



STATE OF MICHIGAN ENTERPRISE PROCUREMENT

Department of Technology, Management, and Budget
525 W. ALLEGAN ST., LANSING, MICHIGAN 48913
P.O. BOX 30026 LANSING, MICHIGAN 48909

CONTRACT CHANGE NOTICE

Change Notice Number 10
to
Contract Number 071B9200252

CONTRACTOR	ROCHE DIAGNOSTICS CORP
	9115 Hague Rd.
	Indianapolis, IN 46250
	Ryan Stephens
	317-840-3301
	ryan.stephens@roche.com
	*****1923

STATE	Program Manager	Connie Good	DHHS
		517-335-8058	
		goodc@Michigan.gov	
	Contract Administrator	Jared Ambrosier	DTMB
		AmbrosierJ@michigan.gov	
		517-284-6398	

CONTRACT SUMMARY				
DESCRIPTION: HIV MONITOR TEST KITS				
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	INITIAL AVAILABLE OPTIONS	EXPIRATION DATE BEFORE CHANGE(S) NOTED BELOW	
September 1, 2009	August 31, 2012	2 - 1 Year	August 31, 2016	
PAYMENT TERMS		DELIVERY TIMEFRAME		
Net 30				
ALTERNATE PAYMENT OPTIONS			EXTENDED PURCHASING	
<input type="checkbox"/> P-card <input type="checkbox"/> Direct Voucher (DV) <input type="checkbox"/> Other			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
MINIMUM DELIVERY REQUIREMENTS				
N/A				
DESCRIPTION OF CHANGE NOTICE				
OPTION	LENGTH OF OPTION	EXTENSION	LENGTH OF EXTENSION	REVISED EXP. DATE
<input type="checkbox"/>		<input checked="" type="checkbox"/>	12 months	August 31, 2017
CURRENT VALUE		VALUE OF CHANGE NOTICE	ESTIMATED AGGREGATE CONTRACT VALUE	
\$ 573,079.52		\$ 0.00	\$ 573,079.52	

DESCRIPTION: Effective August 30, 2016 this contract is hereby extended 12 months. The revised contract expiration date is August 31, 2017.

All other terms, conditions, specifications, and pricing remain the same. Per contractor and agency agreement, DTMB Procurement approval, and State Administrative Board approval on August 30, 2016.

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

CHANGE NOTICE NO. 9
 to
CONTRACT NO. 071B9200252
 between
THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF CONTRACTOR	PRIMARY CONTACT	EMAIL
Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250	Ryan Stephens	Ryan.Stevens@roche.com
	PHONE	VENDOR TAX ID # (LAST FOUR DIGITS ONLY)
	317-840-3301	1923

STATE CONTACTS	AGENCY	NAME	PHONE	EMAIL
PROGRAM MANAGER / CCI	DCH	Connie Good	517-335-8058	GoodC@michigan.gov
CONTRACT ADMINISTRATOR	DTMB	Melissa Sambiagio	517-284-7016	sambiagiom@michigan.gov

CONTRACT SUMMARY			
DESCRIPTION: HIV Monitor Test Kits			
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	INITIAL AVAILABLE OPTIONS	EXPIRATION DATE BEFORE CHANGE(S) NOTED BELOW
9/1/2009	8/31/2012	2 – one year	2/28/2015
PAYMENT TERMS	F.O.B.	SHIPPED TO	
Net 30	Delivery	Bureau of Laboratories Warehouse; 927 Terminal Dr; Lansing, MI 48909	
ALTERNATE PAYMENT OPTIONS			EXTENDED PURCHASING
<input type="checkbox"/> P-card <input type="checkbox"/> Direct Voucher (DV) <input type="checkbox"/> Other			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
MINIMUM DELIVERY REQUIREMENTS			
None			

DESCRIPTION OF CHANGE NOTICE				
EXTEND CONTRACT EXPIRATION DATE	EXERCISE CONTRACT OPTION YEAR(S)	EXTENSION BEYOND CONTRACT OPTION YEARS	LENGTH OF EXTENSION/OPTION	EXPIRATION DATE AFTER CHANGE
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	12 months	8/31/2016
CURRENT VALUE		VALUE/COST OF CHANGE NOTICE	ESTIMATED REVISED AGGREGATE CONTRACT VALUE	
\$533,079.52		\$40,000.00	573,079.52	

DESCRIPTION:
 Effective September 1, 2015, this contract is extended 12 months; and is increased by \$40,000.00. The revised contract expiration date is August 31, 2016. All other terms, conditions, specifications, and pricing remain the same. Per contractor and agency agreement, DTMB Procurement approval, and State Administrative Board approval on July 7, 2015.

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

CHANGE NOTICE NO. 8
 to
CONTRACT NO. 071B9200252
 between
THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF CONTRACTOR:	PRIMARY CONTACT	EMAIL
Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250	Ryan Stephens	Ryan.Stevens@roche.com
	TELEPHONE	CONTRACTOR #, MAIL CODE
	317-840-3301	

STATE CONTACTS	AGENCY	NAME	PHONE	EMAIL
CONTRACT COMPLIANCE INSPECTOR	DCH	Connie Good	517-335-8058	GoodC@michigan.gov
BUYER	DTMB	Melissa Sambiago	517-284-7016	sambiagiom@michigan.gov

CONTRACT SUMMARY:			
DESCRIPTION: HIV Monitor Test Kits			
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	INITIAL AVAILABLE OPTIONS	EXPIRATION DATE BEFORE CHANGE(S) NOTED BELOW
9/1/2009	8/31/2012	2 – one year	2/28/2015
PAYMENT TERMS	F.O.B	SHIPPED	SHIPPED FROM
Net 30	Delivery	Delivered 3 business days ARO	Indianapolis, IN
ALTERNATE PAYMENT OPTIONS:			AVAILABLE TO MIDEAL PARTICIPANTS
<input type="checkbox"/> P-card	<input type="checkbox"/> Direct Voucher (DV)	<input type="checkbox"/> Other	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
MINIMUM DELIVERY REQUIREMENTS:			
None			

DESCRIPTION OF CHANGE NOTICE:				
EXTEND CONTRACT EXPIRATION DATE	EXERCISE CONTRACT OPTION YEAR(S)	EXTENSION BEYOND CONTRACT OPTION YEARS	LENGTH OF OPTION/EXTENSION	EXPIRATION DATE AFTER CHANGE
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	6 months	8/31/2015
VALUE/COST OF CHANGE NOTICE:		ESTIMATED REVISED AGGREGATE CONTRACT VALUE:		
\$0.00		443,079.52		

Effective February 28, 2015, this Contract is hereby extended through August 31, 2015. The Vendor's Primary Contact has been changed to Ryan Stephens. All other terms, conditions, specifications, and pricing remain the same. Per contractor and agency agreement, and DTMB Procurement approval, and State Administrative Board approval on February 24, 2015.

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

CHANGE NOTICE NO. 7
 to
CONTRACT NO. 071B9200252
 between
THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF CONTRACTOR:	PRIMARY CONTACT	EMAIL
Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250	Chad Scott	Chad.scott@roche.com
	TELEPHONE	CONTRACTOR #, MAIL CODE
	(800) 428-5074, ext. 26271	

STATE CONTACTS	AGENCY	NAME	PHONE	EMAIL
CONTRACT COMPLIANCE INSPECTOR	DCH	Connie Good	517-335-8058	GoodC@michigan.gov
BUYER	DTMB	Melissa Sambiagio	517-284-7016	sambiagiom@michigan.gov

CONTRACT SUMMARY:				
DESCRIPTION: HIV Monitor Test Kits				
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	INITIAL AVAILABLE OPTIONS	EXPIRATION DATE BEFORE CHANGE(S) NOTED BELOW	
September 1, 2009	August 31, 2012	2 – one year	August 31, 2014	
PAYMENT TERMS	F.O.B	SHIPPED	SHIPPED FROM	
Net 30	Delivery	3 business days from ARO	Indianapolis, IN	
ALTERNATE PAYMENT OPTIONS:			AVAILABLE TO MiDEAL PARTICIPANTS	
<input type="checkbox"/> P-card <input type="checkbox"/> Direct Voucher (DV) <input type="checkbox"/> Other			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
MINIMUM DELIVERY REQUIREMENTS:				
None				

DESCRIPTION OF CHANGE NOTICE:				
EXTEND CONTRACT EXPIRATION DATE	EXERCISE CONTRACT OPTION YEAR(S)	EXTENSION BEYOND CONTRACT OPTION YEARS	LENGTH OF OPTION/EXTENSION	EXPIRATION DATE AFTER CHANGE
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	6 months	February 28, 2015
VALUE/COST OF CHANGE NOTICE:		ESTIMATED REVISED AGGREGATE CONTRACT VALUE:		
\$90,000.00		443,079.52		
Effective July 18, 2014, this Contract is EXTENDED six (6) months; therefore, the Contract expiration date is hereby CHANGED to February 28, 2015. In addition, this Contract is hereby INCREASED by \$90,000.00. Please note, the buyer has been changed to Melissa Sambiagio. All other terms, conditions, specifications and pricing remain the same. Per vendor and agency agreement and DTMB Procurement approval.				

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

CHANGE NOTICE NO. 6
 to
CONTRACT NO. 071B9200252
 between
THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF CONTRACTOR:	PRIMARY CONTACT	EMAIL
Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250	Chad Scott	Chad.scott@roche.com
	TELEPHONE	CONTRACTOR #, MAIL CODE
	(800) 428-5074, ext. 26271	

STATE CONTACTS	AGENCY	NAME	PHONE	EMAIL
CONTRACT COMPLIANCE INSPECTOR:	DCH	Deborah Stephens	(517) 335-8098	StephensD@michigan.gov
BUYER:	DTMB	Sue Cieciva	(517)373-0301	cieciewas@michigan.gov

CONTRACT SUMMARY:			
DESCRIPTION: HIV Monitor Test Kits – Department of Community Health			
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	AVAILABLE OPTIONS	CURRENT EXPIRATION DATE
September 1, 2009	August 31, 2012	2, 1 Yr. Options	August 31, 2014
PAYMENT TERMS	F.O.B	SHIPPED	SHIPPED FROM
Net 30	Delivered	30 Days from ARO	Indianapolis, IN
ALTERNATE PAYMENT OPTIONS:			AVAILABLE TO MIDEAL PARTICIPANTS
<input type="checkbox"/> P-card <input type="checkbox"/> Direct Voucher (DV) <input type="checkbox"/> Other			<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
MINIMUM DELIVERY REQUIREMENTS:			
N/A			

DESCRIPTION OF CHANGE NOTICE:		
OPTION EXERCISED: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES	IF YES, EFFECTIVE DATE OF CHANGE:	NEW EXPIRATION DATE:
Effective February 10, 2014, the Contract value is INCREASED by \$16,000.00. The new Contract value is \$443,079.52. All other terms, conditions, pricing and specifications remain unchanged.		
Per agency request and DTMB Procurement approval.		
VALUE/COST OF CHANGE NOTICE:	\$16,000.00	
ESTIMATED REVISED AGGREGATE CONTRACT VALUE:	\$443,079.52	

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

CHANGE NOTICE NO. 5
 to
CONTRACT NO. 071B9200252
 between
THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF CONTRACTOR:	PRIMARY CONTACT	EMAIL
Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250	Chad Scott	Chad.scott@roche.com
	TELEPHONE	CONTRACTOR #, MAIL CODE
	(800) 428-5074, ext. 26271	

STATE CONTACTS	AGENCY	NAME	PHONE	EMAIL
CONTRACT COMPLIANCE INSPECTOR:	DCH	Deborah Stephens	(517) 335-8098	StephensD@michigan.gov
BUYER:	DTMB	Sue Cieciva	(517)373-0301	cieciewas@michigan.gov

CONTRACT SUMMARY:			
DESCRIPTION: HIV Monitor Test Kits – Department of Community Health			
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	AVAILABLE OPTIONS	CURRENT EXPIRATION DATE
September 1, 2009	August 31, 2012	2, 1 Yr. Options	August 31, 2013
PAYMENT TERMS	F.O.B	SHIPPED	SHIPPED FROM
Net 30	Delivered	30 Days from ARO	Indianapolis, IN
ALTERNATE PAYMENT OPTIONS:			AVAILABLE TO MiDEAL PARTICIPANTS
<input type="checkbox"/> P-card <input type="checkbox"/> Direct Voucher (DV) <input type="checkbox"/> Other			<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
MINIMUM DELIVERY REQUIREMENTS:			
N/A			

DESCRIPTION OF CHANGE NOTICE:		
OPTION EXERCISED: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES	IF YES, EFFECTIVE DATE OF CHANGE: September 1, 2013	NEW EXPIRATION DATE: August 31, 2014
Effective immediately, the second and final option year available on this Contract is hereby utilized and the contract value is INCREASED by \$40,000.00.		
In addition, the vendor contact has changed to:		
Chad Scott, Account Manager (800) 428-5074, ext. 26271 (317) 625-4712 cell Email: chad.scott@roche.com		
All other terms, conditions, specification, and pricing remain the same.		
Per agency request, vendor agreement and DTMB Procurement approval.		
VALUE/COST OF CHANGE NOTICE:	\$40,000.00	
ESTIMATED REVISED AGGREGATE CONTRACT VALUE:	\$427,079.52	

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

June 27, 2012

CHANGE NOTICE NO. 4
 to
CONTRACT NO. 071B9200252
 between
THE STATE OF MICHIGAN
 and

NAME & ADDRESS OF CONTRACTOR:	PRIMARY CONTACT	EMAIL
Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250	Bill Richmond	bill.richmond@roche.com
	TELEPHONE	CONTRACTOR #, MAIL CODE
	(317) 670-1423	

STATE CONTACTS	AGENCY	NAME	PHONE	EMAIL
CONTRACT COMPLIANCE INSPECTOR:	DCH	Deborah Stephens	(517) 335-8098	StephensD@michigan.gov
BUYER:	DTMB	Sue Cieciewa	(517)373-0301	cieciewas@michigan.gov

CONTRACT SUMMARY:			
DESCRIPTION: HIV Monitor Test Kits – Department of Community Health			
INITIAL EFFECTIVE DATE	INITIAL EXPIRATION DATE	AVAILABLE OPTIONS	CURRENT EXPIRATION DATE
September 1, 2009	August 31, 2012	2, 1 Yr. Options	August 31, 2012
PAYMENT TERMS	F.O.B	SHIPPED	SHIPPED FROM
Net 30	Delivered	30 Days from ARO	Indianapolis, IN
ALTERNATE PAYMENT OPTIONS:			AVAILABLE TO MI DEAL PARTICIPANTS
<input type="checkbox"/> P-card <input type="checkbox"/> Direct Voucher (DV) <input type="checkbox"/> Other			<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
MINIMUM DELIVERY REQUIREMENTS:			
N/A			

DESCRIPTION OF CHANGE NOTICE:		
OPTION EXERCISED: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES	IF YES, EFFECTIVE DATE OF CHANGE: September 1, 2012	NEW EXPIRATION DATE: August 31, 2013
<p>Effective immediately, this Contract is hereby EXTENDED to August 31, 2013 and INCREASED by \$50,000.00.</p> <p>All other terms, conditions, specification, and pricing remain the same.</p> <p>Per agency (ITRAC dated 6/8/12) and vendor (Bill Richmond dated 6/27/12) agreement and DTMB Procurement approval.</p>		
VALUE/COST OF CHANGE NOTICE:	\$50,000.00	
ESTIMATED REVISED AGGREGATE CONTRACT VALUE:	\$387,079.52	

Form No. DMB 234A (Rev. 1/96)
 AUTHORITY: Act 431 of 1984
 COMPLETION: Required
 PENALTY: Failure to deliver in accordance with Contract terms and conditions and this notice may be considered in default of Contract

STATE OF MICHIGAN
DEPARTMENT OF TECHNOLOGY, MANAGEMENT AND BUDGET September 20, 2011
PURCHASING OPERATIONS
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

CHANGE NOTICE NO. 3

TO

CONTRACT NO. 071B9200252
 (Supercedes Contract #071B4200380)

between

THE STATE OF MICHIGAN

and

NAME & ADDRESS OF CONTRACTOR Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 Email: bill.richmond@roche.com	TELEPHONE Bill Richmond (317) 670-1423 CONTRACTOR NUMBER/MAIL CODE BUYER/CA (517) 373-0301 Sue Cieciva
Contract Compliance Inspector: Deborah Stephens HIV Monitor Test Kits – Department of Community Health	
CONTRACT PERIOD: 3 yrs. + 2 one-year options From: September 1, 2009 CONTRACT PERIOD: 3 yrs. + 2 one-year options	
TERMS <p style="text-align: center;">Net 30</p>	SHIPMENT <p style="text-align: center;">30 Days ARO</p>
F.O.B. <p style="text-align: center;">Delivered</p>	SHIPPED FROM <p style="text-align: center;">Indianapolis, IN</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">None</p>	

NATURE OF CHANGE (S):

Effective September 20, 2011, the following product has been added to this Contract:

Product #	Description	Unit Cost
12239272001	LightCycler FastStart DNA Master Hyb Probe	\$715.50

Revised Attachment A, Pricing is attached.

Also, this Contract is hereby INCREASED by \$17,887.50.

In addition, the following contacts for Roche Diagnostic Corporation have been changed:

Title	Name	E-Mail Address	Phone Number
Account Manager	Bill Richmond	bill.richmond@roche.com	317-670-1423 (cell)
Contract Analyst	Stephanie Laffoon	Stephanie.laffoon@roche.com	1-800-428-5076 x 17632
Contract Analyst (back-up)	Tori Buchanan	Tori.buchanan@roche.com	1-800-428-5076 x 17959
Contract Manager	Joe Comito	Joseph.comito@roche.com	1-800-428-5076 x 14193
Regional Business Manager	Bob Glavan	Bob.glavan@roche.com	1-800-845-7355 x 26100
Regional Product Specialist	Sherri Nitz	Sherri.nitz@roche.com	1-800-845-7355 x 27786

All other terms, conditions, specifications and pricing remain the same.

AUTHORITY/REASON:

Per vendor quote, agency request (PRF dated 9/12/2011) and DTMB-Purchasing Operations approval.

INCREASE: \$17,887.50

TOTAL REVISED ESTIMATED CONTRACT VALUE: \$337,079.52

Attachment A, Pricing

Item Number	Description	Quantity per Unit of Measure	Unit Price
05212308190	COBAS® AmpliPrep/COBAS TaqMan® HIV-1 Test V2.0	1 (48)	\$2,060.00
03587797190	System Wash Reagent	5.1 L (96)	\$10.80
03755525001	SPUs	12 x 24 (288)	\$288.00
03137040001	Sample Input Tubes with Barcode Clips	12 x 24 (288)	\$141.12
03287343001	Racks of K-tips	12 x 36 (432)	\$77.76
03137082001	K-tubes, rack	12 x 96 (1152)	\$864.00
28154104001	Seal Tip Grippers	10	\$13.88
28122199001	Reagent Rack	1	\$44.06
28073112001	Reagent Rack Labels, 1-20	20	\$7.50
28048398001	Reagent Rack Barcode Labels, 001-020	20	\$15.00
28173362001	Reagent Tip	1	\$198.72
28048355001	Sample Rack Labels, 1-20	20	\$15.00
28136289001	Sample Rack Barcode Labels, 001-020	20	\$32.94
28136815001	Seal Cap Pipettes	5	\$15.38
28122806001	SPU Rack	1	\$17.18
28122911001	Syringe, 2.5 mL	1	\$235.56
28153744001	Syringe Plungers	2	\$341.57
28127328001	UV Tube Light	1	\$85.94
28035792001	Fan Filters	4	\$4.06
28051763001	Halogen Lamp	1	\$233.99
28150397001	K-carrier	1	\$135.08
03287696001	K-carrier Holder	1	\$44.05
03279995001	K-carrier Labels, 1-25	25	\$29.12
03517519001	K-carrier Transporter	1	\$61.54
03132307001	Power Supply Air Filter	1	\$4.80
28122172001	Sample Rack	1	\$95.25
12239272001	LighCycler FastStart DNA Master Hyb Probe	1	\$715.50

STATE OF MICHIGAN
 DEPARTMENT OF TECHNOLOGY, MANAGEMENT AND BUDGET September 2, 2010
 PURCHASING OPERATIONS
 P.O. BOX 30026, LANSING, MI 48909
 OR
 530 W. ALLEGAN, LANSING, MI 48933

CHANGE NOTICE NO. 2

TO

CONTRACT NO. 071B9200252
 (Supercedes Contract #071B4200380)

between

THE STATE OF MICHIGAN

and

NAME & ADDRESS OF CONTRACTOR Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 Email: teresa.mcaninch@roche.com		TELEPHONE Teresa McAninch (800) 428-5076 ext. 14994
		CONTRACTOR NUMBER/MAIL CODE
		BUYER/CA (517) 373-0301 Sue Cieciva
Contract Compliance Inspector: Deborah Stephens		
HIV Monitor Test Kits – Department of Community Health		
CONTRACT PERIOD: 3 yrs. + 2 one-year options From: September 1, 2009 To: August 31, 2012		
TERMS	Net 30	SHIPMENT
		30 Days ARO
F.O.B.	Delivered	SHIPPED FROM
		Indianapolis, IN
MINIMUM DELIVERY REQUIREMENTS		
None		

NATURE OF CHANGE (S):

Effective immediately, Item Number 03542998190 COBAS® AmpliPrep/COBAS TaqMan® HIV-1 Test V1.0 is hereby DELETED and REPLACED with Item Number 05212308190 COBAS® AmpliPrep/COBAS TaqMan® HIV-1 Test V2.0. The unit price remains the same.

Revised Attachment A, Pricing is attached.

In addition, the Roche Diagnostics Account Manager is hereby changed from Susan Otto to:

Robin Goodrich, Molecular Account manager
 Email: robin.goodrich@roche.com
 Cell: (810) 355-6618
 Fax: (810) 225-8182

All other terms, conditions, specifications and pricing remain the same.

Contract No. 071B9200252
Change Notice No. 2
Page 2

AUTHORITY/REASON:

Per vendor request by email dated August 18, 2010 and agency agreement dated August 30, 2010.

TOTAL ESTIMATED CONTRACT VALUE REMAINS: \$319,192.02

Attachment A, Pricing

Item Number	Description	Quantity per Unit of Measure	Unit Price
05212308190	COBAS® AmpliPrep/COBAS TaqMan® HIV-1 Test V2.0	1 (48)	\$2,060.00
03587797190	System Wash Reagent	5.1 L (96)	\$10.80
03755525001	SPUs	12 x 24 (288)	\$288.00
03137040001	Sample Input Tubes with Barcode Clips	12 x 24 (288)	\$141.12
03287343001	Racks of K-tips	12 x 36 (432)	\$77.76
03137082001	K-tubes, rack	12 x 96 (1152)	\$864.00
28154104001	Seal Tip Grippers	10	\$13.88
28122199001	Reagent Rack	1	\$44.06
28073112001	Reagent Rack Labels, 1-20	20	\$7.50
28048398001	Reagent Rack Barcode Labels, 001-020	20	\$15.00
28173362001	Reagent Tip	1	\$198.72
28048355001	Sample Rack Labels, 1-20	20	\$15.00
28136289001	Sample Rack Barcode Labels, 001-020	20	\$32.94
28136815001	Seal Cap Pipettes	5	\$15.38
28122806001	SPU Rack	1	\$17.18
28122911001	Syringe, 2.5 mL	1	\$235.56
28153744001	Syringe Plungers	2	\$341.57
28127328001	UV Tube Light	1	\$85.94
28035792001	Fan Filters	4	\$4.06
28051763001	Halogen Lamp	1	\$233.99
28150397001	K-carrier	1	\$135.08
03287696001	K-carrier Holder	1	\$44.05
03279995001	K-carrier Labels, 1-25	25	\$29.12
03517519001	K-carrier Transporter	1	\$61.54
03132307001	Power Supply Air Filter	1	\$4.80
28122172001	Sample Rack	1	\$95.25

Persons responsible for administering this Contract:

NAME: Robin Goodrich

NAME: Pamela Rockwell

TITLE: Molecular Account Manager

TITLE: Contract Analyst, Molecular Diagnostics

PHONE: (810) 355-6618

PHONE: (800) 845-5074 ext. 17092

FAX: (810) 225-8182

FAX: (317) 521-6895

E-MAIL: robin.goodrich@roche.com

E-MAIL: pam.rockwell@roche.com

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

October 20, 2009

CHANGE NOTICE NO. 1
TO
CONTRACT NO. 071B9200252
 (Supercedes Contract #071B4200380)
between
THE STATE OF MICHIGAN
and

NAME & ADDRESS OF CONTRACTOR Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 Email: teresa.mcaninch@roche.com	TELEPHONE Teresa McAninch (800) 428-5076 ext. 14994
	CONTRACTOR NUMBER/MAIL CODE
	BUYER/CA (517) 373-0301 Sue Cieciwa
Contract Compliance Inspector: Deborah Stephens HIV Monitor Test Kits – Department of Community Health	
CONTRACT PERIOD: 3 yrs. + 2 one-year options From: September 1, 2009 To: August 31, 2012	
TERMS Net 30	SHIPMENT 30 Days ARO
F.O.B. Delivered	SHIPPED FROM Indianapolis, IN
MINIMUM DELIVERY REQUIREMENTS None	

NATURE OF CHANGE (S):

Effective immediately, the vendor contact is hereby changed to:

Teresa McAninch
 Email: teresa.mcaninch@roche.com
 Phone: (800) 428-5076 ext. 14994
 Fax: (800) 888-1902

All other terms, conditions, specifications and pricing remain the same.

AUTHORITY/REASON:

Per vendor request by email dated October 15, 2009.

TOTAL ESTIMATED CONTRACT VALUE REMAINS: \$319,192.02

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

**NOTICE
 OF
 CONTRACT NO. 071B9200252**
 (Supercedes Contract #071B4200380)
**between
 THE STATE OF MICHIGAN
 and**

NAME & ADDRESS OF CONTRACTOR Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 susan.otto@roche.com		TELEPHONE Susan Otto (734) 735-1238
		CONTRACTOR NUMBER/MAIL CODE
		BUYER/CA (517) 373-0301 Sue Cieciva
Contract Compliance Inspector: Deborah Stephens HIV Monitor Test Kits – Department of Community Health		
CONTRACT PERIOD: 3 yrs. + 2 one-year options From: September 1, 2009 To: August 31, 2012		
TERMS Net 30	SHIPMENT 30 Days ARO	
F.O.B. Delivered	SHIPPED FROM Indianapolis, IN	
MINIMUM DELIVERY REQUIREMENTS None		
MISCELLANEOUS INFORMATION:		

The terms and conditions of this Contract are those of ITB #07119200129, this Contract Agreement and the vendor's quote dated April 13, 2009. In the event of any conflicts between the specifications, and terms and conditions, indicated by the State and those indicated by the vendor, those of the State take precedence.

Estimated Contract Value: \$319,192.02

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

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TERMS <p style="text-align: center;">Net 30</p>	SHIPMENT <p style="text-align: center;">30 Days ARO</p>
F.O.B. <p style="text-align: center;">Delivered</p>	SHIPPED FROM <p style="text-align: center;">Indianapolis, IN</p>
MINIMUM DELIVERY REQUIREMENTS <p style="text-align: center;">None</p>	
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Estimated Contract Value: \$319,192.02	

THIS IS NOT AN ORDER: This Contract Agreement is awarded on the basis of our inquiry bearing the ITB No. 07119200129. Orders for delivery will be issued directly by the Department of Community Health through the issuance of a Purchase Order Form.

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

FOR THE CONTRACTOR:

FOR THE STATE:

 Roche Diagnostics Corporation
 Firm Name

 Authorized Agent Signature

 Authorized Agent (Print or Type)

 Date

 Signature
 Sue Cieciva, Buyer Specialist

 Name/Title
 Commodities Division

 Division

 Date



**STATE OF MICHIGAN
Department of Management and Budget
Purchasing Operations**

Contract No. [071B9200252](#)
HIV Monitor Test Kits – Department of Community Health

Buyer Name: [Sue Ciecwa](#)
Telephone Number: (517) 373-0301
E-Mail Address: Ciecwas@michigan.gov



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 HIV-1 Test
 Ampliprep/TaqMan System



DEFINITIONS

“Days” means calendar days unless otherwise specified.

“24x7x365” means 24 hours a day, seven days a week, and 365 days a year (including the 366th day in a leap year).

“Additional Service” means any Services/Deliverables within the scope of the Contract, but not specifically provided under any Statement of Work, that once added will result in the need to provide the Contractor with additional consideration.

“Audit Period” has the meaning given in **Section 2.093**.

“Business Day,” whether capitalized or not, shall mean any day other than a Saturday, Sunday or State-recognized legal holiday (as identified in the Collective Bargaining Agreement for State employees) from 8:00am EST through 5:00pm EST unless otherwise stated.

“Blanket Purchase Order” is an alternate term for Contract and is used in the States computer system.

“Business Critical” means any function identified in any Statement of Work as Business Critical.

“Chronic Failure” is defined in any applicable Service Level Agreements.

“Deleted – Not Applicable” means that section is not applicable or included in this RFP. This is used as a placeholder to maintain consistent numbering.

“Deliverable” means physical goods and/or commodities as required or identified by a Statement of Work

“DMB” means the Michigan Department of Management and Budget

“Environmentally preferable products” means a product or service that has a lesser or reduced effect on human health and the environment when compared with competing products or services that serve the same purpose. Such products or services may include, but are not limited to, those which contain recycled content, minimize waste, conserve energy or water, and reduce the amount of toxics either disposed of or consumed.

“Excusable Failure” has the meaning given in **Section 2.214**.

“Hazardous material” means any material defined as hazardous under the latest version of federal Emergency Planning and Community Right-to-Know Act of 1986 (including revisions adopted during the term of the Contract).

“Incident” means any interruption in Services.

“ITB” is a generic term used to describe an Invitation to Bid. The ITB serves as the document for transmitting the RFP to potential bidders

“Key Personnel” means any Personnel designated in **Section 1.031** as Key Personnel.

“New Work” means any Services/Deliverables outside the scope of the Contract and not specifically provided under any Statement of Work, that once added will result in the need to provide the Contractor with additional consideration.



“Ozone-depleting substance” means any substance the Environmental Protection Agency designates in 40 CFR part 82 as: (1) Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or (2) Class II, including, but not limited to, hydrochlorofluorocarbons.

“Post-Consumer Waste” means any product generated by a business or consumer which has served its intended end use, and which has been separated or diverted from solid waste for the purpose of recycling into a usable commodity or product, and which does not include post-industrial waste.

“Post-Industrial Waste” means industrial by-products which would otherwise go to disposal and wastes generated after completion of a manufacturing process, but does not include internally generated scrap commonly returned to industrial or manufacturing processes.

“Recycling” means the series of activities by which materials that are no longer useful to the generator are collected, sorted, processed, and converted into raw materials and used in the production of new products. This definition excludes the use of these materials as a fuel substitute or for energy production.

“Reuse” means using a product or component of municipal solid waste in its original form more than once.

“RFP” means a Request for Proposal designed to solicit proposals for services.

“Services” means any function performed for the benefit of the State.

“Source reduction” means any practice that reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment prior to recycling, energy recovery, treatment, or disposal.

“State Location” means any physical location where the State performs work. State Location may include state-owned, leased, or rented space.

“Subcontractor” means a company Contractor delegates performance of a portion of the Services to, but does not include independent contractors engaged by Contractor solely in a staff augmentation role.

“Unauthorized Removal” means the Contractor’s removal of Key Personnel without the prior written consent of the State.

“Waste prevention” means source reduction and reuse, but not recycling.

“Waste reduction”, or “pollution prevention” means the practice of minimizing the generation of waste at the source and, when wastes cannot be prevented, utilizing environmentally sound on-site or off-site reuse and recycling. The term includes equipment or technology modifications, process or procedure modifications, product reformulation or redesign, and raw material substitutions. Waste treatment, control, management, and disposal are not considered pollution prevention, per the definitions under Part 143, Waste Minimization, of the Natural Resources and Environmental Protection Act (NREPA), 1994 PA 451, as amended.

“Work in Progress” means a Deliverable that has been partially prepared, but has not been presented to the State for Approval.

“Work Product” refers to any data compilations, reports, and other media, materials, or other objects or works of authorship created or produced by the Contractor as a result of an in furtherance of performing the services required by this Contract.



Article 1 – Statement of Work (SOW)

1.010 Project Identification

1.011 Project Request

This Contract is for HIV monitor test kits including instrumentation rental and maintenance program for the Department of Community Health (DCH).

1.012 Background

The reagents and instrumentation are used for Viral Load testing for patients who live in the State of Michigan. Without these products, DCH could not perform the testing for these patients. DCH offers HIV Viral Load testing free of charge to the AIDS Drug Assistance Program (ADAP) residents of the State of Michigan. There is a direct association between viral load and severity of clinical disease in HIV-infected patients. There is also a correlation between plasma viremia and antiretroviral therapy. Viral Load measurements provide a way of monitoring patients' viremia and drug therapy. These results are necessary in order for the physician to treat the HIV infected patient and to monitor the disease process.

1.020 Scope of Work and Deliverables

1.21 In Scope

Contractor shall provide HIV monitor test kits including instrumentation rental and maintenance program as specified in Attachment A, Pricing and deliver to the following location:

Bureau of Laboratories Warehouse
927 Terminal Drive
Lansing, MI48909

1.022 Work and Deliverable

Contractor must provide Deliverables/Services and staff, and otherwise do all things necessary for or incidental to the performance of work, as set forth below:

1. The State currently has the following equipment from Roche on a no cost "reagent rental" equipment loan: Cobas AmpliPrep/Cobas TaqMan System.
2. The instrument and reagents provided by the manufacturer must be FDA-cleared or approved as a system.
3. 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.
4. All consumables must be shipped at the laboratory's request only.

Expiration Dates of Products

Contractor guarantees a minimum of 3 months expiration dating from our ship date. However, DCH may make a request on the purchase order for longer-dated material. Contractor is not obligated to fulfill any request for longer-dated material.

5. Software upgrades must be provided without cost to the State of Michigan. The Contractor must provide on-site training after each software change, enhancement, or upgrade. The Contractor must provide and maintain software on the primary equipment set-up and on a backup computer to be provided by the State of Michigan.
6. Contractor shall provide equipment and consumable supplies required for system validation at no cost to DCH.



7. **Interface Allowance** - In connection with the acquisition of Equipment, Contractor agrees to facilitate acquisition of an LIS interface and/or water filtration system (the “Ancillary Item(s)”) by providing a credit up to \$5,000.00 to DCH to be applied against any future Contractor invoice for the Equipment, Reagents and/or Service under this Contract. This credit may be applied only during a twelve (12) month period beginning after the State’s execution of this Contract and will be applied by Contractor only after DCH has: (a) engaged a third party vendor to provide the Ancillary Item(s) and ensured satisfactory installation at DCH site; (b) provided Contractor with reasonable proof that the work has been completed (for example, vendor’s final invoice); and (c) provided Contractor with reasonable proof of payment to vendor. Any portion of the credit not applied to the Contractor invoice during the twelve (12) month period after the State’s execution of this Contract will automatically expire.

Service

1. **Repair/Replacement** - The Contractor is responsible for providing repair and/or replacement of equipment upon failure. Contractor guarantees on-site response within 24 hours of dispatch for instruments covered by Warranty, Premium and Classic contracts. Normally Contractor’s actual on-site response time is within six hours of dispatch. Repair and/or replacement of equipment must be completed within three (3) business days of receipt of notice of equipment failure.
2. **Preventative Maintenance** - All preventative maintenance (PM) to be conducted on the “reagent rental” equipment. Preventative maintenance shall be per equipment manufacturer instructions. All PMs shall be performed Monday through Friday, 8:00 a.m. to 5:00 p.m. (local time) excluding Contractor’s holidays. All labor charges relating to the performance of a PM service call are covered under Contractor’s warranty and service agreements. In addition, while the instrument is under warranty or Service Agreement, Contractor will provide PM kits containing selected replacement parts / components involving the PM. PMs are done first using the appropriate items delivered with the analyzer, then using items from the PM kits that are included with the warranty. Any consumable/expendable parts not included in a PM kit but used in the performance of the PM will be at DCH expense.

The maximum PM frequency for all Levels of Warranty / Service Agreements is defined in the chart below.

Model	Warranty Max	Service Agreement Max
Ampliprep	2	2
Taqman 48	1	1

The frequency of Preventative Maintenance visits is test volume dependent and may be modified as Contractor deems appropriate for optimal system performance.

3. **Roche Technical Support Center (800) 526-1247**
 Staffed 24 hours/day 365 days/year
 -Technical questions about Roche instrumentation, reagents and software
 -Instrument/assay troubleshooting
 -Assistance understanding assays
 -Questions about Roche customer communications
 -Directs calls to Field Support as required



4. **Field and Technical Service Contact**

The Roche Diagnostics Technical Support Center offers emergency telephone assistance 24 Hours per day 7 days per week 365 days per year. The following telephone toll free number should be called for service assistance:

Roche Molecular Diagnostics, PCR (800) 526-1247

1.030 Roles and Responsibilities

1.031 Contractor Staff, Roles, and Responsibilities

The Contractor shall have the capacity to receive orders electronically, by phone, facsimile, and by written order.

Customer Service

Toll Free Number: (800) 428-5076

Hours: Monday - Friday, 8:00 a.m. – 7:00 p.m. Eastern Standard Time

Contractor shall have a Michigan sales representative that will meet with DCH at their site no less than once per year.

Contractors shall have internal controls, approved by Purchasing Operations, 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.

It is the preference of the State of Michigan that the Contractor have an accessible customer service department with an individual specifically assigned to State of Michigan accounts. It is the preference of the State of Michigan that the Contractor has experienced sales representatives make timely personal visits to State accounts. The Contractor's customer service must respond to State agency inquiries promptly. It is the preference of the State of Michigan that the Contractor provides 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 a purchase order, unless otherwise defined within this Contract, orders will be issued by the DCH.

All purchase orders are subject to the terms and conditions of this Contract. In the event of a conflict between a purchase order and the Contract, the Contract shall control.

If mailed, a purchase order is considered "issued" when the State deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods.

1.040 Project Plan

1.041 Project Plan Management – Deleted, Not Applicable

1.042 Reports

1. Contractor shall provide DCH with a Technical Bulletin with each update or enhancement that describes the changes. DCH shall receive a service order with each repair that documents what was done during the repairs.
2. Contractor shall have the capability to provide a summary report detailing an annual or multi-year service history for each piece of equipment, upon request.
3. Contractor shall have the capability to provide an annual or multi-year consumables usage report for all products purchased, upon request.



1.050 Acceptance

1.051 Criteria

The following criteria will be used by the State to determine Acceptance of the Services or Deliverables provided under this SOW:

All consumables, diagnostic testing kits and reagents are in compliance with U.S. and international regulatory requirements.

The sole and exclusive warranty for any Reagents/Supplies acquired will be the written warranty included in the packaging insert.

1.052 Final Acceptance – Deleted, Not Applicable

1.060 Proposal Pricing

1.61 Proposal Pricing

Refer to Attachment A, Pricing for pricing for the items included in this Contract.

Contractor's out-of-pocket expenses are not separately reimbursable by the State unless, on a case-by-case basis for unusual expenses, the State has agreed in advance and in writing to reimburse Contractor for the expense at the State's current travel reimbursement rates. See www.michigan.gov/dmb for current rates.

1.062 Price Term

Prices quoted are the maximum for a period of two (2) years from the date the Contract becomes effective.

After the initial two years of the contract, 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. Purchasing Operations 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). Purchasing Operations 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 Contractor remains responsible for performing according to the contract terms at the contract price for all orders received before price revisions are approved or before the contract is cancelled.

1.063 Tax Excluded from Price

(a) Sales Tax: For purchases made directly by the State, the State is exempt from State and Local Sales Tax. Prices must not include the taxes. Exemption Certificates for State Sales Tax will be furnished upon request.

(b) Federal Excise Tax: The State may be exempt from Federal Excise Tax, or the taxes may be reimbursable, if articles purchased under any resulting Contract are used for the State's exclusive use. Certificates showing exclusive use for the purposes of substantiating a tax-free, or tax-reimbursable sale will be sent upon request. If a sale is tax exempt or tax reimbursable under the Internal Revenue Code, prices must not include the Federal Excise Tax.

1.064 Holdback – Deleted, Not Applicable

1.070 Commodity Requirements and Terms



Product Quality

1.0701 Specifications

Definite Specifications - All commodities and/or services to be furnished hereunder shall conform to the specifications as noted in COBAS AmpliPrep and TaqMan 48 brochure attached.

1.0702 Alternate Bids - Deleted, Not Applicable

1.0703 Research and Development

Contractor shall invest in new product development and research to stay current with ongoing demands.

1.0704 Quality Assurance Program

Contractor shall have a Quality Assurance Program that is currently in place within their organization.

1.0705 Warranty for Products or Services

The Contractor represents and warrants that the equipment/system(s) are in good operating condition and operate and perform to the requirements and other standards of performance contained in this Contract, when installed, at the time of Final Acceptance by the State, and for a period of **one year** commencing upon the first day following Final Acceptance.

Within **three (3) business days** of notification from the State, the Contractor must adjust, repair or replace all equipment that is defective or not performing in compliance with the Contract. The Contractor must assume all costs for replacing parts or units and their installation including transportation and delivery fees, if any.

The Contractor must provide a toll-free telephone number to allow the State to report equipment failures and problems to be remedied by the Contractor.

The Contractor agrees that all warranty service it provides under this Contract must be performed by Original Equipment Manufacturer (OEM) trained, certified and authorized technicians.

The Contractor is the sole point of contact for warranty service. The Contractor warrants that it will pass through to the State any warranties obtained or available from the original equipment manufacturer, including any replacement, upgraded, or additional equipment warranties.

All warranty work must be performed on the State of Michigan worksite(s).

Warranty for an instrument commences at final acceptance of system by the laboratory and is for a term of 12 months from that date. Contractor warrants the services provided will be free from defects and workmanship for a period of 30 days from the date of services. Contractor is responsible for completing installation and addressing any shipment issues or repairs needed at installation. Warranty service will be requested by calling the Roche Technical Telephone Support Center - Roche Molecular Diagnostics (800) 526-1247.

The warranty period for the COBAS Ampliprep/COBAS Taqman 48 currently on-site is valid from 03/18/2009 through 03/17/2010.

Reagents/Supplies - The sole and exclusive warranty for any Reagent/Supplies acquired pursuant to this Contract will be the written warranty included in the packaging insert.

Equipment - Contractor warrants that each unit of Equipment will be free from defects in materials and workmanship (except for consumable items and equipment support products (e.g., lamps, probes, etc.)) and will meet manufacturer's written specifications for a period of one year from the applicable Commencement Date for each unit of Equipment. Contractor warrants consumable items and equipment support products for a period of 90 days from delivery. At Contractor's option, Contractor will either replace or repair free of charge all parts which prove to be defective and are subject to such warranty. Contractor will ship replacement parts to DCH at no cost. If DCH Equipment is rented, the Equipment provided to DCH may be "recertified" used Equipment. Contractor makes no representation and provides no warranty for non-Roche products used on



the Equipment. DCH will hold Contractor harmless from any responsibility or claims that arise from the use of non-Roche products.

Services - Roche warrants that the Services provided will be free from defects in workmanship for a period of 30 days from the date of the Services.

Contractor guarantees on-site response within 24 hours of dispatch for instruments covered by Warranty, Premium and Classic contracts. Normally Contractor's actual on-site response time is within six hours of dispatch.

Customer Part Kits

Contractor ships a Customer Parts Kit with each new system, excluding those that are subject for depot repair only. This kit consists of consumable/expendable/replaceable items as well as common repair parts. This kit is provided to have selected parts already on-site for warranty PMs and to enable DCH to maintain maximum up-time either by having you replace the part yourself or by having the part available for use by Contractor's Field Service Representative. It is your responsibility to order replacements for all consumable/expendable/replaceable parts used from your Customer Parts Kit. Replacement of parts contained in the Customer replaceable parts kit is at your expense. (Service representatives do not normally carry items that are contained in the Customer parts kit.) Failure to properly maintain the stock level in the Customer parts kit could result in unnecessary down time. If an emergency repair is necessary and the needed part has not been maintained in the Customer parts kit, the part would need to be ordered on an emergency basis thereby contributing to possible unnecessary delays in completing the repair.)

If the DCH system is not performing properly, DCH shall contact the Technical Telephone Support Center. The following telephone toll free number should be called for service assistance:

Roche Molecular Diagnostics, PCR (800) 526-1247

1.0706 Training

The following training is included with the purchase of a Roche Diagnostics analyzer:

Initial operator training courses for the majority of Roche Diagnostics' analyzers are provided at the North American headquarters of Roche Diagnostics in Indianapolis, Indiana.

Contractor will pay the following expenses or the training of one (1) operator per analyzer purchased: tuition, lodging, meals, and local ground transportation to and from the training facility in Indianapolis.

Additional training will be provided upon request by DCH or with any updates or changes to the equipment.

1.0707 Special Programs

Technology Upgrade

Acknowledging that Contractor may introduce to the market a new technology that may better serve the needs of DCH during the term of this Contract, Contractor agrees to provide a technology upgrade on the following terms and conditions:

If during the term of this Contract, Contractor offers new FDA-cleared technology in the molecular market, as applicable given the transaction detailed in the Contract, Contractor will analyze DCH current usage of the Equipment and Reagents/Supplies listed on Attachment A, Pricing to determine if the new technology will better meet the needs of DCH. If Contractor determines this to be the case, Contractor will work with Purchasing Operations to negotiate per the terms of Section 2.024 Change Requests utilizing the new technology.

Monthly Standing Order(s)

Contractor agrees to pay freight, standard shipping and delivery charges associated with one standing order of Reagents/Supplies per month. DCH will remain responsible for freight, shipping and delivery charges (including expedited freight) for all Reagents/Supplies orders other than this monthly standing order.



Please refer to **Art. 1.081 Product Returns for Molecular Diagnostics.**

1.0708 Security

This Contract may 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, the 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.

Upon review of the security measures by the Contractor, the State will decide whether to issue State ID badges to the Contractor's delivery personnel or accept the ID badge issued to delivery personnel by the Contractor.

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 would also be helpful).

The Contractor and its subcontractors shall comply with the security access requirements of individual State facilities; see section 2.051, Background Checks and Security.

Delivery Capabilities

1.0709 Time Frames

The Contractor must be able to supply all items listed on multiple delivery schedules as determined by the laboratory.

All orders shall be delivered within **three (3) business days** after receipt of order. Orders requested to be delivered within **two (2) business days** will require expedited freight at an additional charge.

Contractor will immediately notify the State of any product back order and provide a shipping date when products will be available. Contractor shall provide a website MyLabOnline.com to provide DCH with instant access to order status tracking and product bulletins.

Contractor will provide DCH, Bureau of Laboratories advance notification of product discontinuation.

Contractor will not substitute products.

1.0710 Minimum Order

There is **no minimum order requirement** for this Contract.

1.0711 Packaging

The Contractor shall provide packaging that most closely meets these packaging sizes.

Packaging and containers, etc., shall be in accordance with supplier's commercial practice and shall meet the requirements of Department of Transportation (D.O.T.) and rail and motor carrier freight classifications in effect at time of shipment, which will permit application of the lowest freight rate.

1.0712 Palletizing

Shipments shall be palletized whenever possible and shall conform to the following:

- Manufacturer's standard 4-way shipping pallets are acceptable.
- Maximum height: 5'6"; including pallet.
- Maximum weight: 3500 pounds; including pallet.



- Pallets are to be securely banded or shrink-wrapped.
- The cost of palletizing must be included in the unit price.

On occasion, the Contractor may ship product on a standard European pallet (dimension 31" x 47").

1.0713 Delivery Term

Contractor agrees to pay freight, standard shipping and delivery charges associated with one standing order of Reagents/Supplies per month. DCH will remain responsible for freight, shipping and delivery charges (including expedited freight) for all Reagents/Supplies orders other than this monthly standing order.

1.0714 Contract Performance

The Contractor has not had a contract terminated for default in the last three years. Termination for default is defined as notice to stop performance which was delivered to the Contractor due to the Contractor's non-performance or poor performance and the issue of performance was either (a) not litigated due to inaction on the part of the Contractor, or (b) litigated and determined that the Contractor was in default.

1.0715 Place of Performance

The Contractor will service this Contract from the address noted below:

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

1.0716 Environmental Requirements

Energy Efficiency Purchasing Policy – The State shall seek wherever possible to purchase energy efficient products. This may include giving preference to U.S. Environmental Protection Agency (EPA) certified 'Energy Star' products for any category of products for which EPA has established Energy Star certification. For other purchases, the State may include energy efficiency as one of the priority factors to consider when choosing among comparable bids.

Environmental Purchasing Policy – The State of Michigan has committed to encourage the use of products and services that impact the environment less than competing products. This can be best accomplished by including environmental considerations in purchasing decisions, while remaining fiscally responsible, to promote practices that improve worker health, conserve natural resources, and prevent pollution.

Environmental components that may be considered in Best Value Purchasing evaluation include: recycled content and recyclability; energy efficiency; and the presence of undesirable materials in the products, especially those toxic chemicals which are persistent and bio-accumulative. Bidders able to supply products containing recycled and environmentally preferable materials that meet performance requirements are encouraged to offer them in bids and proposals. Information on any relevant third party certification (such as Green Seal, Energy Star, etc.) should also be provided.

I. Recycled Content and Recyclability

A. Recycled Packaging. Contractor may offer some or all of the following items listed below or provide alternative proposal as to how packaging materials can be reduced, eliminated or otherwise made more environmentally preferable. It is desirable that Bidders offer packaging which:

- a. is made from recycled content which meets or exceeds all federal and state recycled content guidelines (currently 35% post-consumer for all corrugated cardboard)
- b. minimizes or eliminates the use of polystyrene or other difficult to recycle materials
- c. minimizes or eliminates the use packaging and containers and, in the alternative, minimizes or eliminates the use of non-recyclable packaging and containers
- d. provides for a return program where packaging can be returned to a specific location for recycling
- e. contains materials which are easily recyclable in Michigan.

Contractor has indicated below an estimate of the percentage of recycled materials, if any, contained in each



item bid. Higher percentages of recycled materials are preferred. Product performance is paramount, whether containing recycled material or not; however, preference will be given to products that perform up to specification and are environmentally preferable without compromising quality.

41% (Total estimated percentage of recovered material)

40% (Estimated percentage of post-consumer material)

n/a % (Estimated percentage of post-industrial waste)

Certification

I, Mike Golightly (name of certifier), am an officer or employee responsible for the performance of this contract and hereby certify that the percentage of recovered material content for EPA-designated products met the applicable contract specifications.

MG (Initial)

II. Materials Identification and Tracking

A. Hazardous Material Identification. 'Hazardous material', as used in this clause, includes any material defined as hazardous under the latest version of federal Emergency Planning and Community Right-to-Know Act of 1986 (including revisions adopted during the term of the contract).

(1) The Contractor must list any hazardous material, as defined in §370.20 (a) of 40 CFR, to be delivered under this contract. The hazardous material shall be properly identified and include any applicable identification number, such as National Stock Number or Special Item Number. This information shall also be included on the Material Safety Data Sheet submitted under this contract.

Material (if none, enter 'None')	Identification Number
None	

(2) This list must be updated during performance of the contract whenever the Contractor determines that any other material to be delivered under this contract is hazardous.

(3) The apparently successful bidder agrees to submit, for each item as required prior to award, a Material Safety Data Sheet for each hazardous material identified in paragraph (1) of this clause. Data shall be submitted in accordance with Section 312 of the federal Emergency Planning and Community Right-to-Know Act, whether or not the apparently successful bidder is the actual manufacturer of these items. Failure to submit the Material Safety Data Sheet prior to award may result in the apparently successful bidder being considered non-responsive and ineligible for award.

B. Mercury Content. It is the clear intent of state agencies to avoid purchasing products that contain intentionally-added mercury whenever possible. Bidders shall offer mercury-free product alternatives whenever available. Should mercury-free alternatives not exist, as presently is the case with a few select products and devices such as fluorescent lamps or where the alternative is not yet cost competitive, such as dental amalgam, bidders shall offer the lowest mercury content available for a given application. Bidders shall disclose whenever products contain added-mercury by using the following format.

() Product contains added-Mercury (attach an explanation that includes: the amount or concentration of mercury and justification as to why this particular product is essential).

In addition, the Bidder shall also ensure that all products to be purchased containing intentionally added-mercury shall be labeled as: "product contains mercury/recycle or dispose of properly." For instances where space constraints limit the amount or size of print, the chemical symbol "Hg" followed by a picture of a trash container with a diagonal line through it shall suffice for labeling requirements.

CONTRACTORS PLEASE NOTE: Michigan Law Prohibits the sale of mercury-containing thermostats, thermometers, sphygmomanometers (blood pressure monitors) and other types of medical devices. For



specific details visit: http://www.michigan.gov/deq/0,1607,7-135-3307_29693_4175-160230--,00.html

C. Brominated Flame Retardants (BFR). Contractor shall disclose whether the products being offered contain toxic flame retardants. Contractor is encouraged to provide BFR-free alternatives when available.

(X) Product does not contain BFR's

() Product does contain BFR's (attach an explanation)

D. Ozone Depleting Substances

'Ozone-depleting substance', as used in this clause, means any substance the Environmental Protection Agency designates in 40 CFR part 82 as:

(1) Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or

(2) Class II, including, but not limited to, hydrochlorofluorocarbons.

The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), and (d) and 40 CFR part 82, Subpart E, as follows:

'Warning: Contains (or manufactured with, if applicable) _____ (insert the name of the substance(s).), a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere.'

A. Clean Air and Water

Vendor certifies that any facility to be used in the performance of this contract has all the necessary environmental permits and is in consistent compliance with all applicable environmental requirements and has no outstanding unresolved violations.

The vendor will immediately notify the state, before award, of the receipt of any communication from the Environmental Protection Agency or any state environmental agency, of civil or criminal enforcement for any facility that the vendor proposes to use in the performance of this contract.

____JT____ (Initial)

B. Emergency Planning and Community Right-to-Know Reporting - By signing this offer, the bidder certifies that:

(1) The owner or operator of each facility that will be used in the performance of this contract is in compliance with the filing and reporting requirements described in sections 302, 304, 311, 312 and 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11001, et. seq.) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101, et. seq.). EPCRA filing and reporting requirements include emergency planning notification, release reporting, hazardous chemical inventory reporting, and toxic chemical release inventory (TRI) reporting.

(2) The owner or operator of each facility that will be used in the performance of this contract will maintain compliance with the filing and reporting requirements described in sections 302, 304, 311, 312 and 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11001, et. seq.) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101, et. seq.) for the life of the contract.

____JT____ (Initial)

1.0717 Subcontractors – Deleted, Not Applicable

**1.0718 Reports and Meetings**

Upon the State's request Contractor's Sales Representative will work with the State to provide any requested reports or meetings noted below.

- (a) Reports.
Within thirty (30) days after the Effective Date, the parties shall determine an appropriate set of periodic reports to be issued by Contractor to the State. Such reports may include:
- (i) separately address Contractor's performance in each area of the Services;
 - (ii) for each area of the Services, assess the degree to which Contractor has attained or failed to attain the pertinent objectives in that area, including on-time completion and delivery of Deliverables;
 - (iii) explain the reasons for any failure to achieve on-time completion and delivery of Deliverables and include a plan for corrective action where appropriate;
 - (iv) describe any circumstances that Contractor anticipates will impair or prevent on-time completion and delivery of Deliverables in upcoming reporting periods;
 - (v) include plans for corrective action or risk mitigation where appropriate and describe the status of ongoing problem resolution efforts;
 - (vi) provide reports setting forth a comparison of actual hours spent by Contractor (including its augmented personnel and Subcontractors) in performing the Project versus hours budgeted by Contractor.
 - (vii) set forth a record of the material personnel changes that pertain to the Services and describe planned changes during the upcoming month that may affect the Services.
 - (viii) include such documentation and other information may be mutually agreed to verify compliance with, and meeting the objectives of, this Contract.
 - (ix) set forth an updated schedule that provides information on the status of upcoming Deliverables, expected dates of delivery (or redelivery) of such Deliverables and estimates on timing for completion of the Project.
- (b) Meetings.
Within thirty (30) days after the Effective Date, the parties shall determine an appropriate set of meetings to be held between representatives of the State and Contractor. Contractor shall prepare and circulate an agenda sufficiently in advance of each such meeting to give participants an opportunity to prepare for the meeting. Contractor shall incorporate into such agenda items that the State desires to discuss. At the State's request, Contractor shall prepare and circulate minutes promptly after a meeting.

1.0719 Samples/Models - Deleted, Not Applicable**1.080 Additional Requirements****1.081 Product Returns for Molecular Diagnostics**

Please refer to Attachment B, Product Returns for Molecular Diagnostics.



Article 2, Terms and Conditions

2.000 Contract Structure and Term

2.001 Contract Term

This Contract is for a period of **three (3) years** beginning **September 1, 2009** through **August 31, 2012**. All outstanding Purchase Orders must also expire upon the termination (cancellation for any of the reasons listed in **Section 2.150**) of the Contract, unless otherwise extended under the Contract. Absent an early termination for any reason, Purchase Orders issued but not expired, by the end of the Contract's stated term, will remain in effect for the balance of the fiscal year for which they were issued.

2.002 Options to Renew

This Contract may be renewed in writing by mutual agreement of the parties not less than 30 days before its expiration. The Contract may be renewed for up to **two (2) additional one (1) year periods**.

2.003 Legal Effect

Contractor shall show acceptance of this Contract by signing two copies of the Contract and returning them to the Contract Administrator. The Contractor shall not proceed with the performance of the work to be done under the Contract, including the purchase of necessary materials, until both parties have signed the Contract to show acceptance of its terms, and the Contractor receives a contract release/purchase order that authorizes and defines specific performance requirements.

Except as otherwise agreed in writing by the parties, the State assumes no liability for costs incurred by Contractor or payment under this Contract, until Contractor is notified in writing that this Contract (or Change Order) has been approved by the State Administrative Board (if required), approved and signed by all the parties, and a Purchase Order against the Contract has been issued.

2.004 Attachments & Exhibits

All Attachments and Exhibits affixed to any and all Statement(s) of Work, or appended to or referencing this Contract, are incorporated in their entirety and form part of this Contract.

2.005 Ordering

The State will issue a written Purchase Order, Blanket Purchase Order, Direct Voucher or Procurement Card Order, which must be approved by the Contract Administrator or the Contract Administrator's designee, to order any Services/Deliverables under this Contract. All orders are subject to the terms and conditions of this Contract. No additional terms and conditions contained on either a Purchase Order or Blanket Purchase Order apply unless they are also specifically contained in that Purchase Order's or Blanket Purchase Order's accompanying Statement of Work. 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. Contractor shall provide all that the State requires.

2.006 Order of Precedence

(a) The Contract, including any Statements of Work and Exhibits, to the extent not contrary to the Contract, each of which is incorporated for all purposes, constitutes the entire agreement between the parties with respect to the subject matter and supersedes all prior agreements, whether written or oral, with respect to the subject matter and as additional terms and conditions on the purchase order must apply as limited by **Section 2.005**.

(b) In the event of any inconsistency between the terms of the Contract and a Statement of Work, the terms of the Statement of Work will take precedence (as to that Statement of Work only); provided, however, that a Statement of Work may not modify or amend the terms of the Contract, which may be modified or amended only by a formal Contract amendment.



2.007 Headings

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

2.008 Form, Function & Utility

If the Contract is for use of more than one State agency and if the Deliverable/Service does not meet the form, function, and utility required by that State agency, that agency may, subject to State purchasing policies, procure the Deliverable/Service from another source.

2.009 Reformation and Severability

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

2.010 Consents and Approvals

Except as expressly provided otherwise in the Contract, if either party requires the consent or approval of the other party for the taking of any action under the Contract, the consent or approval must be in writing and must not be unreasonably withheld or delayed.

2.011 No Waiver of Default

If a party fails to insist upon strict adherence to any term of the Contract then the party has not waived the right to later insist upon strict adherence to that term, or any other term, of the Contract.

2.012 Survival

Any provisions of the Contract that impose continuing obligations on the parties, including without limitation the parties' respective warranty, indemnity and confidentiality obligations, survive the expiration or termination of the Contract for any reason. Specific references to survival in the Contract are solely for identification purposes and not meant to limit or prevent the survival of any other section.

2.020 Contract Administration

2.021 Issuing Office

This Contract is issued by the Department of Management and Budget, Purchasing Operations and [Department of Community Health-Bureau of Laboratories \(DCH-BOL\)](#) (collectively, including all other relevant State of Michigan departments and agencies, the "State"). Purchasing Operations is the sole point of contact in the State with regard to all procurement and contractual matters relating to the Contract. Purchasing Operations **is the only State office authorized to change, modify, amend, alter or clarify the prices, specifications, terms and conditions of this Contract.** The Contractor Administrator within Purchasing Operations for this Contract is:

Sue Ciecwiwa, Buyer Specialist
Purchasing Operations
Department of Management and Budget
Mason Bldg, 2nd Floor
PO Box 30026
Lansing, MI 48909
Email: Ciecibas@michigan.gov
Phone: (517) 373-0301
Fax: (517) 335-0046

2.022 Contract Compliance Inspector (CCI)

After DMB-PurchOps receives the properly executed Contract, it is anticipated that the Director of Purchasing Operations, in consultation with DCH-BOL, will direct the person named below, or any other person so designated, to monitor and coordinate the activities for the Contract on a day-to-day basis during its term. However, monitoring of this Contract implies **no authority to change, modify, clarify, amend, or otherwise alter the prices, terms, conditions and specifications of the Contract as that authority is retained by DMB Purchasing Operations.** The Contract Compliance Inspector for this Contract is:



Deborah Stephens
Department of Community Health
Bureau of Laboratories
3350 N. Martin Luther King, Jr. Blvd.
Lansing, MI 48909
Email: StephensD@michigan.gov
Phone: 517-335-8098
Fax: 517-335-9631

2.023 Project Manager – Deleted, Not Applicable

2.024 Change Requests

The State reserves the right to request from time to time any changes to the requirements and specifications of the Contract and the work to be performed by the Contractor under the Contract. During the course of ordinary business, it may become necessary for the State to discontinue certain business practices or create Additional Services/Deliverables. At a minimum, to the extent applicable, the State would like the Contractor to provide a detailed outline of all work to be done, including tasks necessary to accomplish the services/deliverables, timeframes, listing of key personnel assigned, estimated hours for each individual per task, and a complete and detailed cost justification.

If the Contractor does not so notify the State, the Contractor has no right to claim thereafter that it is entitled to additional compensation for performing that service or providing that deliverable.

Change Requests:

- (a) By giving Contractor written notice within a reasonable time, the State must be entitled to accept a Contractor proposal for Change, to reject it, or to reach another agreement with Contractor. Should the parties agree on carrying out a Change, a written Contract Change Notice must be prepared and issued under this Contract, describing the Change and its effects on the Services and any affected components of this Contract (a "Contract Change Notice").
- (b) No proposed Change must be performed until the proposed Change has been specified in a duly executed Contract Change Notice issued by the Department of Management and Budget, Purchasing Operations.
- (c) If the State requests or directs the Contractor to perform any activities that Contractor believes constitute a Change, the Contractor must notify the State that it believes the requested activities are a Change before beginning to work on the requested activities. If the Contractor fails to notify the State before beginning to work on the requested activities, then the Contractor waives any right to assert any claim for additional compensation or time for performing the requested activities. If the Contractor commences performing work outside the scope of this Contract and then ceases performing that work, the Contractor must, at the request of the State, retract any out-of-scope work that would adversely affect the Contract.

2.025 Notices

Any notice given to a party under the Contract must be deemed effective, if addressed to the 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 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.

State:
State of Michigan
Purchasing Operations
Attention: Sue Cieciva
PO Box 30026
530 West Allegan
Lansing, Michigan 48909



Contractor:
Roche Diagnostics Corporation
Attn: Law Department
9115 Hague Road, P.O. Box 50457
Indianapolis, IN 46250-0457

Either party may change its address where notices are to be sent by giving notice according to this Section.

2.026 Binding Commitments

Representatives of Contractor must have the authority to make binding commitments on Contractor's behalf within the bounds set forth in the table. Contractor may change the representatives from time to time upon written notice.

2.027 Relationship of the Parties

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

2.028 Covenant of Good Faith

Each party must act reasonably and in good faith. Unless stated otherwise in the Contract, the parties will not unreasonably delay, condition or withhold the giving of any consent, decision or approval that is either requested or reasonably required of them in order for the other party to perform its responsibilities under the Contract.

2.029 Assignments

(a) Neither party may assign the Contract, or assign or delegate any of its duties or obligations under the Contract, to any other party (whether by operation of law or otherwise), without the prior written consent of the other party; provided, however, that the State may assign the Contract to any other State agency, department, division or department without the prior consent of Contractor and Contractor may assign the Contract to an affiliate so long as the affiliate is adequately capitalized and can provide adequate assurances that the affiliate can perform the Contract. The State may withhold consent from proposed assignments, subcontracts, or novations when the transfer of responsibility would operate to decrease the State's likelihood of receiving performance on the Contract or the State's ability to recover damages.

(b) Contractor may not, without the prior written approval of the State, assign its right to receive payments due under the Contract. If the State permits an assignment, the Contractor is not relieved of its responsibility to perform any of its contractual duties, and the requirement under the Contract that all payments must be made to one entity continues.

(c) If the Contractor intends to assign the contract or any of the Contractor's rights or duties under the Contract, the Contractor must notify the State in writing at least 90 days before the assignment. The Contractor also must provide the State with adequate information about the assignee within a reasonable amount of time before the assignment for the State to determine whether to approve the assignment.

2.030 General Provisions

2.031 Media Releases

News releases (including promotional literature and commercial advertisements) pertaining to the RFP 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 RFP and Contract are to be released without prior written approval of the State and then only to persons designated.

**2.032 Contract Distribution**

Purchasing Operations retains the sole right of Contract distribution to all State agencies and local units of government unless other arrangements are authorized by Purchasing Operations.

2.033 Permits

Contractor must obtain and pay any associated costs for all required governmental permits, licenses and approvals for the delivery, installation and performance of the Services. The State must pay for all costs and expenses incurred in obtaining and maintaining any necessary easements or right of way.

2.034 Website Incorporation

The State is not 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 the content and has expressly agreed to be bound by it in a writing that has been manually signed by an authorized representative of the State.

2.035 Future Bidding Preclusion

Contractor acknowledges that, to the extent this Contract involves the creation, research, investigation or generation of a future RFP, it may be precluded from bidding on the subsequent RFP. The State reserves the right to disqualify any bidder if the State determines that the bidder has used its position (whether as an incumbent Contractor, or as a Contractor hired to assist with the RFP development, or as a Vendor offering free assistance) to gain a competitive advantage on the RFP.

2.036 Freedom of Information

All information in any proposal submitted to the State by Contractor and this Contract is subject to the provisions of the Michigan Freedom of Information Act, 1976 Public Act No. 442, as amended, MCL 15.231, et seq (the "FOIA").

2.037 Disaster Recovery

Contractor and the State recognize that the State provides essential services in times of natural or man-made disasters. Therefore, except as so mandated by Federal disaster response requirements, Contractor personnel dedicated to providing Services/Deliverables under this Contract will provide the State with priority service for repair and work around in the event of a natural or man-made disaster.

2.040 Financial Provisions**2.041 Fixed Prices for Services/Deliverables - Deleted Not Applicable****2.042 Adjustments for Reductions in Scope of Services/Deliverables**

If the scope of the Services/Deliverables under any Statement of Work issued under this Contract is subsequently reduced by the State, the parties shall negotiate an equitable reduction in Contractor's charges under such Statement of Work commensurate with the reduction in scope.

2.043 Services/Deliverables Covered

For all Services/Deliverables to be provided by Contractor (and its Subcontractors, if any) under this Contract, the State shall not be obligated to pay any amounts in addition to the charges specified in this Contract.

2.044 Invoicing and Payment – In General

Contractor will begin billing the State for all Products (other than Contractor installed Equipment) upon delivery of the Products. If Contractor installed Equipment is listed on a Contract, Contractor will begin billing the State for the Equipment on the applicable Commencement Date. Contractor will provide the State with payment terms of net thirty (30) days from the date of invoice. Failure to pay invoices when due may result in non-shipment of all future orders of products that the State may purchase from Contractor or the State being notified by Contractor that the State is in default.

2.045 Pro-ration - Deleted Not Applicable

**2.046 Antitrust Assignment**

The Contractor assigns to the State any claim for overcharges resulting from antitrust violations to the extent that those violations concern materials or services supplied by third parties to the Contractor, toward fulfillment of this Contract.

2.047 Final Payment

The making of final payment by the State to Contractor does not constitute a waiver by either party of any rights or other claims as to the other party's continuing obligations under the Contract, nor will it constitute a waiver of any claims by one party against the other arising from unsettled claims or failure by a party to comply with this Contract, including claims for Services and Deliverables not reasonably known until after acceptance to be defective or substandard. Contractor's acceptance of final payment by the State under this Contract shall constitute a waiver of all claims by Contractor against the State for payment under this Contract, other than those claims previously filed in writing on a timely basis and still unsettled.

2.048 Electronic Payment Requirement

Electronic transfer of funds is required for payments on State Contracts. Contractors are required to register with the State electronically at <http://www.cpexpress.state.mi.us>. As stated in Public Act 431 of 1984, all contracts that the State enters into for the purchase of goods and services shall provide that payment will be made by electronic fund transfer (EFT). Remittance information will be included in EFT payment and will be in CTX format.

2.050 Taxes**2.051 Employment Taxes**

Contractors are expected to collect and pay all applicable federal, state, and local employment taxes, including the taxes.

2.052 Sales and Use Taxes

Contractors are required to be registered and to remit sales and use taxes on taxable sales of tangible personal property or services delivered into the State. Contractors that lack sufficient presence in Michigan to be required to register and pay tax must do so as a volunteer. This requirement extends to: (1) all members of any controlled group as defined in § 1563(a) of the Internal Revenue Code and applicable regulations of which the company is a member, and (2) all organizations under common control as defined in § 414(c) of the Internal Revenue Code and applicable regulations of which the company is a member that make sales at retail for delivery into the State are registered with the State for the collection and remittance of sales and use taxes. In applying treasury regulations defining "two or more trades or businesses under common control" the term "organization" means sole proprietorship, a partnership (as defined in § 701(a)(2) of the Internal Revenue Code), a trust, an estate, a corporation, or a limited liability company.

2.060 Contract Management**2.061 Contractor Personnel Qualifications**

All persons assigned by Contractor to the performance of Services under this Contract must be employees of Contractor or its majority-owned (directly or indirectly, at any tier) subsidiaries (or a State-approved Subcontractor) and must be fully qualified to perform the work assigned to them. Contractor must include a similar provision in any subcontract entered into with a Subcontractor. For the purposes of this Contract, independent contractors engaged by Contractor solely in a staff augmentation role must be treated by the State as if they were employees of Contractor for this Contract only; however, the State understands that the relationship between Contractor and Subcontractor is an independent contractor relationship.

2.062 Contractor Key Personnel

- (a) The Contractor must provide the Contract Compliance Inspector with the names of the Key Personnel.
- (b) Key Personnel must be dedicated as defined in the Statement of Work to the Project for its duration in the applicable Statement of Work with respect to other individuals designated as Key Personnel for that Statement of Work.



(c) The State will have the right to recommend and approve in writing the initial assignment, as well as any proposed reassignment or replacement, of any Key Personnel. Before assigning an individual to any Key Personnel position, Contractor will notify the State of the proposed assignment, will introduce the individual to the appropriate State representatives, and will provide the State with a resume and any other information about the individual reasonably requested by the State. The State reserves the right to interview the individual before granting written approval. In the event the State finds a proposed individual unacceptable, the State will provide a written explanation including reasonable detail outlining the reasons for the rejection.

(d) Contractor must not remove any Key Personnel from their assigned roles on the Contract without the prior written consent of the State. The Contractor's removal of Key Personnel without the prior written consent of the State is an unauthorized removal ("Unauthorized Removal"). Unauthorized Removals does not include replacing Key Personnel for reasons beyond the reasonable control of Contractor, including illness, disability, leave of absence, personal emergency circumstances, resignation or for cause termination of the Key Personnel's employment. Unauthorized Removals does not include replacing Key Personnel because of promotions or other job movements allowed by Contractor personnel policies or Collective Bargaining Agreement(s) as long as the State receives prior written notice before shadowing occurs and Contractor provides 30 days of shadowing unless parties agree to a different time period. The Contractor with the State must review any Key Personnel replacements, and appropriate transition planning will be established. Any Unauthorized Removal may be considered by the State to be a material breach of the Contract, in respect of which the State may elect to exercise its termination and cancellation rights.

(e) The Contractor must notify the Contract Compliance Inspector and the Contract Administrator at least 10 business days before redeploying non-Key Personnel, who are dedicated to primarily to the Project, to other projects. If the State does not object to the redeployment by its scheduled date, the Contractor may then redeploy the non-Key Personnel.

2.063 Re-assignment of Personnel at the State's Request

The State reserves the right to require the removal from the Project of Contractor personnel found, in the judgment of the State, to be unacceptable. The State's request must be written with reasonable detail outlining the reasons for the removal request. Additionally, the State's request must be based on legitimate, good-faith reasons. Replacement personnel for the removed person must be fully qualified for the position. If the State exercises this right, and the Contractor cannot immediately replace the removed personnel, the State agrees to an equitable adjustment in schedule or other terms that may be affected by the State's required removal. If any incident with removed personnel results in delay not reasonably anticipatable under the circumstances and which is attributable to the State, the applicable SLAs for the affected Service will not be counted for a time as agreed to by the parties.

2.064 Contractor Personnel Location

All staff assigned by Contractor to work on the Contract will perform their duties either primarily at Contractor's offices and facilities or at State facilities. Without limiting the generality of the foregoing, Key Personnel will, at a minimum, spend at least the amount of time on-site at State facilities as indicated in the applicable Statement of Work. Subject to availability, selected Contractor personnel may be assigned office space to be shared with State personnel.

2.065 Contractor Identification

Contractor employees must be clearly identifiable while on State property by wearing a State-issued badge, as required. Contractor employees are required to clearly identify themselves and the company they work for whenever making contact with State personnel by telephone or other means.

2.066 Cooperation with Third Parties

Contractor agrees to cause its personnel and the personnel of any Subcontractors to cooperate with the State and its agents and other contractors including the State's Quality Assurance personnel. As reasonably requested by the State in writing, the Contractor will provide to the State's agents and other contractors reasonable access to Contractor's Project personnel, systems and facilities to the extent the access relates to activities specifically associated with this Contract and will not interfere or jeopardize the safety or operation of the systems or facilities. The State acknowledges that Contractor's time schedule for the Contract is very



specific and agrees not to unnecessarily or unreasonably interfere with, delay or otherwise impeded Contractor's performance under this Contract with the requests for access.

2.067 Contract Management 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 the anticipated Contract. If any part of the work is to be subcontracted, the 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 the Contract. Any change in subcontractors must be approved by the State, in writing, prior to such change.

2.068 Contractor Return of State Equipment/Resources

The Contractor must return to the State any State-furnished equipment, facilities and other resources when no longer required for the Contract in the same condition as when provided by the State, reasonable wear and tear excepted.

2.070 Subcontracting by Contractor

2.071 Contractor full Responsibility

Contractor shall have full responsibility for the successful performance and completion of all of the Services and Deliverables. The State will consider Contractor to be the sole point of contact with regard to all contractual matters under this Contract, including payment of any and all charges for Services and Deliverables.

2.072 State Consent to delegation

Contractor shall not delegate any duties under this Contract to a Subcontractor unless the Department of Management and Budget, Purchasing Operations has given written consent to such delegation. The State shall have the right of prior written approval of all Subcontractors and to require Contractor to replace any Subcontractors found, in the reasonable judgment of the State, to be unacceptable. The State's request shall be written with reasonable detail outlining the reasons for the removal request. Additionally, the State's request shall be based on legitimate, good-faith reasons. Replacement Subcontractor(s) for the removed Subcontractor shall be fully qualified for the position. If the State exercises this right, and the Contractor cannot immediately replace the removed Subcontractor, the State will agree to an equitable adjustment in schedule or other terms that may be affected by the State's required removal. If any such incident with a removed Subcontractor results in delay not reasonable anticipatable under the circumstances and which is attributable to the State, the applicable SLA for the affected Work will not be counted in time agreed upon by the parties.

2.073 Subcontractor bound to Contract

In any subcontracts entered into by Contractor for the performance of the Services, Contractor shall require the Subcontractor, to the extent of the Services to be performed by the Subcontractor, to be bound to Contractor by the terms of this Contract and to assume toward Contractor all of the obligations and responsibilities that Contractor, by this Contract, assumes toward the State. The State reserves the right to receive copies of and review all subcontracts, although Contractor may delete or mask any proprietary information, including pricing, contained in such contracts before providing them to the State. The management of any Subcontractor will be the responsibility of Contractor, and Contractor shall remain responsible for the performance of its Subcontractors to the same extent as if Contractor had not subcontracted such performance. Contractor shall make all payments to Subcontractors or suppliers of Contractor. Except as otherwise agreed in writing by the State and Contractor, the State will not be obligated to direct payments for the Services other than to Contractor. The State's written approval of any Subcontractor engaged by Contractor to perform any obligation under this Contract shall not relieve Contractor of any obligations or performance required under this Contract. Attached as **Exhibit A** is a list of the Subcontractors, if any, approved by the State as of the execution of this Contract, together with a copy of the applicable subcontract.

**2.074 Flow Down**

Except where specifically approved in writing by the State on a case-by-case basis, Contractor shall flow down the obligations in **Sections 2.031, 2.060, 2.100, 2.110, 2.120, 2.130, 2.200** in all of its agreements with any Subcontractors.

2.075 Competitive Selection

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.

2.080 State Responsibilities**2.081 Equipment**

The State will provide only the equipment and resources identified in the Statements of Work and other Contract Exhibits.

2.082 Facilities

The State must designate space as long as it is available and as provided in the Statement of Work, to house the Contractor's personnel whom the parties agree will perform the Services/Deliverables at State facilities (collectively, the "State Facilities"). The Contractor must have reasonable access to, and unless agreed otherwise by the parties in writing must observe and comply with all rules and regulations relating to each of the State Facilities (including hours of operation) used by the Contractor in the course of providing the Services. Contractor agrees that it will not, without the prior written consent of the State, use any State Facilities or access any State information systems provided for the Contractor's use, or to which the Contractor otherwise gains access in the course of performing the Services, for any purpose other than providing the Services to the State.

2.090 Security**2.091 Background Checks**

On a case-by-case basis, the State may investigate the Contractor's personnel before they may have access to State facilities and systems. The scope of the background check is at the discretion of the State and the results will be used to determine Contractor personnel eligibility for working within State facilities and systems. The investigations will include Michigan State Police Background checks (ICHAT) and may include the National Crime Information Center (NCIC) Finger Prints. Proposed Contractor personnel may be required to complete and submit an RI-8 Fingerprint Card for the NCIC Finger Print Check. Any request for background checks will be initiated by the State and will be reasonably related to the type of work requested.

All Contractor personnel will also be expected to comply with the State's security and acceptable use policies for State IT equipment and resources. See <http://www.michigan.gov/dit>. Furthermore, Contractor personnel will be expected to agree to the State's security and acceptable use policies before the Contractor personnel will be accepted as a resource to perform work for the State. It is expected the Contractor will present these documents to the prospective employee before the Contractor presents the individual to the State as a proposed resource. Contractor staff will be expected to comply with all Physical Security procedures in place within the facilities where they are working.

2.092 Security Breach Notification

If the Contractor breaches this Section, the Contractor must (i) promptly cure any deficiencies and (ii) comply with any applicable federal and state laws and regulations pertaining to unauthorized disclosures. Contractor and the State will cooperate to mitigate, to the extent practicable, the effects of any breach, intrusion, or unauthorized use or disclosure. Contractor must report to the State in writing any use or disclosure of Confidential Information, whether suspected or actual, other than as provided for by the Contract within 10 days of becoming aware of the use or disclosure or the shorter time period as is reasonable under the circumstances.



2.093 PCI Data Security Requirements – Deleted, Not Applicable

2.100 Confidentiality

2.101 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 must mean all non-public proprietary information of Contractor (other than Confidential Information of the State as defined below) which is marked confidential, restricted, proprietary or with a similar designation. “Confidential Information” of the State must mean any information which is retained in confidence by the State (or otherwise required to be held in confidence by the State under applicable federal, state and local laws and regulations) or which, in the case of tangible materials provided to Contractor by the State under its performance under this Contract, is marked as confidential, proprietary or with a similar designation by the State. “Confidential Information” excludes any information (including this Contract) that is publicly available under the Michigan FOIA.

2.102 Protection and Destruction of Confidential Information

The State and Contractor will each use at least the same degree of care to prevent disclosing 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 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) the disclosure is necessary or otherwise naturally occurs in connection with work that is within the 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 the Confidential Information from unauthorized use or disclosure.

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

2.103 Exclusions

Notwithstanding the foregoing, the provisions of **Section 2.100** 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 the 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 **Section 2.100** will not apply to any particular Confidential Information to the extent the receiving party is required by law to disclose the 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 the disclosure as reasonably requested by the furnishing party.

2.104 No Implied Rights

Nothing contained in this Section must 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.



2.105 Respective Obligations

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

2.110 Records and Inspections

2.111 Inspection of Work Performed

The State's authorized representatives must at all reasonable times and with 10 days prior written request, have the right to enter Contractor's premises, or any other places, where the Services are being performed, and must have access, upon reasonable request, to interim drafts of Deliverables or work-in-progress. Upon 10 Days prior written notice and at all reasonable times, the State's representatives must be allowed to inspect, monitor, or otherwise evaluate the work being performed and to the extent that the access will not reasonably interfere or jeopardize the safety or operation of the systems or facilities. Contractor must provide all reasonable facilities and assistance for the State's representatives.

2.112 Examination of Records

For seven years after the Contractor provides any work under this Contract (the "Audit Period"), the State may examine and copy any of Contractor's books, records, documents and papers pertinent to establishing Contractor's compliance with the Contract and with applicable laws and rules. The State must notify the Contractor 20 days before examining the Contractor's books and records. The State does not have the right to review any information deemed confidential by the Contractor to the extent access would require the confidential information to become publicly available. This provision also applies to the books, records, accounts, documents and papers, in print or electronic form, of any parent, affiliated or subsidiary organization of Contractor, or any Subcontractor of Contractor performing services in connection with the Contract.

2.113 Retention of Records

Contractor must maintain at least until the end of the Audit Period all pertinent financial and accounting records (including time sheets and payroll records, and information pertaining to the Contract and to the Services, equipment, and commodities provided under the Contract) pertaining to the Contract according to generally accepted accounting principles and other procedures specified in this Section. Financial and accounting records must be made available, upon 20 days advance request, to the State at any time during the Audit Period. If an audit, litigation, or other action involving Contractor's records is initiated before the end of the Audit Period, the records must be retained until all issues arising out of the audit, litigation, or other action are resolved or until the end of the Audit Period, whichever is later.

2.114 Audit Resolution

If necessary, the Contractor and the State will meet to review each audit report promptly after issuance. The Contractor will respond to each audit report in writing within 30 days from receipt of the report, unless a shorter response time is specified in the report. The Contractor and the State must develop, agree upon and monitor an action plan to promptly address and resolve any deficiencies, concerns, and/or recommendations in the audit report.

2.115 Errors

(a) If the audit demonstrates any errors in the documents provided to the State, then the amount in error must be reflected as a credit or debit on the next invoice and in subsequent invoices until the amount is paid or refunded in full. However, a credit or debit may not be carried for more than four invoices. If a balance remains after four invoices, then the remaining amount will be due as a payment or refund within 45 days of the last quarterly invoice that the balance appeared on or termination of the contract, whichever is earlier.

2.120 Warranties

2.121 Warranties and Representations

The Contractor represents and warrants:



- (a) It is capable in all respects of fulfilling and must fulfill all of its obligations under this Contract. The performance of all obligations under this Contract must be provided in a timely, professional, and workman-like manner and must meet the performance and operational standards required under this Contract.
- (b) The Contract Appendices, Attachments and Exhibits identify the equipment and software and services necessary for the Deliverable(s) to perform and Services to operate in compliance with the Contract's requirements and other standards of performance.
- (c) It 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 licensed use, as applicable, of any and all Deliverables. None of the Deliverables provided by Contractor to the State under this Contract, nor their use by the State, will infringe the patent, copyright, trade secret, or other proprietary rights of any third party.
- (d) 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 the items in this Contract, Contractor must assign or otherwise transfer to the State or its designees, or afford the State the benefits of, any manufacturer's warranty for the Deliverable.
- (e) The contract signatory has the power and authority, including any necessary corporate authorizations, necessary to enter into this Contract, on behalf of Contractor.
- (f) It is qualified and registered to transact business in all locations where required.
- (g) Neither the Contractor nor any Affiliates, nor any employee of either, has, must have, or must 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 must notify the State about the nature of the conflict or appearance of impropriety within two days of learning about it.
- (h) Neither Contractor nor any Affiliates, nor any employee of either has accepted or must accept anything of value based on an understanding that the actions of the Contractor or Affiliates or employee on behalf of the State would be influenced. Contractor must not attempt to influence any State employee by the direct or indirect offer of anything of value.
- (i) Neither Contractor nor any Affiliates, nor any employee of either has paid or agreed to pay any person, other than bona fide employees and consultants working solely for Contractor or the Affiliate, any fee, commission, percentage, brokerage fee, gift, or any other consideration, contingent upon or resulting from the award or making of this Contract.
- (j) The prices proposed by Contractor were arrived at independently, without consultation, communication, or agreement with any other bidder for the purpose of restricting competition; the prices quoted were not knowingly disclosed by Contractor to any other bidder; and no attempt was made by Contractor to induce any other person to submit or not submit a proposal for the purpose of restricting competition.
- (k) All financial statements, reports, and other information furnished by Contractor to the State as part of its response to the RFP 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 the financial statements, reports, other information. Since the respective dates or periods covered by the financial statements, reports, or other information, there have been no material adverse change in the business, properties, financial condition, or results of operations of Contractor.



(l) All written information furnished to the State by or for the 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 the information not misleading.

(m) It is not in material default or breach of any other contract or agreement that it may have with the State or any of its departments, commissions, boards, or agencies. Contractor further represents and warrants that it has not been a party to any contract with the State or any of its departments that was terminated by the State or the department within the previous five years for the reason that Contractor failed to perform or otherwise breached an obligation of the contract.

(n) If any of the certifications, representations, or disclosures made in the Contractor's original bid response change after contract award, the Contractor is required to report those changes immediately to the Department of Management and Budget, Purchasing Operations.

2.122 Warranty of Merchantability

Goods provided by Contractor under this agreement shall be merchantable. All goods provided under this Contract shall be of good quality within the description given by the State, shall be fit for their ordinary purpose, shall be adequately contained and packaged within the description given by the State, shall conform to the agreed upon specifications, and shall conform to the affirmations of fact made by the Contractor or on the container or label.

2.123 Warranty of Fitness for a Particular Purpose

When the Contractor has reason to know or knows any particular purpose for which the goods are required, and the State is relying on the Contractor's skill or judgment to select or furnish suitable goods, there is a warranty that the goods are fit for such purpose.

2.124 Warranty of Title

Contractor shall, in providing goods to the State, convey good title in those goods, whose transfer is right and lawful. All goods provided by Contractor shall be delivered free from any security interest, lien, or encumbrance of which the State, at the time of contracting, has no knowledge. Goods provided by Contractor, under this Contract, shall be delivered free of any rightful claim of any third person by or infringement or the like.

2.125 Equipment Warranty

To the extent Contractor is responsible under this Contract for maintaining equipment/system(s), Contractor represents and warrants that it will maintain the equipment/system(s) in good operating condition and will undertake all repairs and preventive maintenance according to the applicable manufacturer's recommendations for the period specified in this Contract.

The Contractor represents and warrants that the equipment/system(s) are in good operating condition and operate and perform to the requirements and other standards of performance contained in this Contract, when installed, at the time of Final Acceptance by the State, and for a period of **one year** commencing upon the first day following Final Acceptance.

Within **three (3) business days** of notification from the State, the Contractor must adjust, repair or replace all equipment that is defective or not performing in compliance with the Contract. The Contractor must assume all costs for replacing parts or units and their installation including transportation and delivery fees, if any.

The Contractor must provide a toll-free telephone number to allow the State to report equipment failures and problems to be remedied by the Contractor.

The Contractor agrees that all warranty service it provides under this Contract must be performed by Original Equipment Manufacturer (OEM) trained, certified and authorized technicians.



The Contractor is the sole point of contact for warranty service. The Contractor warrants that it will pass through to the State any warranties obtained or available from the original equipment manufacturer, including any replacement, upgraded, or additional equipment warranties.

All warranty work must be performed on the State of Michigan worksite(s).

2.126 Equipment to be New

If applicable, all equipment provided under this Contract by Contractor shall be new where Contractor has knowledge regarding whether the equipment is new or assembled from new or serviceable used parts that are like new in performance or has the option of selecting one or the other. Equipment that is assembled from new or serviceable used parts that are like new in performance is acceptable where Contractor does not have knowledge or the ability to select one or other, unless specifically agreed otherwise in writing by the State.

2.127 Prohibited Products

The State will not accept salvage, distressed, outdated or discontinued merchandise. Shipping of such merchandise to any State agency, as a result of an order placed against the Contract, shall be considered default by the Contractor of the terms and conditions of the Contract and may result in cancellation of the Contract by the State. The brand and product number offered for all items shall remain consistent for the term of the Contract, unless Purchasing Operations has approved a change order pursuant to **Section 2.024**.

2.128 Consequences For Breach

In addition to any remedies available in law, if the Contractor breaches any of the warranties contained in this section, the breach may be considered as a default in the performance of a material obligation of this Contract.

2.130 Insurance

2.131 Liability Insurance

The Contractor must provide proof of the minimum levels of insurance coverage as indicated below. The insurance must 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 the 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.

Contractor may be allowed the use of self-insurance for any of the coverages listed provided that the self-insurance meets any applicable state laws and regulations, and Contractor provides evidence that their self-insurance program is fully funded. The state reserves the sole right to allow or disallow the use of self-insurance through its own discretion at any time.

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 under this Contract.

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

The insurance must 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 must have an A.M. Best rating of A or better, or as otherwise approved in writing by the State, or if the ratings are no longer available, with a comparable rating from a recognized insurance rating agency. All policies of insurance required in this Contract must be issued by companies that have been approved to do business in the State.

See www.michigan.gov/dleg.



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

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

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 according to applicable laws governing the employees and employers work activities in the state of the Contractor's domicile. If the applicable coverage is provided by a self-insurer, 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 must 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 must 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 the office space, including without limitation, those contents used by Contractor to provide the Services to the State, up to its replacement value, where the office space and its contents are under the care, custody and control of Contractor. The policy must 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 must be endorsed on the policy as a loss payee as its interests appear.

2.132 Subcontractor Insurance Coverage

Except where the State has approved in writing a Contractor subcontract with other insurance provisions, Contractor must 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) must 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.

2.133 Certificates of Insurance and Other Requirements

Contractor must furnish to DMB-PurchOps, certificate(s) of insurance verifying insurance coverage or providing satisfactory evidence of self-insurance as required in this Section (the "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) must contain a provision indicating that coverages afforded under the policies WILL NOT BE CANCELLED, MATERIALLY CHANGED, OR NOT RENEWED without 30 days prior written notice, except for 10 days for non-payment of premium, having been given to the Director of Purchasing Operations, Department of Management and Budget. The notice must include the Contract or Purchase Order number affected. Before the Contract is signed, and not less than 20 days before the insurance expiration date every year thereafter, the Contractor must provide evidence that the State and its agents, officers and employees are listed as additional insureds 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.

The Contractor must maintain all required insurance coverage throughout the term of the Contract and any extensions and, in the case of claims-made Commercial General Liability policies, must secure tail coverage for at least three years following the expiration or termination for any reason of this Contract. The minimum limits of coverage specified above are not intended, and must not be construed, to limit any liability or indemnity of Contractor under this Contract to any indemnified party or other persons. Contractor is responsible for all deductibles with regard to the insurance. If the 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, then the State may, after the State has given the Contractor at least 30 days written notice, pay the premium or procure similar insurance coverage from another company or companies. The State may deduct any part of the cost from any payment due the Contractor, or the Contractor must pay that cost upon demand by the State.

2.140 Indemnification

2.141 General Indemnification

To the extent permitted by law, the Contractor must indemnify, defend and hold harmless the State from liability, including all claims and losses, and all related costs and expenses (including reasonable attorneys' fees and costs of investigation, litigation, settlement, judgments, interest and penalties), accruing or resulting to any person, firm or corporation that may be injured or damaged by the Contractor in the performance of this Contract and that are attributable to the negligence or tortious acts of the Contractor or any of its subcontractors, or by anyone else for whose acts any of them may be liable.



2.142 Code Indemnification – Deleted, Not Applicable

2.143 Employee Indemnification

In any claims against the State of Michigan, its departments, divisions, agencies, sections, commissions, officers, employees and agents, by any employee of the Contractor or any of its subcontractors, the indemnification obligation under the Contract must not be limited in any way by the amount or type of damages, compensation or benefits payable by or for the Contractor or any of its subcontractors under worker's disability compensation acts, disability benefit acts or other employee benefit acts. This indemnification clause is intended to be comprehensive. Any overlap in provisions, 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 provisions.

2.144 Patent/Copyright Infringement Indemnification

To the extent permitted by law, the Contractor must indemnify, defend and hold harmless the State from and against all losses, liabilities, damages (including taxes), and all related costs and expenses (including reasonable attorneys' fees 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 the 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 the equipment, software, commodity or service, or the use or reproduction of any documentation provided with the equipment, software, commodity or service infringes any United States patent, copyright, trademark or trade secret of any person or entity, which is enforceable under the laws of the United States.

Notwithstanding the foregoing, the Contractor has no obligation to indemnify or defend the State for, or to pay any costs, damages or attorneys' fees related to, any claim based upon (i) equipment developed based on written specifications of the State; (ii) use of the equipment in a configuration other than implemented or approved in writing by the Contractor, including, but not limited to, any modification of the equipment by the State; or (iii) the combination, operation, or use of the equipment with equipment or software not supplied by the Contractor under this Contract.

2.145 Continuation of Indemnification Obligations

The Contractor's duty to indemnify under this Section continues in full force and effect, notwithstanding the expiration or early cancellation of the Contract, with respect to any claims based on facts or conditions that occurred before expiration or cancellation.

2.146 Indemnification Procedures

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

(a) After the State receives notice of the action or proceeding involving a claim for which it will seek indemnification, the State must promptly notify Contractor of the 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 notify the Contractor relieves the Contractor of its indemnification obligations except to the extent that the Contractor can prove damages attributable to the failure. Within 10 business days following receipt of written notice from the State relating to any claim, the Contractor must 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 before the State receiving Contractor's Notice of Election, the State is entitled to defend against the claim, at the Contractor's expense, and the Contractor will be responsible for any reasonable costs incurred by the State in defending against the claim during that period.

(b) If Contractor delivers a Notice of Election relating to any claim: (i) the State is entitled to participate in the defense of the claim and to employ counsel at its own expense to assist in the handling of the claim and to monitor and advise the State about the status and progress of the defense; (ii) the Contractor must, at the request of the State, demonstrate to the reasonable satisfaction of the State, the Contractor's financial ability to carry out its defense and indemnity obligations under this Contract; (iii) the Contractor must periodically advise the State about the status and progress of the defense and must obtain the prior written approval of the State



before entering into any settlement of the claim or ceasing to defend against the claim and (iv) to the extent that any principles of Michigan governmental or public law may be involved or challenged, the State has the right, at its own expense, to control the defense of that portion of the claim involving the principles of Michigan governmental or public law. But the State may retain control of the defense and settlement of a claim by notifying the Contractor in writing within 10 days after the State's receipt of Contractor's information requested by the State under clause (ii) of this paragraph if the State determines that the Contractor has failed to demonstrate to the reasonable satisfaction of the State the Contractor's financial ability to carry out its defense and indemnity obligations under this Section. Any litigation activity on behalf of the State, or any of its subdivisions under this Section, must be coordinated with the Department of Attorney General. In the event the insurer's attorney represents the State under 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 may defend the claim in the 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 must promptly reimburse the State for all the reasonable costs and expenses.

2.150 Termination/Cancellation

2.151 Notice and Right to Cure

If the Contractor breaches the contract, and the State in its sole discretion determines that the breach is curable, then the State will provide the Contractor with written notice of the breach and a time period (not less than 30 days) to cure the Breach. The notice of breach and opportunity to cure is inapplicable for successive or repeated breaches 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.

2.152 Termination for Cause

(a) The State may terminate this contract, for cause, by notifying the Contractor in writing, if the Contractor (i) breaches any of its material duties or obligations under this Contract (including a Chronic Failure to meet any particular SLA), or (ii) fails to cure a breach within the time period specified in the written notice of breach provided by the State

(b) If this Contract is terminated for cause, the Contractor must pay all costs incurred by the State in terminating this Contract, including but not limited to, State administrative costs, reasonable attorneys' fees and court costs, and any reasonable additional costs the State may incur to procure the Services/Deliverables required by this Contract from other sources. Re-procurement costs are not consequential, indirect or incidental damages, and cannot be excluded by any other terms otherwise included in this Contract, provided the costs are not in excess of 50% more than the prices for the Service/Deliverables provided under this Contract.

(c) If the State chooses to partially terminate this Contract for cause, charges payable under this Contract will be equitably adjusted to reflect those Services/Deliverables that are terminated and the State must pay for all Services/Deliverables for which Final Acceptance has been granted provided up to the termination date. Services and related provisions of this Contract that are terminated for cause must cease on the effective date of the termination.

(d) If the State terminates this Contract for cause under this Section, and it is determined, for any reason, that Contractor was not in breach of contract under the provisions of this section, that termination for cause must be deemed to have been a termination for convenience, effective as of the same date, and the rights and obligations of the parties must be limited to that otherwise provided in this Contract for a termination for convenience.



2.153 Termination for Convenience

The State may terminate this Contract for its convenience, in whole or part, if the State determines that a termination is in the State's best interest. Reasons for the termination must be left to the sole discretion of the State and may include, but not necessarily be limited to (a) the State no longer needs the Services or products specified in the Contract, (b) relocation of office, program changes, changes in laws, rules, or regulations make implementation of the Services no longer practical or feasible, (c) unacceptable prices for Additional Services or New Work requested by the State, or (d) falsification or misrepresentation, by inclusion or non-inclusion, of information material to a response to any RFP issued by the State. The State may terminate this Contract for its convenience, in whole or in part, by giving Contractor written notice at least 30 days before the date of termination. If the State chooses to terminate this Contract in part, the charges payable under this Contract must be equitably adjusted to reflect those Services/Deliverables that are terminated. Services and related provisions of this Contract that are terminated for cause must cease on the effective date of the termination.

2.154 Termination for Non-Appropriation

(a) 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 Contract. If funds to enable the State to effect continued payment under this Contract are not appropriated or otherwise made available, the State must terminate this Contract and all affected Statements of Work, in whole or in part, at the end of the last period for which funds have been appropriated or otherwise made available by giving written notice of termination to Contractor. The State must give Contractor at least 30 days advance written notice of termination for non-appropriation or unavailability (or the time as is available if the State receives notice of the final decision less than 30 days before the funding cutoff).

(b) If funding for the Contract is reduced by law, or funds to pay Contractor for the agreed-to level of the Services or production of Deliverables to be provided by Contractor are not appropriated or otherwise unavailable, the State may, upon 30 days written notice to Contractor, reduce the level of the Services or the change the production of Deliverables in the manner and for the periods of time as the State may elect. The charges payable under this Contract will be equitably adjusted to reflect any equipment, services or commodities not provided by reason of the reduction.

(c) If the State terminates this Contract, eliminates certain Deliverables, or reduces the level of Services to be provided by Contractor under this Section, the State must pay Contractor for all Work-in-Process performed through the effective date of the termination or reduction in level, as the case may be and as determined by the State, to the extent funds are available. This Section will not preclude Contractor from reducing or stopping Services/Deliverables or raising against the State in a court of competent jurisdiction, any claim for a shortfall in payment for Services performed or Deliverables finally accepted before the effective date of termination.

2.155 Termination for Criminal Conviction

The State may terminate this Contract immediately and without further liability or penalty in the event Contractor, an officer of Contractor, or an owner of a 25% or greater share of Contractor is convicted of a criminal offense related to a State, public or private Contract or subcontract.

2.156 Termination for Approvals Rescinded

The State may terminate this Contract if any final administrative or judicial decision or adjudication disapproves a previously approved request for purchase of personal services under Constitution 1963, Article 11, § 5, and Civil Service Rule 7-1. In that case, the State will pay the Contractor for only the work completed to that point under the Contract. 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 the written notice.

2.157 Rights and Obligations upon Termination

(a) If the State terminates this Contract for any reason, the Contractor must (a) stop all work as specified in the notice of termination, (b) take any action that may be necessary, or that the State may direct, for preservation and protection of Deliverables or other property derived or resulting from this Contract that may be in Contractor's possession, Contractor may immediately enter the State premises to retake possession of the Equipment without the order of any court, but without causing any breach of peace, require the State pay for the pro rata remaining value of any products and associated Discounts provided as "included", Contractor



may exercise any and all other remedies available at law or in equity, (c) return all materials and property provided directly or indirectly to Contractor by any entity, agent or employee of the State, (d) transfer title in, and deliver to, the State, unless otherwise directed, all Deliverables intended to be transferred to the State at the termination of the Contract and which are resulting from the Contract (which must be provided to the State on an "As-Is" basis except to the extent the amounts paid by the State in respect of the items included compensation to Contractor for the provision of warranty services in respect of the materials), and (e) take any action to mitigate and limit any potential damages, or requests for Contractor adjustment or termination settlement costs, to the maximum practical extent, including terminating or limiting as otherwise applicable those subcontracts and outstanding orders for material and supplies resulting from the terminated Contract.

(b) If the State terminates this Contract before its expiration for its own convenience, the State must pay Contractor for all charges due for Services provided before the date of termination and, if applicable, as a separate item of payment under this Contract, for Work In Process, on a percentage of completion basis at the level of completion determined by the State. All completed or partially completed Deliverables prepared by Contractor under this Contract, at the option of the State, becomes the State's property, and Contractor is entitled to receive equitable fair compensation for the Deliverables. Regardless of the basis for the termination, the State is not obligated to pay, or otherwise compensate, Contractor for any lost expected future profits, costs or expenses incurred with respect to Services not actually performed for the State.

(c) Upon a good faith termination, the State may assume, at its option, any subcontracts and agreements for services and deliverables provided under this Contract, and may further pursue completion of the Services/Deliverables under this Contract by replacement contract or otherwise as the State may in its sole judgment deem expedient.

2.158 Reservation of Rights

Any termination of this Contract or any Statement of Work issued under it by a party must be with full reservation of, and without prejudice to, any rights or remedies otherwise available to the party with respect to any claims arising before or as a result of the termination.

2.160 Termination by Contractor

2.161 Termination by Contractor

If the State breaches the Contract, and the Contractor in its sole discretion determines that the breach is curable, then the Contractor will provide the State with written notice of the breach and a time period (not less than 30 days) to cure the breach. The Notice of Breach and opportunity to cure is inapplicable for successive and repeated breaches.

The Contractor may terminate this Contract if the State (i) materially breaches its obligation to pay the Contractor undisputed amounts due and owing under this Contract, (ii) breaches its other obligations under this Contract to an extent that makes it impossible or commercially impractical for the Contractor to perform the Services, or (iii) does not cure the breach within the time period specified in a written notice of breach. But the Contractor must discharge its obligations under **Section 2.160** before it terminates the Contract.

2.170 Transition Responsibilities – Deleted, Not Applicable

2.171 Contractor Transition Responsibilities – Deleted, Not Applicable

2.172 Contractor Personnel Transition – Deleted, Not Applicable

2.173 Contractor Information Transition – Deleted, Not Applicable

2.174 Contractor Software Transition – Deleted, Not Applicable

2.175 Transition Payments – Deleted, Not Applicable

2.176 State Transition Responsibilities – Deleted, Not Applicable



2.180 Stop Work

2.181 Stop Work Orders

The State may, at any time, by written stop work order to Contractor, require that Contractor stop all, or any part, of the work called for by the Contract for a period of up to 90 calendar days after the stop work order is delivered to Contractor, and for any further period to which the parties may agree. The stop work order must be identified as a stop work order and must indicate that it is issued under this **Section 2.150**. Upon receipt of the stop work order, Contractor must immediately comply with its terms and take all reasonable steps to minimize incurring 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 must either: (a) cancel the stop work order; or (b) terminate the work covered by the stop work order as provided in **Section 2.130**.

2.182 Cancellation or Expiration of Stop Work Order

The Contractor must resume work if the State cancels a Stop Work Order or if it expires. The parties will agree upon an equitable adjustment in the delivery schedule, the Contract price, or both, and the Contract must be modified, in writing, accordingly, if: (a) the stop work order results in an increase in the time required for, or in Contractor's costs properly allocable to, the performance of any part of the Contract; and (b) Contractor asserts its right to an equitable adjustment within 30 calendar 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 Contractor proposal submitted at any time before final payment under the Contract. Any adjustment will conform to the requirements of **Section 2.024**.

2.183 Allowance of Contractor Costs

If the stop work order is not canceled and the work covered by the stop work order is terminated for reasons other than material breach, the termination must be deemed to be a termination for convenience under **Section 2.130**, and the State will pay reasonable costs resulting from the stop work order in arriving at the termination settlement. For the avoidance of doubt, the State is not be liable to Contractor for loss of profits because of a stop work order issued under this **Section 2.150**.

2.190 Dispute Resolution

2.191 In General

Any claim, counterclaim, or dispute between the State and Contractor arising out of or relating to the Contract or any Statement of Work must be resolved as follows. For all Contractor claims seeking an increase in the amounts payable to Contractor under the Contract, or the time for Contractor's performance, Contractor must submit a letter, together with all data supporting the claims, executed by Contractor's Contract Administrator or the Contract Administrator's designee certifying that (a) the claim is made in good faith, (b) the amount claimed accurately reflects the adjustments in the amounts payable to Contractor or the time for Contractor's performance for which Contractor believes the State is liable and covers all costs of every type to which Contractor is entitled from the occurrence of the claimed event, and (c) the claim and the supporting data are current and complete to Contractor's best knowledge and belief.

2.192 Informal Dispute Resolution

(a) All disputes between the parties must be resolved under the Contract Management procedures in this Contract. If the parties are unable to resolve any disputes after compliance with the processes, the parties must meet with the Director of Purchasing Operations, DMB, or designee, for the purpose of attempting to resolve the dispute without the need for formal legal proceedings, as follows:

(i) The representatives of Contractor and the State must meet as often as the parties reasonably deem necessary to gather and furnish to each other all information with respect to the matter in issue which the parties believe to be appropriate and germane in connection with its resolution. The representatives must discuss the problem and negotiate in good faith in an effort to resolve the dispute without the necessity of any formal proceeding.

(ii) During the course of negotiations, all reasonable requests made by one party to another for non-privileged information reasonably related to the Contract will be honored in order that each of the parties may be fully advised of the other's position.



(iii) The specific format for the discussions will be left to the discretion of the designated State and Contractor representatives, but may include the preparation of agreed upon statements of fact or written statements of position.

(iv) Following the completion of this process within 60 calendar days, the Director of Purchasing Operations, DMB, or designee, must issue a written opinion regarding the issue(s) in dispute within 30 calendar days. The opinion regarding the dispute must be considered the State's final action and the exhaustion of administrative remedies.

(b) This Section will not be construed to prevent either party from instituting, and a party is authorized to institute, formal proceedings earlier to avoid the expiration of any applicable limitations period, to preserve a superior position with respect to other creditors, or under **Section 2.163**.

(c) The State will not mediate disputes between the Contractor and any other entity, except state agencies, concerning responsibility for performance of work under the Contract.

2.193 Injunctive Relief

The only circumstance in which disputes between the State and Contractor will not be subject to the provisions of **Section 2.192** is where a party makes a good faith determination that a breach of the terms of the Contract by the other party is the that the damages to the party resulting from the breach will be so immediate, so large or severe and so incapable of adequate redress after the fact that a temporary restraining order or other immediate injunctive relief is the only adequate remedy.

2.194 Continued Performance

Each party agrees to continue performing its obligations under the Contract while a dispute is being resolved except to the extent the issue in dispute precludes performance (dispute over payment must not be deemed to preclude performance) and without limiting either party's right to terminate the Contract as provided in **Section 2.150**, as the case may be.

2.200 Federal and State Contract Requirements

2.201 Nondiscrimination

In the performance of the Contract, Contractor agrees not to discriminate against any employee or applicant for employment, with respect to his or her hire, tenure, terms, conditions or privileges of employment, or any matter directly or indirectly related to employment, because of race, color, religion, national origin, ancestry, age, sex, height, weight, marital status, physical or mental disability. Contractor further agrees that every subcontract entered into for the performance of this Contract or any purchase order resulting from this Contract will contain a provision requiring non-discrimination in employment, as specified here, binding upon each Subcontractor. This covenant is required under the Elliot Larsen Civil Rights Act, 1976 PA 453, MCL 37.2101, et seq., and the Persons with Disabilities Civil Rights Act, 1976 PA 220, MCL 37.1101, et seq., and any breach of this provision may be regarded as a material breach of the Contract.

2.202 Unfair Labor Practices

Under 1980 PA 278, MCL 423.321, et seq., the State must not award a Contract or subcontract to an employer whose name appears in the current register of employers failing to correct an unfair labor practice compiled under section 2 of the Act. This information is compiled by the United States National Labor Relations Board. A Contractor of the State, in relation to the Contract, must not enter into a contract with a Subcontractor, manufacturer, or supplier whose name appears in this register. Under section 4 of 1980 PA 278, MCL 423.324, the State may void any Contract if, after award of the Contract, the name of Contractor as an employer or the name of the Subcontractor, manufacturer or supplier of Contractor appears in the register.

2.203 Workplace Safety and Discriminatory Harassment

In performing Services for the State, the Contractor must comply with the Department of Civil Services Rule 2-20 regarding Workplace Safety and Rule 1-8.3 regarding Discriminatory Harassment. In addition, the Contractor must comply with Civil Service regulations and any applicable agency rules provided to the Contractor. For Civil Service Rules, see <http://www.mi.gov/mdcs/0,1607,7-147-6877---,00.html>.



2.204 Prevailing Wage

The rates of wages and fringe benefits to be paid each class of individuals employed by the Contractor, its subcontractors, their subcontractors, and all persons involved with the performance of this Contract in privity of contract with the Contractor shall not be less than the wage rates and fringe benefits established by the Michigan Department of Labor and Economic Development, Wage and Hour Bureau, schedule of occupational classification and wage rates and fringe benefits for the local where the work is to be performed. The term Contractor shall include all general contractors, prime contractors, project managers, trade contractors, and all of their contractors or subcontractors and persons in privity of contract with them.

The Contractor, its subcontractors, their subcontractors and all persons involved with the performance of this contract in privity of contract with the Contractor shall keep posted on the work site, in a conspicuous place, a copy of all wage rates and fringe benefits as prescribed in the contract. You must also post, in a conspicuous place, the address and telephone number of the Michigan Department of Labor and Economic Development, the office responsible for enforcement of the wage rates and fringe benefits. You shall keep an accurate record showing the name and occupation of the actual wage and benefits paid to each individual employed in connection with this contract. This record shall be available to the State upon request for reasonable inspection.

If any trade is omitted from the list of wage rates and fringe benefits to be paid to each class of individuals by the Contractor, it is understood that the trades omitted shall also be paid not less than the wage rate and fringe benefits prevailing in the local where the work is to be performed.

2.210 Governing Law

2.211 Governing Law

The Contract must in all respects be governed by, and construed according to, the substantive laws of the State of Michigan without regard to any Michigan choice of law rules that would apply the substantive law of any other jurisdiction to the extent not inconsistent with, or pre-empted by federal law.

2.212 Compliance with Laws

Contractor shall comply with all applicable state, federal and local laws and ordinances in providing the Services/Deliverables.

2.213 Jurisdiction

Any dispute arising from the Contract must be resolved in the State of Michigan. With respect to any claim between the parties, Contractor consents to venue in Ingham County, Michigan, and irrevocably waives any objections it may have to the jurisdiction on the grounds of lack of personal jurisdiction of the court or the laying of venue of the court or on the basis of forum non conveniens or otherwise. Contractor agrees to appoint agents in the State of Michigan to receive service of process.

2.220 Limitation of Liability

2.221 Limitation of Liability

Neither the Contractor nor the State is liable to each other, regardless of the form of action, for consequential, incidental, indirect, or special damages. This limitation of liability does not apply to claims for infringement of United States patent, copyright, trademark 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; or to court costs or attorney's fees awarded by a court in addition to damages after litigation based on this Contract.

2.230 Disclosure Responsibilities

2.231 Disclosure of Litigation

(a) Disclosure. Contractor must disclose any material criminal litigation, investigations or proceedings involving the Contractor (and each Subcontractor) or any of its officers or directors or any litigation, investigations or proceedings under the Sarbanes-Oxley Act. In addition, each Contractor (and each



Subcontractor) must notify the State of any material civil litigation, arbitration or proceeding which arises during the term of the Contract and extensions, to which Contractor (or, to the extent Contractor is aware, any Subcontractor) is a party, and which involves: (i) disputes that might reasonably be expected to adversely affect the viability or financial stability of Contractor or any Subcontractor; or (ii) a claim or written allegation of fraud against Contractor or, to the extent Contractor is aware, any Subcontractor by a governmental or public entity arising out of their business dealings with governmental or public entities. The Contractor must disclose in writing to the Contract Administrator any litigation, investigation, arbitration or other proceeding (collectively, "Proceeding") within 30 days of its occurrence. Details of settlements which are prevented from disclosure by the terms of the settlement may be annotated. Information provided to the State from Contractor's publicly filed documents referencing its material litigation will be deemed to satisfy the requirements of this Section.

(b) Assurances. If any Proceeding disclosed to the State under this Section, or of which the State otherwise becomes aware, during the term of this Contract would cause a reasonable party to be concerned about:

- (i) the ability of Contractor (or a Subcontractor) to continue to perform this Contract according to its terms and conditions, or
- (ii) whether Contractor (or a Subcontractor) in performing Services for the State is engaged in conduct which is similar in nature to conduct alleged in the Proceeding, which conduct would constitute a breach of this Contract or a violation of Michigan law, regulations or public policy, then the Contractor must provide the State all reasonable assurances requested by the State to demonstrate that:
 - (a) Contractor and its Subcontractors will be able to continue to perform this Contract and any Statements of Work according to its terms and conditions, and
 - (b) Contractor and its Subcontractors have not and will not engage in conduct in performing the Services which is similar in nature to the conduct alleged in the Proceeding.

(c) Contractor must make the following notifications in writing:

- (1) Within 30 days of Contractor becoming aware that a change in its ownership or officers has occurred, or is certain to occur, or a change that could result in changes in the valuation of its capitalized assets in the accounting records, Contractor must notify DMB PurchOps.
- (2) Contractor must also notify DMB PurchOps 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.
- (3) Contractor must also notify DMB PurchOps within 30 days whenever changes to company affiliations occur.

2.232 Call Center Disclosure

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

2.233 Bankruptcy

The State may, without prejudice to any other right or remedy, terminate this Contract, in whole or in part, and, at its option, may take possession of the "Work in Process" and finish the Works in Process by whatever appropriate method the State may deem expedient if:

- (a) the Contractor files for protection under the bankruptcy laws;
- (b) an involuntary petition is filed against the Contractor and not removed within 30 days;
- (c) the Contractor becomes insolvent or if a receiver is appointed due to the Contractor's insolvency;
- (d) the Contractor makes a general assignment for the benefit of creditors; or
- (e) the Contractor or its affiliates are unable to provide reasonable assurances that the Contractor or its affiliates can deliver the services under this Contract.



Contractor will fix appropriate notices or labels on the Work in Process to indicate ownership by the State. To the extent reasonably possible, materials and Work in Process must be stored separately from other stock and marked conspicuously with labels indicating ownership by the State.

2.240 Performance

2.241 Time of Performance

- (a) Contractor must use commercially reasonable efforts to provide the resources necessary to complete all Services and Deliverables according to the time schedules contained in the Statements of Work and other Exhibits governing the work, and with professional quality.
- (b) Without limiting the generality of **Section 2.241(a)**, Contractor must notify the State in a timely manner upon becoming aware of any circumstances that may reasonably be expected to jeopardize the timely and successful completion of any Deliverables/Services on the scheduled due dates in the latest State-approved delivery schedule and must inform the State of the projected actual delivery date.
- (c) If the Contractor believes that a delay in performance by the State has caused or will cause the Contractor to be unable to perform its obligations according to specified Contract time periods, the Contractor must notify the State in a timely manner and must use commercially reasonable efforts to perform its obligations according to the Contract time periods notwithstanding the State's failure. Contractor will not be in default for a delay in performance to the extent the delay is caused by the State.

2.242 Service Level Agreements (SLAs) – Deleted, Not Applicable

2.243 Liquidated Damages – Deleted, Not Applicable

2.244 Excusable Failure

Neither party will be liable for any default, damage or delay in the performance of its obligations under the Contract to the extent the default, damage or delay is caused by government regulations or requirements (executive, legislative, judicial, military or otherwise), power failure, electrical surges or current fluctuations, lightning, earthquake, war, water or other forces of nature or acts of God, delays or failures of transportation, equipment shortages, suppliers' failures, or acts or omissions of common carriers, fire; riots, civil disorders; strikes or other labor disputes, embargoes; 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 a party; provided the non-performing party and its Subcontractors are without fault in causing the default or delay, and the default or delay could not have been prevented by reasonable precautions and cannot reasonably be circumvented by the non-performing party through the use of alternate sources, workaround plans or other means, including disaster recovery plans.

If a party does not perform its contractual obligations for any of the reasons listed above, the non-performing party will be excused from any further performance of its affected obligation(s) for as long as the circumstances prevail. But the party must use commercially reasonable efforts to recommence performance whenever and to whatever extent possible without delay. A party must promptly notify the other party in writing immediately after the excusable failure occurs, and also when it abates or ends.

If any of the above-enumerated circumstances substantially prevent, hinder, or delay the Contractor's performance of the Services/provision of Deliverables for more than 10 Business 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/Deliverables from an alternate source, and the State is not be liable for payment for the unperformed Services/ Deliverables not provided under the Contract for so long as the delay in performance continues; (b) the State may terminate any portion of the Contract so affected and the charges payable will be equitably adjusted to reflect those Services/Deliverables terminated; or (c) the State may terminate the affected Statement of Work without liability to Contractor as of a date specified by the State in a written notice of termination to the Contractor, except to the extent that the State must pay for Services/Deliverables provided through the date of termination.



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/Deliverables not provided as a result of the Excusable Failure condition. Defaults or delays in performance by Contractor which are caused by acts or omissions of its Subcontractors will not relieve Contractor of its obligations under the Contract except to the extent that a Subcontractor is itself subject to an Excusable Failure condition described above and Contractor cannot reasonably circumvent the effect of the Subcontractor's default or delay in performance through the use of alternate sources, workaround plans or other means.

2.250 Approval of Deliverables

2.251 Delivery Responsibilities

Unless otherwise specified by the State within an individual order, the following must be applicable to all orders issued under this Contract.

- (a) Shipment responsibilities - Services performed/Deliverables provided under this Contract must be delivered "F.O.B. Destination, within Government Premises." The Contractor must have complete responsibility for providing all Services/Deliverables to all site(s) unless otherwise stated. Actual delivery dates will be specified on the individual purchase order.
- (b) Delivery locations - Services will be performed/Deliverables will be provided at every State of Michigan location within Michigan unless otherwise stated in the SOW. Specific locations will be provided by the State or upon issuance of individual purchase orders.
- (c) Damage Disputes - At the time of delivery to State Locations, the State must examine all packages. The quantity of packages delivered must be recorded and any obvious visible or suspected damage must be noted at time of delivery using the shipper's delivery document(s) and appropriate procedures to record the damage.

Where there is no obvious or suspected damage, all deliveries to a State Location must be opened by the State and the contents inspected for possible internal damage not visible externally within 14 days of receipt. Any damage must be reported to the Contractor within five days of inspection.

2.252 Delivery of Deliverables

Where applicable, the Statements of Work/POs contain lists of the Deliverables to be prepared and delivered by Contractor including, for each Deliverable, the scheduled delivery date and a designation of whether the Deliverable is a document ("Written Deliverable"), a good ("Physical Deliverable") or a Service. All Deliverables must be completed and delivered for State review and written approval and, where applicable, installed according to the State-approved delivery schedule and any other applicable terms and conditions of the Contract.

2.253 Testing

- (a) Before delivering any of the above-mentioned Statement of Work Physical Deliverables or Services to the State, Contractor will first perform all required quality assurance activities to verify that the Physical Deliverable or Service is complete and conforms with its specifications listed in the applicable Statement of Work or Purchase Order. Before delivering a Physical Deliverable or Service to the State, Contractor must certify to the State that (1) it has performed the quality assurance activities, (2) it has performed any applicable testing, (3) it has corrected all material deficiencies discovered during the quality assurance activities and testing, (4) the Deliverable or Service is in a suitable state of readiness for the State's review and approval, and (5) the Deliverable/Service has all Critical Security patches/updates applied.
- (b) If a Deliverable includes installation at a State Location, then Contractor must (1) perform any applicable testing, (2) correct all material deficiencies discovered during the quality assurance activities and testing, and (3) inform the State that the Deliverable is in a suitable state of readiness for the State's review and approval. To the extent that testing occurs at State Locations, the State is entitled to observe or otherwise participate in testing.

2.254 Approval of Deliverables, In General

- (a) All Deliverables (Physical Deliverables and Written Deliverables) and Services require formal written approval by the State, according to the following procedures. Formal approval by the State requires the State



to confirm in writing that the Deliverable meets its specifications. Formal approval may include the successful completion of Testing as applicable in **Section 2.253**, to be led by the State with the support and assistance of Contractor. The approval process will be facilitated by ongoing consultation between the parties, inspection of interim and intermediate Deliverables and collaboration on key decisions.

- (b) The State's obligation to comply with any State Review Period is conditioned on the timely delivery of Deliverables/Services being reviewed.
- (c) Before commencement of its review or testing of a Deliverable/Service, the State may inspect the Deliverable/Service to confirm that all components of the Deliverable/Service have been delivered without material deficiencies. If the State determines that the Deliverable/Service has material deficiencies, the State may refuse delivery of the Deliverable/Service without performing any further inspection or testing of the Deliverable/Service. Otherwise, the review period will be deemed to have started on the day the State receives the Deliverable or the Service begins, and the State and Contractor agree that the Deliverable/Service is ready for use and, where applicable, certification by Contractor according to **Section 2.223**.
- (d) The State will approve in writing a Deliverable/Service after confirming that it conforms to and performs according to its specifications without material deficiency. The State may, but is not be required to, conditionally approve in writing a Deliverable/Service that contains material deficiencies if the State elects to permit Contractor to rectify them post-approval. In any case, Contractor will be responsible for working diligently to correct within a reasonable time at Contractor's expense all deficiencies in the Deliverable/Service that remain outstanding at the time of State approval.
- (e) If, after three opportunities (the original and two repeat efforts), the Contractor is unable to correct all deficiencies preventing Final Acceptance of a Deliverable/Service, the State may: (i) demand that the Contractor cure the failure and give the Contractor additional time to cure the failure at the sole expense of the Contractor; or (ii) keep the Contract in force and do, either itself or through other parties, whatever the Contractor has failed to do, and recover the difference between the cost to cure the deficiency and the contract price plus an additional sum equal to 10% of the cost to cure the deficiency to cover the State's general expenses provided the State can furnish proof of the general expenses; or (iii) terminate the particular Statement of Work for default, either in whole or in part by notice to Contractor provided Contractor is unable to cure the breach. Notwithstanding the foregoing, the State cannot use, as a basis for exercising its termination rights under this Section, deficiencies discovered in a repeat State Review Period that could reasonably have been discovered during a prior State Review Period.
- (f) The State, at any time and in its reasonable discretion, may halt the testing or approval process if the process reveals deficiencies in or problems with a Deliverable/Service in a sufficient quantity or of a sufficient severity that renders continuing the process unproductive or unworkable. If that happens, the State may stop using the Service or return the applicable Deliverable to Contractor for correction and re-delivery before resuming the testing or approval process.

2.255 Process For Approval of Written Deliverables

The State Review Period for Written Deliverables will be the number of days set forth in the applicable Statement of Work following delivery of the final version of the Deliverable (and if the Statement of Work does not state the State Review Period, it is by default five Business Days for Written Deliverables of 100 pages or less and 10 Business Days for Written Deliverables of more than 100 pages). The duration of the State Review Periods will be doubled if the State has not had an opportunity to review an interim draft of the Written Deliverable before its submission to the State. The State agrees to notify Contractor in writing by the end of the State Review Period either stating that the Deliverable is approved in the form delivered by Contractor or describing any deficiencies that must be corrected before approval of the Deliverable (or at the State's election, after approval of the Deliverable). If the State notifies the Contractor about deficiencies, the Contractor will correct the described deficiencies and within 30 Business Days resubmit the Deliverable in a form that shows all revisions made to the original version delivered to the State. Contractor's correction efforts will be made at no additional charge. Upon receipt of a corrected Deliverable from Contractor, the State will have a reasonable additional period of time, not to exceed the length of the original State Review Period, to review the corrected Deliverable to confirm that the identified deficiencies have been corrected.



2.256 Process for Approval of Services

The State Review Period for approval of Services is governed by the applicable Statement of Work (and if the Statement of Work does not state the State Review Period, it is by default 30 Business Days for Services). The State agrees to notify the Contractor in writing by the end of the State Review Period either stating that the Service is approved in the form delivered by the Contractor or describing any deficiencies that must be corrected before approval of the Services (or at the State's election, after approval of the Service). If the State delivers to the Contractor a notice of deficiencies, the Contractor will correct the described deficiencies and within 30 Business Days resubmit the Service in a form that shows all revisions made to the original version delivered to the State. The Contractor's correction efforts will be made at no additional charge. Upon implementation of a corrected Service from Contractor, the State will have a reasonable additional period of time, not to exceed the length of the original State Review Period, to review the corrected Service for conformity and that the identified deficiencies have been corrected.

2.257 Process for Approval of Physical Deliverables

The State Review Period for approval of Physical Deliverables is governed by the applicable Statement of Work (and if the Statement of Work does not state the State Review Period, it is by default 30 continuous Business Days for a Physical Deliverable). The State agrees to notify the Contractor in writing by the end of the State Review Period either stating that the Deliverable is approved in the form delivered by the Contractor or describing any deficiencies that must be corrected before approval of the Deliverable (or at the State's election, after approval of the Deliverable). If the State delivers to the Contractor a notice of deficiencies, the Contractor will correct the described deficiencies and within 30 Business Days resubmit the Deliverable in a form that shows all revisions made to the original version delivered to the State. The Contractor's correction efforts will be made at no additional charge. Upon receipt of a corrected Deliverable from the Contractor, the State will have a reasonable additional period of time, not to exceed the length of the original State Review Period, to review the corrected Deliverable to confirm that the identified deficiencies have been corrected.

2.258 Final Acceptance

Unless otherwise stated in the Article 1, Statement of Work or Purchase Order, "Final Acceptance" of each Deliverable must occur when each Deliverable/Service has been approved by the State following the State Review Periods identified in **Sections 2.251-2.257**. Payment will be made for Deliverables installed and accepted. Upon acceptance of a Service, the State will pay for all Services provided during the State Review Period that conformed to the acceptance criteria.

2.260 Ownership – Deleted, Not Applicable

2.270 State Standards

2.271 Existing Technology Standards

The Contractor will adhere to all existing standards as described within the comprehensive listing of the State's existing technology standards at <http://www.michigan.gov/dit>.

2.272 Acceptable Use Policy

To the extent that Contractor has access to the State computer system, Contractor must comply with the State's Acceptable Use Policy, see <http://www.michigan.gov/ditservice>. All Contractor employees must be required, in writing, to agree to the State's Acceptable Use Policy before accessing the State system. The State reserves the right to terminate Contractor's access to the State system if a violation occurs.

2.273 Systems Changes

Contractor is not responsible for and not authorized to make changes to any State systems without written authorization from the Project Manager. Any changes Contractor makes to State systems with the State's approval must be done according to applicable State procedures, including security, access and configuration management procedures.

2.280 Extended Purchasing



2.281 MiDEAL – Deleted, Not Applicable

2.282 State Employee Purchases – Deleted, Not Applicable

2.290 Environmental Provision

2.291 Environmental Provision

Energy Efficiency Purchasing Policy – The State seeks wherever possible to purchase energy efficient products. This includes giving preference to U.S. Environmental Protection Agency (EPA) certified ‘Energy Star’ products for any category of products for which EPA has established Energy Star certification. For other purchases, the State may include energy efficiency as one of the priority factors to consider when choosing among comparable products.

Environmental Purchasing Policy – The State of Michigan is committed to encouraging the use of products and services that impact the environment less than competing products. The State is accomplishing this by including environmental considerations in purchasing decisions, while remaining fiscally responsible, to promote practices that improve worker health, conserve natural resources, and prevent pollution.

Environmental components that are to be considered include: recycled content and recyclability; energy efficiency; and the presence of undesirable materials in the products, especially those toxic chemicals which are persistent and bioaccumulative. The Contractor should be able to supply products containing recycled and environmentally preferable materials that meet performance requirements and is encouraged to offer such products throughout the duration of this Contract. Information on any relevant third party certification (such as Green Seal, Energy Star, etc.) should also be provided.

Hazardous Materials:

For the purposes of this Section, “Hazardous Materials” is a generic term used to describe asbestos, ACBMs, PCBs, petroleum products, construction materials including paint thinners, solvents, gasoline, oil, and any other material the manufacture, use, treatment, storage, transportation or disposal of which is regulated by the federal, state or local laws governing the protection of the public health, natural resources or the environment. This includes, but is not limited to, materials the as batteries and circuit packs, and other materials that are regulated as (1) “Hazardous Materials” under the Hazardous Materials Transportation Act, (2) “chemical hazards” under the Occupational Safety and Health Administration standards, (3) “chemical substances or mixtures” under the Toxic Substances Control Act, (4) “pesticides” under the Federal Insecticide Fungicide and Rodenticide Act, and (5) “hazardous wastes” as defined or listed under the Resource Conservation and Recovery Act.

(a) The Contractor must use, handle, store, dispose of, process, transport and transfer any material considered a Hazardous Material according to all federal, State and local laws. The State must provide a safe and suitable environment for performance of Contractor’s Work. Before the commencement of Work, the State must advise the Contractor of the presence at the work site of any Hazardous Material to the extent that the State is aware of the Hazardous Material. If the Contractor encounters material reasonably believed to be a Hazardous Material and which may present a substantial danger, the Contractor must immediately stop all affected Work, notify the State in writing about the conditions encountered, and take appropriate health and safety precautions.

(b) Upon receipt of a written notice, the State will investigate the conditions. If (a) the material is a Hazardous Material that may present a substantial danger, and (b) the Hazardous Material was not brought to the site by the Contractor, or does not result in whole or in part from any violation by the Contractor of any laws covering the use, handling, storage, disposal of, processing, transport and transfer of Hazardous Materials, the State must order a suspension of Work in writing. The State must proceed to have the Hazardous Material removed or rendered harmless. In the alternative, the State must terminate the affected Work for the State’s convenience.

(c) Once the Hazardous Material has been removed or rendered harmless by the State, the Contractor must resume Work as directed in writing by the State. Any determination by the Michigan Department of Community Health or the Michigan Department of Environmental Quality that the Hazardous Material has either been removed or rendered harmless is binding upon the State and Contractor for the purposes of



resuming the Work. If any incident with Hazardous Material results in delay not reasonable anticipatable under the circumstances and which is attributable to the State, the applicable SLAs for the affected Work will not be counted in time as mutually agreed by the parties.

(d) If the Hazardous Material was brought to the site by the Contractor, or results in whole or in part from any violation by the Contractor of any laws covering the use, handling, storage, disposal of, processing, transport and transfer of Hazardous Material, or from any other act or omission within the control of the Contractor, the Contractor must bear its proportionate share of the delay and costs involved in cleaning up the site and removing and rendering harmless the Hazardous Material according to Applicable Laws to the condition approved by applicable regulatory agency(ies).

Michigan has a Consumer Products Rule pertaining to labeling of certain products containing volatile organic compounds. For specific details visit http://www.michigan.gov/deq/0,1607,7-135-3310_4108-173523--,00.html

Refrigeration and Air Conditioning:

The Contractor shall comply with the applicable requirements of Sections 608 and 609 of the Clean Air Act (42 U.S.C. 7671g and 7671h) as each or both apply to this contract.

Environmental Performance:

Waste Reduction Program - Contractor shall establish a program to promote cost-effective waste reduction in all operations and facilities covered by this contract. The Contractor's programs shall comply with applicable Federal, State, and local requirements, specifically including Section 6002 of the Resource Conservation and Recovery Act (42 U.S.C. 6962, et seq.).

2.300 Other Provisions

2.311 Forced Labor, Convict Labor, or Indentured Servitude Made Materials

Bidder represents and certifies that, to the best of its knowledge and belief no foreign (outside of the U.S.) made equipment, materials, or supplies, will be furnished to the State under any resulting Contract, that have been produced in whole or in part by forced labor, convict labor, or indentured servitude.

___JT___ (Initial)

2.321 Knowledge of Child Labor for Listed End Products

(a) "Forced or indentured child labor" means all work or service:

- (i) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or
- (ii) Performed by any person under the age of 18 under a contract the enforcement of which can be accomplished by process or penalties.

(b) *Listed end products.* The following end product(s) being acquired under this solicitation is (are) included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, identified by their country of origin. There is a reasonable basis to believe that listed end products from the listed countries of origin may have been mined, produced, or manufactured by forced or indentured child labor.

Listed End Product	Listed Country of Origin
Not Applicable	

(c) *Certification.* The State will not make award to a Bidder unless the Bidder, by checking the appropriate block, certifies to one of the following:

- (X) The Contractor will not supply any end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in a corresponding country as listed for that end product.



() The Contractor may supply an end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The Bidder certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture the end product. On the basis of those efforts, the Bidder certifies that it is not aware of any the use of child labor.

___JT___ (Initial)



Attachment A, Pricing

Item Number	Description	Quantity per Unit of Measure	Unit Price
03542998190	COBAS® AmpliPrep/COBAS TaqMan® HIV-1 Test	1 (48)	\$2,060.00
03587797190	System Wash Reagent	5.1 L (96)	\$10.80
03755525001	SPUs	12 x 24 (288)	\$288.00
03137040001	Sample Input Tubes with Barcode Clips	12 x 24 (288)	\$141.12
03287343001	Racks of K-tips	12 x 36 (432)	\$77.76
03137082001	K-tubes, rack	12 x 96 (1152)	\$864.00
28154104001	Seal Tip Grippers	10	\$13.88
28122199001	Reagent Rack	1	\$44.06
28073112001	Reagent Rack Labels, 1-20	20	\$7.50
28048398001	Reagent Rack Barcode Labels, 001-020	20	\$15.00
28173362001	Reagent Tip	1	\$198.72
28048355001	Sample Rack Labels, 1-20	20	\$15.00
28136289001	Sample Rack Barcode Labels, 001-020	20	\$32.94
28136815001	Seal Cap Pipettes	5	\$15.38
28122806001	SPU Rack	1	\$17.18
28122911001	Syringe, 2.5 mL	1	\$235.56
28153744001	Syringe Plungers	2	\$341.57
28127328001	UV Tube Light	1	\$85.94
28035792001	Fan Filters	4	\$4.06
28051763001	Halogen Lamp	1	\$233.99
28150397001	K-carrier	1	\$135.08
03287696001	K-carrier Holder	1	\$44.05
03279995001	K-carrier Labels, 1-25	25	\$29.12
03517519001	K-carrier Transporter	1	\$61.54
03132307001	Power Supply Air Filter	1	\$4.80
28122172001	Sample Rack	1	\$95.25

Persons responsible for administering this Contract:

NAME: Susan Otto

NAME: Pamela Rockwell

TITLE: Regional Product Specialist

TITLE: Contract Analyst, Molecular Diagnostics

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Attachment B, Product Returns for Molecular Diagnostics

Molecular Diagnostics Product return policy

The following are acceptable return reasons:

- **RD shipping Error**
Includes the following:
 - Incorrect product or quantity received
 - Delivered to the wrong destination
 - RD must be notified of the shipping error within 10 business days of the receipt of the shipment
- **Damaged in Transit**
 - If goods are damaged in transit, please note the damage when signing for the shipment.
 - Contact Roche Diagnostics Customer Service with in 10 business days after receipt of product to report the damage.
 - RD must be *contacted to discuss product disposition alternatives*.
- **Customer Order Error**
 - RD must be notified of the error within 10 business days of receipt of the shipment to discuss product disposition.
 - Customer order errors may be subject to a 15% restocking fee.
 - All shipping and handling charges associated with the return are the responsibility of the customer

The following is required for credit:

- An RD Return Authorization number (RA) from Customer service. Any product received without an RA number clearly marked on the exterior of the shipment will be destroyed and no credit will be issued.
- Product must be received and inspected by Roche Diagnostics prior to credit being issued
- Credit will be issued as a credit memo to the customers account

The following products are not eligible for return under this policy:

- Hazardous products
- Expired product
- Refrigerated or frozen products
- Dirty or damaged products
- Product where the original packaging has been opened or tampered
- Product delayed, lost or damaged once a shipment is tendered to the customer's carrier
- Any products not approved for distribution in the United States

Do Not return any products without receiving an RD return authorization from customer service.

Non-eligible molecular products for customer return

Unauthorized Returns

- Any Product that has been sent back without prior Return Authorization will be destroyed and no credit will be issued.
- Credit will be issues for product once it is received and inspected at RD.
- Credit will be issued for authorized returns in the form of a credit memo to your account within 10 business days after receipt.

Credit for Returns

There is a 15% restocking fee on all return products

Charge for Returns

Step 1:

Inventory products to be returned and then contact Roche Diagnostics Customer service representative by fax, mail or phone:

- Mail to Customer Service
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Returns Goods Procedure



- Or Call TOLL Free 1-800-428-5076 and follow prompt to press 1 for hospital lab or clinical facility press
- Or Fax 1-800-722-7222

Step 2:

The Roche Diagnostics Customer service representative will issue an RA number. An RA is valid for 45 days from date of issue. If returns are shipped after 45 days a new RA is required.

Step 3:

The RA number must be clearly marked on the outside of each shipping carton. Each carton must indicate the total number of boxes. For example (1 of 5), (2 of 5) etc

Step 4:

Credit will be issued to the customer within 10 business days after receipt of the authorized return unless a dispute raised after inspection of all return products.

Any Product that has been sent back without prior Return Authorization will be destroyed and no credit will be issued



COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test

FOR *IN VITRO* DIAGNOSTIC USE.

COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test	<input type="text" value="HIMCAP"/>	48 Tests	P/N: 03542998 190
COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent	<input type="text" value="PG WR"/>	5.1 Liters	P/N: 03587797 190

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INTENDED USE

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is an *in vitro* nucleic acid amplification test for the quantitation of Human Immunodeficiency Virus Type 1 (HIV-1) RNA in human plasma using the COBAS® AmpliPrep Instrument for automated specimen processing and COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The Test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection.

The test can quantitate HIV-1 RNA over the range of 48 - 10,000,000 copies/mL. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 International Units (IU) based on the WHO 1st International Standard for HIV-1 RNA for Nucleic Acid-Based Techniques (NAT) (NIBSC 97/656).



SUMMARY AND EXPLANATION OF THE TEST

Human Immunodeficiency Virus (HIV) is the etiologic agent of Acquired Immunodeficiency Syndrome (AIDS)¹⁻³. HIV infection can be transmitted by sexual contact, exposure to infected blood or blood products, or by an infected mother to the fetus⁴. Within three to six weeks of exposure to HIV, infected individuals generally develop a brief, acute syndrome characterized by flu-like symptoms and associated with high levels of viremia in the peripheral blood⁵⁻⁸. In most infected individuals this is followed by an HIV-specific immune response and a decline of plasma viremia, usually within four to six weeks of the onset of symptoms^{9,10}. After seroconversion, infected individuals typically enter a clinically stable, asymptomatic phase that can last for years¹¹⁻¹³. The asymptomatic period is characterized by persistent, low level plasma viremia¹⁴ and a gradual depletion of CD4⁺ T lymphocytes, leading to severe immunodeficiency, multiple opportunistic infections, malignancies and death¹⁵. Although virus levels in the peripheral blood are relatively low during the asymptomatic phase of the infection, virus replication and clearance appear to be dynamic processes in which high rates of virus production and infection of CD4⁺ cells are balanced by equally high rates of virus clearance, death of infected cells and replenishment of CD4⁺ cells, resulting in relatively stable levels of both plasma viremia and CD4⁺ cells¹⁶⁻¹⁸.

Quantitative measurements of HIV viremia in the peripheral blood have shown that higher virus levels may be correlated with increased risk of clinical progression of HIV disease, and that reductions in plasma virus levels may be associated with decreased risk of clinical progression¹⁹⁻²¹. Virus levels in the peripheral blood can be quantitated by measurement of the HIV p24 antigen in serum, by quantitative culture of HIV from plasma, or by direct measurement of viral RNA in plasma using nucleic acid amplification or signal amplification technologies²²⁻²⁶.

p24 antigen is the principal core protein of HIV and is found in serum either free or bound by anti-p24 antibody. Free p24 antigen can be measured with commercially available enzyme immunoassays (EIA), although the usefulness of p24 antigen as a marker of viral load is limited since the antigen is detectable in only 20% of asymptomatic patients and 40-50% of symptomatic patients. Procedures to dissociate antigen-antibody complexes improve the sensitivity of the p24 antigen tests, but the viral protein remains undetectable in most asymptomatic patients²².

Infectious HIV in plasma can be cultured by inoculation into activated peripheral blood mononuclear cells (PBMC) from normal donors. Quantitation is achieved by inoculating PBMC with serial dilutions of the plasma specimen. Quantitative culture has limited utility for monitoring virus levels in infected individuals since only a small fraction of virus particles is infectious *in vitro*. Infectious virus is often undetectable in asymptomatic individuals²².

HIV RNA in plasma can be quantitated by nucleic acid amplification technologies, such as the Polymerase Chain Reaction (PCR)²⁷⁻²⁹. The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test uses PCR technology to achieve high sensitivity and dynamic range for the quantitative detection of HIV-1 RNA in EDTA anti-coagulated plasma.

PRINCIPLES OF THE PROCEDURE

The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test is a nucleic acid amplification test for the quantitation of Human Immunodeficiency Virus Type 1 (HIV-1) RNA in human plasma. Specimen preparation is automated using the COBAS[®] AmpliPrep Instrument with amplification and detection automated using the COBAS[®] TaqMan[®] Analyzer or the COBAS[®] TaqMan[®] 48 Analyzer.

The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test is based on three major processes: (1) specimen preparation to isolate HIV-1 RNA; (2) reverse transcription of the target RNA to generate complementary DNA (cDNA), and (3) simultaneous PCR amplification of target cDNA and detection of cleaved dual-labeled oligonucleotide probe specific to the target.

The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test permits automated specimen preparation followed by automated reverse transcription, PCR amplification and detection of HIV-1 target RNA and HIV-1 Quantitation Standard (QS) Armored RNA. The Master Mix reagent contains primers and probes specific for both HIV-1 RNA and HIV-1 QS RNA. The Master Mix has been developed to ensure equivalent quantitation of group M subtypes of HIV-1. The detection of amplified DNA is performed using a target-specific and a QS-specific dual-labeled oligonucleotide probe that permit independent identification of HIV-1 amplicon and HIV-1 QS amplicon.

The quantitation of HIV-1 viral RNA is performed using the HIV-1 QS. It compensates for effects of inhibition and controls the preparation and amplification processes, allowing a more accurate quantitation of HIV-1 RNA in each specimen. The HIV-1 QS is a non-infectious Armored RNA construct that contains HIV sequences with identical primer binding sites as the HIV-1 target RNA and a unique probe binding region that allows HIV-1 QS amplicon to be distinguished from HIV-1 target amplicon.

The HIV-1 QS is added to each specimen at a known copy number and is carried through the specimen preparation, reverse transcription, PCR amplification and detection steps of cleaved dual-labeled oligonucleotide detection probes. The COBAS[®] TaqMan[®] Analyzer or COBAS[®] TaqMan[®] 48 Analyzer calculates the HIV-1 RNA concentration in the test specimens by comparing the HIV-1 signal to the HIV-1 QS signal for each specimen and control.



Target Selection

Selection of the target RNA sequence for HIV-1 depends on identification of regions within the HIV-1 genome that show maximum sequence conservation among the various group M HIV-1 subtypes. Generic silica based specimen preparation is used to capture the HIV-1 RNA and HIV-1 QS RNA and defined oligonucleotides are used as primers in amplification of the HIV-1 RNA and HIV-1 QS RNA. A target-specific and a QS-specific dual-labeled oligonucleotide probe permit independent identification of HIV-1 amplicon and HIV-1 QS amplicon. Accordingly, the appropriate selection of the primers and the dual-labeled oligonucleotide probe is critical to the ability of the test to amplify and detect the HIV-1 subtypes. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test uses reverse transcription and PCR amplification primers that define a sequence within the highly conserved region of the HIV-1 *gag* gene³². The *gag* region encodes the group-specific antigens or core structural proteins of the virion. The nucleotide sequence of the primers has been optimized to yield comparable amplification of group M subtypes of HIV-1.

Specimen Preparation

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test utilizes automated specimen preparation on the COBAS® AmpliPrep Instrument by a generic silica-based capture technique. The procedure processes 850 µL of plasma. The HIV-1 virus particles are lysed by incubation at elevated temperature with a protease and chaotropic lysis/binding buffer that releases nucleic acids and protects the released HIV-1 RNA from RNases in plasma. Protease and a known number of HIV-1 QS Armored RNA molecules are introduced into each specimen along with the lysis reagent and magnetic glass particles. Subsequently, the mixture is incubated and the HIV-1 RNA and HIV-1 QS RNA are bound to the surface of the magnetic glass particles. Unbound substances, such as salts, proteins and other cellular impurities, are removed by washing the magnetic glass particles. After separating the magnetic glass particles and completing the washing steps, the adsorbed nucleic acids are eluted at elevated temperature with an aqueous solution. The processed specimen, containing the magnetic glass particles as well as released HIV-1 RNA and HIV-1 QS RNA, is added to the amplification mixture and transferred to the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer. The HIV-1 target RNA and the HIV-1 QS RNA are then reverse transcribed, amplified and simultaneously detected by cleavage of a target-specific and a QS-specific dual-labeled oligonucleotide probe.

Reverse Transcription and PCR Amplification

The reverse transcription and PCR amplification reaction is performed with the thermostable recombinant enzyme *Thermus specie* DNA Polymerase (Z05). In the presence of manganese (Mn²⁺) and under the appropriate buffer conditions, Z05 has both reverse transcriptase and DNA polymerase activity^{30,31}. This allows both reverse transcription and PCR amplification to occur together with real-time detection of the amplicon.

Processed specimens are added to the amplification mixture in amplification tubes (K-tubes) in which both reverse transcription and PCR amplification occur. The reaction mixture is heated to allow a downstream primer to anneal specifically to the HIV-1 target RNA and to the HIV-1 QS RNA. In the presence of Mn²⁺ and excess deoxynucleotide triphosphates (dNTPs), including deoxyadenosine, deoxyguanosine, deoxycytidine, deoxyuridine and deoxythymidine triphosphates, Z05 polymerase extends the annealed primers forming a DNA strand complementary to the RNA target.

Target Amplification

Following reverse transcription of the HIV-1 target RNA and the HIV-1 QS RNA, the Thermal Cycler in the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer heats the reaction mixture to denature the RNA:cDNA hybrid and to expose the specific primer target sequences. As the mixture cools, the primers anneal to the target DNA. The thermostable *Thermus specie* Z05 DNA Polymerase (Z05) in the presence of Mn²⁺ and excess deoxynucleotide triphosphates (dNTPs), including deoxyadenosine, deoxyguanosine, deoxycytidine, deoxyuridine and deoxythymidine triphosphates, extends the annealed primers along the target template to produce a double-stranded DNA molecule termed an amplicon. The COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer automatically repeats this process for a designated number of cycles, with each cycle intended to double the amount of amplicon DNA. The required number of cycles is preprogrammed into the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer. Amplification occurs only in the region of the HIV-1 genome between the primers; the entire HIV-1 genome is not amplified.

Selective Amplification

Selective amplification of target nucleic acid from the specimen is achieved in the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test by the use of AmpErase (uracil-N-glycosylase) enzyme and deoxyuridine triphosphate (dUTP). The AmpErase enzyme recognizes and catalyzes the destruction of DNA strands containing deoxyuridine³³, but not DNA containing deoxythymidine. Deoxyuridine is not present in naturally occurring DNA, but is always present in amplicon due to the use of deoxyuridine triphosphate as one of the dNTPs in the Master Mix reagent; therefore, only amplicon contains deoxyuridine. Deoxyuridine renders contaminating amplicon susceptible to destruction by the AmpErase enzyme prior to amplification of the target DNA. Also, any nonspecific product formed after initial activation of the Master Mix by manganese is destroyed by the AmpErase enzyme. The AmpErase enzyme, which is included in the Master Mix reagent, catalyzes the cleavage of deoxyuridine-containing DNA at the deoxyuridine residues by opening the deoxyribose chain at the C1-position. When heated in the first thermal cycling



step, the amplicon DNA chain breaks at the position of the deoxyuridine, thereby rendering the DNA non-amplifiable. The AmpErase enzyme remains inactive for a prolonged period of time once exposed to temperatures above 55°C, i.e. throughout the thermal cycling steps, and therefore does not destroy target amplicon formed after PCR.

Detection of PCR Products in a COBAS® TaqMan® Test

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test utilizes real-time^{34,35} PCR technology. The use of dual-labeled fluorescent probes allows for real-time detection of PCR product accumulation by monitoring of the emission intensity of fluorescent reporter dyes released during the amplification process. The probes consist of HIV-1 and HIV-1 QS-specific oligonucleotide probes with a reporter dye and a quencher dye. In the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, the HIV-1 and HIV-1 QS probes are labeled with different fluorescent reporter dyes. When these probes are intact, the fluorescence of the reporter dye is suppressed by the proximity of the quencher dye due to Förster-type energy transfer effects. During PCR, the probe hybridizes to a target sequence and is cleaved by the 5' → 3' nuclease activity of the thermostable Z05 DNA polymerase. Once the reporter and quencher dyes are released and separated, quenching no longer occurs, and the fluorescent activity of the reporter dye is increased. The amplification of HIV-1 RNA and HIV-1 QS RNA are measured independently at different wavelengths. This process is repeated for a designated number of cycles, each cycle effectively increasing the emission intensity of the individual reporter dyes, permitting independent identification of HIV-1 RNA and HIV-1 QS RNA. The PCR cycle where a growth curve starts exponential growth is related to the amount of starting material at the beginning of the PCR.

Fundamentals of COBAS® TaqMan® Test Quantitation

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is inherently quantitative over a very wide dynamic range since the monitoring of amplicon is performed during the exponential phase of amplification. The higher the HIV-1 titer of a specimen, the earlier the fluorescence of the reporter dye of the HIV-1 probe rises above the baseline fluorescence level (see Figure 1). Since the amount of HIV-1 QS RNA is constant between all specimens, the fluorescence of the reporter dye of the HIV-1 QS probe should appear at the same cycle for all specimens (see Figure 2). In specimens where the QS fluorescence is affected, the concentration is adjusted accordingly. The appearance of the specific fluorescent signals is reported as a critical threshold value (Ct). The Ct is defined as the fractional cycle number where reporter dye fluorescence exceeds a pre-determined threshold (the Assigned Fluorescence Level), and starts the exponential growth phase of this signal (see Figure 3). A higher Ct value indicates a lower titer of initial HIV-1 target material. A 2-fold increase in titer correlates with a decrease of 1 Ct for target HIV-1 RNA, while a 10-fold increase in titer correlates with a decrease of 3.3 Ct.

Figure 1 shows the target growth curves for a dilution series spanning a 5- \log_{10} range. As the concentration of the virus increases, the growth curves shift to earlier cycles. Therefore, the leftmost growth curve corresponds to the highest viral titer level, whereas, the rightmost growth curve corresponds to the lowest viral titer level.

Figure 1
Target Growth Curves for a Dilution Series Spanning a 5- \log_{10} Range

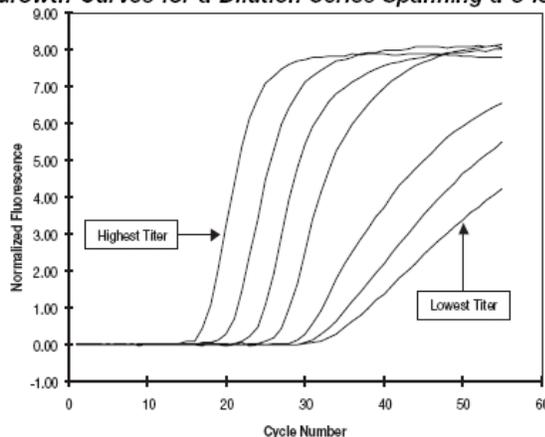


Figure 2 shows the Quantitation Standard growth curves for specimens from a viral dilution series that spans a 5- \log_{10} range. The amount of Quantitation Standard added to each specimen is constant for each reaction. The Ct value of the Quantitation Standard is similar regardless of the target viral titer.



Figure 2
Quantitation Standard Growth Curves for Specimens from a Viral Dilution Series that Spans a 5-log₁₀ Range

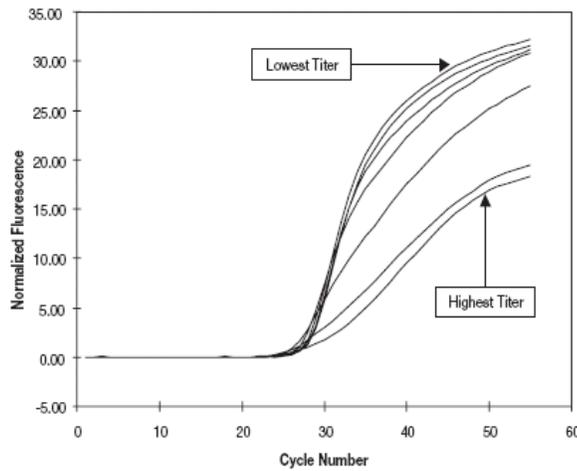
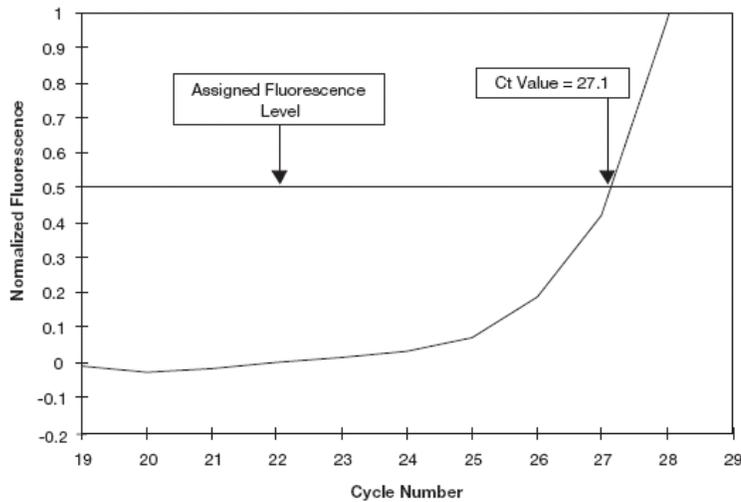


Figure 3 provides an example of how the fluorescence values at every cycle are normalized for each growth curve. The critical threshold value (Ct) is calculated where the fluorescence signal crosses the Assigned Fluorescence Level.

Figure 3
Normalization of Fluorescence Values at Every Cycle for Each Growth Curve



HIV-1 RNA Quantitation

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test quantitates HIV-1 viral RNA by utilizing a second target sequence (HIV-1 Quantitation Standard) that is added to each test specimen at a known concentration. The HIV-1 QS is a non-infectious Armored RNA construct, containing fragments of HIV-1 sequences with primer binding regions identical to those of the HIV-1 target sequence. The HIV-1 QS contains HIV-1 primer binding regions and generates an amplification product of the same length and base composition as the HIV-1 target RNA. The detection probe binding region of the HIV-1 QS has been modified to differentiate HIV-1 QS amplicon from HIV-1 target amplicon.

During the annealing phase of the PCR on the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer, the specimens are illuminated and excited by filtered light and filtered emission fluorescence



data are collected for each specimen. The readings from each specimen are then corrected for instrumental fluctuations. These fluorescence readings are sent by the instrument to the AMPLILINK software and stored in a database. Pre-Checks are used to determine if the HIV-1 RNA and HIV-1 QS RNA data represent sets that are valid, and flags are generated when the data lie outside the preset limits. After all Pre-Checks are completed and passed, the fluorescence readings are processed to generate Ct values for the HIV-1 RNA and the HIV-1 QS RNA. The lot-specific calibration constants provided with the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test are used to calculate the titer value for the specimens and controls based upon the HIV-1 RNA and HIV-1 QS RNA Ct values. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is standardized against the WHO 1st International Standard for HIV-1 RNA for Nucleic Acid-Based Techniques (NAT) (NIBSC 97/656)³⁶. Titer results are reported in copies/mL (cp/mL). The conversion factor between reported HIV-1 RNA copies/mL and HIV-1 International Units/mL has been determined by Roche Molecular Systems, Inc. to be 0.6 cp/IU (1.7 IU/cp).

REAGENTS

COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test	HIMCAP	48 Tests
(P/N: 03542998 190)		
HIV-1 CS1		1 x 48 Tests
(HIV-1 Magnetic Glass Particles Reagent Cassette)		1 x 7.0 mL
Magnetic glass particles		
93% Isopropanol		
Xi		93% (w/w) Isopropanol
	Irritant	
F		93% (w/w) Isopropanol
	Highly Flammable	
HIV-1 CS2		1 x 48 Tests
(HIV-1 Lysis Reagent Cassette)		1 x 78 mL
Sodium citrate dihydrate		
42.5% Guanidine thiocyanate		
< 14% Polydocanol		
0.9% Dithiothreitol		
Xn		42.5% (w/w) Guanidine thiocyanate
	Harmful	
HIV-1 CS3		1 x 48 Tests
HIV-1 Multi-Reagent Cassette containing:		
Pase		1 x 3.8 mL
(Proteinase Solution)		
Tris buffer		
< 0.05% EDTA		
Calcium chloride		
Calcium acetate		
≤ 7.8% Proteinase		
Glycerol		
Xn		≤ 7.8% (w/w) Proteinase
	Harmful	
EB		1 x 7.0 mL
(Elution Buffer)		
Tris-base buffer		
0.2% Methylparaben		



HIV-1 CS4	1 x 48 Tests
HIV-1 Test-Specific Reagent Cassette containing:	
HIV-1 QS (HIV-1 Quantitation Standard)	1 x 3.6 mL
Tris-HCl buffer EDTA < 0.005% Poly rA RNA (synthetic) < 0.001% Armored HIV-1 RNA construct containing HIV-1 primer binding sequences and a unique probe binding region (non-infectious RNA in MS2 bacteriophage) 0.05% Sodium azide	
HIV-1 MMX (HIV-1 Master Mix)	1 x 2.5 mL
Tricine buffer Potassium acetate Potassium hydroxide 20% Dimethylsulfoxide Glycerol < 0.04% dATP, dCTP, dGTP, dUTP, dTTP < 0.003% Upstream and downstream primers to the GAG region of HIV-1 < 0.003% Oligonucleotide aptamer < 0.003% Fluorescent-labeled oligonucleotide probes specific for HIV-1 and the HIV-1 QS < 0.05% Z05 DNA Polymerase (microbial) < 0.1% AmpErase (uracil-N-glycosylase) enzyme (microbial) 0.09% Sodium azide	
CAP/CTM Mn²⁺ (CAP/CTM Manganese Solution)	1 x 19.8 mL
< 0.5% Manganese acetate Glacial acetic acid 0.09% Sodium azide	
HIV-1 H(+)C (HIV-1 High Positive Control)	4 x 1.0 mL
< 0.001% Armored HIV-1 RNA construct containing HIV-1 sequences (non-infectious RNA in MS2 bacteriophage) Negative Human Plasma, non-reactive by FDA licensed tests for antibody to HCV, antibody to HIV-1/2, HIV p24 antigen and HBsAg; HIV-1 RNA, HCV RNA and HBV DNA not detectable by PCR methods 0.1% ProClin [®] 300 preservative	
HIV-1 L(+)C (HIV-1 Low Positive Control)	4 x 1.0 mL
< 0.001% Armored HIV-1 RNA construct containing HIV-1 sequences (non-infectious RNA in MS2 bacteriophage) at a mean concentration at least 100 fold lower than the mean concentration of Armored HIV-1 RNA in HIV-1 H(+) C Negative Human Plasma, non-reactive by FDA licensed tests for antibody to HCV, antibody to HIV-1/2, HIV p24 antigen and HBsAg; HIV-1 RNA, HCV RNA and HBV DNA not detectable by PCR methods 0.1% ProClin [®] 300 preservative	
CTM (-) C [COBAS [®] TaqMan [®] Negative Control (Human Plasma)]	4 x 1.0 mL
Negative Human Plasma, non-reactive by FDA licensed tests for antibody to HCV, antibody to HIV-1/2, HIV p24 antigen and HBsAg; HIV-1 RNA, HCV RNA and HBV DNA not detectable by PCR methods 0.1% ProClin [®] 300 preservative	
HIV-1 H(+)C Clip (HIV-1 High Positive Control Barcode Clip)	1 x 4 Clips



HIV-1 L(+)C** Clip** 1 x 4 Clips
 (HIV-1 Low Positive Control Barcode Clip)

HIV-1 (-) **C Clip** 1 x 4 Clips
 (HIV-1 Negative Control Barcode Clip)

COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent PG WR
 (P/N: 03587797 190)

PG WR 1 x 5.1 L
 (COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent)
 Sodium citrate dihydrate
 < 0.1% N-Methylisothiazolone-HCl

WARNINGS AND PRECAUTIONS

- A. **FOR IN VITRO DIAGNOSTIC USE.**
- B. This test is for use with human plasma collected in the anticoagulant EDTA.
- C. Do not pipet by mouth.
- D. Do not eat, drink or smoke in laboratory work areas. Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and test reagents.
- E. Avoid microbial and ribonuclease contamination of reagents when removing aliquots from control vials.
- F. The use of sterile disposable pipets and RNase-free pipet tips is recommended.
- G. Do not pool controls from different lots or from different vials of the same lot.
- H. Do not mix reagent cassettes or controls from different kits.
- I. Do not allow reagent cassettes to come to ambient temperature outside the COBAS® AmpliPrep Instrument.
- J. Do not open COBAS® AmpliPrep cassettes and exchange, mix, remove or add bottles.
- K. Dispose of unused reagents, waste and specimens in accordance with country, federal, state and local regulations.
- L. Do not use a kit after its expiration date.
- M. Material Safety Data Sheets (MSDS) are available on request from your local Roche office.
- N. Specimens and controls should be handled as if infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories*³⁷ and in the CLSI Document M29-A3³⁸. Thoroughly clean and disinfect all work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in deionized or distilled water.

NOTE: Commercial liquid household bleach typically contains sodium hypochlorite at a concentration of 5.25%. A 1:10 dilution of household bleach will produce a 0.5% sodium hypochlorite solution. Do not autoclave bleach solution.

- O. **CAUTION: CTM (-) C, HIV-1 L(+)**C** and HIV-1 H(+)**C**** contain Human Plasma derived from human blood. The source material has been tested by FDA licensed tests and found non-reactive for the presence of Hepatitis B Surface Antigen (HBsAg), antibodies to HIV-1/2 and HCV, and HIV p24 Antigen. Testing of Negative Human Plasma by PCR methods showed no detectable HIV-1 RNA, HCV RNA or HBV DNA. No known test methods can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all human sourced material should be considered potentially infectious. **CTM (-) C, HIV-1 L(+)**C** and HIV-1 H(+)**C**** should be handled as if infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories*³⁷ and in the CLSI Document M29-A3³⁸. Thoroughly clean and disinfect all work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in deionized or distilled water.
- P. **HIV-1 QS, CAP/CTM Mn²⁺ and HIV-1 MMX** contain sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. While disposing of sodium azide-containing solutions down laboratory sinks, flush the drains with a large volume of water to prevent azide buildup.
- Q. Wear eye protection, laboratory coats and disposable gloves when handling any reagent. Avoid contact of these materials with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water. Burns can occur if left untreated. If spills of these reagents occur, dilute with water before wiping dry.



- R. Do not allow **HIV-1 CS2** and liquid waste from the COBAS® AmpliPrep Instrument, which contain guanidine thiocyanate, to contact sodium hypochlorite (bleach) solution. These mixtures can produce a highly toxic gas.
- S. When disposing of used COBAS® AmpliPrep Sample Processing Units (SPUs), which contain guanidine thiocyanate, avoid any contact with sodium hypochlorite (bleach) solution. These mixtures can produce a highly toxic gas.

STORAGE AND HANDLING REQUIREMENTS

- A. *Do not freeze reagents or controls.*
- B. Store **HIV-1 CS1, HIV-1 CS2, HIV-1 CS3** and **HIV-1 CS4** at 2-8°C. Unused, these reagents are stable until the expiration date indicated. Once used, these reagents are stable for 28 days at 2-8°C or until the expiration date, whichever comes first. **HIV-1 CS1, HIV-1 CS2, HIV-1 CS3** and **HIV-1 CS4** can be used for a maximum of 4 instrument cycles, up to a maximum of 64 hours cumulative on board the COBAS® AmpliPrep Instrument. Reagents must be stored at 2-8°C between instrument cycles.
- C. Store **HIV-1 H(+)**C, **HIV-1 L(+)**C and **CTM (-) C** at 2-8°C. The controls are stable until the expiration date indicated. Once opened, any unused portion must be discarded.
- D. Store Barcode clips [**HIV-1 H(+)**C Clip, **HIV-1 L(+)**C Clip and **HIV-1 (-) C Clip**] at 2-30°C.
- E. Store **PG WR** at 2-30°C. **PG WR** is stable until the expiration date indicated. Once opened, this reagent is stable for 28 days at 2-30°C or until the expiration date, whichever comes first.

MATERIALS PROVIDED

- A. **COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test**
(P/N: 03542998 190)

- HIV-1 CS1**
(HIV-1 Magnetic Glass Particles Reagent Cassette)
- HIV-1 CS2**
(HIV-1 Lysis Reagent Cassette)
- HIV-1 CS3**
(HIV-1 Multi-Reagent Cassette)
- HIV-1 CS4**
(HIV-1 Test-Specific Reagent Cassette)
- HIV-1 H(+)**C
(HIV-1 High Positive Control)
- HIV-1 L(+)**C
(HIV-1 Low Positive Control)
- CTM (-) C**
[COBAS® TaqMan® Negative Control (Human Plasma)]
- HIV-1 H(+)**C Clip
(HIV-1 High Positive Control Barcode Clip)
- HIV-1 L(+)**C Clip
(HIV-1 Low Positive Control Barcode Clip)
- HIV-1 (-) C Clip**
(HIV-1 Negative Control Barcode Clip)

HIMCAP

- B. **COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent**
(P/N: 03587797 190)

- PG WR**
(COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent)

PG WR

MATERIALS REQUIRED BUT NOT PROVIDED

Instrumentation and Software

- COBAS® AmpliPrep Instrument
- COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer
- Optional: Docking Station
- AMPLILINK Software
- Data Station for the AMPLILINK software, with printer



If the Data Station for AMPLILINK software is installed with AMPLILINK software v3.1 Series, use the following four Manuals:

- COBAS® AmpliPrep Instrument Manual for use with the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer and the AMPLILINK Software, Version 3.1.0 Series
- COBAS® TaqMan® Analyzer (plus optional Docking Station) Instrument Manual for use with AMPLILINK Software, Version 3.1.0 Series
- COBAS® TaqMan® 48 Analyzer Instrument Manual for use with AMPLILINK Software, Version 3.1.0 Series
- AMPLILINK Software Version 3.1 Series Application Manual for use with the COBAS® AmpliPrep Instrument, COBAS® TaqMan® Analyzer, and COBAS® TaqMan® 48 Analyzer

If the Data Station for AMPLILINK Software is installed with AMPLILINK Software v3.2 Series, use the following four manuals:

- COBAS® AmpliPrep Instrument Manual for use with the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer, COBAS® AMPLICOR® Analyzer and the AMPLILINK Software, Version 3.2 Series
- COBAS® TaqMan® Analyzer (plus optional Docking Station) Instrument Manual for use with AMPLILINK Software, Version 3.2 Series Application Manual
- COBAS® TaqMan® 48 Analyzer Instrument Manual for use with AMPLILINK Software, Version 3.2 Series Application Manual
- AMPLILINK Software Version 3.2 Series Application Manual For use with the COBAS® AmpliPrep Instrument, COBAS® TaqMan® Analyzer, COBAS® TaqMan® 48 Analyzer, and COBAS® AMPLICOR® Analyzer

Disposables

- Sample processing units: SPUs
- Sample input tubes (S-tubes) with barcode clips (P/N: 03137040001)
- Racks of K-tips (P/N: 03287343001)
- K-tube Box of 12 x 96 (P/N: 03137082001)

OTHER MATERIALS REQUIRED BUT NOT PROVIDED

- Sample Rack (SK 24 rack) (P/N: 28122172001)
- Reagent Rack (P/N: 28122199001)
- SPU rack (P/N: 28122806001)
- K-tube capper, motorized (P/N: 03516539001)
- K-tube capper (P/N: 03339874001)
- K-carrier (P/N: 28150397001)
- K-carrier Transporter (P/N: 03517519001)
- K-carrier rack (P/N: 03286436001)
- Pipettors with aerosol barrier or positive displacement RNase-free tips (capacity 1000 µL)*
- Disposable gloves, powderless
- Vortex mixer

* Pipettors should be accurate within 3% of stated volume. Aerosol barrier or positive displacement RNase-free tips must be used where specified to prevent specimen and amplicon cross-contamination.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

NOTE: Handle all specimens and controls as if they are capable of transmitting infectious agents.

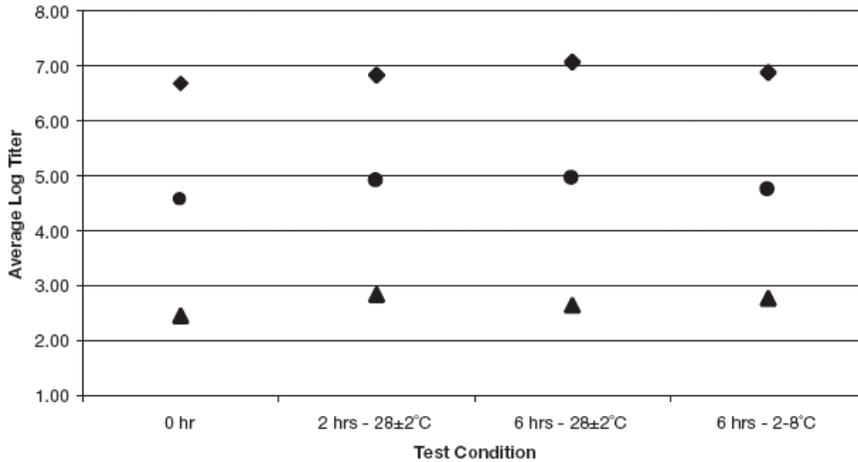
A. Specimen Collection

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is for use with plasma specimens. Blood should be collected in sterile tubes using EDTA (lavender top) as the anticoagulant.

Store whole blood at 2-25°C for no longer than 6 hours. Separate plasma from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer plasma to a sterile polypropylene tube. Figures 4 and 5 show the data from specimen collection studies. These studies were performed using the COBAS® TaqMan® HIV-1 Test for use with the High Pure System (HPS), P/N: 03501752 190 and 03502295 001).



Figure 4
HIV-1 Stability in Whole Blood with EDTA Anticoagulant



B. Specimen Transport

Transportation of whole blood or plasma must comply with country, federal, state and local regulations for the transport of etiologic agents³⁹. Whole blood must be transported at 2-25°C and centrifuged within 6 hours of collection. Plasma may be stored at room temperature for up to 1 day, at 2-8°C for up to 5 days or frozen at -20°C to -80°C for longer storage. Figure 5 shows the stability for HIV-1 in EDTA plasma.

C. Specimen Storage

Plasma specimens may be stored at room temperature for up to 1 day, at 2-8°C for up to 5 days or frozen at -20°C to -80°C. It is recommended that specimens be stored in 1100-1200 µL aliquots in sterile, 2.0 mL polypropylene screw-cap tubes (such as Sarstedt 72.694.006). Plasma specimens may be frozen and thawed up to five times without a loss of HIV-1 RNA. Figure 6 shows the data from a freeze/thaw study (study was performed using COBAS® TaqMan® HIV-1 Test for use with the High Pure System (HPS), P/N: 03501752 190 and 03502295 001).

Figure 5
HIV-1 Stability in EDTA-Plasma

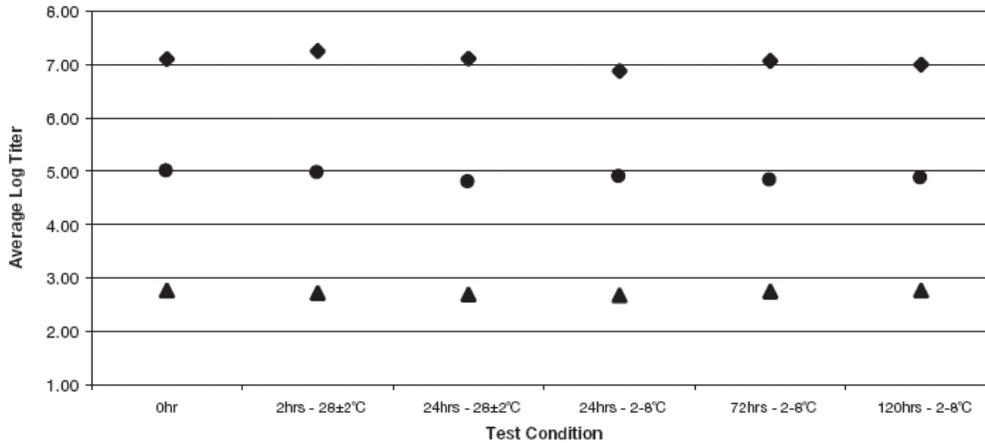
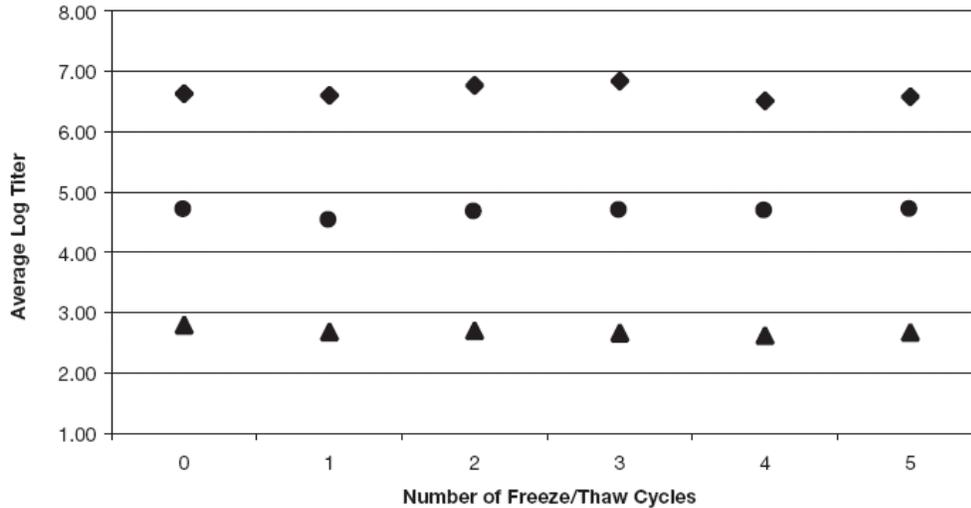




Figure 6
HIV-1 Results after up to Five Freeze/Thaw Cycles



INSTRUCTIONS FOR USE

NOTE: For detailed operating instructions, a detailed description of the possible configurations, printing results and interpreting flags, comments and error messages, refer to (1) the COBAS® AmpliPrep Instrument Instrument Manual for use with the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer and the AMPLILINK Software, Version 3.1.x Series or the COBAS® AmpliPrep Instrument Instrument Manual for use with the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer; COBAS® AMPLICOR® Analyzer and the AMPLILINK Software, Version 3.2 Series; (2) the COBAS® TaqMan® Analyzer (plus optional Docking Station) Instrument Manual for use with AMPLILINK Software, Version 3.1.x Series or the COBAS® TaqMan® Analyzer (plus optional Docking Station) Instrument Manual for use with AMPLILINK Software, Version 3.2 Series Application Manual; (3) the COBAS® TaqMan® 48 Analyzer Instrument Manual for use with AMPLILINK Software, Version 3.1.x Series or the COBAS® TaqMan® 48 Analyzer Instrument Manual for use with AMPLILINK Software, Version 3.2 Series Application Manual; (4) the AMPLILINK Software Version 3.1 Series Application Manual for use with the COBAS® AmpliPrep Instrument, COBAS® TaqMan® Analyzer, and COBAS® TaqMan® 48 Analyzer or the AMPLILINK Software Version 3.2 Series Application Manual For use with the COBAS® AmpliPrep Instrument, COBAS® TaqMan® Analyzer, COBAS® TaqMan® 48 Analyzer, and COBAS® AMPLICOR® Analyzer.

Batch Size:

Each kit contains reagents sufficient for 48 tests, which may be performed in batches of 12 to 24 tests. At least one replicate each of CTM (-) C, HIV-1 L(+)C and HIV-1 H(+)C must be included in each batch (see "Quality Control" section).

Workflow:

The COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer run must be started within 120 minutes following completion of specimen and control preparation of a specific batch.

NOTE: If this time limit is exceeded, processed specimens and controls must be discarded.

(Processing time for one specimen on the COBAS® AmpliPrep Instrument is 216 seconds. The COBAS® AmpliPrep Instrument can process three racks of 24 specimens (n = 72) in approximately 5 hours. The amplification and detection cycle takes 3 hours, 5 minutes on both the COBAS® TaqMan® Analyzer and COBAS® TaqMan® 48 Analyzer. Completion of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test takes approximately 8 hours 10 minutes and 7 hours 35 minutes for sample processing and result generation, using the CTM 48 and CTM 96 workflows, respectively).

NOTE: DO NOT FREEZE or STORE processed specimens and controls at 2-8°C.

Specimen and Control Preparation



NOTE: *If using frozen specimens, place the specimens at room temperature until completely thawed and vortex for 3-5 seconds before use. Controls should be removed from 2-8°C storage and equilibrated to ambient temperature before use.*

COBAS® AmpliPrep Instrument Set-up

Part A. Maintenance and Priming

- A1. The COBAS® AmpliPrep Instrument is ready for operation in stand-by mode.
- A2. Turn the Data Station for the AMPLILINK software **ON**. Prepare the Data Station as follows:
 - a. Log onto Windows® XP.
 - b. Double click the AMPLILINK software icon.
 - c. Log onto AMPLILINK software by entering the assigned User ID and password.
- A3. Check the supply of **PG WR** using the **Status** Screen and replace if necessary.
- A4. Perform all Maintenance that is listed in the Due Tab. The COBAS® AmpliPrep Instrument will automatically prime the system.

Part B. Loading of Reagent Cassettes

NOTE: *All reagent cassettes should be removed from 2-8°C storage, immediately loaded onto the COBAS® AmpliPrep Instrument and allowed to equilibrate to ambient temperature on the instrument for at least 30 minutes before the first specimen is to be processed. Do not let reagent cassettes come to ambient temperature outside the instrument.*

- B1. Place **HIV-1 CS1** onto a reagent rack. Place **HIV-1 CS2**, **HIV-1 CS3** and **HIV-1 CS4** onto a separate reagent rack.
- B2. Load the reagent rack containing **HIV-1 CS1** onto rack position **A** of the COBAS® AmpliPrep Instrument.
- B3. Load the reagent rack containing **HIV-1 CS2**, **HIV-1 CS3** and **HIV-1 CS4** onto rack position **B**, **C**, **D** or **E** of the COBAS® AmpliPrep Instrument (see Table 1 for additional information).

Part C. Loading of Disposables

NOTE: *Determine the number of COBAS® AmpliPrep reagent cassettes, Sample Processing Units (SPUs), Input Sample tubes (S-tubes), K-tips and K-tubes needed. One SPU, one Input S-tube, one K-tip and one K-tube are needed for each specimen or control.*

Multiple configurations for use of the COBAS® AmpliPrep Instrument with the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer are possible. For reference, see Table 1 below. Depending on the configuration used, load the appropriate number of reagent cassette racks, sample racks with Input S-tubes, SPU racks, K-tip racks, K-tube racks and K-carriers on K-carrier racks onto the respective rack positions of the COBAS® AmpliPrep Instrument (see Table 1 for additional information).

- C1. Place the SPUs in the SPU rack(s) and load the rack(s) onto rack position **J**, **K** or **L** of the COBAS® AmpliPrep Instrument.
- C2. Depending on the configuration used, load full K-tube rack(s) onto rack position **M**, **N**, **O** or **P** of the COBAS® AmpliPrep Instrument.
- C3. Load full K-tip rack(s) onto rack position **M**, **N**, **O** or **P** of the COBAS® AmpliPrep Instrument.
- C4. For configurations 3 to 5 using the COBAS® TaqMan® 48 Analyzer, load K-carriers on K-carrier rack(s) onto rack position **M**, **N**, **O** or **P** of the COBAS® AmpliPrep Instrument.



Table 1
Possible Configurations for using COBAS® AmpliPrep Instrument with
COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer

Configuration	Transfer mode to COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer	Racks, carriers and disposables	Position on COBAS® AmpliPrep Instrument
1. COBAS® AmpliPrep Instrument plus Docking Station plus COBAS® TaqMan® Analyzer	Automated transfer of K-carrier	K-tubes in full K-tube racks K-tips in full K-tips racks Input S-tubes containing specimens and controls on sample racks SPUs in SPU racks CS1 on Cassette rack CS2, CS3, CS4 on Cassette rack	M-P M-P F-H J-L A B-E
2 COBAS® AmpliPrep Instrument plus COBAS® TaqMan® Analyzer	Manual transfer of K-tubes via sample rack(s) onto COBAS® TaqMan® Analyzer	K-tubes in full K-tube racks K-tips in full K-tips racks Input S-tubes on sample racks SPUs in SPU racks CS1 on Cassette rack CS2, CS3, CS4 on Cassette rack <u>After specimen processing is finished:</u> K-tubes on sample racks (ready for manual transfer)	M-P M-P F-H J-L A B-E Same as above (F-H)
3. & 4. COBAS® AmpliPrep Instrument plus 1-2 COBAS® TaqMan® 48 Analyzer(s)	Manual transfer of K-carrier via K-carrier rack(s) onto COBAS® TaqMan® 48 Analyzer	K-tubes on sample racks K-tips in full K-tips racks Input S-tubes on sample racks SPUs in SPU racks CS1 on Cassette rack CS2, CS3, CS4 on Cassette rack Empty barcoded K-carrier on K-carrier rack <u>After specimen processing is finished:</u> K-tubes in K-carrier on K-carrier rack	F-H M-P F-H J-L A B-E M-P Same as above (M-P)
5. COBAS® AmpliPrep Instrument plus COBAS® TaqMan® Analyzer plus COBAS® TaqMan® 48 Analyzer	Manual transfer of K-tubes on sample rack to COBAS® TaqMan® Analyzer. Manual transfer of K-carrier via K-carrier rack to COBAS® TaqMan® 48 Analyzer	Same as configurations 2 and 3	Same as configurations 2 and 3

**Part D. Ordering and Loading of Specimens**

- D1. Prepare sample racks as follows: Attach a barcode label clip to each sample rack position where a specimen (S-tube) is to be placed. Attach one of the specific barcode label clips for the controls [CTM (-) C, HIV-1 L(+)C and HIV-1 H(+)C] to each sample rack position where the controls (S-tube) are to be placed. The barcode label clips for controls must have the same control lot number as the lot number on the control vials in the kit. Take care in assigning the correct control to the position with the appropriate control barcode clip. Place one Input S-tube into each position containing a barcode label clip.
- D2. Using the AMPLILINK software, create specimen orders for each specimen and control in the **Orders** window **Sample** folder. Select the appropriate test file and complete by saving.
- D3. Assign specimen and control orders to sample rack positions in the **Orders** window **Sample Rack** folder. The sample rack number must be entered for the rack prepared in Step D1.
- D4. Print the **Sample Rack Order** report to use as a worksheet.
- D5. Prepare specimen and control racks in the designated area for specimen and control addition as follows: Vortex each specimen and control [CTM (-) C, HIV-1 L(+)C and HIV-1 H(+)C] for 3 to 5 seconds. Avoid contaminating gloves when manipulating the specimens and controls.
- D6. Transfer 1000 to 1050 µL of each specimen and control [CTM (-) C, HIV-1 L(+)C and HIV-1 H(+)C] to the appropriate barcode labeled Input S-tube using a micropipettor with an aerosol barrier or positive displacement RNase-free tip. **Avoid transferring particulates and/or fibrin clots from the original specimen to the Input S-tube.** Specimens and controls should be transferred to tube positions as assigned and recorded on the worksheet in step D4. The barcode label clips for controls must have the same control lot number as the lot number on the control vials in the kit. Assign the correct control to the position with the appropriate control barcode clip. **Avoid contaminating the upper part of the S-tubes with specimens or controls.**
- D7. For configurations 1 and 2 using the COBAS® TaqMan® Analyzer, load the sample rack(s) filled with Input S-tubes onto rack positions **F, G** or **H** of the COBAS® AmpliPrep Instrument.
- D8. For configurations 3 to 5 using the COBAS® TaqMan® 48 Analyzer, load sample rack(s) with Input S-tubes and K-tubes (one for each Input S-tube, loaded in the correct position adjacent to Input S-tubes) onto rack position **F, G** or **H** of the COBAS® AmpliPrep Instrument.

Part E. Start of COBAS® AmpliPrep Instrument Run

- E1. Start the COBAS® AmpliPrep Instrument using the AMPLILINK software.

Part F. End of COBAS® AmpliPrep Instrument Run and Transfer to COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer (only for configurations 2-5)

- F1. Check for flags or error messages.
- F2. Remove processed specimens and controls from the COBAS® AmpliPrep Instrument on either sample racks (for COBAS® TaqMan® Analyzer without docking station) or K-carrier racks (for COBAS® TaqMan® 48 Analyzer), depending on the configuration (for further details see Part G).
- F3. Remove waste from COBAS® AmpliPrep Instrument.

NOTE: All processed specimens and controls should not be exposed to light after completion of specimen and control preparation.



Amplification and Detection

COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer Set-up

The COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer run must be started within 120 minutes following completion of specimen and control preparation. If this time limit is exceeded, the processed specimens and controls must be discarded.

NOTE: DO NOT FREEZE or STORE processed specimens and controls at 2-8°C.

Part G. Loading Processed Specimens

G1. Depending on the instrument configuration, perform the appropriate steps to transfer the K-tubes to the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer:

Configuration 1: Automated transfer of K-carrier via docking station to COBAS® TaqMan® Analyzer. Manual intervention is unnecessary.

Configuration 2 and 5: Manual transfer of K-tubes in sample rack(s) to COBAS® TaqMan® Analyzer

Configuration 3, 4 and 5: Manual transfer of K-carrier on K-carrier rack(s) to the COBAS® TaqMan® 48 Analyzer. Manual transfer of K-carriers into COBAS® TaqMan® 48 Analyzer using the K-carrier Transporter.

Part H. Start of COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer Run

H1. Start the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer by one of the options below depending on the instrument configuration used:

Configuration 1: No intervention necessary.

Configuration 2 and 5: Automatic start of the COBAS® TaqMan® Analyzer after insertion of sample rack(s).

Configuration 3, 4 and 5: Fill K-carrier with empty K-tubes if there are fewer than 6 K-tubes on the K-carrier. Filling is guided by the AMPLILINK software. Open thermal cyclers cover, load K-carrier into thermal cycler and close lid. Start the COBAS® TaqMan® 48 Analyzer run.

Part I. End of COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer Run

I1. At the completion of the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer run, print Results Report. Check for flags or error messages in the Result Report. Specimens with flags and comments are interpreted as described in the *Results* section. After acceptance, store data in archive.

I2. Remove used K-tubes from the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer. If using the COBAS® TaqMan® Analyzer, tubes are transferred to a waste container, which should be emptied.

NOTE: Caution! K-carrier may be hot after cycling.



RESULTS

The COBAS® TaqMan® Analyzer or the COBAS® TaqMan® 48 Analyzer automatically determines the HIV-1 RNA concentration for the specimens and controls. **The HIV-1 RNA concentration is expressed in copies (cp)/mL. The conversion factor between HIV-1 RNA copies/mL and HIV-1 International Units (IU)/mL is 0.6 cp/IU, using the WHO 1st International Standard for HIV-1 RNA for Nucleic Acid-Based Techniques (NAT) (NIBSC 97/656).**

AMPLILINK Software:

- Determines the Cycle Threshold value (Ct) for the HIV-1 RNA and the HIV-1 QS RNA.
- Determines the HIV-1 RNA concentration based upon the Ct values for the HIV-1 RNA and HIV-1 QS RNA and the lot-specific calibration coefficients provided on the cassette barcodes.
- Determines that the calculated cp/mL for **HIV-1 L(+)**C and **HIV-1 H(+)**C fall within the assigned ranges.

Batch Validation

Check AMPLILINK software results window or printout for flags and comments to ensure that the batch is valid.

For control orders, a check is made to determine if the cp/mL value for the control is within its specified range. If the cp/mL value for the control lies outside of its range, a FLAG is generated to show the control has failed.

The batch is valid if no flags appear for any of the controls [**HIV-1 H(+)**C, **HIV-1 L(+)**C, **CTM (-)** C]. The following results are obtained for a valid batch:

Control	Result	Interpretation
Negative Control	Target Not Detected	Control within range
Low Positive Control	A numeric titer, X.XXE+XX cp/mL	Control within range
High Positive Control	A numeric titer, X.XXE+XX cp/mL	Control within range

The batch is not valid if any of the following flags appear for the HIV-1 Controls:

Negative Control:

Flag	Result	Interpretation
__N_NC_INVALID	Invalid	An invalid result or a "valid" result that was not negative for HIV-1 target



HIV-1 Low Positive Control:

Flag	Result	Interpretation
__L_LPCINVALID	< 4.80E+01 cp/mL (< 48 cp/mL)	Control below range
__L_LPCINVALID	Target Not Detected	Control below range
__L_LPCINVALID	A numeric titer, X.XXE+XX cp/mL	Control out of range
__L_LPCINVALID	> 1.00E+07 cp/mL (> 10,000,000 cp/mL)	Control above range
__L_LPCINVALID	Invalid	An invalid result

Flag	Result	Interpretation
__H_HPCINVALID	< 4.80E+01 cp/mL (< 48 cp/mL)	Control below range
__H_HPCINVALID	Target Not Detected	Control below range
__H_HPCINVALID	A numeric titer, X.XXE+XX cp/mL	Control out of range
__H_HPCINVALID	> 1.00E+07 cp/mL (> 10,000,000 cp/mL)	Control above range
__H_HPCINVALID	Invalid	An invalid result

HIV-1 High Positive Control:

If the batch is invalid, repeat the entire batch including specimen and control preparation, amplification and detection.

Interpretation of Results:

For a valid batch, check each individual specimen for flags or comments on the result printout. Interpret the results as follows:

⇒ A valid batch may include both valid and invalid specimen results depending on whether flags

Titer Result	Interpretation
Target Not Detected	Ct value for HIV-1 above the limit for the assay or no Ct value for HIV-1 obtained. Report results as "HIV-1 RNA not detected".
< 4.80E+01 cp/mL (< 48 cp/mL)	Calculated cp/mL are below the Limit of Detection of the assay. Report results as "HIV-1 RNA detected, less than 48 HIV-1 RNA cp/mL".
≥ 4.80E+01 cp/mL and ≤ 1.00E+07 cp/mL (≥ 48 cp/mL and ≤ 10,000,000 cp/mL)	Calculated results greater than or equal to 48 cp/mL and less than or equal to 10,000,000 cp/mL are within the Linear Range of the assay.
> 1.00E+07 cp/mL (> 10,000,000 cp/mL)	Calculated cp/mL are above the range of the assay. Report results as "greater than 10,000,000 HIV-1 RNA cp/mL". If quantitative results are desired, the original specimen should be diluted with HIV-1-negative human EDTA-plasma and the test repeated. Multiply the reported result by the dilution factor.

and/or comments are obtained for the individual specimens.

Specimen results are interpreted as follows:

NOTE: *Specimens above the range of the assay may also produce an Invalid result with a flag "QS_INVALID". If quantitative results are desired, the original specimen should be diluted with HIV-1-negative human EDTA-plasma and the test repeated. Multiply the reported result by the dilution factor.*



QUALITY CONTROL

One replicate each of the COBAS® TaqMan® Negative Control, the HIV-1 Low Positive Control and the HIV-1 High Positive Control must be included in each test batch. The batch is valid if no flags appear for any of the controls [HIV-1 H(+)**C**, HIV-1 L(+)**C** and CTM (-) **C**].

There are no requirements regarding the position of the controls on the sample rack.

Check the batch printout for flags and comments to ensure that the batch is valid.

Negative Control

The CTM (-) **C** must yield a "Target Not Detected" result. If the CTM (-) **C** is flagged as invalid, then the entire batch is invalid. Repeat the entire process (specimen and control preparation, amplification and detection). If CTM (-) **C** is consistently invalid in multiple batches, contact your local Roche office for technical assistance.

Positive Controls

The assigned range for HIV-1 L(+)**C** and HIV-1 H(+)**C** is specific for each lot of reagents, and is provided on the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test reagent cassette barcodes.

The HIV-1 RNA cp/mL for HIV-1 L(+)**C** and HIV-1 H(+)**C** should fall within their assigned ranges. If one or both of the positive controls are flagged as invalid, then the entire batch is invalid. Repeat the entire process (specimen and control preparation, amplification and detection). If the HIV-1 RNA titer of one or both of the positive controls is consistently outside the assigned ranges in multiple batches, contact your local Roche office for technical assistance.

PROCEDURAL PRECAUTIONS

1. As with any test procedure, good laboratory technique is essential to the proper performance of this assay.

PROCEDURAL LIMITATIONS

1. This test has been validated for use with only human plasma collected in EDTA anticoagulant. Testing of other specimen types may result in inaccurate results.
2. The performance of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test has neither been evaluated with specimens containing HIV-1 groups O and N, nor with specimens containing HIV-2.
3. Reliable results are dependent on adequate specimen collection, transport, storage and processing procedures.
4. The presence of AmpErase enzyme in the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Master Mix reduces the risk of amplicon contamination. However, contamination from HIV-1 positive controls and clinical specimens can be avoided only by good laboratory practices and careful adherence to the procedures specified in this Package Insert.
5. Use of this product should be limited to personnel trained in the techniques of PCR.
6. This product can only be used with the COBAS® AmpliPrep Instrument and the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer.
7. Detection of HIV-1 RNA is dependent on the number of virus particles present in the specimen and may be affected by specimen collection methods and patient factors (i.e., age, presence of symptoms, and/or stage of the infection).
8. Though rare, mutations within the highly conserved region of the viral genome covered by the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test primers and/or probe may result in the under-quantitation of or failure to detect the virus.
9. Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform correlation studies in their laboratory to quantify technology differences.



INTERFERING SUBSTANCES

Elevated levels of triglycerides, bilirubin, albumin, hemoglobin and human DNA in specimens as well as the presence of autoimmune diseases such as Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA) and Antinuclear Antibody (ANA) have been shown not to interfere with the quantitation of HIV-1 RNA or impact the specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test.

The following drug compounds tested at the Peak Plasma Level (C_{max}) and at 3 times the C_{max} have been shown not to interfere with the quantitation of HIV-1 RNA or impact the specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test with the exception of Nevirapine, for which absence of interference has only been shown at the Peak Plasma Level (C_{max}):

<p>Nucleotide DNA Polymerase Inhibitors Tenofvir Adefovir dipivoxil</p>	<p>Nucleoside Reverse Transcriptase and DNA Polymerase Inhibitors Lamivudine Zidovudine Stavudine Abacavir Didanosine</p>
<p>HIV Protease Inhibitors Indinavir Saquinavir Ritonavir Nelfinavir Amprenavir Lopinavir/Ritonavir</p>	<p>Non-nucleoside HIV Reverse Transcriptase Inhibitors Nevirapine Efavirenz</p> <p>HIV Fusion Inhibitor Enfuvirtide</p>
<p>Immune Modulators Interferon alpha-2a Interferon alpha-2b Peginterferon alpha-2a Peginterferon alpha-2a + Ribavirin Interferon alpha-2b + Ribavirin</p>	<p>Antidepressants Paroxetine HCl Fluoxetine Sertraline</p>
<p>Nucleoside Inhibitors Ribavirin</p>	<p>Compounds for the Treatment of Herpes Viruses Ganciclovir Valganciclovir Acyclovir</p>



NON-CLINICAL PERFORMANCE EVALUATION

A. Limit of Detection

The limit of detection of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was determined by analysis of three independent dilution series of a HIV-1 Secondary Standard (prepared from the HIV-1B strain 8E5 LAV in HIV-1-negative human EDTA plasma). The concentration of the HIV-1 Secondary Standard is traceable to the WHO 1st International Standard for HIV-1 RNA for Nucleic Acid-Based Techniques (NAT) (NIBSC 97/656). A total of 108 replicates per concentration level were tested.

The concentration of HIV-1 RNA in EDTA plasma that can be detected with a positivity rate of greater than 95% as determined by probit analysis is 48 cp/mL. The study was performed for three lots of COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test reagents and the combined results are shown in Table 2.

Table 2
Limit of Detection of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test determined with HIV-1B Secondary Standard in EDTA plasma

Level No.	HIV-1B Input Conc. (copies/mL)	Total Number of Replicates Tested	Number of Positives	Hit Rate
1	100	108	108	100%
2	75	108	108	100%
3	50	108	107	99%
4	40	108	99	92%
5	30	108	98	91%
6	20	108	81	75%
7	10	108	55	51%

B. Precision

Precision and linearity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test were determined by analysis of serial dilutions prepared from a highly concentrated cell culture stock of the HIV-1B in HIV-1-negative human EDTA plasma. The concentration assignment of the HIV-1B linearity panel was performed by a method that ensures traceability to the WHO 1st International Standard for HIV-1 RNA for Nucleic Acid-Based Techniques (NAT) (NIBSC 97/656).

Within-Run, Run-to-Run and Total Precision were evaluated in accordance with the methods defined in the CLSI Guideline EP5-A, "Evaluation of Precision Performance of Clinical Chemistry Devices".⁴¹ A run, consisting of 5 dilution levels and 7 replicates at each level, was performed daily for 15 days. Each sample was carried through the entire COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test procedure, including specimen preparation, amplification and detection using different systems operated by multiple users. Therefore, the precision reported here represents all aspects of the test procedure. The study was performed for three lots of COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test reagents, and the results are shown in Table 3.

Table 3
Total Precision for three lots of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test

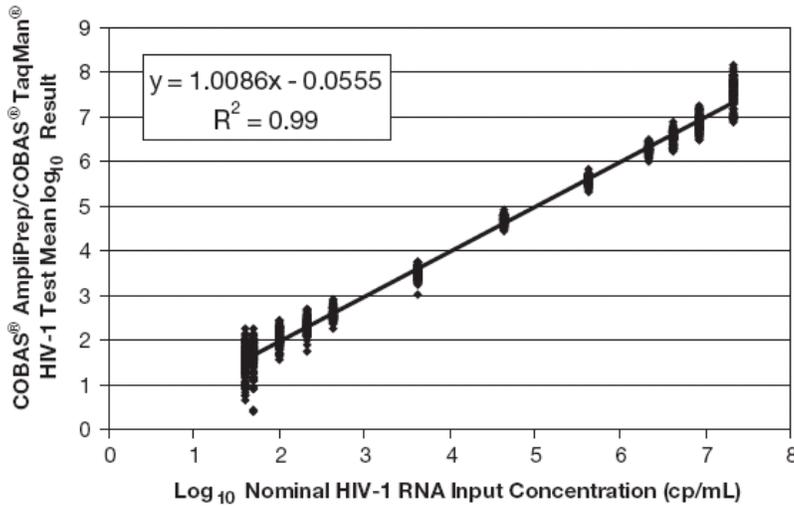
Nominal HIV-1 Conc. Levels [cp/mL]	Log ₁₀ of Nominal Conc.	Lot 1		Lot 2		Lot 3	
		Total CV [%]	Total precision as SD [log ₁₀]	Total CV [%]	Total precision as SD [log ₁₀]	Total CV [%]	Total precision as SD [log ₁₀]
100	2.000	39.5	0.18	41.4	0.18	41.8	0.18
4,310	3.634	24.5	0.11	29.3	0.13	23.1	0.10
43,100	4.634	20.0	0.09	20.6	0.09	16.9	0.08
431,000	5.634	22.4	0.10	20.0	0.09	22.8	0.10
2,150,000	6.333	24.0	0.10	23.5	0.10	24.7	0.10



C. Linear Range

As shown in Figure 7, the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was found to give a linear response from 48 HIV-1 RNA cp/mL to 10,000,000 HIV-1 RNA cp/mL applying the accuracy acceptance criterion of $\pm 0.3 \log_{10}$ from the nominal input concentration. The study was performed using one lot of COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test reagents, with 103 – 105 replicates per level.

Figure 7
Linear range of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test



D. Inclusivity

Eight subtype categories have been proposed for HIV-1 group M based on nucleotide divergence. These subtypes are designated with capital alphabetical letters from A through H⁴⁰.

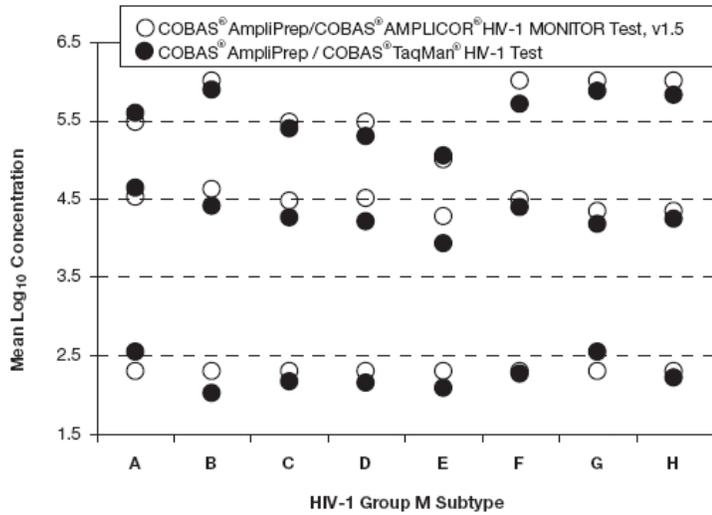
Similar Subtype Quantitation

The performance of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test on HIV-1 subtypes was evaluated by analysis of cell culture stock material of representatives of each HIV-1 group M subtype A through H. The assignment of nominal concentrations of the cell culture stock solutions was performed by the COBAS® AmpliPrep/COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 assay method (Figure 8). Based on the determined stock concentrations, the HIV-1 target concentrations of 200, 19,000 - 33,000 and 100,000 - 1,000,000 cp/mL were prepared for each HIV-1 subtype by exact dilution of the cell culture stock solution in EDTA plasma. Afterwards the concentrations were determined by the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test in n=7 replicates per level of each subtype using one reagent lot. Results were compared to the input concentrations as determined by the reference method.

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test gave equivalent results for all tested representatives of the HIV-1 group M subtypes (see Figure 8). Mean observed log₁₀ concentration results were within $\pm 0.3 \log_{10}$ of the respective reference method input concentration.



Figure 8
Performance of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test on HIV-1 group M Subtypes A through H compared against the reference method COBAS® AmpliPrep/COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5



Subtype Limit of Detection

Parent solutions containing HIV-1 cell culture material representing HIV-1 subtypes A to H have been obtained as frozen stocks from German National Reference Centre for Retrovirology at University Erlangen-Nuremberg, Germany. The certified parent input concentration as determined by the VERSANT® HIV-1 RNA 3.0 Assay (bDNA) reference method was used to prepare the Subtype LOD-panels. Two independent dilution series of the different HIV-1 subtypes, each consisting of seven members with concentrations ranging from 15 to 150 cp/mL, were evaluated on two days with one lot of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test in a total of 24 replicates per concentration level for each subtype representative. The results of the probit analyses at 95% hit rate demonstrate that the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test has a sensitivity of ≤ 50 cp/mL across all subtypes ranging from < 15 to 46 cp/mL of HIV-1 group M as shown in Table 4.



Table 4
Inclusivity as Limit of Detection of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test as determined with cell-cultured viral stocks of the different HIV-1 subtypes diluted in EDTA plasma

Subtype	Isolate Designation	95% hit rate conc. by probit model [cp/mL]	95% Confidence Interval [cp/mL]		Lowest level with ≥ 95% hit rate [cp/mL]
			Lower	Upper	
A	92UG029	20			30
A	92UG037	52			50
A	4237A/98	< 15			15
A combined	92UG029/92UG037/ 4237A/98	23	12	34	40
B	HIV-1 Secondary Standard (8E5 LAV)	38			40
B	WHO 1 st Int. Std. for HIV-1 RNA (97/656)	46			50
B	MVP-899-87	35			50
B combined	HIV-1 Secondary Standard (8E5 LAV)/ WHO 1 st Int. Std. for HIV-1 RNA (97/656)/ MVP-899-87	40	33	50	50
C	92BR025	16			30
C	98TZ017	50			50
C	3777A/97	16			15
C combined	92BR025/98TZ017/ 3777A/97	31	25	41	40
D	92UG021	35			40
D	92UG035	< 15			15
D	92UG024	17			30
D combined	92UG021/92UG035/ 92UG024	26	22	34	40
E	92TH022	< 15			15
E	92TH009	44			50
E	92TH001	34			50
E combined	92TH022/92TH009/ 92TH001	33	27	44	50
F	93BR020	46	34	82	40
G	ARP173/RU570	< 15	NA	NA	15
H	ARP175/HIV V1557	< 15	NA	NA	15

NA - not applicable (no analysis possible since the statistical software does not allow calculating a confidence interval based on the observed hit rate profile)

E. Specificity

The clinical specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was determined by analysis of HIV-1-negative EDTA plasma specimens from blood donors. A total of 513 individual EDTA plasma specimens were tested. All specimens were negative for HIV-1 RNA. Based on these results, the clinical specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is 100% with the confidence interval ranging from 99.3 to 100%.



F. Analytical Specificity

The analytical specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was evaluated by adding cultured organisms (viruses, bacteria, yeast) or DNA (HTLV-2) at 50,000 particles/mL input concentration into HIV-1-negative human EDTA plasma and into HIV-1-positive human EDTA plasma at 10,000 cp/mL HIV-1 (see Table 5). The cultured organisms added to specimens have been shown not to interfere with the quantitation of HIV-1 RNA or impact the specificity of COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test.

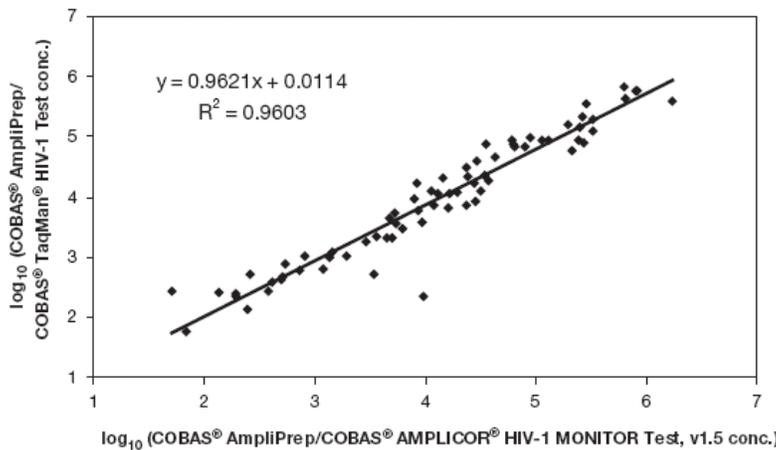
Table 5
Analytical Specificity Organisms

<p>Virus</p> <p><i>Adenovirus type 2</i></p> <p><i>Cytomegalovirus</i></p> <p><i>Epstein-Barr Virus</i></p> <p><i>Human Herpes Virus type 6</i></p> <p><i>Herpes simplex virus type 1</i></p> <p><i>Herpes simplex virus type 2</i></p> <p><i>Human T-Cell Lymphotropic virus type 1</i></p> <p><i>Human T-Cell Lymphotropic virus type 2</i></p> <p><i>Influenza A</i></p> <p><i>Hepatitis A virus</i></p> <p><i>Hepatitis B virus</i></p> <p><i>Hepatitis C virus</i></p>	<p>Bacteria</p> <p><i>Staphylococcus aureus</i></p> <p><i>Propionibacterium acnes</i></p>
	<p>Yeast</p> <p><i>Candida albicans</i></p>

G. Method Correlation

The performance of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was compared to the COBAS® AmpliPrep/COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5, to the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 and to the VERSANT HIV-1 RNA 3.0 Assay (bDNA) by analysis of n=71 undiluted clinically characterized plasma specimens from HIV-1 infected patients. Specimens were obtained from Teragenix (Fort Lauderdale, FL, USA). Correlation was determined using the specimens for which quantitative results were obtained with each method under comparison. Specimens with a concentration result above the measuring range of the COBAS® AmpliPrep/COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 using the ultrasensitive procedure (PHS) were prediluted to fall into the measuring range of the PHS. Bivariate linear regression analysis was performed on those specimens that yielded results within the linear range as shown in Figures 9, 10 and 11. The results obtained with the three methods under comparison showed high correlation.

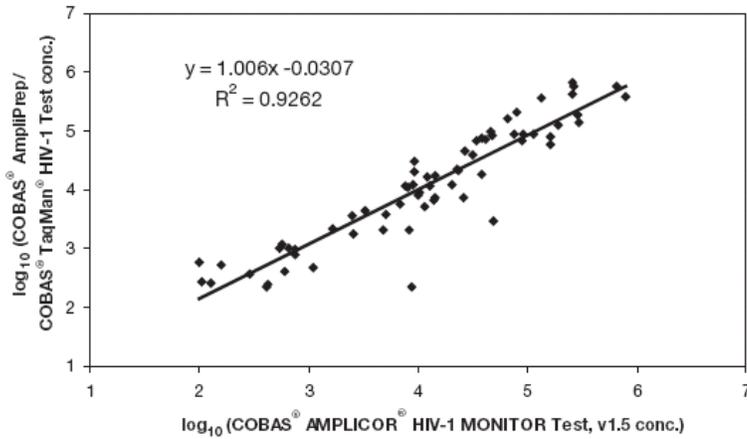
Figure 9
Correlation of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test and the COBAS® AmpliPrep/COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5



Note: Approximately 1.5% of all samples tested showed lower quantitation by > 0.5 log when compared to the COBAS® AmpliPrep/COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5.

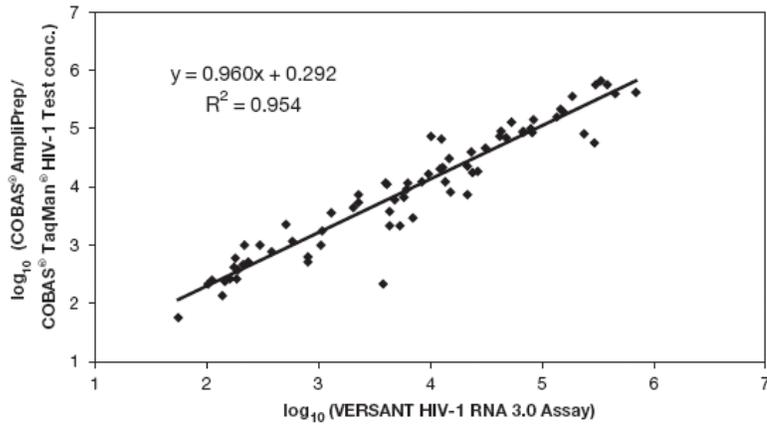


Figure 10
Correlation of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test
and the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5



Note: Approximately 1.5% of all samples tested showed lower quantitation by > 0.5 log when compared to the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5

Figure 11
Correlation of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test
and the VERSANT HIV-1 RNA 3.0 Assay (bDNA)





CLINICAL PERFORMANCE EVALUATION

A. Reproducibility

This study was conducted to evaluate the reproducibility of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test in EDTA plasma. Well characterized HIV-1 group M, subtype B virus stock cultures and EDTA plasma that was negative for HIV-1 RNA and HIV 1/2 antibodies were used to construct a 10-member panel. The study was designed to measure inter-run, intra-run, lot to lot, day to day, site to site, and operator to operator variability. Each panel was tested by multiple operators at each of three sites; one internal Roche Molecular Systems, Inc. (RMS) site, and two sites external to RMS. Each operator performed 5 days of testing on each of 3 lots of reagents with each panel. Each operator was to complete 1 run per day. Each run comprised a single panel with each panel member tested in duplicate.

Precision was evaluated using a random effects model with terms for lot, site/instrument, operator within site, between day/run and within-run components.

Table 6 shows the total precision variance and total precision standard deviation as determined by analysis of variance. Analysis of variance provides an estimate of the total precision of the test that properly weights the between-lot, between-site/instrument, between-operator, between-day/run (day-to-day) and within-run components. The total precision reported as lognormal variance was less than 35% for all panel members except the panel member with the lowest concentration (100 copies/mL). The within-run component contributed the most variability (56% to 100%), followed by lot-to-lot variability. The site/instrument, operator and day/run components contributed less to variability.

Table 7 summarizes the results for the HIV-1 Negative Panel Member. The negative panel member was used to estimate the analytical specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test. One false positive result was observed out of 179 valid test results giving a specificity of 99% [95% Confidence Interval (CI) = (0.97, 1.00)].

Table 6
Reproducibility Results Summary

HIV-1 RNA Concentration (log10 cp/mL)			Contribution to Total Variance (%)					Total Precision
Expected	Observed (Average)	N	Lot	Site / Instrument	Operator	Day / Run	Within Run	Standard Deviation (Lognormal %CV)
2.000	2.020	147	0%	0%	0%	0%	100%	0.19 (46%)
2.699	2.743	173	2%	6%	4%	20%	68%	0.14 (34%)
3.000	2.995	178	0%	8%	0%	8%	84%	0.14 (32%)
3.699	3.743	178	16%	5%	3%	18%	57%	0.14 (34%)
4.301	4.410	179	14%	6%	2%	5%	74%	0.14 (32%)
4.699	4.836	178	21%	1%	0%	2%	76%	0.12 (29%)
5.398	5.501	178	32%	0%	0%	6%	62%	0.13 (31%)
5.699	5.837	178	28%	0%	0%	3%	68%	0.14 (34%)
6.699	6.871	108	32%	4%	0%	9%	56%	0.13 (30%)

Note: Within assay range results are from 4.80E+1 cp/mL to 1.00E+7 cp/mL inclusive.

Table 7
HIV-1 Negative Panel Member Summary

Total Valid Results	Target Not Detected	Target Detected	Analytical Specificity	Exact 95% CI
179	178	1	0.99	(0.97, 1.00)



Clinical Sensitivity and Specificity

Methodology

This study was designed to evaluate the clinical specificity and sensitivity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test by testing fresh and frozen samples collected from normal healthy donors and patients with HIV-1. This study compared Test results obtained with the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test to those obtained with an FDA-approved test, ie, the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5. Clinical specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was evaluated by testing 399 frozen samples and 120 fresh samples, in EDTA plasma, collected from normal healthy blood donors who were negative for HIV-1 antibodies. Frozen samples were randomly distributed across testing sites. Fresh samples were distributed to testing sites in a non-random manner. Clinical sensitivity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was evaluated testing 351 frozen samples with HIV-1 RNA concentrations ≥50 cp/mL and 122 fresh samples in EDTA plasma, collected from HIV-1-positive blood donors. Frozen samples were randomly distributed across testing sites, stratified by CD4 count category. Fresh samples were distributed to testing sites in a non-random manner. Frozen samples used in this study were previously tested with COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 and, therefore, were not retested in this study on that platform. Collection of frozen normal donor (HIV-1-negative) samples occurred at 4 sites: 1 each in Tennessee, Florida, Pennsylvania, and California. Collection of frozen HIV-1-positive samples occurred at 6 sites: 1 each in California, New Jersey, Maryland, and Missouri, and at 2 sites in Florida. Collection of fresh samples occurred at 5 sites, as follows: HIV-1-positive samples were collected at 4 sites: 2 in Florida, 2 in California; samples from normal healthy donors were collected at 1 site in Tennessee. Fresh samples collected for this study were tested prospectively on the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 platform. Testing was performed at 3 sites, with 1 COBAS® AmpliPrep/COBAS® TaqMan® 48 Analyzer system per site, with at least 3 reagent lots.

Statistical Methods

Normal subjects were considered evaluable if they contributed both valid COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test and COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 results (where the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 result was Target Not Detected). HIV-1 subjects were considered evaluable if they contributed both valid COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test and COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 results (where the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 result was ≥50 cp/mL).

COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical specificity was calculated as the percentage (95% exact confidence interval [CI]) of normal subjects with Target Not Detected COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 results, who had Target Not Detected COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test results. COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical specificity was calculated overall and by sample type (fresh and frozen separately).

COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical sensitivity was calculated as the percentage (95% exact CI) of HIV-1 subjects with COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 results ≥50 cp/mL, who had detectable HIV-1 viral load on the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test. COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical sensitivity was calculated overall and by CD4 count category (<200, 200-500, >500 cells/μL) and sample type (fresh and frozen separately).

Results

Table 8 summarizes the number of fresh and frozen samples from evaluable normal and HIV-1 subjects in this study.

Table 8
Number of Evaluable Normal and HIV-1 Subjects by Sample Type

Sample Type	Normal Subjects	HIV-1 Subjects	Total
Fresh	120 (23.1%)	122 (25.8%)	242
Frozen	399 (76.9%)	351 (74.2%)	750
Total	519	473	992

Table 9 shows the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical specificity results from the 519 evaluable normal subjects. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical specificity was 99.4% (516/519; 95% CI = 98.3% to 99.9%). The HIV-1-positive COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test results were all <48 cp/mL.



Table 9
COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Specificity - Evaluable Normal Subjects

COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 Result	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Result		Total	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Clinical Specificity (95% Exact CI)
	HIV-1 Positive	HIV-1 Negative		
HIV-1 Negative	3 (0.6%)	516 (99.4%)	519	99.4% (98.3%, 99.9%)

Note: CI = Confidence Interval

Table 10 shows the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical sensitivity results from the 473 evaluable HIV-1 subjects. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical sensitivity was 98.3% (465/473; 95% CI = 96.7% to 99.3%).

Table 10
COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Sensitivity - Evaluable HIV-1 Subjects

COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 Result	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Result		Total	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Clinical Sensitivity (95% Exact CI)
	HIV-1 Positive	HIV-1 Negative		
HIV-1 Positive	465 (98.3%)	8 (1.7%)	473	98.3% (96.7%, 99.3%)

*All 8 samples that were determined to be positive for HIV-1 by COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 but not by COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test had a low copy number: 6 of the 8 had HIV-1 titers of < 100 cp/mL, 1 had a titer of 253 cp/mL, and the remaining sample had a titer of 479 cp/mL.

Note: CI = Confidence Interval

Table 11 shows the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test clinical sensitivity by CD4 count category (<200, 200-500, >500 cells/μL).

Table 11
COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Sensitivity by CD4 Count Category - Evaluable HIV-1 Subjects

CD4 Count Category (cells/μL)	COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 Result	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Result		Total	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Clinical Sensitivity (95% Exact CI)
		HIV-1 Positive	HIV-1 Negative		
<200	HIV-1 Positive	141 (99.3%)	1 (0.7%)	142	99.3% (96.1%, 100.0%)
200 – 500	HIV-1 Positive	212 (98.6%)	3 (1.4%)	215	98.6% (96.0%, 99.7%)
>500	HIV-1 Positive	112 (96.6%)	4 (3.4%)	116	96.6% (91.4%, 99.1%)

Note: CI = Confidence Interval



Conclusion

When compared with results from the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5, clinical specificity of the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was 99.4%, and clinical sensitivity was 98.3%, indicating similar performance of both tests. Furthermore, in both fresh and frozen samples, the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test showed similar specificity (>98%) and sensitivity (>98%), indicating comparable test performance for both sample types.

Selection of the HIV-1 samples included in this study was based on a single test result with the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5. For low titer samples, the results from the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 are subject to large variability (coefficient of variation = 50% at 100 cp/mL). All 8 samples that were determined to be positive for HIV-1 by the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 but not by the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test had a low copy number: 6 of the 8 had HIV-1 titers of <100 cp/mL, 1 had a titer of 253 cp/mL, and the remaining sample had a titer of 479 cp/mL. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test was able to detect 111 out of the 119 samples with titers <480 cp/mL. The observed results are consistent with what is expected with low-titer samples. Furthermore, the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test and the COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5 appeared to show comparable agreement across the linear range.

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test also showed similar clinical sensitivity among CD4 count categories (>96% overall), suggesting comparable performance in samples from HIV-1 patients with various CD4 counts.



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Efficiency. Enhanced Reproducibility. Confidence.

The COBAS AmpliPrep System provides automated sample preparation, “walk-away” technology and significantly reduces hands-on time so your staff can focus on more valuable tasks.

Features and benefits

- 72 samples can be loaded at once and processed within 4 hours to meet high-volume testing demands
- Continuous sample and reagent loading without operation interruption minimizes downtime and maximizes hands-off time for the operator
- Bar-coded sample racks and reagents provide positive sample identification and reagent tracking to reduce hands-on time
- Dedicated and disposable sample processing units minimize the potential for cross-contamination
- Ready-to-use, compact reagent cassettes are designed to eliminate manual preparation time and prevent manual preparation errors





COBAS AmpliPrep System Specifications

Physical Dimensions	65" x 29" x 37" (W x D x H)
Weight	683 lbs.
Electrical Power Requirements	Line voltage: 100 – 125 & 200 – 240 VAC (+10, -15%) Frequency: 50 – 60 Hz
Power Consumption	1,000 VA (instrument) 200 VA (data station)
Technology	Solution-phase magnetic bead separation
Reagents	Requires test-specific, bar-coded, ready-to-use COBAS AmpliPrep Kits
Throughput	Up to 144 specimens per day, based on testing combinations and laboratory workflow
Samples	Serum or plasma, collected in appropriate anticoagulant if necessary
Sample Volume	250 – 1,100 µL (depending on extraction protocol)
On-board Capacity	72 samples per run (maximum)
Incubator Blocks	6 independently programmed incubators with 24 positions each • 3 maintained at 60°C • 3 maintained at 37°C
Controls	An Internal Control/Quantitation Standard (IC/QS) can be incorporated into each individual sample and is carried through the sample preparation. It compensates for any potential loss of target and/or traces of potential inhibitors in the consecutive amplification step. • Controls included as part of reagent kit and required for each preparation run for FDA-approved assays
Wash Reservoir	2 pre-packaged, 4-liter cube containers of wash reagent (with pressure sensor)
Waste Container	20-liter capacity (with pressure sensor)
Data Station	Custom-built PC (included) with Microsoft® Windows® (NT v. 4.0 and higher) and AMPLILINK® Software to control COBAS AmpliPrep System
Bar-code Scanner	<i>On COBAS AmpliPrep System:</i> on-board bar-code scanner for reagent racks, reagent cassettes and specimen clips <i>On AMPLILINK Data Station:</i> handheld bar-code scanner for original specimen/specimen clip
Host Interfaces	Bi-directional RS-232C interface for host connection
Printer Interfaces	LPT interface via parallel port
Certifications	UL, IEC, FCC, JIS, UL 3101-1, IEC C1010-1, FCC and JIS C1010-1

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The COBAS® TaqMan® 48 Analyzer is a fully automated, closed-tube system that makes molecular testing practical for everyday lab use. This real-time PCR analyzer is compact and robust, provides a broad linear range, and integrates easily into your lab.



Features and benefits

- Real-time TaqMan® PCR methodology provides unmatched accuracy, superior linear range, and the potential to run one test for quantitative and qualitative requirements
- Run sizes of 6 to 48 samples provide flexibility and maximum efficiency
- The utility channel adds flexibility and cost effectiveness by allowing the laboratory to run IVD and user-defined assays on one fast, easy, and accurate platform
- Two independently operating thermal cyclers provide approximate run times of 90 to 120 minutes to increase workflow flexibility and minimize the need for multiple platforms
- AMPLILINK® Software is Windows® driven for easy navigation, and provides the security of positive sample ID throughout the run, as well as enhanced LIS capabilities





COBAS® TaqMan® 48 Analyzer Specifications

Physical Dimensions	18" x 30" x 20" (W x D x H)		
Weight	121 lbs.		
Technology	Fully automated amplification and detection analyzer for homogenous 5' nuclease assays		
Software	AMPLILINK Software is a Windows-based, LIS-compatible user interface that manages up to 3 COBAS® TaqMan® 48 Analyzers		
Host Interfaces	RS232 or LAN connections using ASTM protocol interface to the laboratory host computer		
Printer Interfaces	LPT interface via parallel port or LAN for remote printing		
Data Station	Custom-built PC supplied with the COBAS® TaqMan® 48 Analyzer; data station runs Microsoft® Windows XP Professional operating system and AMPLILINK Software		
Certifications	UL, IEC, CSA, UL 61010A-1, EN/IEC 61010-1, CAN/CSA C22.2 No. 1010.1		
Electrical Power Requirements	Line voltage: 120 or 240 VAC Frequency: 50 or 60 Hz Power Consumption: 600 VA (analyzer); 200 VA (data station)		
Thermal Cycler Segments	2 segments x 24 tests		
Loading Capacity	Up to 2 different tests on board simultaneously; each thermal cycler can run individual PCR profiles		
Samples	PCR-ready set-up samples		
Sample Volumes	70 µL – 100 µL		
Utility Channel Definitions	Up to 10 different PCR profiles (methods) can be stored and protected from unintentional modifications		
Temperature Control Range	40°C – 98°C		
Temperature Accuracy	± 1°C over the range of 40°C – 98°C		
Number of Color Detections	Up to 4 different wavelength combinations are supported (filterwheel)		
Filter Specifications	Filter	Excitation Filter	Emission Filter
	Set 1	485 nm	520 nm
	Set 2	540 nm	575 nm
	Set 3	485 nm	645 nm
	Set 4	485 nm	725 nm

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