CITY OF CHICAGO DEPARTMENT OF PROCUREMENT SERVICES ROOM 403, CITY HALL, 121 N. LA SALLE ST.

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IUSTIFICATION FOR NON-COMPETITIVE PROCUREMENT FILE COPY

COMPLETE TH	IIS SECTION IF NEW	CONTRACT			
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City of Chicago Richard M. Daley, Mayor

Chicago Dept. of Public Health

Dr. Terry Mason, M.D., F.A.C.S., Commissioner

HIV / AIDS Training Unit 31st Street STD Clinic 530 E. 31st Street Chicago, Illinois 60616 (312) 745-0531 (312) 745-2250 (FAX) To: Montel/M. Gayles

Chiff Procurement Officer

City of Chicago Department of Procurement Services

From: Terry Mason, M.d., F.A.C.S

Commissioner, Chicago Department of Public Health

Date: 06/18/08

RE: Sole Source Justification with Trinity Biotech

The Chicago Department of Public Health (CDPH) requires a Sole Source contract with Trinity Biotech, Inc. Trinity BioTech, Inc. is the sole manufacturer and distributor of the Uni-GoldTM Recombigen® HIV assay and Uni-GoldTM Recombigen® HIV controls.

Uni-Gold™ Recombigen® HIV is a single use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold™ Recombigen® HIV is intended for use in point of care settings as an aid in diagnosis of infection with HIV-1. This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

Uni-Gold™ Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 in human serum, plasma and whole blood (venipuncture and fingerstick). In addition, the Uni-Gold™ Recombigen® HIV is the only rapid HIV assay based on the most current FDA approved 3rd generation enzyme immunoassay..

The Uni-Gold™ Recombigen® HIV device is easily adapted to a lab-based HIV testing algorithm that will facilitate the Health Department's ability to implement routine, opt-out HIV testing in accordance with the Center's for Disease Control and Preventions (CDC's) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings (2006).

Thank you for your assistance with this matter. If you have questions or need additional information, please contact Rosemary Lebron at 312.747.9657.

cc: Rosemary Lebron

PU079G_Pre-Appd_Req_DPS_Schedul ed_Dept_Burst_APSRPT.rep Page 1 of 1 Run 06/27/2008 04:31

CITY OF CHICAGO PURCHASE REQUISITION

Copy (Department)

DELIVER TO:

041- DEPAUL 2FL 333 S. STATE ST. 2ND FLOOR Chicago, IL 60604 **REQUISITION: 38986**

PAGE:

DEPARTMENT: 41 - DEPARTMENT OF HEALTH

PREPARER:

Richard W Rzeszutko

NEEDED:

APPROVED: 6/26/2008

REQUISITION DESCRIPTION

SOLE SOURCE CONTRACT WITH TRINITY BIOTECH, INC. FOR UNI-GOLD RAPID HIV TESTING DEVICES AND CONTROLS SPECIFICATION NUMBER: 67049

COMMODITY INFORMATION

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REQUISITION TOTAL:

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Sole Source Justification: Trinity Biotech Plc.

In September 2007, the Chicago Department of Public Health, Division of STD/HIV/AIDS Public Policy and Programs received a three-year award from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA under Funding Opportunity Announcement number *PS07-768*, *Expanded and Integrated Human Immunodeficiency Virus (HIV) Testing for Populations Disproportionately Affected by HIV, Primarily African Americans*. The overall purpose of this initiative is to test 1.5 million persons for HIV and identify 20,000 HIV infected persons who are unaware of their status. Chicago has an annual goal of 70,000 HIV tests under this initiative.

Funding in this announcement was available for health departments to increase HIV testing opportunities for populations disproportionately affected by HIV—primarily African Americans who are unaware of their HIV status. 100% (one hundred percent) of the funds are required to support HIV testing, screening and related activities including linkage to care, Partner Counseling and Referral Services (PCRS) and the purchase of HIV Rapid Tests (blood and oral fluid).

The Chicago Department of Public Health has partnered with the following community-based providers

to integrate routine rapid HIV testing in their clinical settings:

Organization	Clinical Setting Type
Ruth M. Rothstein CORE Center	STD Clinic
Cermak Health Services/Cook County Jail	Correctional
Provident Hospital	ED/Inpatient/Urgent Care
John Stroger Hospital	ED/Urgent Care
Mt Sinai Hospital	ED
Advocate/Trinity Hospital	ED

In order to achieve this goal -and fulfill contractual obligations- many of the partner sites have decided to integrate a lab-based HIV test algorithm. This allows them to conduct more testing on a daily basis and employ a rapid HIV test based the most current 3rd generation enzyme immunoassay (EIA).

Uni-Gold is the only single use rapid immunoassay based on the most current FDA approved 3rd generation enzyme immunoassay (EIA). In addition, it is the only rapid HIV test with a ten-minute read time. Trinity BioTech, Plc., is the sole manufacturer and distributor of the Uni-GoldTM Recombigen® HIV assay and Uni-GoldTM Recombigen® HIV controls.

• Specification:

- O Uni-Gold™ Recombigen® HIV is a single use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold™ Recombigen® HIV is intended for use in point of care settings as an aid in diagnosis of infection with HIV-1.
- This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

• Principle

- O Uni-Gold™ Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 in human serum, plasma and whole blood (venipuncture and fingerstick).
- O Uni-Gold™ Recombigen® HIV uses proteins representing regions of the HIV virus. If antibodies to HIV-1 are present in the sample, they combine with these proteins and a color reagent and this complex binds to the proteins in the test forming a visible pink/red band in the test region of the device adjacent to the word 'Test'.
- The control line should always appear as a visible pink/red band in the control region of the
 device to indicate that the test device is functioning correctly.
 - o A reactive result is indicated by a pink/red band in the test region of the device.
 - O A non-reactive result occurs in the absence of detectable levels of antibodies to HIV-1 in the specimen; consequently no visually detectable band develops in the test region of the device.

Description

- o CLIA complexity;
 - Waived for whole blood fingerstick and venipuncture samples
 - Moderate complexity for serum and plasma samples

• Controls:

- Intended Use
 - Uni-GoldTM Recombigen® HIV Controls are intended for use only with the Uni-GoldTM Recombigen® HIV test.
 - Uni-Gold™ Recombigen® HIV Controls have been designed for use with the Uni-Gold™ Recombigen® HIV assay to validate the correct performance of the device in the hands of the user.
 - Uni-GoldTM Recombigen® HIV Positive Control is prepared from inactivated human serum or plasma. It is negative for HbsAg and anti-HCV by U.S. FDA licensed test procedures. Source materials are reactive for antigens to HIV-1.
 - Positive Controls do not have assigned quantitative values, each lot of material has been designed to produce a positive reaction within a target range, when tested on the Uni-GoldTM Recombigen® HIV assay.
 - Uni-GoldTM Recombigen® HIV Negative Controls are prepared from defibrinated delipidised human serum which has been screened for Anti-HIV-1 and HIV-2, HbsAg and Anti-HCV. Uni-GoldTM Recombigen® HIV Negative Controls have been designed to give a negative reaction when tested on the Uni-GoldTM Recombigen® HIV assay.

These supplies will be shipped to the following CDPH clinics in care of the following individuals.

CDPH Mile Square

ATTN: Felicia Hinton/Tracy Martin

2045 W. Washington

Chicago, IL 60612

Phone: 312.413.0090

Estimated Cost:

109,090 Uni-Gold™ Recombigen® HIV-1 Test Devices@ \$8.25ea = \$899,992.50

4,018 Uni-Gold™ Recombigen® HIV Controls@ \$22.40ea = \$90,003.20

Total Estimated Cost: \$989,995.70



Phone: 800-325-3424 Fax: 908-898-1063 www.trinitybiotech.com

QUOTATION

Account Manager:	Heather Wilson	Da	Date: 6/10/08				
Account Name:	Chicago Dept of Public Health						
Account Address:	333 S. State St., 2 nd FI	oor					
	Chicago, IL 60604						
Contact Name:	Paul LaKosky, M.A.						
Title & Department:	Director of HIV Counse	eling & Testing Service	es				
Telephone:	312-747-9655	Fax: <u>312-747-</u> 9	9663				
Catalog #	Description	Price per Test	Total Price				
1206506	Uni-Gold HIV kit	\$8.25	\$165				
1206530	Uni-Gold HIV Controls		\$22.40				
Pricing Valid Until: 9	-10-2008	Authorized By: Heath	ner Wilson				
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IMPORTANT: PLEASE READ AND FOLLOW THE INSTRUCTIONS FOR COMPLETING THE PROJECT CHECKLIST AND CONTACT THE APPROPRIATE UNIT MANAGER IF YOU HAVE ANY FURTHER QUESTIONS. ALL INFORMATION SHOULD BE COMPLETED, ATTACH ALL REQUIRED MATERIALS AND SUBMIT FOR HANDLING TO THE DEPARTMENT OF PROCUREMENT SERVICES, ROOM 403, CITY HALL, 121 N. LASALLE STREET, CHICAGO, ILLINOIS 60602.

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PRE BID/SUBMITTAL REQUIREMENTS: Requesting Pre Bid/Submittal Conference? Yes ⊠No Requesting Site Visit? □Yes ⊠No ARCHITECTURAL/ENGINEERING SUPPLEMENTAL CHECKLIST Required Attachments: Scope of Services, including location, description of project, services required, deliverables, and other information as required Risk Management Will services be performed within 50 feet of CTA train or other railroad property? □Yes □No Will services be performed on or near a waterway?]Yes ∏No If applicable, Pre-Qualification Category No. Category Description: For Pre-Qualification Program, attach list of suggested firms to be solicited Other Agency Concurrence Required: None State Federal Other (fill in) AVIATION CONSTRUCTION SUPPLEMENTAL CHECKLIST DOA sign-off for final design documents: Yes No **Required Attachments:** Copy of Draft Contract Documents and Detailed Specifications. Risk Management: Current Insurance Requirements prepared/approved by Risk Management: Yes No Will work be performed within 50 feet of CTA or ATS structure or property? Yes \overline{\overline{1}}\text{ No }\overline{\overline{1}}\text{ Will work be performed airside? Yes ☐ No ☐ *NOTE: Any non-construction Aviation request, complete the applicable section. **COMMODITIES SUPPLEMENTAL CHECKLIST** Required Attachments: Detailed Specifications (Scope of Services) including detailed description of the product, delivery location, user department contact, price escalation considerations, Bidder's qualification, contract term and extension options, Contractor's qualifications, citation of any applicable City/State/Federal statutes or regulations, citation of any applicable technical standards and Price Lists/Catalogs, technical drawings and other exhibits and attachments as appropriate. If Modification request, please verify and provide the following: Contractor's Name: Contractor's Address: Contractor's e-mail Address: Contractor's Phone Number: Contractor's Contact Person: CONSTRUCTION SUPPLEMENTAL CHECKLIST Required attachments: Copy of Draft (80% Completion), Contract Documents and Detailed Specifications Risk Management Will services be performed within 50 feet of CTA train or other railroad property? Yes \(\bar{\text{No}}\) Will services be performed on or near a waterway?

Yes ☐ No

VEHICLES/HEAVY EQUIPMENT SUPPLEMENTAL CHECKLIST

Detailed Specifications including detailed description of the vehicle(s) or equipment, mounted equipment, if any, and options/accessories. Special Provisions (Delivery, Warranty, Manuals, Training, Additional Unit Purchase Options, Bid Submittal Information, etc.) Delivery Location(s) Technical Literature Drawings, if any
Part Number List (Manufacturer; or Dealer; or Other Source:) Current Price List(s)/Catalog(s) Special Approval Form Exhibits and Attachments
If Modification request, please verify and provide the following:
Contractor's Name:
Contractor's Address:
Contractor's e-mail Address:
Contractor's Phone Number:
Contractor's Contact Person:
PROFESSIONAL SERVICES SUPPLEMENTAL CHECKLIST
☐ Detailed description of project listing obligations of each party. ☐ The Schedule of Compensation
☐ Deliverables ☐ Request for individual contract services (if applicable) ☐ The appropriate EPS form ☐ ITSC (approved by BIS) ☐ OBM (approved by Budget form/memo) ☐ Grant document attached
☐ Deliverables ☐ Request for individual contract services (if applicable) ☐ The appropriate EPS form ☐ ITSC (approved by BIS) ☐ OBM (approved by Budget form/memo) ☐ Grant document attached Attach any documentation indicating any previous purchase activity to assist in the procurement process
Deliverables Request for individual contract services (if applicable) The appropriate EPS form ITSC (approved by BIS) OBM (approved by Budget form/memo) Grant document attached Attach any documentation indicating any previous purchase activity to assist in the procurement process TELECOMMUNICATIONS AND UTILITIES SUPPLEMENTAL CHECKLIST
☐ Deliverables ☐ Request for individual contract services (if applicable) ☐ The appropriate EPS form ☐ ITSC (approved by BIS) ☐ OBM (approved by Budget form/memo) ☐ Grant document attached Attach any documentation indicating any previous purchase activity to assist in the procurement process

Form Dated 04/24/2007

WORK SERVICES/FACILITY MAINTENANCE SUPPLEMENTAL CHECKLIST

Required Attachments: Detailed Specifications (Scope of Services) including detailed description of the work, locations (with supporting detail), user department contacts, work hours/days, laborer/supervisor mix, compensation and price escalation considerations, Bidder's qualification, contract term and extension options, Contractor's qualifications, citation of any applicable City/State/Federal statutes or regulations, citation of any applicable technical standards and Price Lists/Catalogs, technical drawings and other exhibits and attachments as appropriate.

Risk Management:		
Will services be performed within 50 feet (50') of CTA train or other railroad property?	□Yes	□No
Will services be performed on or near a waterway?	□Yes	□No
Will services require the handling of hazardous/bio-waste material?	□Yes	□No
Will services require the blocking of streets or sidewalks which may affect public safety?	□Yes	□No
If Modification or Amendment request, please verify and provide the following:		
Contractor's Name:		
Contractor's Address:		
Contractor's e-mail Address:		
Contractor's Phone Number:		
Contractor's Contact Person:		

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CDPH Mile Square ATTN: Felicia Hinton/Tracy Martin

2045 W. Washington Chicago, IL 60612

Phone: 312.413.0090

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IMPORTANT: PLEASE READ AND FOLLOW THE INSTRUCTIONS FOR COMPLETING THE PROJECT CHECKLIST AND CONTACT THE APPROPRIATE UNIT MANAGER IF YOU HAVE ANY FURTHER QUESTIONS. ALL INFORMATION SHOULD BE COMPLETED, ATTACH ALL REQUIRED MATERIALS AND SUBMIT FOR HANDLING TO THE DEPARTMENT OF PROCUREMENT SERVICES, ROOM 403, CITY HALL, 121 N. LASALLE STREET, CHICAGO, ILLINOIS 60602.

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	esting Pre Bid/Submittal Conference? ☐Yes ☑No Requesting Site Visit? ☐Yes ☑No										
	ARCHITECTURAL ENGINEERING SUPPLEMENTAL CHECKLIST										
	Required Attachments: Scope of Services, including location, description of project, services required, deliverables, and other information as required Risk Management Will services be performed within 50 feet of CTA train or other railroad property? Will services be performed on or near a waterway? If applicable, Pre-Qualification Category No. Category Description: For Pre-Qualification Program, attach list of suggested firms to be solicited Other Agency Concurrence Required: None State Federal Other (fill in)										
-	AVIATION CONSTRUCTION SUPPLEMENTAL CHECKLIST										
	DOA sign-off for final design documents: \[Yes \] No Required Attachments: Copy of Draft Contract Documents and Detailed Specifications. Risk Management: Current Insurance Requirements prepared/approved by Risk Management: Yes \[No \] Will work be performed within 50 feet of CTA or ATS structure or property? Yes \[No \] Will work be performed airside? Yes \[No \] *NOTE: Any non-construction Aviation request, complete the applicable section.										
	COMMODITIES SUPPLEMENTAL CHECKLIST										
	Required Attachments: Detailed Specifications (Scope of Services) including detailed description of the product, delivery location, user department contact, price escalation considerations, Bidder's qualification, contract term and extension options, Contractor's qualifications, citation of any applicable City/State/Federal statutes or regulations, citation of any applicable technical standards and Price Lists/Catalogs, technical drawings and other exhibits and attachments as appropriate.										
	If Modification request, please verify and provide the following:										
	Contractor's Name:										
	Contractor's Address:										
	Contractor's e-mail Address:										
	Centractor's Phone Number:										
	Contractor's Contact Person:										
	CONSTRUCTION SUPPLEMENTAL CHECKLIST										
	Required attachments:										
	Copy of Draft (80% Completion), Contract Documents and Detailed Specifications Risk Management										
	Will services be performed within 50 feet of CTA train or other railroad property? Will services be performed on or near a waterway?										

VEHICLES/HEAVY EQUIPMENT SUPPLEMENTAL CHECKLIST

Required Attachments: Detailed Specifications if any, and options/acces Special Provisions (Deliable Submittal Information Delivery Location(s) Technical Literature Drawings, if any	ssories. very, Warranty, Manu:			
☐ Part Number List (☐ Current Price List(s)/Cat☐ Special Approval Form☐ Exhibits and Attachmen		Oealer;	or Other Source:)
If Modification request, pl	ease verify and provid	le the following		
Contractor's Name:				
Contractor's Address:				
Contractor's e-mail Address	5 :			
Contractor's Phone Numbe	r ;			
Contractor's Contact Perso	n:			
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Form Dated 04/24/2007

WORK SERVICES/FACILITY MAINTENANCE SUPPLEMENTAL CHECKLIST

Required Attachments: Detailed Specifications (Scope of Services) including detailed description of the work, locations (with supporting detail), user department contacts, work hours/days, laborer/supervisor mix, compensation and price escalation considerations. Bidder's qualification, contract term and extension options, Contractor's qualifications, citation of any applicable City/State/Federal statutes or regulations, citation of any applicable technical standards and Price Lists/Catalogs, technical drawings and other exhibits and attachments as appropriate.

Risk Management:		
Will services be performed within 50 feet (50') of CTA train or other railroad property?	□Yes □	ON
Will services be performed on or near a waterway?	□Yes □	JNo
Will services require the handling of hazardous/bio-waste material?	□Yes □]No
Will services require the blocking of streets or sidewalks which may affect public safety?	□Yes □]No
If Modification or Amendment request, please verify and provide the following:		
Contractor's Name:		
Contractor's Address;		
Contractor's e-mail Address:		
Contractor's Phone Number:		
Contractor's Contact Person:		

Sole Source Justification: Trinity Biotech Plc.

In September 2007, the Chicago Department of Public Health, Division of STD/HIV/AIDS Public Policy and Programs received a three-year award from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA under Funding Opportunity Announcement number PS07-768, Expanded and Integrated Human Immunodeficiency Virus (HIV) Testing for Populations Disproportionately Affected by HIV, Primarily African Americans. The overall purpose of this initiative is to test 1.5 million persons for HIV and identify 20,000 HIV infected persons who are unaware of their status. Chicago has an annual goal of 70,000 HIV tests under this initiative.

Funding in this announcement was available for health departments to increase HIV testing opportunities for populations disproportionately affected by HIV-primarily African Americans who are unaware of their HIV status. 100% (one hundred percent) of the funds are required to support HIV testing, screening and related activities including linkage to care, Partner Counseling and Referral Services (PCRS) and the purchase of HIV Rapid Tests (blood and oral fluid).

The Chicago Department of Public Health has partnered with the following community-based providers

to integrate routine rapid HIV testing in their clinical settings:

Organization	Clinical Setting Type					
Ruth M. Rothstein CORE Center	STD Clinic					
Cermak Health Services/Cook County Jail	Correctional					
Provident Hospital	ED/Inpatient/Urgent Care					
John Stroger Hospital	ED/Urgent Care					
Mt Sinai Hospital	ED					
Advocate/Trinity Hospital	ED					

In order to achieve this goal -and fulfill contractual obligations- many of the partner sites have decided to integrate a lab-based HIV test algorithm. This allows them to conduct more testing on a daily basis and employ a rapid HIV test based the most current 3rd generation enzyme immunoassay (EIA).

Uni-Gold is the only single use rapid immunoassay based on the most current FDA approved 3rd generation enzyme immunoassay (EIA). In addition, it is the only rapid HIV test with a ten-minute read time. Trinity BioTech, Plc., is the sole manufacturer and distributor of the Uni-Gold™ Recombigen® HIV assay and Uni-Gold™ Recombigen® HIV controls.

• Specification:

- Uni-GoldTM Recombigen® HIV is a single use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-GoldTM Recombigen® HIV is intended for use in point of care settings as an aid in diagnosis of infection with HIV-1.
- o This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

Principle

- O Uni-GoldTM Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 in human serum, plasma and whole blood (venipuncture and fingerstick).
- O Uni-GoldTM Recombigen® HIV uses proteins representing regions of the HIV virus. If antibodies to HIV-1 are present in the sample, they combine with these proteins and a color reagent and this complex binds to the proteins in the test forming a visible pink/red band in the test region of the device adjacent to the word 'Test'.
- The control line should always appear as a visible pink/red band in the control region of the device to indicate that the test device is functioning correctly.
 - O A reactive result is indicated by a pink/red band in the test region of the device.
 - A non-reactive result occurs in the absence of detectable levels of antibodies to HIV-1 in the specimen; consequently no visually detectable band develops in the test region of the device.

• Description

- o CLIA complexity;
 - Waived for whole blood fingerstick and venipuncture samples
 - Moderate complexity for serum and plasma samples

Controls:

- o Intended Use
 - Uni-Gold™ Recombigen® HIV Controls are intended for use only with the Uni-Gold™ Recombigen® HIV test.
 - Uni-Gold[™] Recombigen® HIV Controls have been designed for use with the Uni-Gold[™] Recombigen® HIV assay to validate the correct performance of the device in the hands of the user.
 - Uni-GoldTM Recombigen® HIV Positive Control is prepared from inactivated human serum or plasma. It is negative for HbsAg and anti-HCV by U.S. FDA licensed test procedures. Source materials are reactive for antigens to HIV-1.
 - * Positive Controls do not have assigned quantitative values, each lot of material has been designed to produce a positive reaction within a target range, when tested on the Uni-GoldTM Recombigen® HIV assay.
 - Uni-GoldTM Recombigen ® HIV Negative Controls are prepared from defibrinated delipidised human serum which has been screened for Anti-HIV-1 and HIV-2. HbsAg and Anti-HCV. Uni-GoldTM Recombigen® HIV Negative Controls have been designed to give a negative reaction when tested on the Uni-GoldTM Recombigen® HIV assay.

These supplies will be shipped to the following CDPH clinics in care of the following individuals.

CDPH Mile Square

ATTN: Felicia Hinton/Tracy Martin

2045 W. Washington

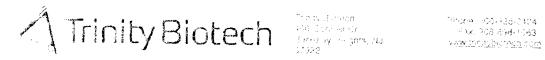
Chicago, IL 60612 Phone: 312.413.0090

Estimated Cost:

109,090 Uni-Gold™ Recombigen® HIV-1 Test Devices@ \$8.25ea = \$899,992.50

4,018 Uni-Gold™ Recombigen® HIV Controls@ \$22.40ea = \$90,003.20

Total Estimated Cost: \$989,995.70



QUOTATION

Account Manager: Account Name:	Heather Wilson Chicago Dept of Public Health	Date: Account Number:	6/10/08 US1810				
Account Address: Contact Name:	333 S. State St., 2 rd Fl Chicago, IL 60604 Paul LaKosky, M.A.						
Title & Department		eling & Testing Services					
Telephone:	312-747-9655						
Catalog #	Description	Price per Test	Total Price				
1206506	Uni-Gold HIV kit	58.25	\$165				
1206530	Uni-Gold HIV Controls		\$22.40				
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City of Chicago Richard M. Daley, Mayor

Chicago Dept. of Public Health

Dr. Terry Mason, M.D., F.A.C.S., Commissioner

HIV / AIDS Training Unit 31st Street STD Clinic 530 E. 31st Street Chicago, Illinois 60616 (312) 745-0531 (312) 745-2250 (FAX) To: Montel/M. Gayles

Chief Procurement Officer

City of Chicago Department of Procurement Services

From: Terry Mason, M.d., F.A.C.S.

Commissioner, Chicago Department of Public Health

Date: 06/18/08

RE: Sole Source Justification with Trinity Biotech

The Chicago Department of Public Health (CDPH) requires a Sole Source contract with Trinity Biotech, Inc. Trinity BioTech, Inc. is the sole manufacturer and distributor of the Uni-GoldTM Recombigen® HIV assay and Uni-GoldTM Recombigen® HIV controls.

Uni-Gold™ Recombigen® HIV is a single use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold™ Recombigen® HIV is intended for use in point of care settings as an aid in diagnosis of infection with HIV-1. This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

Uni-GoldTM Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 in human serum, plasma and whole blood (venipuncture and fingerstick). In addition, the Uni-GoldTM Recombigen® HIV is the only rapid HIV assay based on the most current FDA approved 3rd generation enzyme immunoassay..

The Uni-GoldTM Recombigen® HIV device is easily adapted to a lab-based HIV testing algorithm that will facilitate the Health Department's ability to implement routine, opt-out HIV testing in accordance with the Center's for Disease Control and Preventions (CDC's) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings (2006).

Thank you for your assistance with this matter. If you have questions or need additional information, please contact Rosemary Lebron at 312.747.9657.

cc: Rosemary Lebron

PU079G_Pre-Appd_Req_DPS_Schedul ed_Dept_Burst_APSRPT.rep Page 1 of 1 Run 06/27/2008 04:31

CITY OF CHICAGO PURCHASE REQUISITION

Copy (Department)

DELL	VER TO:						RE	QUISITION:	38986			
333 2NI	041- DEPAUL 2FL 333 S. STATE ST. 2ND FLOOR Chicago, IL 60604						DE PR NE	PAGE: 1 DEPARTMENT: 41 - DEPARTMENT OF HEALTH PREPARER: Richard W Rzeszutko NEEDED: APPROVED: 6/26/2008				
SOLE SPEC	IFICATION N	ONTRAC IUMBEF	CT WITH R: 67049	TRINITY BIOT	ECH, INC	C. FOR UN	J-GOLD R/	APID HIV TES	STING DE\	/ICES AND	CONTROLS	
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Where a commodity is for a particular or unique use other than standard quality decides, color place as the second