remain the same.

**AUTHORITY/REASON:**

Per request of Department of Community Health, Ad Board approval on 06/16/09, and DMB/Purchasing Operations' approval.

**REVISED CURRENT AUTHORIZED SPEND LIMIT: \$741,175.44**

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

November 25, 2008

**CHANGE NOTICE NO. 4**  
**TO**  
**CONTRACT NO. 071B5200120**  
**between**  
**THE STATE OF MICHIGAN**  
**and**

NAME & ADDRESS OF VENDOR  <b>Detroit Bio-Medical Laboratories, Inc.</b> <b>23955 Freeway Park Drive</b> <b>Farmington Hills, MI 48335</b>  detroitbio@aol.com		TELEPHONE (284) 471-4111 <b>Richard Zakaria</b>
		BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Dr. Ruby Roc (734) 367-8512 rocr@michigan.gov <b>Clinical Laboratory Services – Department of Community Health - WRPH</b>		
CONTRACT PERIOD: From: <b>January 3, 2005</b> To: <b>December 31, 2009</b>		
TERMS  <b>Net 30</b>	SHIPMENT  <b>Contractor</b>	
F.O.B.  <b>Delivered</b>	SHIPPED FROM  <b>N/A</b>	
MINIMUM DELIVERY REQUIREMENTS <b>N/A</b>		

**NATURE OF CHANGE (S):**

Effective immediately, this Contract is hereby **EXTENDED** through December 31, 2009, and **INCREASED** by \$150,000.00. All other terms, conditions, specifications, and pricing remain the same.

**AUTHORITY/REASON:**

Per request of Department of Community Health, Ad Board approval on 11/18/08, and DMB/Purchasing Operations' approval.

**TOTAL REVISED ESTIMATED CONTRACT VALUE: \$641,175.00**

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

August 30, 2007

**CHANGE NOTICE NO. 3**  
**TO**  
**CONTRACT NO. 071B5200120**  
**between**  
**THE STATE OF MICHIGAN**  
**and**

NAME & ADDRESS OF VENDOR  <b>Detroit Bio-Medical Laboratories, Inc.</b> <b>23955 Freeway Park Drive</b> <b>Farmington Hills, MI 48335</b>  <small>detroitbio@aol.com</small>		TELEPHONE (284) 471-4111 <b>Richard Zakaria</b>
		BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Dr. Ruby Roc (734) 367-8512 rocr@michigan.gov <b>Clinical Laboratory Services – Department of Community Health - WRPB</b>		
CONTRACT PERIOD: From: <b>January 3, 2005</b> To: <b>December 31, 2008</b>		
TERMS  <b>Net 30</b>	SHIPMENT  <b>Contractor</b>	
F.O.B.  <b>Delivered</b>	SHIPPED FROM  <b>N/A</b>	
MINIMUM DELIVERY REQUIREMENTS <b>N/A</b>		

**NATURE OF CHANGE (S):**

Effective immediately, this Contract is hereby **EXTENDED** through December 31, 2008, and **INCREASED** by \$125,000.00. All other terms, conditions and pricing of this Contract shall remain the same.

**AUTHORITY/REASON:**

Per request of Department of Community Health (PRF dated 6/29/07) and Ad Board approval on 8/21/07.

**TOTAL REVISED ESTIMATED CONTRACT VALUE: \$491,175.00**

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

May 24, 2007

**CHANGE NOTICE NO. 2  
 TO  
 CONTRACT NO. 071B5200120  
 between  
 THE STATE OF MICHIGAN  
 and**

NAME & ADDRESS OF VENDOR		TELEPHONE (284) 471-4111 <b>Richard Zakaria</b>
<b>Detroit Bio-Medical Laboratories, Inc.</b> <b>23955 Freeway Park Drive</b> <b>Farmington Hills, MI 48335</b>  detroitbio@aol.com		BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Dr. Ruby Roc (734) 367-8512 rocr@michigan.gov <b>Clinical Laboratory Services – Department of Community Health - WRPH</b>		
CONTRACT PERIOD: From: <b>January 3, 2005</b> To: <b>January 1, 2008</b>		
TERMS	<b>Net 30</b>	SHIPMENT <b>Contractor</b>
F.O.B.	<b>Delivered</b>	SHIPPED FROM <b>N/A</b>
MINIMUM DELIVERY REQUIREMENTS <b>N/A</b>		

**NATURE OF CHANGE (S):**

Effective May 22, 2007, the Contract Compliance Inspector is hereby CHANGED to:

**Dr. Ruby Roc**  
**Director of Medical Services**  
**(734) 367-8512**  
**Rocr@michigan.gov**

All other terms, conditions and pricing of this Contract shall remain the same.

**AUTHORITY/REASON:**

Per request of Department of Community Health (email from Livonia Marshall dated 5/1/07)

**TOTAL ESTIMATED CONTRACT VALUE REMAINS: \$399,175.44**

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 14, 2005

**CHANGE NOTICE NO. 1**  
**TO**  
**CONTRACT NO. 071B5200120**  
**between**  
**THE STATE OF MICHIGAN**  
**and**

NAME & ADDRESS OF VENDOR		TELEPHONE (284) 471-4111 <b>Richard Zakaria</b>
<b>Detroit Bio-Medical Laboratories, Inc.</b> <b>23955 Freeway Park Drive</b> <b>Farmington Hills, MI 48335</b>  detroitbio@aol.com		
		BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Ron Denstedt (734) 367-8400 <b>Clinical Laboratory Services – Department of Community Health - WRPH</b>		
CONTRACT PERIOD: From: <b>January 3, 2005</b> To: <b>January 1, 2008</b>		
TERMS	SHIPMENT	
<b>Net 30</b>	<b>Contractor</b>	
F.O.B.	SHIPPED FROM	
<b>Delivered</b>	<b>N/A</b>	
MINIMUM DELIVERY REQUIREMENTS <b>N/A</b>		

**NATURE OF CHANGE (S):**

Effective April 14, 2005, this Contract is hereby amended as follows:

1. Pricing for the following CPT Codes are hereby changed:

CPT	Description	Price Per
80164	Valporic Acid/Depakote	\$15.25
80178	Lithium 473	\$7.50
84443	TSH590	\$14.75
85025	CBC Including Differential Platelet	\$7.75

2. The daily charge for Phlebotomist services are hereby removed.

All other terms, conditions and pricing of this Contract shall remain the same.

**AUTHORITY/REASON:**

Per request from Agency and agreement from Vendor in an email dated 4/13/04.

**TOTAL ESTIMATED CONTRACT VALUE REMAINS: \$399,175.44**

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

January 10, 2005

**NOTICE  
 TO  
 CONTRACT NO. 071B5200120  
 between  
 THE STATE OF MICHIGAN  
 and**

NAME & ADDRESS OF VENDOR		TELEPHONE (284) 471-4111
<b>Detroit Bio-Medical Laboratories, Inc.</b> <b>23955 Freeway Park Drive</b> <b>Farmington Hills, MI 48335</b>  <small>detroitbio@aol.com</small>		<b>Richard Zakaria</b>
		BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Ron Denstedt (734) 367-8400 <b>Clinical Laboratory Services – Department of Community Health - WRPH</b>		
CONTRACT PERIOD: From:		To:
TERMS	SHIPMENT	
<b>Net 30</b>	<b>Contractor</b>	
F.O.B.	SHIPPED FROM	
<b>Delivered</b>	<b>N/A</b>	
MINIMUM DELIVERY REQUIREMENTS <b>N/A</b>		

The terms and conditions of this Contract are attached.

Estimated Contract Value: **\$399,175.44**

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

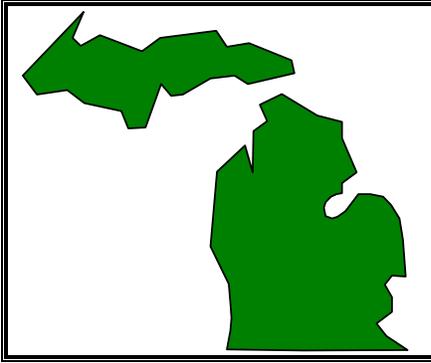
**CONTRACT NO. 071B5200120  
 between  
 THE STATE OF MICHIGAN  
 and**

NAME & ADDRESS OF VENDOR  <b>Detroit Bio-Medical Laboratories, Inc.          23955 Freeway Park Drive          Farmington Hills, MI 48335</b>  <div style="text-align: right; font-size: small;">detroitbio@aol.com</div>		TELEPHONE (284) 471-4111 <b>Richard Zakaria</b>  BUYER/CA (517) 373-6535 <b>William C. Walsh, CPPB</b>
Contract Compliance Inspector: Ron Denstedt (734) 367-8400 <b>Clinical Laboratory Services – Department of Community Health - WRPH</b>		
CONTRACT PERIOD: From: _____ To: _____		
TERMS <p style="text-align: center;"><b>Net 30</b></p>	SHIPMENT <p style="text-align: center;"><b>Contractor</b></p>	
F.O.B. <p style="text-align: center;"><b>Delivered</b></p>	SHIPPED FROM <p style="text-align: center;"><b>N/A</b></p>	
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;"><b>N/A</b></p>		
MISCELLANEOUS INFORMATION:  <p><b>The terms and conditions of this Contract are attached.</b></p>  <p><b>Estimated Contract Value:           \$399,175.44</b></p>		

**THIS IS NOT AN ORDER:** This Contract Agreement is awarded on the basis of our inquiry and your quote. A Purchase Order Form will be issued only as the requirements of the State Departments are submitted to Acquisition Services. Orders for delivery of equipment will 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.**

<p><b>FOR THE VENDOR:</b></p> <p style="text-align: center;"><b>Detroit Bio-Medical Laboratories, Inc.</b></p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Firm Name</p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Authorized Agent Signature</p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Authorized Agent (Print or Type)</p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Date</p>	<p><b>FOR THE STATE:</b></p> <p style="text-align: center;">Signature</p> <p style="text-align: center;"><b>William C. Walsh, CPPB, Buyer Manager</b></p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Name</p> <p style="text-align: center;"><b>Tactical Purchasing, Acquisition Services</b></p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Title</p> <hr style="border: 0; border-top: 1px solid black;"/> <p style="text-align: center;">Date</p>
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**STATE OF MICHIGAN**  
**Department of Management and Budget**  
**Acquisition Services**

Contract #071B5200120  
Laboratory Services

Buyer Name: William C. Walsh  
Telephone Number: (517) 373-6535  
E-Mail Address: walshw@michigan.gov

**Estimated Timeline:**

<b>Key Milestone:</b>	<b>Date:</b>
Issue Date	08-18-04
Pre-Bid Meeting/Site Visit	Not Required
Questions Due	09-09-04
Bid Due Date	09-23-04
Award Date	12-16-04
Contract Start Date	1-1-05

## Laboratory Services

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**Attachments:**

- APPENDIX A - PRICING SHEET
- APPENDIX B – QUALITY ASSURANCE PROGRAMS



## Article1 – Statement of Work (SOW)

### 1.0 Introduction

#### 1.001 DEFINING DOCUMENT

This document contains or incorporates defined requirements, the specifications and scope of work, and all contractual terms and conditions.

#### 1.002 PROJECT TITLE AND DESCRIPTION

This Contract is for Laboratory Services for the Department of Community Health (DCH) , Walter P. Reuther Psychiatric Hospital.

#### 1.003 PROJECT CONTROL

##### Project Control

- a. The Contractor, Detroit Bio-Medical Laboratories, Inc. (DBML) will carry out this project under the direction and control of the Department of Community Health, Walter Reuther Psychiatric Hospital.
- b. Although there will be continuous liaison with the Contractor team, the client agency's project director will meet monthly for the first six months of the Contract starting in February 2005 and then quarterly, with the Contractor's project manager for the purpose of reviewing progress and providing necessary guidance to the Contractor in solving problems that arise.
- c. The Contractor will submit brief written quarterly summaries of progress 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 significant deviation from previously agreed-upon work plans. A copy of this report will be forwarded to the named buyer in Acquisition Services.
- 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 an action plan, which must include the following:

The Contractor's project organizational structure.

- (1) 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.
- (2) The project breakdown showing sub-projects, activities and tasks, and resources required and allocated to each.
- (3) The time-phased plan in the form of a graphic display, showing each event, task, and decision point in your work plan.

##### Reports

The Contractor will provide one written copy of the following reports as specified to the Contract Compliance Inspector for Walter Reuther Psychiatric Hospital.

- a. Written results of specified routine laboratory tests are to be returned the following day by 8:00 AM (unless a routine test requires longer).
- b. Test results that significantly exceed expected normal levels should be telephoned and faxed to appropriate personnel as soon as tests are available.



- c. By the fifteenth (15<sup>th</sup>) of each month, an itemized statement of costs by procedure incurred in the preceding month.
- d. Monthly Quality Assurance Reports.

#### **1.004 COMMENCEMENT OF WORK**

Contractor shall show acceptance of this agreement by signing a copy of this Contract and returning it to the Contract Administrator. Contractor shall not proceed with performance of the work to be done under this agreement, including the purchase of necessary materials, until both parties have signed this agreement to show acceptance of its terms.

### **1.1 Product Quality**

#### **1.101 SPECIFICATIONS**

Definite Specifications - All commodities and/or services to be furnished hereunder shall conform to the specifications as noted in the "Invitation To Bid" and/or copies of specifications attached.

#### **STANDARD LABORATORY SERVICES**

- a. DBML will draw the blood/collect specimens from each unit between 6:00 AM and 10:00 AM daily, Monday through Friday unless otherwise agreed upon by WRPB and DBML. DBML will start with one phlebotomist and, if indicated, suggest further phlebotomy support to the WRPB management team. If additional hours of phlebotomy are approved by WRPB management, these hours will be supplied using the hourly rate indicated in the "Appendix A Pricing Sheet".
- b. Printed results of routine laboratory tests, including blood levels of anticonvulsants and psychotropic drugs will be printed by 8:00 AM the next day.
- c. Abnormal or life-threatening results will be telephoned and faxed to the WRPB immediately upon their completion and re-check as by CLIA and CAP policy.
- d. Culture and other procedures that require longer than 18 hours to determine the result will be made available to WRPB when they are completed. Copies of all culture, serology (VDRL, RPR, Hepatitis screens), will be made available to the Infection Control Coordinator.
- e. DBML maintains a Certificate of Accreditation from CMS Center for Medicaid and Medicare Services in accordance with CLIA '88 and CAP (College of American Pathologists). The current and updated license and certificate will be provided to the Director of Medical Services upon request. It is DBML's position that a J.C.A.H.O. accreditation (Joint Commission on Accreditation of Hospitals Organizations) is more appropriate for hospital laboratories and is an accreditation that is not intended for a commercial laboratory.
- f. DBML maintains a license as a clinical medical laboratory through the Michigan Department of Public Health. DBML will continue to maintain this license or will risk immediate cancellation of this contract.
- g. DBML has included a copy of its Quality Assurance Program as part of this ITB. A copy of this document will be supplied annually to the Agency.
- h. DBML will provide all supplies, materials, and equipment required to obtain and transport specimens to its lab. These items can be ordered by phone and will be delivered the next day. DBML will be responsible for disposal of all infectious waste.
- i. DBML will provide a competent phlebotomist to the agency for the hours 6:00 AM until 10:00 AM, Monday through Friday, at the charges indicated in Appendix A. Proof of competency of the phlebotomist will be provided upon request.
- j. DBML will provide in-service training to agency personnel in the proper collection and handling of specimens.



- k. DBML will provide serially numbered requisition forms for the staff to use when ordering laboratory testing. An in-service will be provided for the staff at which time they will be instructed on where to place the name, case number, and current location of the client and the requesting physician. The phlebotomist will verify patient name and date of birth and initial in the check box provided on the requisition form.
- l. DBML will provide a monthly bill for services performed. This bill will be created using the exact agreed upon contract pricing. DBML will never bill a third party for any services.
- m. DBML will bill the agency by the 15th of each month for the previous month. The statement will include case number, name and date of service, procedure name, procedure HCPCS number, DBML test number, and cost for each patient.
- n. DBML will provide a computer terminal for transmission/receiving of test results at WRPH. A printer will also be included in order for WRPH to receive final results by 8:00 AM the next morning. DBML has other options for computer transmission/receiving of test orders/results. DBML's newest form is a Web-Based (PowerWeb) product that will greatly enhance WRPH ordering/reporting capabilities.
- o. DBML will provide and maintain a terminal, quiet-type printer and telephone equipment at WRPH for the receiving of laboratory reports at no additional cost to the Agency.
- p. DBML will provide at no additional charge to the agency, the service of a qualified/certified consulting pathologist. This service will be provided Monday through Friday from 8:00 AM to 4:30 PM. DBML will provide a copy of pathologist's current credentials. A copy of the license and board certification shall be provided to the WRPH Director of Medical Services. Updated copies shall be automatically submitted to WRPH when issued.
- q. DBML will provide a pathologist that will read both gross and microscopic specimens.
- r. DBML will provide, at no extra cost to the agency, in-services in order to assist WRPH personnel in selecting the most effective method of ordering tests and providing lab services as identified by DBML or the agency.
- s. DBML will provide supervisory personnel that will be available by telephone, 7:00 AM to 4:30 PM Monday through Friday for the purpose of discussing scheduling problems or other lab-related questions.
- t. DBML as a routine, saves blood specimens for a minimum of seven (7) days. This process does exclude CBC and PT/PTT specimens.
- u. DBML will retain for seven (7) years, all slides of Class 3A-5 pap smears at DBML's facility. This service will be provided at no additional cost to the agency.
- v. DBML will supply monthly microbiology summaries to the Agency for epidemiological studies. These summaries will minimally include:
1. Chronological summary of all cultures submitted during the month with patient identification, source/site of culture material and organism(s) isolated;
  2. A summary of positive cultures grouped by organism(s) identified, to include so of culture material and patient identification;
  3. A summary of all cultures grouped by source/site, to include patient identification and organism(s) identified.
- w. DBML will return all patient identifying information upon termination of the contract.
- x. For those tests not specifically listed in Appendix A Pricing Sheet, i.e., Not on Contract, DBML is attaching a complete copy of it's Fee Schedule. When ordered by the agency, these tests will be subjected to a 40% discount and this discounted pricing will be reflected on the monthly billings to the agency.
- y. Working Conditions



1. All work is to be conducted between the hours of 6:00 AM and 10:00 AM Monday through Friday unless otherwise agreed upon between the Contractor and Walter Reuther Psychiatric Hospital.
2. Unattended vehicles should be locked at all times.
3. All equipment must be accounted for at all times.
4. While working at WRPB, the Contractor may encounter information relative to our patients, including their identity. The Contractor shall maintain confidentiality of patients at all times, under the HIPPA requirements.
5. All Personal Protection Equipment (PPE) must be used when appropriate.
6. All Federal (OSHA) and State (MIOSHA) standards and NFPA (National Fire Protection Association) Life Safety Codes must be followed during the course of any work or service being performed at this Agency.

### STAT LABORATORY SERVICES

- a. WRPB personnel or the phlebotomist when still in-house, will collect STAT specimens and samples for testing. Additionally, each DBML specimen requisition includes specimen requirements immediately adjacent the test description. This will cover all STAT test that are available by reasonable industry standards.
- b. DBML will pick up specimens for STAT requests at no additional cost to the agency. A pick up box will be located at the Safety Office for STAT tests.
- c. STAT or emergency requests will be processed and the results telephoned and faxed to the designated agency personnel within four (4) hours of request to DBML . DBML will make this service available to WRPB seven (7) days a week, twenty-four (24) hours per day. The written report will be delivered via printer by 8 AM the following day.
- d. DBML will make available any lab test ordered as STAT by a physician and will report the results with four (4) hours from the time the request is made. The exception would be those test that are not available as STATs according to industry standards.
- e. DBML maintains a Certificate of Accreditation from CMS Center for Medicaid and Medicare Services in accordance with CLIA '88 and CAP (College of American Pathologists). Current and updated license and certificate will be provided to the Director of Medical Services upon request. DBML realizes that failure to maintain this license and certificate will result in immediate cancellation of this contract. It is DBML's position that a J.C.A.H.O. accreditation (Joint Commission on Accreditation of Hospital Organizations) is more appropriate for hospital laboratories and is an accreditation that is not intended for a commercial laboratory. For this reason, very few, if any non-hospital based laboratories possess a J.C.A.H.O. accreditation.
- f. DBML maintains a license as a clinical medical laboratory through the Michigan Department of Public Health. A current and updated copy of this license will be made available to the Director of Medical Services. DBML will continue to maintain this license or will risk the immediate cancellation of this contract.
- g. DBML has included a copy of it's Quality Assurance Program as part of this ITB. A copy of this Quality Assurance Document will be provided to the Agency on an annual basis.
- h. DBML will provide all supplies, materials, and equipment required to obtain and transport specimens to it's lab. These items can be ordered by phone and will be delivered the next day.
- i. DBML will provide in-service training to agency personnel in the proper collection and handling of specimens.
- j. DBML will provide serially numbered requisition forms for the staff to use when ordering laboratory testing. An in-service will be provided for the staff at which time they will be instructed on where to place the name, case number, and current location of the client and the requisition physician.
- k. DBML will provide on a monthly bill for services performed within the content of the ITB. This bill will be created using the exact agreed upon contract pricing. DBML will never bill a third party for any services.



- l. DBML will bill the agency by the 15th of each month for the previous month. The statement will include case number, name and date of service, procedure name, procedure HCPCS number, DBML test number, and cost for each patient.
- m. DBML will provide a computer terminal for transmission/receiving of test results at WRPH. A printer will also be included in order for WRPH to receive final results by 8:00 AM the next morning. DBML has other options for computer transmission/receiving of test orders/results. DBML's newest form is a Web-Based (PowerWeb) product that will greatly enhance WRPH ordering/reporting capabilities. The options will be made available to WRPH upon their wishes if DBML is awarded the Bid.
- n. DBML will provide and maintain a terminal, quiet-type printer and telephone equipment at WRPH for the receiving of laboratory reports at no additional cost to the Agency.
- o. DBML will provide at no additional charge to the agency, the service of a qualified/certified consulting pathologist. This service will be provided Monday through Friday from 8:00 AM to 4:30 PM. DBML will provide a copy of pathologist's current certificate.
- p. DBML will provide a pathologist that will read both gross and microscopic specimens.
- q. DBML will provide supervisory personnel that will be available by telephone, 7:00 AM to 4:30 PM, Monday through Friday for the purpose of discussing scheduling problems or other lab-related questions.
- r. DBML as a routine, saves blood specimens for a minimum of seven (7) days. This process does exclude CBC and PT/PTT specimens.
- s. DBML will return all patient identifying information upon termination of the contract.
- t. For those tests not specifically listed in Appendix A Pricing Sheet, i.e., Not on Contract, DBML is attaching a complete copy of it's Fee Schedule. When ordered by the agency, these tests will be subjected to a **40%** discount and this discounted pricing will be reflected on the monthly billings to the agency.

**PROJECT CONTROL – SEE SECTION 1.003.**

**1.102 RESERVED**

**1.103 QUALITY ASSURANCE PROGRAM**

See Appendix B

**1.104 RESERVED**

**1.2 Service Capabilities**

**1.201 CUSTOMER SERVICE/ORDERING**

Contractor shall have internal controls, approved by Acquisition Services, to insure that authorized individuals with the State place orders. The Contractor shall verify orders that have quantities that appear to be abnormal or excessive. DBML personnel will report to WRPH Security for the number of draws needed for each ward.

The Contractor shall have an accessible customer service department with an individual specifically assigned to State of Michigan accounts. The Contractor shall have experienced sales representatives make timely personal visits to State accounts. The Contractor's customer service must respond to State agency inquiries promptly. The Contractor shall provide a statewide toll-free number for customer service calls.

Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule.



All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

**1.202 TRAINING**

The Contractor shall provide training to individual agencies, when necessary, on aspects of ordering, shipping, billing, and receiving. At the request of the Contract Administrator, the Contractor shall provide in-service training to agency personnel on products, installation, and product safety issues. The Contractor shall also provide agency training jointly with the State as needed during the period covered by the contract at no additional charge. WRPB will provide basic infectious control safety procedure training to all phlebotomist's assigned to this Contract.

**1.203 REPORTING**

Contractor shall provide various reports, when requested by the State. The Contract Compliance Inspector shall provide a detailed list of all required reports and shall meet with the Contractor at least monthly to review report compliance.

**1.204 SPECIAL PROGRAMS - RESERVED****1.205 SECURITY**

This Contract will require frequent deliveries to State of Michigan facilities. The Contractor shall ensure the security and safety of these buildings. This shall include, but is not limited to, performance of security background checks on all personnel assigned to State of Michigan facilities (i.e. delivery people) and how they are performed, what the security check consists of, the name of the company that performs the security checks, use of uniforms and ID badges, etc. If security background checks are performed on staff, th Contractor shall indicate the name of the company that performs the check as well as provide a document stating that each employee has satisfactorily completed a security check and is suitable for assignment to State facilities. Upon request by the State, the Contractor shall provide the results of all security background checks.

The State may decide to also perform a security background check. If so, the Contractor will be required to provide to the State a list of all delivery people that will service State of Michigan facilities, including name and date of birth, social security number, or driver license number.

The Contractor and its subcontractors shall comply with the security access requirements of individual State facilities.

**1.3 Delivery Capabilities****1.301 TIME FRAMES**

The Contractor shall provide services in the time frames noted in section 1.101 of this Contract.

**1.302 RESERVED****1.303 RESERVED****1.304 RESERVED****1.305 RESERVED****1.306 RESERVED****1.4 Project Price****1.401 PROPOSAL PRICING**

Prices shall be in accordance with those listed in Appendix A of this Contract.

**1.402 QUICK PAYMENT TERMS**

There are no quick payment terms for this Contract.

**1.403 PRICE TERM**

Prices quoted are the maximum for a period of 365 days from the date the Contract becomes effective.

Prices are subject to change at the end of each 365-day period. Such changes shall be based on changes in actual costs incurred. Documentation of such changes must be provided with the request for price change in order to substantiate any requested change. Acquisition Services reserves the right to consider various pertinent information sources to evaluate price increase requests (such as the CPI and PPI, US City Average, as published by the US Department of Labor, Bureau of Labor Statistics). Acquisition Services also reserves the right to consider other information related to special economic and/or industry circumstances, when evaluating a price change request. Changes may be either increases or decreases, and may be requested by either party. Approved changes shall be firm for the remainder of the contract period unless further revised at the end of the next 365-day period.

Requests for price changes shall be RECEIVED IN WRITING AT LEAST TEN DAYS PRIOR TO THEIR EFFECTIVE DATE, and are subject to written acceptance before becoming effective. In the event new prices are not acceptable, the CONTRACT may be cancelled. The continued payment of any charges due after September 30th of any fiscal year will be subject to the availability of an appropriation for this purpose.

**1.5 Quantity term**

Contractor agrees to supply all that the state requires

**1.6 Reserved**



## Article 2 – General Terms and Conditions

### 2.0 Introduction

#### 2.001 GENERAL PURPOSE

This Contract is for Laboratory Services, both standard and STAT, for the State of Michigan. Exact quantities to be purchased are unknown, however the Contractor will be required to furnish all such materials and services as may be ordered during the CONTRACT period. Quantities specified if any, are estimates based on prior purchases, and the State is not obligated to purchase in these or any other quantities. Orders for delivery will be issued directly to the Contractor by Walter Reuther Hospital on the Purchase Order Contract Release Form.

#### 2.002 ISSUING OFFICE AND CONTRACT ADMINISTRATOR

This Contract is issued by Acquisition Services, State of Michigan, Department of Management and Budget, hereinafter known as Acquisition Services, for the Department of Community Health, hereinafter known as DCH. Where actions are a combination of those of Acquisition Services and the State agencies, the authority will be known as the State.

Acquisition Services is the sole point of contact in the State with regard to all contractual matters relating to the commodities and/or services described herein. Acquisition Services is the only office authorized to negotiate, change, modify, amend, alter, clarify, etc., the specifications, terms, and conditions of the Contract. Acquisition Services will remain the SOLE POINT OF CONTACT throughout the Contract period.

**Contractor proceeds at its own risk if it takes negotiation, changes, modification, alterations, amendments, clarification, etc., of the specifications, terms, or conditions of the contract from any individual or office other than Acquisition Services and the listed contract administrator**

All communications covering this procurement must be addressed to contract administrator indicated below:

Department of Management and Budget  
Acquisition Services  
**Attn: William C. Walsh, CPPB**  
2nd Floor, Mason Building  
P.O. Box 30026  
Lansing, Michigan 48909  
(517) 373-6535  
*walshw@michigan.gov*

#### 2.003 NOTICE

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.

#### 2.004 CONTRACT TERM

The term of this Contract will be for three (3) years and will commence with the issuance of a Contract. This will be approximately 1-1-05 through 1-1-08.

**Option.** The State reserves the right to exercise two (2) one-year options, at the sole option of the State. Contractor performance, quality of products, price, cost savings, and the contractor's ability to deliver on time are some of the criteria that will be used as a basis for any decision by Acquisition Services to exercise an option year.



**Extension.** At the sole option of the State, this Contract may also be extended. Contractor performance, quality of products, price, cost savings, and the contractor's ability to deliver on time are some of the criteria that will be used as a basis for any decision by Acquisition Services to exercise an option year.

Written notice will be provided to the Contractor within 30 days, provided that the State gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the Contract expires. The preliminary notice does not commit the Government to an extension. If the State exercises this option, the extended contract shall be considered to include this option clause.

## 2.005 GOVERNING LAW

This Contract shall in all respects be governed by, and construed in accordance with, the laws of the State of Michigan. By signing this agreement, Contractor consents to personal jurisdiction in the state of Michigan. Any dispute arising herein shall be resolved in the State of Michigan.

## 2.006 APPLICABLE STATUTES

The following statutes, rules, and laws are applicable to the performance of this contract; some statutes are reflected in the clauses of this contract. This list is NOT exhaustive.

MI Uniform Commercial Code (MIUCC) MCL 440. (All sections unless otherwise altered by agreement)

MI OSHA MCL §§ 408.1001 – 408.1094

Freedom of Information Act (FIOA) MCL §§ 15.231, et seq.

Natural Resources and Environmental Protection Act MCL §§ 324.101, et seq.

MI Consumer Protection Act MCL §§ 445.901 – 445.922

Laws relating to wages, payments of wages, and fringe benefits on state projects MCL §§ 408.551 – 408.558, 408.471 – 408.490, 1965 PA 390.

Department of Civil Service Rules and regulations

Elliot Larsen Civil Rights Act MCL §§ 37.2201, et seq.

Persons with disabilities Civil Rights Act MCL §§ 37.1101, et seq.

MCL §§ 423.321, et seq.

MCL § 18.1264 (law regarding debarment)

Davis-Bacon Act (DBA) 40 USCU §§ 276(a), et seq.

Contract Work Hours and Safety Standards Act (CWHSSA) 40 USCS § 327, et seq.

Business Opportunity Act for Persons with Disabilities MCL §§ 450.791 – 450.795

Rules and regulations of the Environmental Protection Agency

Internal Revenue Code

Rules and regulations of the Equal Employment Opportunity Commission (EEOC)

The Civil Rights Act of 1964, USCS Chapter 42

Title VII, 42 USCS §§ 2000e et seq.

The Americans with Disabilities Act (ADA), 42 USCS §§ 12101 et seq.

The Age Discrimination in Employment Act of 1967 (ADEA), 29 USCS §§ 621, 623 et seq.

The Old Workers Benefit and Protection Act of 1990 (OWBPA), 29 USCS §§ 626, et seq.

The Family Medical Leave Act of 1993 (FMLA), 29 USC §§ 651 et seq.

The Fair Labor Standards Act (FLSA), 29 USC §§ 201 et seq.

Pollution Prevention Act of 1990 (PPA) 42 U.S.C. §13106

Sherman Act, 15 U.S.C.S. § 1 et seq.

Robinson-Patman Act, 15 U.S.C.S. § 13 et. seq.

Clayton Act, 15 U.S.C.S. § 14 et seq.

## 2.007 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.

**2.008 HEADINGS**

Captions and headings used in this 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.

**2.009 MERGER**

This Contract constitutes the complete, final, and exclusive agreement between the parties. All other prior writings and negotiations are ineffective.

**2.010 SEVERABILITY**

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

**2.011 SURVIVORSHIP**

Any provisions of this 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.

**2.012 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 this Contract.

**2.013 PURCHASE ORDERS**

Orders for delivery of commodities and/or services may be issued directly by the State Departments through the issuance of a Purchase Order Form referencing this Contract (Blanket Purchase Order) agreement and the terms and conditions contained herein. Contractor is asked to reference the Purchase Order Number on all invoices for payment.

**2.1 Contractor/Contractor Obligations****2.101 ACCOUNTING RECORDS**

The Contractor and all subcontractors shall maintain all pertinent financial and accounting records and evidence pertaining to this 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 Auditor General at any time during the Contract period and any extension thereof, and for three years from expiration date and final payment on this Contract or extension thereof.

**2.102 NOTIFICATION OF OWNERSHIP**

The Contractor shall make the following notifications in writing:

1. When the Contractor becomes aware that a change in its ownership or officers has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records, the Contractor shall notify Acquisition Services within 30 days.
2. The Contractor shall also notify the Acquisition Services within 30 days whenever changes to asset valuations or any other cost changes have occurred or are certain to occur as a result of a change in ownership or officers.



The Contractor shall:

1. Maintain current, accurate, and complete inventory records of assets and their costs;
2. Provide Acquisition Services or designated representative ready access to the records upon request;
3. Ensure that all individual and grouped assets, their capitalized values, accumulated depreciation or amortization, and remaining useful lives are identified accurately before and after each of the Contractor's ownership or officer changes; and
4. Retain and continue to maintain depreciation and amortization schedules based on the asset records maintained before each Contractor ownership or officer change.

## 2.103 LIABILITY INSURANCE

### A. Insurance

The Contractor is required to provide proof of the minimum levels of insurance coverage as indicated below. The purpose of this coverage shall be to protect the State from claims which may arise out of or result from the Contractor's performance of services under the terms of this Contract, whether such services are performed by the Contractor, or by any subcontractor, or by anyone directly or indirectly employed by any of them, or by anyone for whose acts they may be liable.

The Contractor waives all rights against the State of Michigan, its departments, divisions, agencies, offices, commissions, officers, employees and agents for recovery of damages to the extent these damages are covered by the insurance policies the Contractor is required to maintain pursuant to this Contract.

All insurance coverage provided relative to this Contract/Purchase Order is PRIMARY and NON-CONTRIBUTING to any comparable liability insurance (including self-insurances) carried by the State.

The insurance shall be written for not less than any minimum coverage specified in this Contract or required by law, whichever is greater.

The insurers selected by Contractor shall have an A.M. Best rating of A or better, or as otherwise approved in writing by the State, or if such ratings are no longer available, with a comparable rating from a recognized insurance rating agency. Companies that have been approved to do business in the State shall issue all policies of insurance required in this Contract.

See [www.michigan.gov/cis](http://www.michigan.gov/cis)

Where specific limits are shown, they are the minimum acceptable limits. If Contractor's policy contains higher limits, the State shall be entitled to coverage to the extent of such higher limits.

Before both parties sign the Contract or before the purchase order is issued by the State, the Contractor must furnish to the Director of Acquisition Services, certificate(s) of insurance verifying insurance coverage ("Certificates"). The Certificate must be on the standard "accord" form or equivalent. **THE CONTRACT OR PURCHASE ORDER NO. MUST BE SHOWN ON THE CERTIFICATE OF INSURANCE TO ASSURE CORRECT FILING.** All Certificate(s) are to be prepared and submitted by the Insurance Provider. All Certificate(s) shall contain a provision indicating that coverage afforded under the policies WILL NOT BE CANCELLED, MATERIALLY CHANGED, OR NOT RENEWED without THIRTY (30) days prior written notice, except for ten (10) days for non-payment of premium, having been given to the Director of Acquisition Services, Department of Management and Budget. The notice must include the Contract or Purchase Order number affected and be mailed to: Director, Acquisition Services, Department of Management and Budget, P.O. Box 30026, Lansing, Michigan 48909. Failure to provide evidence of coverage, may, at the State's sole option, result in this Contract's termination.



The Contractor is required to pay for and provide the type and amount of insurance checked **below**:

1. Commercial General Liability with the following minimum coverage:
- |             |  |
|-------------|--|
| \$2,000,000 | General Aggregate Limit other than Products/Completed Operations |
| \$2,000,000 | Products/Completed Operations Aggregate Limit                    |
| \$1,000,000 | Personal & Advertising Injury Limit                              |
| \$1,000,000 | Each Occurrence Limit  |
| \$500,000   | Fire Damage Limit (any one fire)                                 |
- The Contractor must list the State of Michigan, its departments, divisions, agencies, offices, commissions, officers, employees and agents as ADDITIONAL INSUREDS on the Commercial General Liability certificate. The Contractor also agrees to provide evidence that insurance policies contain a waiver of subrogation by the insurance company.
2. If a motor vehicle is used to provide services or products under this Contract, the Contractor must have vehicle liability insurance on any auto including owned, hired and non-owned vehicles used in Contractor's business for bodily injury and property damage as required by law.
- The Contractor must list the State of Michigan, its departments, divisions, agencies, offices, commissions, officers, employees and agents as ADDITIONAL INSUREDS on the vehicle liability certificate. The Contractor also agrees to provide evidence that insurance policies contain a waiver of subrogation by the insurance company.
3. Workers' compensation coverage must be provided in accordance with applicable laws governing the employees and employers work activities in the state of the Contractor's domicile. If a self-insurer provides the applicable coverage, proof must be provided of approved self-insured authority by the jurisdiction of domicile. For employees working outside of the state of qualification, Contractor must provide appropriate certificates of insurance proving mandated coverage levels for the jurisdictions where the employees' activities occur.
- Any certificates of insurance received must also provide a list of states where the coverage is applicable.
- The Contractor also agrees to provide evidence that insurance policies contain a waiver of subrogation by the insurance company. This provision shall not be applicable where prohibited or limited by the laws of the jurisdiction in which the work is to be performed.
4. Employers liability insurance with the following minimum limits:
- |           |                          |
|-----------|--------------------------|
| \$100,000 | each accident            |
| \$100,000 | each employee by disease |
| \$500,000 | aggregate disease        |
5. Employee Fidelity, including Computer Crimes, insurance naming the State as a loss payee, providing coverage for direct loss to the State and any legal liability of the State arising out of or related to fraudulent or dishonest acts committed by the employees of Contractor or its Subcontractors, acting alone or in collusion with others, in a minimum amount of one million dollars (\$1,000,000.00) with a maximum deductible of fifty thousand dollars (\$50,000.00).
6. Umbrella or Excess Liability Insurance in a minimum amount of ten million dollars (\$10,000,000.00), which shall apply, at a minimum, to the insurance required in Subsection 1 (Commercial General Liability) above.



- 7. Professional Liability (Errors and Omissions) Insurance with the following minimum coverage: three million dollars (\$3,000,000.00) each occurrence and three million dollars (\$3,000,000.00) annual aggregate.
- 8. Fire and Personal Property Insurance covering against any loss or damage to the office space used by Contractor for any reason under this Contract, and the equipment, software and other contents of such office space, including without limitation, those contents used by Contractor to provide the Services to the State, up to the replacement value thereof, where such office space and its contents are under the care, custody and control of Contractor. Such policy shall cover all risks of direct physical loss or damage, including without limitation, flood and earthquake coverage and coverage for computer hardware and software. The State shall be endorsed on the policy as a loss payee as its interests appear.

**B. Subcontractors**

Except where the State has approved in writing a Contractor subcontract with other insurance provisions, Contractor shall require all of its Subcontractors under this Contract to purchase and maintain the insurance coverage as described in this Section for the Contractor in connection with the performance of work by those Subcontractors. Alternatively, Contractor may include any Subcontractors under Contractor's insurance on the coverage required in this Section. Subcontractor(s) shall fully comply with the insurance coverage required in this Section. Failure of Subcontractor(s) to comply with insurance requirements does not limit Contractor's liability or responsibility.

**C. Certificates of Insurance and Other Requirements**

Contractor shall furnish to the Office of Acquisition Services certificate(s) of insurance verifying insurance coverage or providing satisfactory evidence of self-insurance as required in this Section (the "Certificates"). Before the Contract is signed, and not less than 20 days before the insurance expiration date every year thereafter, the Contractor shall provide evidence that the State and its agents, officers and employees are listed as additional insureds, but only to the extent of liabilities assumed by Contractor as set forth in Indemnification Section of this Contract, under each commercial general liability and commercial automobile liability policy. In the event the State approves the representation of the State by the insurer's attorney, the attorney may be required to be designated as a Special Assistant Attorney General by the Attorney General of the State of Michigan.

Contractor shall maintain all required insurance coverage throughout the term of the Contract and any extensions thereto and, in the case of claims-made Commercial General Liability policies, shall secure tail coverage for at least three (3) years following the expiration or termination for any reason of this Contract. The minimum limits of coverage specified above are not intended, and shall not be construed, to limit any liability or indemnity of Contractor under this Contract to any indemnified party or other persons. Contractor shall be responsible for all deductibles with regard to such insurance. If Contractor fails to pay any premium for required insurance as specified in this Contract, or if any insurer cancels or significantly reduces any required insurance as specified in this Contract without the State's written consent, at the State's election (but without any obligation to do so) after the State has given Contractor at least thirty (30) days written notice, the State may pay such premium or procure similar insurance coverage from another company or companies; and at the State's election, the State may deduct the entire cost (or part thereof) from any payment due Contractor, or Contractor shall pay the entire cost (or any part thereof) upon demand by the State.

**2.104 CONFIDENTIALITY**

Contractor and the State each acknowledge that the other possesses and will continue to possess confidential information that has been developed or received by it. As used in this Section, "Confidential Information" of Contractor shall mean all non-public proprietary information of Contractor (other than Confidential Information of the State as defined below) that is marked confidential, restricted, proprietary, or with a similar designation.



“Confidential Information” of the State shall mean any information which is retained in confidence by the State (or otherwise required to be held in confidence by the State pursuant to applicable federal, state and local laws and regulations) or which, in the case of tangible materials provided to Contractor by the State pursuant to its performance under this Contract, is marked as confidential, proprietary or with a similar designation by the State. In the case of information of either Contractor or the State “Confidential Information” shall exclude any information (including this Contract) that is publicly available pursuant to the Michigan FOIA.

#### Protection of Confidential Information

The State and Contractor will each use at least the same degree of care to prevent its closing to third parties the Confidential Information of the other as it employs to avoid unauthorized disclosure, publication or dissemination of its own confidential information of like character, but in no event less than reasonable care. Neither Contractor nor the State will (i) make any use of the Confidential Information of the other except as contemplated by this Contract, (ii) acquire any right in or assert any lien against the Confidential Information of the other, or (iii) if requested to do so, refuse for any reason to promptly return the other party's Confidential Information to the other party. Each party will limit disclosure of the other party's Confidential Information to employees and Subcontractors who must have access thereto in order to fulfill the purposes of this Contract. Disclosure to, and use by, a Subcontractor is permissible where (A) use of a Subcontractor is authorized under this Contract, (B) such disclosure is necessary or otherwise naturally occurs in connection with work that is within such Subcontractor's scope of responsibility, and (C) Contractor obligates the Subcontractor in a written Contract to maintain the State's Confidential Information in confidence. At the State's request, any employee of Contractor and of any Subcontractor having access or continued access to the State's Confidential Information may be required to execute an acknowledgment that the employee has been advised of Contractor's and the Subcontractor's obligations under this Section and of the employee's obligation to Contractor or Subcontractor, as the case may be, to protect such Confidential Information from unauthorized use or disclosure.

#### News releases

News releases (including promotional literature and commercial advertisements) pertaining to the ITB and Contract or project to which it relates shall 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 activities associated with the ITB and Contract are to be released without prior written approval of the State and then only to persons designated.

#### Exclusions

Notwithstanding the foregoing, the provisions of this Section will not apply to any particular information which the State or Contractor can demonstrate (i) was, at the time of disclosure to it, in the public domain; (ii) after disclosure to it, is published or otherwise becomes part of the public domain through no fault of the receiving party; (iii) was in the possession of the receiving party at the time of disclosure to it without an obligation of confidentiality; (iv) was received after disclosure to it from a third party who had a lawful right to disclose such information to it without any obligation to restrict its further disclosure; or (v) was independently developed by the receiving party without reference to Confidential Information of the furnishing party. Further, the provisions of this Section will not apply to any particular Confidential Information to the extent the receiving party is required by law to disclose such Confidential Information, provided that the receiving party (i) promptly provides the furnishing party with notice of the legal request, and (ii) assists the furnishing party in resisting or limiting the scope of such disclosure as reasonably requested by the furnishing party.

#### No Implied Rights

Nothing contained in this Section shall be construed as obligating a party to disclose any particular Confidential Information to the other party, or as granting to or conferring on a party, expressly or impliedly, any right or license to the Confidential Information of the other party.



### Remedies

Each party acknowledges that, if it breaches (or attempts or threatens to breach) its obligations under this Section, the other party may be irreparably harmed. Accordingly, if a court of competent jurisdiction should find that a party has breached (or attempted or threatened to breach) any such obligations, the non-breaching party shall be entitled to seek an injunction preventing such breach (or attempted or threatened breach).

### Survival

The parties' respective obligations under this Section shall survive the termination or expiration of this Contract for any reason.

### Destruction of Confidential Information

Promptly upon termination or cancellation of the Contract for any reason, Contractor shall certify to the State that Contractor has destroyed all State Confidential Information.

## **2.105 FREEDOM OF INFORMATION ACT**

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

## **2.106 DISCLOSURE OF LITIGATION**

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.

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 preceding 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.

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.

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.

\*\*\* 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.

## **2.107 PAYROLL AND BASIC RECORDS**

Payrolls and basic records relating to the performance of this Contract shall be maintained by the Contractor during the course of the work and preserved for a period of 3 years thereafter. Such records shall contain the name, address, and social security number of each such worker, his or her correct classification, hourly rates of wages paid (including rates of contributions or costs anticipated for bona fide fringe benefits or cash equivalents thereof of the types described in section 1(b)(2)(B) of the Davis-Bacon Act), daily and weekly number of hours worked, deductions made, and actual wages paid. Contractors employing apprentices or trainees under approved programs shall maintain written evidence of the registration of apprenticeship programs and certification of trainee programs, the registration of the apprentices and trainees, and the ratios and wage rates prescribed in the applicable programs.

The Contractor shall submit a copy of all payrolls to the Contract Administrator upon request. The payrolls submitted shall set out accurately and completely all of the information required to be maintained as indicated above.

The Prime Contractor is responsible for the submission of copies of payrolls by all subcontractors upon request from the Contract Administrator

The Contractor or subcontractor shall permit the Contract Administrator or representatives of the Contract Administrator or the State of Michigan to interview employees during working hours on the job.

If the Contractor or subcontractor fails to submit required records or to make them available, the Contract Administrator may, after written notice to the Contractor, take such action as may be necessary to cause the suspension of any further payment. Furthermore, failure to submit the required records upon request or to make such records available may be grounds for debarment.

## **2.108 COMPETITION IN SUB-CONTRACTING**

The Contractor shall select subcontractors (including suppliers) on a competitive basis to the maximum practical extent consistent with the objectives and requirements of the contract.

## **2.109 CALL CENTER DISCLOSURE**

Contractor and/or all subcontractors involved in the performance of this Contract providing call or contact center services to the State of Michigan must disclose the location of its call or contact center services to inbound callers. Failure to disclose this information shall be a material breach of this agreement.

## **2.2 Contract Performance**

### **2.201 TIME IS OF THE ESSENCE**

Contractor is on notice that time is of the essence in the performance of this Contract. Late performance will be considered a material breach of this Contract, giving the State a right to invoke all remedies available to it under this Contract.



## 2.202 CONTRACT PAYMENT SCHEDULE

All invoices should reflect actual work done. Specific details of invoices and payments will be agreed upon between the Contract Compliance Inspector and the Contractor after the Contract Agreement has been signed and accepted by both the Contractor and the Director of Acquisition Services, Department of Management & Budget.

The schedule should show payment amount and should reflect actual work done by the payment dates, less any penalty cost charges accrued by those dates. As a general policy statements shall be forwarded to the designated representative by the 15th day of the following month.

## 2.203 RESERVED

## 2.204 RESERVED

## 2.205 ELECTRONIC PAYMENT AVAILABILITY

Electronic transfer of funds is available to State contractors. Contractors are encouraged to register with the State of Michigan Office of Financial Management so the State can make payments related to this Contract electronically at [www.cpexpress.state.mi.us](http://www.cpexpress.state.mi.us).

## 2.206 RESERVED

## 2.3 Contract Rights and Obligations

### 2.301 INCURRING COSTS

The State of Michigan is not liable for any cost incurred by the Contractor prior to signing of the Contract. The State fiscal year is October 1st through September 30th. The Contractor(s) should realize that payments in any given fiscal year are contingent upon enactment of legislative appropriations. Total liability of the State is limited to terms and conditions of this Contract.

### 2.302 CONTRACTOR RESPONSIBILITIES

The Contractor will be required to assume responsibility for all contractual activities, 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 payment of any and all charges resulting from this Contract. If any part of the work is to be subcontracted, this Contract must include a list of subcontractors, including firm name and address, contact person and a complete description of work to be subcontracted. The State reserves the right to approve subcontractors and to require the Contractor to replace subcontractors found to be unacceptable. The Contractor is totally responsible for adherence by the subcontractor to all provisions of this Contract. Any change in subcontractors must be approved by the State, in writing, prior to such change.

### 2.303 ASSIGNMENT AND DELEGATION

The Contractor shall not have the right to assign this Contract, to assign its rights under this Contract, or delegate any of its duties or obligations under this Contract to any other party (whether by operation of law or otherwise), without the prior written consent of the State. 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 this Contract without the prior written consent of the Director of Acquisition Services.

The Contractor shall not delegate any duties or obligations under this Contract to a subcontractor other than a subcontractor named and approved in this Contract unless the Director of Acquisition Services has given written consent to the delegation.

**The Contractor must obtain the approval of the Director of Acquisition Services before using a place of performance that is different from the address that bidder provided in the bid.**



## 2.304 TAXES

Sales Tax: For purchases made directly by the State of Michigan, the State is exempt from State and Local Sales Tax. Prices shall not include such taxes. Exemption Certificates for State Sales Tax will be furnished upon request.

Federal Excise Tax: The State of Michigan may be exempt for Federal Excise Tax, or such taxes may be reimbursable, if articles purchased under this Contract are used for the State's exclusive use. Certificates exclusive use for the purposes of substantiating a tax-free, or tax-reimbursable sale will be sent to the Contractor upon request. If a sale is tax exempt or tax reimbursable under the Internal Revenue Code, prices shall not include the Federal Excise Tax.

The State's Tax Exempt Certification is available for Contractor viewing upon request to the Contract Administrator.

## 2.305 INDEMNIFICATION

### General Indemnification

To the fullest extent permitted by law, 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 employees and agents arising out of or resulting from (1) the product provided or (2) performance of the work, duties, responsibilities, actions or omissions of the Contractor or any of its subcontractors under this Contract.
2. Any claim, demand, action, citation or legal proceeding against the State, its employees and agents arising out of or resulting from a breach by the Contractor of any representation or warranty made by the Contractor in this Contract;
3. Any claim, demand, action, citation or legal proceeding against the State, its 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 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 solely 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 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.



### Patent/Copyright Infringement Indemnification

To the fullest extent permitted by law, the Contractor shall indemnify, defend and hold harmless the State, its employees and agents from and against all losses, liabilities, 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 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, or the use or reproduction of any documentation provided with 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.

### Code Indemnification

To the extent permitted by law, the Contractor shall indemnify, defend and hold harmless the State from any claim, loss, or expense arising from Contractor's breach of the No Surreptitious Code Warranty.

### Indemnification Obligation Not Limited

In any and all claims against the State of Michigan, or any of its agents or employees, 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 benefits acts, or other employee benefits acts. This indemnification clause is intended to be comprehensive. Any overlap in sub clauses, 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 sub clause.

### Continuation of Indemnification Obligation

The duty to indemnify will continue in full force and affect not withstanding the expiration or early termination of the Contract with respect to any claims based on facts or conditions, which occurred prior to termination.

### Indemnification Procedures

The procedures set forth below shall apply to all indemnity obligations under this Contract.

- (a) After receipt by the State of notice of the action or proceeding involving a claim in respect of which it will seek indemnification, the State shall promptly notify Contractor of such claim in writing and take or assist Contractor in taking, as the case may be, any reasonable action to avoid the imposition of a default judgment against Contractor. No failure to so notify Contractor shall relieve Contractor of its indemnification obligations except to the extent that Contractor can demonstrate damages attributable to such failure. Within ten (10) days following receipt of written notice from the State relating to any claim, Contractor shall notify the State in writing whether Contractor agrees to assume control of the defense and settlement of that claim (a "Notice of Election").



After notifying Contractor of a claim and prior to the State receiving Contractor's Notice of Election, the State shall be entitled to defend against the claim, at Contractor's expense, and Contractor will be responsible for any reasonable costs incurred by the State in defending against the claim during such period.

- (b) If Contractor delivers a Notice of Election relating to any claim: (i) the State shall be entitled to participate in the defense of such claim and to employ counsel at its own expense to assist in the handling of such claim and to monitor and advise the State about the status and progress of the Defense; (ii) Contractor shall, at the request of the State, demonstrate to the reasonable satisfaction of the State, Contractor's financial ability to carry out its defense and indemnity obligations under this Contract; (iii) Contractor shall periodically advise the State about the status and progress of the defense and shall obtain the prior written approval of the State before entering into any settlement of such claim or ceasing to defend against such claim and (iv) to the extent that any principles of Michigan governmental or public law may be involved or challenged, the State shall have the right, at its own expense, to control the defense of that portion of such claim involving the principles of Michigan governmental or public law. Notwithstanding the foregoing, the State may retain control of the defense and settlement of a claim by written notice to Contractor given within ten (10) days after the State's receipt of Contractor's information requested by the State pursuant to clause (ii) of this paragraph if the State determines that Contractor has failed to demonstrate to the reasonable satisfaction of the State Contractor's financial ability to carry out its defense and indemnity obligations under this Section. Any litigation activity on behalf of the State of Michigan, or any of its subdivisions pursuant to this Section, must be coordinated with the Department of Attorney General. In the event the insurer's attorney represents the State pursuant to this Section, the insurer's attorney may be required to be designated as a Special Assistant Attorney General by the Attorney General of the State of Michigan.
- (c) If Contractor does not deliver a Notice of Election relating to any claim of which it is notified by the State as provided above, the State shall have the right to defend the claim in such manner as it may deem appropriate, at the cost and expense of Contractor. If it is determined that the claim was one against which Contractor was required to indemnify the State, upon request of the State, Contractor shall promptly reimburse the State for all such reasonable costs and expenses.

### **2.306 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 apply to claims for infringement of United States patent, copyright, trademarks or trade secrets; to claims for personal injury or damage to property caused by the gross negligence or willful misconduct of the Contractor; to claims covered by other specific provisions of this Contract calling for liquidated damages; to Contractor's indemnification obligations (2.305); or to court costs or attorney's fees awarded by a court in addition to damages after litigation based on this Contract.

The State's liability for damages to the Contractor shall be limited to the value of the Contract.

### **2.307 CONTRACT DISTRIBUTION**

Acquisition Services shall retain the sole right of Contract distribution to all State agencies and local units of government unless other arrangements are authorized by Acquisition Services.

### **2.308 FORM, FUNCTION, AND UTILITY**

If this Contract is for use of more than one State agency and if the good or service provided under this Contract do not meet the form, function, and utility required by a State agency, that agency may, subject to State purchasing policies, procure the good or service from another source.



### 2.309 ASSIGNMENT OF ANTITRUST CAUSE OF ACTION

For and in consideration of the opportunity to submit a quotation and other good and valuable consideration, the bidder hereby assigns, sells and transfers to the State of Michigan all rights, title and interest in and to all causes of action it may have under the antitrust laws of the United States or this State for price fixing, which causes of action have accrued prior to the date of payment and which relate solely to the particular goods, commodities, or services purchased or procured by this State pursuant to this transaction.

### 2.310 RESERVED

### 2.311 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 120 days 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.

### 2.312 RESERVED

### 2.313 RESERVED

### 2.314 WEBSITE INCORPORATION

State expressly states that it will not be bound by any content on the Contractor's website, even if the Contractor's documentation specifically referenced that content and attempts to incorporate it into any other communication, unless the State has actual knowledge of such content and has expressly agreed to be bound by it in a writing that has been manually signed by an authorized representation of the State.

## 2.4 Contract Review and Evaluation

### 2.401 CONTRACT COMPLIANCE INSPECTOR

Upon receipt at Acquisition Services of the properly executed Contract Agreement(s), the person named below will be allowed to oversee the Contract performance on a day-to-day basis during the term of the Contract. However, overseeing the Contract implies **no authority to negotiate, change, modify, clarify, amend, or otherwise alter the terms, conditions, and specifications of such Contract(s). That authority is retained by Acquisition Services.** The Contract Compliance Inspector for this project is:

**Ron Denstedt**

Department of Community Health  
Walter P. Reuther Psychiatric Hospital  
30901 Palmer Road  
Westland, MI 48186  
(734) 367-8400  
email: Denstedt@michigan.gov

### 2.402 PERFORMANCE REVIEWS

Acquisition Services in conjunction with the Department of Community Health may review with the Contractor their performance under this Contract. Performance reviews shall be conducted quarterly, semi-annually or annually depending on Contractor's past performance with the State.



Performance reviews shall include, but not limited to, quality of products/services being delivered and provided, timeliness of delivery, percentage of completion of orders, the amount of back orders, status of such orders, accuracy of billings, customer service, completion and submission of required paperwork, the number of substitutions and the reasons for substitutions, and other requirements of this Contract.

Upon a finding of poor performance, which has been documented by Acquisition Services, the Contractor shall be given an opportunity to respond and take corrective action. If corrective action is not taken in a reasonable amount of time as determined by Acquisition Services, the Contract may be canceled for default. Delivery by the Contractor of unsafe and/or adulterated or off-condition products to any State agency is considered a material breach of Contract subject to the cancellation provisions contained herein.

#### **2.403 AUDIT OF CONTRACT COMPLIANCE/ RECORDS AND INSPECTIONS**

The Contractor agrees that the State may, upon 24-hour notice, perform an audit at Contractor's location(s) to determine if the Contractor is complying with the requirements of the Contract. The Contractor agrees to cooperate with the State during the audit and produce all records and documentation that verifies compliance with the Contract requirements.

### **2.5 Quality and Warranties**

#### **2.501 RESERVED**

#### **2.502 RESERVED**

#### **2.503 RESERVED**

#### **2.504 RESERVED**

#### **2.505 CONTRACTOR WARRANTIES**

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;
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 is capable in all respects of fulfilling and shall fulfill all of its obligations under this contract.
9. The contract appendices, attachments, and exhibits identify all equipment and software services necessary for the deliverable(s) to perform and operate in compliance with the contract's requirements.



10. The Contractor is the lawful owner or licensee of any Deliverable licensed or sold to the state by Contractor or developed by Contractor under this contract, and Contractor has all of the rights necessary to convey to the state the ownership rights or license use, as applicable, of any and all Deliverables.
11. If, under this Contract, Contractor procures any equipment, software or other Deliverable for the State (including equipment, software and other Deliverables manufactured, re-marketed or otherwise sold by Contractor under Contractor's name), then in addition to Contractor's other responsibilities with respect to such items as set forth in this Contract, Contractor shall assign or otherwise transfer to the State or its designees, or afford the State the benefits of, any manufacturer's warranty for the Deliverable.
12. The Contract signatory has the power and authority, including any necessary corporate authorizations, necessary to enter this contract, on behalf of Contractor.
13. The Contractor is qualified and registered to transact business in all locations where required.
14. Neither the Contractor nor any Affiliates, nor any employee of either, has, shall have, or shall acquire, any contractual, financial, business, or other interest, direct or indirect, that would conflict in any manner or degree with Contractor's performance of its duties and responsibilities to the State under this Contract or otherwise create an appearance of impropriety with respect to the award or performance of this Agreement. Contractor shall notify the State within two (2) days of any such interest that may be incompatible with the interests of the State.
15. All financial statements, reports, and other information furnished by Contractor to the State as part of its response to the ITB or otherwise in connection with the award of this Contract fairly and accurately represent the business, properties, financial condition, and results of operations of Contractor as of the respective dates, or for the respective periods, covered by such financial statements, reports, other information. Since the respective dates or periods covered by such financial statements, reports, or other information, there have been no material adverse changes in the business, properties, financial condition, or results of operations of Contractor. All written information furnished to the State by or behalf of Contractor in connection with this Contract, including its bid, is true, accurate, and complete, and contains no untrue statement of material fact or omits any material fact necessary to make such information not misleading.

#### 2.506 STAFF

The State reserves the right to approve 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 the State's prior written approval 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. Removal of Key Personnel without the written consent of the State may be considered by the State to be a material breach of this Contract. The prohibition against removal or reassignment shall not apply where Key Personnel must be replaced for reasons beyond the reasonable control of the Contractor including but not limited to illness, disability, resignation or termination of the Key Personnel's employment.

Contractor Key Personnel for this Contract are:

Richard Zakaria	Lab Manager
Raymond Zakaria	Accounting Manager
Toni Zajechowski	QA/QC Supervisor
Jim Fradette	Sales Manager

#### 2.507 RESERVED

**2.508 RESERVED****2.509 RESERVED****2.6 Breach of Contract****2.601 BREACH DEFINED**

Failure to comply with articles, sections, or subsections of this agreement, or making any false statement in this agreement will be considered a material breach of this agreement giving the state authority to invoke any and all remedies available to it under this agreement.

In addition to any remedies available in law and by the terms of this contract, if the Contractor breaches Sections 2.508, 2.509, or 2.510, such a breach may be considered as a default in the performance of a material obligation of this contract.

**2.602 NOTICE AND THE 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 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 or if the State determines in its sole discretion 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.

**2.603 EXCUSABLE FAILURE**

1. Neither party shall be liable for any default or delay in the performance of its obligations under the Contract if and to the extent such default or delay is caused, directly or indirectly, by: fire, flood, earthquake, 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, workaroud 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 hereunder 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, workaroud plans or other means.



## 2.7 Remedies

### 2.701 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 re-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.

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.

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 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. Approvals Rescinded. The State may terminate this Contract without further liability or penalty 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 7. Termination may be in whole or in part and may be immediate as of the date of the written notice to Contractor or may be effective as of the date stated in such written notice.

## 2.702 RIGHTS UPON CANCELLATION

**Termination Assistance.** If this Contract (or any Statement of Work issued under it) is terminated for any reason prior to completion, Contractor agrees to provide for up to six (6) months after the termination all reasonable termination assistance requested by the State to facilitate the orderly transfer of such Services to the State or its designees in a manner designed to minimize interruption and adverse effect. Such termination assistance will be deemed by the parties to be governed by the terms and conditions of this Contract (notwithstanding its termination) other than any terms or conditions that do not reasonably apply to such termination assistance. Such termination assistance shall be at no additional charge to the State if the termination is for Contractor's Default pursuant to Section 2.602; otherwise the State shall compensate Contractor for such termination assistance on a time and materials basis in accordance with the Amendment Labor Rates identified within this Contract agreement.

## 2.703 RESERVED

## 2.704 STOP WORK

1. The State may, at any time, 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 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 immediately 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. The State 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.



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.

## 2.705 SUSPENSION OF WORK

The Contract Administrator may order the Contractor, in writing, to suspend, delay, or interrupt all or any part of the work of this contract for the period of time that the Contract Administrator determines appropriate for the convenience of the State.

If the performance of all or any part of the work is, for an unreasonable period of time, suspended, delayed, or interrupted (1) by an act of the Contract Administrator in the administration of this contract, or (2) by the Contract Administrator's failure to act within the time specified in this contract (or within a reasonable time if not specified), an adjustment shall be made for any increase in the cost of performance of this contract (excluding profit) necessarily caused by the unreasonable suspension, delay, or interruption, and the contract modified in writing accordingly. However, no adjustment shall be made under this clause for any suspension, delay, or interruption to the extent that performance would have been so suspended, delayed, or interrupted by any other cause, including the fault or negligence of the Contractor, or for which an equitable adjustment is provided for or excluded under any other term or condition of this contract.

A claim under this clause shall not be allowed:

- (1) For any costs incurred more than 20 days before the Contractor shall have notified the Contract Administrator in writing of the act or failure to act involved (but this requirement shall not apply as to a claim resulting from a suspension order); and
- (2) Unless the claim, in an amount stated, is asserted in writing as soon as practicable after the termination of the suspension, delay, or interruption, but not later than the date of final payment under the contract.

## 2.8 Changes, Modifications, and Amendments

### 2.801 APPROVALS

This Contract may not be 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.

### 2.802 TIME EXTENTIONS

Time extensions for Contract changes will depend upon the extent, if any, by which the changes cause delay in the completion of the various elements of performance as described in the statement of work. The change order granting the time extension may provide that the contract completion date will be extended only for those specific elements related to the changed work and that the remaining contract completion dates for all other portions of the work will not be altered. The change order also may provide an equitable readjustment of liquidated damages under the new completion schedule.

### 2.803 MODIFICATION

Acquisition Services reserves the right to modify this contract at any time during the contract term. Such modification may include changing the locations to be serviced, additional locations to be serviced, method or manner of performance of the work, number of days service is to be performed, addition or deletion of tasks to be performed, addition or deletion of items, and/or any other modifications deemed necessary. Any changes in pricing proposed by the Contractor resulting from the proposed changes are subject to acceptance by the State. Changes may be increases or decreases. **IN THE EVENT PRICES ARE NOT ACCEPTABLE TO THE STATE, THE CONTRACT SHALL BE SUBJECT TO COMPETITIVE BIDDING BASED UPON THE NEW SPECIFICATION.**

**The State reserves the right to add an item(s) that is not described on the item listing and is available from the Contract Contractor.** The item(s) may be included on the Contract, only if prior written approval has been granted by Acquisition Services.

**2.804 AUDIT AND RECORDS UPON MODIFICATION**

DEFINITION: records includes books, documents, accounting procedures and practices, and other data, regardless of whether such items are in written form, electronic form, or in any other form

Contractor shall be required to submit cost or pricing data with the pricing of any modification of this contract to the Contract Administrator in Acquisition Services. Data may include accounting records, payroll records, employee time sheets, and other information the state deems necessary to perform a fair evaluation of the modification proposal. Contract Administrator or authorized representative of the state shall have the right to examine and audit all of the contractor's records, including computations and projections, related to:

1. The proposal for modification;
2. The discussions conducted on the proposal, including those related to negotiation;
3. Pricing of the modification; or
4. Performance of the modification.

Contractor shall make available at its office at all reasonable times the materials described in the paragraphs above.

If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement.

**2.805 CHANGES**

- (a) The Contract Administrator may, at any time, without notice to the sureties, if any, by written order designated or indicated to be a change order, make changes in the work within the general scope of the contract, including changes:
  - (1) In the specifications (including drawings and designs);
  - (2) In the method or manner of performance of the work;
  - (3) In the Government-furnished facilities, equipment, materials, services, or site; or
  - (4) Directing acceleration in the performance of the work.
- (a) Any other written or oral order (which, as used in this paragraph (b), includes direction, instruction, interpretation, or determination) from the Contract Administrator that causes a change shall be treated as a change order under this clause; Provided, that the Contractor gives the Contract Administrator written notice stating:
  - (1) The date, circumstances, and source of the order; and
  - (2) That the Contractor regards the order as a change order.
- (b) Except as provided in this clause, no order, statement, or conduct of the Contract Administrator shall be treated as a change under this clause or entitle the Contractor to an equitable adjustment.



APPENDIX A PRICING SHEET

CPT CODE	DESCRIPITON	ESTIMATED USAGE	COST PER TEST	YEARLY TOTAL
80048	<b>BMP Test</b>	1,600	\$8.00	\$12,800.00
80053	<b>Compreshensive Metabolic Panel</b> Albumin Alkaline Phosphates ALT AST Bilirubin, Total BUN Calcium Chloride CO2 Creatinine Glucose Potassium Protein, Total Sodium	500	\$15.00	\$7,500.00
80051	<b>Electrolytes Panel</b> Sodium Potassium Chloride CO2	1638	\$5.00	\$8,190.00
80061	<b>Lipid Panel</b> Cholesterol Triglycerides HDL LDL VLDL	500	\$15.00	\$7,500.00
80101	<b>Urine Drug Screen</b> PCP/Phenoclidine 83992 Methadone 80101 Propozyphene 80101 Opiates 83925 Benzodiazepines 80154 Methaqualone 80101 Amphethamines 82145 Cannabinoid/THC100 80101	100	\$25.00	\$2,500.00



Cocaine 82520

Barbiturates 82205

CPT CODE	DESCRIPTION	ESTIMATED USAGE	COST PER TEST	YEARLY TOTAL
<b>Hepatitis B</b>				
87340	Hepatitis B Surface Antigen	74	\$11.00	\$814.00
	Hepatitis B Surface Antibody Titer	74	\$11.00	\$814.00
<b>Vitamin B12/ Folate</b>				
82607	Vitamin B12 plus Folic Acid	98	\$10.00	\$980.00
82746	(Folate)	98	\$10.00	\$980.00
<b>Iron Profile</b>				
83550	Iron	59	\$3.00	\$177.00
83540	TIBC	93	\$6.00	\$558.00
82728	Ferritin	66	\$9.50	\$627.00

The Following are Individual Tests:

80100	Drug Screen	288	\$10.00	\$2,880.00
80154	Benzodiazepines	6	\$5.00	\$30.00
80156	Tegretol/Carbamazepine	12	\$12.50	\$150.00
80160	Impramine/Desipramine	8	\$33.38	\$267.04
80162	Digoxin	11	\$9.10	\$100.10
80164	Valporic Acid/Depakote	1263	\$10.00	\$12,630.00
80178	Lithium	473	\$5.25	\$2,483.25
80182	Amitriptyline/Nortriptyline	3	\$46.50	\$139.50
80184	Phenobarbital	5	\$12.50	\$62.50
80185	Phenytoin/Dilantin	96	\$11.00	\$1,056.00
80198	Theophylline	8	\$12.50	\$100.00
80299	Quantitation of drug, not elsewhere specified	1	\$100.00	\$100.00
81000	Urinalysis,Leukocyte Estrase & Micro	359	\$5.50	\$1,974.50
82040	Albumin	348	\$1.00	\$348.00
82043	Albumin, Urine	29	\$1.00	\$29.00
82150	Amylase	42	\$8.00	\$336.00
82248	Bilirubin, Direct	255	\$1.00	\$255.00
82250	Bilirubin, Total	333	\$1.00	\$333.00
82270	Occult Blood	100	\$3.00	\$300.00
82310	Calcium	210	\$1.00	\$210.00
82378	Carcinogenic Antigen (CEA)	3	\$15.00	\$45.00
82465	Cholesterol	663	\$1.00	\$663.00

**TERMS AND CONDITIONS****CONTRACT #071B5200120**

CPT CODE	DESCRIPITON	ESTIMATED USAGE	COST PER TEST	YEARLY TOTAL
82533	Cortisol, Total	2	\$15.00	\$30.00
82550	CPK	9	\$1.00	\$9.00
82553	Creatine kinase, MB fraction only	2	\$13.70	\$27.40
82565	Creatinine, Blood	780	\$1.00	\$780.00
82570	Creatinine, Urine 24hr	3	\$1.00	\$3.00
82575	Creatinine Clearance	2	\$4.00	\$8.00
82607	Vitamin B-12	98	\$10.00	\$980.00
82746	Folic Acid	98	\$10.00	\$980.00
82947	Glucose, gestational, 1 hour	1059	\$1.75	\$1,853.25
82977	GGTP	17	\$4.50	\$76.50
83001	FSH	3	\$20.00	\$60.00
83002	Lutenizing Hormone	6	\$20.00	\$120.00
83020	Hemoglobin Electrophoresis	2	\$15.00	\$30.00
83036	Glycohemoglobin	252	\$7.50	\$1,890.00
83540	Iron	93	\$3.00	\$279.00
83615	LDH	98	\$1.00	\$98.00
83690	Lipase	2	\$8.00	\$16.00
83718	High Density Liprprotein HDL	626	\$7.00	\$4,382.00
83721	LDL-Direct	492	\$15.00	\$7,380.00
83735	Magnesium	192	\$4.00	\$768.00
83930	Osmololity Blood	3	\$15.00	\$45.00
83935	Osmololity Urine	2	\$15.00	\$30.00
84075	Alkaline Phosphatase	353	\$1.00	\$353.00
84100	Phosphorous	110	\$1.00	\$110.00
84132	Potassium	2	\$1.00	\$2.00
84146	Prolactin	30	\$20.00	\$600.00
84153	PSA	155	\$22.00	\$3,410.00
84155	Protein, Total	92	\$1.00	\$92.00
84295	Sodium	6	\$1.00	\$6.00
84402	Testosterone, Free	2	\$30.00	\$60.00
84403	Testosterone	5	\$20.00	\$100.00
84436	T4	56	\$5.00	\$280.00
84439	T4 Free	266	\$10.00	\$2,660.00
84443	TSH	590	\$10.75	\$6,342.50
84450	SGOT/AST	755	\$1.00	\$755.00
84460	SGPT/ALT	1155	\$1.00	\$1,155.00
84478	Triglycerides	654	\$1.00	\$654.00
84479	T3 Assay of Thyroid	26	\$5.00	\$130.00
84480	T3 Triodothrone	87	\$12.00	\$1,044.00
84484	Troponin, Quantitative	6	\$13.75	\$82.50
84545	Urea Nitrogen (BUN)	1032	\$1.00	\$1,032.00

**TERMS AND CONDITIONS**

**CONTRACT #071B5200120**



CPT CODE	DESCRIPITON	ESTIMATED USAGE	COST PER TEST	YEARLY TOTAL
84702	Gonadotropin, Chorionic, Quantitative (hCG)	18	\$20.80	\$374.40
84703	Preg Test Urine	24	\$6.50	\$156.00
85048	WBC	1031	\$3.50	\$3,608.50
85025	CBC Including Differential Platelet	1622	\$5.00	\$8,110.00
85044	Reticulocyte Count	3	\$5.67	\$17.01
85610	Prothrombin Time	105	\$6.00	\$630.00
85651	ESR	11	\$4.00	\$44.00
85660	Sickle Cell	8	\$9.00	\$72.00
85730	PTT	24	\$8.30	\$199.20
86038	Anti-Nuclear Antibody	5	\$15.00	\$75.00
86140	C Reative Protein	7	\$10.00	\$70.00
86430	Rheumatoid factor, qualitative	3	\$7.50	\$22.50
86592	RPR	500	\$4.50	\$2,250.00
86701	HIV-1	45	\$30.00	\$1,350.00
86704	Hepatitis B Core Antibody	68	\$11.00	\$748.00
86706	Hepatitis B Surface Antibody	74	\$11.00	\$814.00
86708	Hepatitis A Antibody, Total	30	\$20.00	\$600.00
86800	Thyroglobulin Antibody	2	\$20.11	\$40.22
86803	Hepatitis C Antibody (HCV)	68	\$18.08	\$1,229.44
88804	Hep C AB RIBA	9	\$205.53	\$1,849.77
87070	Culture any source except urine,blood,stool	81	\$14.00	\$1,134.00
87081	Culture, presumptive,pathOrganisms,screen	3	\$8.00	\$24.00
87086	Urine Culture & Colony Count	58	\$10.00	\$580.00
87110	Chlamydia Culture	14	\$105.95	\$1,483.30
87118	AFB Culture, Sputum **	2	\$37.73	\$75.46
87206	AFB Smear, Sputum	2		
87186	MIC	114	\$12.00	\$1,368.00
87340	Hepatitis B Surface Antigen	74	\$11.00	\$814.00
87521	Hepatitis C Screen- not PCR	8	\$18.08	\$144.64
88164	Pap Smear (single slide)	101	\$15.00	\$1,515.00

Total for 1 year testing \$122,058.48

Grand Total for 3 year Contract \$366,175.44

**Daily Fee for Phlebotomist Based on 4 hr \$52.00**

Daily Fee is Based upon one Phlebotomist

\*\* AFB Culture and Smear will be billed together

When an individual test is ordered and it is not specifically listed in Appendix A Pricing Sheet, this test would be subjected to a **40%** discount from the cost identified in the current DBML Fee Schedule.



## APPENDIX B – QUALITY ASSURANCE PROGRAMS

Assurance is a system for assuring the quality of the total laboratory performance. The system identifies a problem as it arises and outline procedures for the resolution of the problem.

The system consists of two programs:

1. QUALITY ASSURANCE PROGRAM

Quality Assurance is designed to provide for defining, monitoring, interpreting and correlating test results with appropriate patient care and to correlate the amount and type of testing with what is considered to be successful treatment and outcome.

2. QUALITY CONTROL PROGRAM

Quality Control is the primary means of ensuring medically reliable, high-quality laboratory testing through internal and external quality control programs. It is basically a scientific and technical process that is implemented on a daily basis by the technical staff of the laboratory and is supervised by the Director.

The Quality Assurance program adds to the Director's responsibilities the application of medical judgment in recommending appropriate laboratory tests, interpreting test results, choosing alternate methods of testing, or choosing to send tests to another accredited laboratory.

The Quality Control program consists of a documented QC program for each section of the laboratory. The general quality control program includes, but is not limited to, the following:

1. EXTERNAL QC

Use of proficiency surveys for tests in each section of the laboratory.

When the proficiency samples are received in the laboratory, they are treated and analyzed in the same manner as a patient sample, recognizing the need for any reconstituting required for the proficiency samples. The survey results are mailed to the Computer Center for evaluation.

Records are maintained of all proficiency tests performed for a minimum of two years and makes such records available to the inspecting agencies.

The Director reviews the evaluation from the Computer Center and if any unsatisfactory results occur, the reasons for this occurrence are pinpointed, and remedial action initiated immediately. This action is documented on the proficiency survey reports.

2. INTERNAL QC

The laboratory has a multi-phase system for internal quality control:

1. DESIGN CONTROL

The laboratory-facility design and staffing pattern handle efficiently the workload of the selected assay procedures for the mix of health-care physicians and clients served by the laboratory. Personnel must meet set criteria of education, experience, certification and training.

2. MATERIALS CONTROL

Incoming material involves receiving or stocking, at the most economical levels of quality, only those materials and equipment meeting the laboratory's specifications.



The validity of the clinical data is dependent upon the use of specific reagent and materials. Specimen collection and handling are carefully controlled. Specific instructions are provided to collecting personnel to assure optimum specimen procurement and adequate requisitions. Unacceptable specimens are rejected or discussed with the ordering physician.

### 3. PROCESS CONTROL

Process control involve internal control to calibrate and control the process and external control to monitor and refine proficiency.

Large lots of control materials are used so that the limits for day-to day variation of the process can be determined and compared to the variation between days and month of the year, to document temporal precision and stability of the assay procedure.

"Blind sampling is interspersed randomly among the clinical specimens and the fact that these specimens are control specimens is unknown to the analysts. This allows the Director to obtain an independent assessment of all procedures performed in the laboratory.

The data from both types of QC specimens is assessed and a monthly statistical summary and review of apparent problems are prepared.

The proficiency testing program is the external QC program as described above.

### 4. OUTPUT CONTROL

Output control involves the patients test results. The laboratory report is sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result is preserved by the laboratory for a period of at least two years after the date of submittal of the report. The reports are filled for ready identification and accessibility. No results are sent to the patient concerned, except with the written consent of the physician or authorized person who requested the test.

Referred specimens are sent to an accredited reference laboratory whose name is included on the report.

Preventive maintenance ensures the proper operation of the equipment and instruments with a planned, written schedule of servicing. Remedial action is taken for any defects.

### 5. RELIABILITY CONTROL

The laboratory provides results of qualitative and quantitative tests with meaningful normal values.

### 6. VERIFICATION CONTROL

Verification control includes the CLIA inspection and accreditation.

### SUMMARY

The Director actively monitors and facilitates the entire QA and QC programs and reviews all records for each section in the laboratory.

The QA and QC reports are filed and retained for a period of two years.



## QUALITY ASSURANCE

### QUALITY CONTROL

The purpose of quality control is to ensure the reliability of each patient value. There are two requirements for all quality control systems: (1) should lead to decisions regarding the reliability of the analytical data and (2) should be related to the medical purposes for which the analyses are being done. Quality control actions should end with decision regarding not only analytical significance, but also the medical significance of the quality data.

Quality control consists of many steps in a chain of events from the preparation of the patient and collection of the sample to the delivery of the results to the physician. Many interlined items detail the points where quality control is important, such as training and experience of laboratory personnel, patient preparation, transportation and specimen handling, storage of specimen, instrument maintenance, quality of reagents used and a variety of other factors.

Working in a laboratory requires personnel to have good technical skills. It is impossible to have consistently good laboratory performance without an adequately trained technical staff. Recognizing that specimens are from patients and erroneous data can have serious consequences, identifying and correcting lapses in lab performance, altering physicians at once with extremely abnormal results and have a willingness to provide extra effort and time when the situation demands it and recognizing the need to keep informed on new developments in the field are just a few items that make up a technologist with good judgment. Good judgment is acquired over time and cannot be taught. The precision of the method over the entire analytical range, normal and abnormal must be known and monitored with various levels of controls. Control charts must be kept up to date, organized and monitored on a regular basis.

The use of a "blind control" is used to randomly monitor the performance of the analytical testing. Corrective action in cases of "out of control" situations are documented. Participation in a multi sample survey, such as CAP, is very important in the evaluation of the laboratory performance.

All the above mentioned items are an important part of the quality control system. They are all needed to provide the physician with results that will aid him/her in diagnosing and treating the patient.

**QUALITY ASSURANCE****CONTROL MATERIAL**

Control material need to be stable material available in sufficient quantity to be analyzed over a reasonable time frame. They should have the same matrix as the patient samples and should produce values in a minimum of two ranges; one normal and one abnormal. The goal of the control is to target the corresponding concentration which is used to monitor performance of an assay at different medical decision levels. It is important that care be taken to reconstitute lyophilized materials. Mixing too quickly or vigorously may interfere with the solubility. Follow the instructions provided by the manufacturer of the control material.

**QUALITY ASSURANCE****CRITICAL VALUES**

All highly unusual results are repeated using a diluted sample, if needed, or a fresh non-diluted sample. If the same result as the original is obtained the result is considered valid and can be released to the ordering physician. If a different result from the original is obtained, the test is to be rerun with sample obtained from the primary sample tube. When two consecutive duplicate results are obtained, the result is considered valid and can then be released to the physician. If two (2) consecutive duplicate answers cannot be obtained, the instrument and/or reagent become suspect and results should be held until the problem can be resolved.



**QUALITY ASSURANCE**  
**CRITICAL VALUE REPORTING**

The laboratory has set critical values for several laboratory tests. These values are programmed into the computer and are used to generate the abnormal call list that is printed every morning. Results that exceed the critical values are reported to the ordering physician or their representative in a timely manner. The time, name of person giving the results and the name of the person receiving the results will be recorded on the abnormal log.



**QUALITY ASSURANCE**  
**UNSATISFACTORY SPECIMENS**

The laboratory recognizes the importance of a properly collected specimen to provide accurate test results to the physician. When receiving sample the laboratory will make note of any name discrepancy between the request form and the samples. Any discrepancies must be corrected prior to reporting of any results. Contact the person submitting the sample to verify the information. Samples submitted using the incorrect anticoagulant will be rejected by the laboratory. Specimens that may yield inaccurate results based upon the specimen condition, such as gross lipemic or gross hemolysis, will be rejected by the laboratory.



**QUALITY ASSURANCE**  
**PREVENTIVE MAINTENANCE**

The laboratory will maintain all instruments and equipment that is used in the laboratory according to the manufacturer recommendations. The maintenance functions follow the guidelines set by the manufacturer. Maintenance will be performed on a daily, weekly and monthly basis as required. Yearly maintenance will be performed by an independent engineering company or a service representative of the manufacturer. If a problem is found at any time during the performance of this function, it will be brought to the attention of the director at once. If this problem can not be corrected in a timely manner by the technologist performing the assays, a service representative will be called in to repair the observed malfunction. No results will be reported out until this deficiency is corrected.

**QUALITY ASSURANCE****CLERICAL ERRORS**

The system for the detection of clerical errors is as follows:

1. Technologist will perform the ordered assays.
2. Results will then be transferred to a worksheet.
3. The results from the worksheet will be transferred to the patient result form.
4. After this transcription and before the release of the results, a technologist will review the results to check for an possible clerical errors.
5. After the review by the technologist the results forms are ready to be released to the ordering physician.



**QUALITY ASSURANCE**  
**TEST TURN AROUND TIME**

The laboratory is in operation 7 days a week. The laboratory will monitor turn around times to continue to provide timely patient results to the physician to aid them in the treatment of their patients. All routine Chemistry, Hematology, TDM and Thyroid function have a turn around time to the ordering physician of 24-48 hours.

All routine Microbiology samples have a preliminary report available in 1-2 days and a final report within 2-3 days.

Pathology has a preliminary report available within 24-48 hours and a completed report within 4 working days. Some complex cases may take one to two weeks for a final report to be generated.

The laboratory monitors turn around times to continue to provide timely patient results to the physician to aid them in the treatment of their patients.

**QUALITY ASSURANCE****PROFICIENCY TESTING**

The laboratory participates in a nationally recognized proficiency survey program supplied through the College of American Pathologists and the WSHL. The laboratory subscribes to all surveys that are available for assays that are performed in the laboratory. The survey order is reviewed on an annual basis to assure that the laboratory participates in all survey available for the current assays performed. Proficiency testing will be treated in the same manner as the patient samples, recognizing the need for special handling due to the need for reconstitution and special time restraints. The results of the proficiency surveys are reviewed by the Pathologist or designee when they are received by the laboratory. The appropriate supervisor will then review the results and any unacceptable results will be investigated to determine the problem. After the investigation the results will be recorded on the PT Corrective Action Log sheet. The corrective action log will then be reviewed by the Pathologist to assure that the correct conclusion has been reached. All past survey, the corrective action and the summary report will be kept in the CAP Survey Books, available for review by all employees.



**QUALITY ASSURANCE**  
**TRANSPORTATION AND HANDLING**  
**OF BLOOD SPECIMENS**

Several potential problem areas exist in the transportation and handling of blood specimens. Specific concerns relate to prolonged contact of serum or plasma with cells or with tube stoppers, laboratory induced hemolysis, analyte concentration change due to evaporation, incorrect storage temperature and the use of anticoagulants, serum/plasma separator devices and incorrect transportation. Recognition and control of these variables should reduce error and contribute to the medical usefulness of patient test results. All blood samples are to be treated with "universal precautions" because it is often impossible to know which specimen might be infectious.

Tubes of blood are to be kept in a vertical, stopper up position. This positioning promotes complete clot formation and reduces agitation of the tube contents which in turn reduces the potential for hemolysis. Gentle handling of collected specimen helps to minimize erythrocyte damage. Blood collected using a tube containing a clotting activator can be processed as early as 10 to 15 minutes after the blood is drawn. It is recommended that serum or plasma be physically separated from contact with cells as soon as possible with a maximum time of 2 hours from the time of collection. Tubes of blood are to be kept closed at all times, they should be centrifuged with stoppers in place. Tubes of blood intended for whole blood analysis are not to be centrifuged and separated.

Separated serum should remain at 22°C (room temperature) for no longer than 8 hours. If assays will not be completed in 8 hours, serum should be refrigerated. Whole blood samples should remain at 22°C for no longer than 4 hours. For longer storage, specimen should be refrigerated.

Specimens must be transported to the laboratory in as short item as possible. Prepare the sample to be transported to the laboratory by placing them in a secondary container. This secondary container should allow the request form to be physically separated from the specimen. The secondary container must be capable of containing any possible spillage derived from the primary container. A constant transportation temperature should be maintained. This can be accomplished with the use of varying cooling devices, such as, ice packs or refrigerated coolers.

**QUALITY ASSURANCE****SPECIMEN REQUIREMENTS**

The laboratory has determined the volume of samples required to perform the assays in this laboratory. This volume has been based upon the different method utilized by this laboratory. The ideal specimen requirements have been placed on the laboratory requisition form to allow easy access to this information at the time of the phlebotomy. The laboratory staff is available to answer any and all questions concerning the specimen volume and the specimen type that is needed for all assays not listed on the requisition form.

The laboratory will attempt to perform the requested assays on the specimen submitted as long as it does not jeopardize the integrity of the results.

If it is noted that a physician, his/her employee or a phlebotomist employed by the laboratory is obtaining an excessive amount of blood, the proper person will be contacted. The laboratory will inform them of the adverse consequences of excess vein punctures to both the patient and the health care workers involved.