

FILE COPY

JUSTIFICATION FOR NON-COMPETITIVE PROCUREMENT

COMPLETE THIS SECTION IF NEW CONTRACT

For contracts in this request, answer applicable questions in each of the 4 major subject areas below in accordance with the Instructions for Preparation of Non-Competitive Procurement Form on the reverse side.

Request that negotiations be conducted only with Trinity Biotech, Inc. for the product and/or services described herein.
 (Name of Person or Firm)
 This is a request for _____ (One-Time Contractor Requisition # _____, copy attached) or XXX Term Agreement or Delegate Agency _____ (Check one). If Delegate Agency, this request is for "blanket approval" of all contracts within the _____ (Attach List)
 Pre-Assigned Specification No. (Program Name) _____
 Pre-Assigned Contract No. _____

COMPLETE THIS SECTION IF AMENDMENT OR MODIFICATION TO CONTRACT

Describe in detail the change in terms of dollars, time period, scope of services, etc., its relationship to the original contract and the specific reasons for the change. Indicate both the original and the adjusted contract amount and/or expiration date with this change, as applicable. Attach copy of all supporting documents. Request approval for a contract amendment or modification to the following:

Contract #: _____ Company or Agency Name: _____
 Specification #: _____ Contract or Program Description: _____
 Mod. #: _____ (Attach List, if multiple)

Paul LaKoosy/Cathy Yanda 7-9655/7-0656 _____ Health 05/10/08
 Originator Name Telephone Signature Department Date

Indicate SEE ATTACHED in each box below if additional space needed:

<input type="checkbox"/> PROCUREMENT HISTORY Trinity Biotech PLC has no procurement history with the City of Chicago	S.S.R.R. DATE <u>5/11/08</u> APPROVED <u>50</u> CONDITIONALLY APPROVED _____ RETURN TO DEPT. _____ DISAPPROVED _____
<input type="checkbox"/> ESTIMATED COST $\$329,998.56 \times 3 \text{ years} = \$989,995.70$ (Total)	APPROVED _____ RETURN TO DEPT. _____ DISAPPROVED _____
<input type="checkbox"/> SCHEDULE REQUIREMENTS See attached price quotes	
<input type="checkbox"/> EXCLUSIVE OR UNIQUE CAPABILITY Trinity BioTech, Inc. is the sole manufacturer and distributor of the Uni-Gold™ Recombigen® HIV assay and Uni-Gold™ Recombigen® HIV controls. Uni-Gold is a ten-minute single use rapid immunoassay and based on the most current FDA approved 3 rd generation enzyme immunoassay.	
<input type="checkbox"/> OTHER	

APPROVED BY: [Signature] 06/19/08 [Signature] 7/1/08
 DEPARTMENT HEAD OR DESIGNEE DATE BOARD CHAIRPERSON DATE



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-Gold™ Recombigen® HIV assay and Uni-Gold™ 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

**CITY OF CHICAGO
 PURCHASE REQUISITION**

Copy (Department)

DELIVER TO: 041- DEPAUL 2FL 333 S. STATE ST. 2ND FLOOR Chicago, IL 60604	REQUISITION: 38986 PAGE: 1 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

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST							
1	1934041500	109,090.00	Each	0.00	0.00							
HIV TESTING KITS AND SUPPLIES - UNI-GOLD RECOMBIGEN HIV, A SINGLE USE RAPID IMMUNOASSAY, FDA APPROVED 3RD GENERATION ENZYME IMMUNOASSAY (EIA)												
SUGGESTED VENDOR: TRINITY BIOTECH, INC.						REQUESTED BY: Richard W Rzeszutko						
DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.	
1	008	0100	0413350	9129	220340	0000	00000000	000000	00000	0000	0.00	
LINE TOTAL:											0.00	
LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST							
2	1934041502	4,018.00	Each	0.00	0.00							
HIV TESTING KITS AND SUPPLIES - UNI-GOLD RECOMBIGEN HIV CONTROLS FOR USE WITH UNI-GOLD RECOMBIGEN HIV TEST												
SUGGESTED VENDOR: TRINITY BIOTECH, INC.						REQUESTED BY: Richard W Rzeszutko						
DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.	
1	008	0100	0413350	9129	220342	0000	00000000	000000	00000	0000	0.00	
LINE TOTAL:											0.00	
REQUISITION TOTAL:											0.00	

Where a commodity is for a particular or unique use other than standard quality, grades, color, size or other characteristics, give details of how it will be and for what purpose
 Requisitions prepared incorrectly will be returned to the using department.

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-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

- 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).
- 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.
 - 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
 - CLIA complexity;
 - Waived for whole blood fingerstick and venipuncture samples
 - Moderate complexity for serum and plasma samples
- Controls:
 - 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-Gold™ 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-Gold™ Recombigen® HIV assay.
 - Uni-Gold™ 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-Gold™ Recombigen® HIV Negative Controls have been designed to give a negative reaction when tested on the Uni-Gold™ 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



Trinity Biotech
400 Connell Dr
Berkeley Heights, NJ
07922

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

QUOTATION

Account Manager: Heather Wilson Date: 6/10/08
Account Name: Chicago Dept of Public Health Account Number: US1810

Account Address: 333 S. State St., 2nd Floor
Chicago, IL 60604

Contact Name: Paul LaKosky, M.A.
Title & Department: Director of HIV Counseling & Testing Services

Telephone: 312-747-9655 Fax: 312-747-9663

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: Heather Wilson

DPS PROJECT CHECKLIST

For DPS Use Only	
Date Received	_____
Date Returned	_____
Date Accepted	_____
CA/CN's Name	_____

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.

GENERAL INFORMATION:

Date: 6-19-08
REQ No.: 38986
Specification No.: (if known): 67049
PO No.: (if known):
Modification No.: (if known):
Project Description: UNI-GOLD RAPID HIV TESTING DEVICES AND CONTROLS

Contact Person: Cathy Yanda
Tel: 7-9656 **Fax:** 7-9663 **E-mail:** yanda_cathy@cityofchicago.org
Project Manager:
Tel: **Fax:** **E-mail:** @cityofchicago.org
Previous PO No.: (if known):

FUNDING:

City: Corporate Bond Enterprise Grant* Other
 State: IDOT/Transit IDOT/Highway Grant* Other
 Federal: FHWA FTA FAA Grant* Other

LINE	FY	FUND	DEPT	ORGN	APPR	ACTV	OBJT	PROJECT	RPTG	\$ DOLLAR AMOUNT
1	09	0100	041	3350	9129	220342				989995

Estimated Value \$989,995.70

*IF GRANT FUNDED, A COPY OF THE APPROVED GRANT AND APPLICATION ARE REQUIRED and any other Terms and Conditions that may apply.

SCOPE STATEMENT:

Attached is a Detailed Scope of Services and/or Specification

IMPORTANT: THIS IS A CRITICAL PORTION OF YOUR SUBMITTAL. IN ORDER FOR DPS TO ACCEPT YOUR SUBMITTAL YOU MUST COMPLETE THE SPECIFIC SCOPE REQUIREMENTS AS SET FORTH IN THE SUPPLEMENTAL CHECKLIST FOR THAT UNIT.

The following is a general description of what should be included in a Scope of Services or Specification:
 A clear description of all anticipated services and products, including: time frame for completion, special qualifications of prospective vendors, special requirements or needs of the project, locations, anticipated participating user departments, citation of any applicable City ordinance or state/federal regulation or statute.

TYPE OF PROCUREMENT REQUESTED (check all that apply):

NEW REQUEST

Blanket Agreement
 Standard Agreement
 Small Orders

MOD/AMENDMENT

Time Extension
 Vendor Limit Increase
 Scope Change/Price Increase/Additional Line Item(s)
 Other (specify):

FORMS: Requisition Special Approvals Non-Competitive Review Board (NCRB)

CONTRACT TERM: 3 YEARS **Requested Term (number of months):** 36 MONTHS

DPS PROJECT CHECKLIST

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 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:

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 No

Will services be performed on or near a waterway? Yes No

DPS PROJECT CHECKLIST

VEHICLES/HEAVY EQUIPMENT SUPPLEMENTAL CHECKLIST

Required Attachments:

- 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

Attach any documentation indicating any previous purchase activity to assist in the procurement process

TELECOMMUNICATIONS AND UTILITIES SUPPLEMENTAL CHECKLIST

Required Attachments: Detailed Scope of Services/Specification which sets forth all of the anticipated services and products the user department wants provided, including time frame for completion, special qualifications of prospective vendors, special requirements or needs of the project, locations, anticipated participating user departments, citation of any applicable City ordinance or state/federal regulation or statute.

Has the project been reviewed by BIS? Yes No

Attach copy of BIS Recommendation; Reservation(s); or participate under current contract.

Does the project include software? Yes No

If yes, is signed ITSC form attached? Yes No

Does the location involve:

A public way? Yes No

Any concession in the City's facilities? Yes No

Is it anticipated City Council approval of the project or contract will be required? Yes No

DPS PROJECT CHECKLIST

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:

CHICAGO DEPARTMENT OF HEALTH
EXPENDITURE PROCESSING FORM - [E.P.F.]

PROGRAM NAME: STD/HIV/AIDS **BH#**

COST CENTER NAME: 3350

INITIATOR: Lakosky/Yanda

TELEPHONE: Lakosky- 7-9655
 Yanda- 7-9656

VENDOR NAME: Trinity Biotech

VENDOR ADDRESS: 400 Cornell Dr.,
 Berkeley Heights, NJ 07922

PETTY CASH CHECK PAYABLE TO (LIMIT \$150): **PC CHECK RECEIVED BY:**

NEW CONTRACT REQUEST OR AMENDMENT: X

PURCHASE ORDER: BY DIRECT VOUCHER

PURCHASE ORDER: ON CONTRACT

PETTY CASH

BFY	FUND#	COST CENTER	APPR#	ACCT.#	ACTV.#	PROJECT#	RPT CAT#	AMOUNT	APPROVALS	DATE
	008	0100	0413350	9129	220342			\$989,995.70	Over \$50,000 needs signature of CFO Program Director/Manager <i>[Signature]</i>	6/12/08
									Card/Neba	
									Finance Officer <i>[Signature]</i>	
									CFO	
TOTAL								\$989,995.70		

COMMODITY CODE	DESCRIPTION OF ITEM/S	Quantity	Unit Cost	Total Amount
	Uni-Gold™ Recombigen® HIV assay	109,090	\$8.25ea	\$899,992.50
	Uni-Gold™ Recombigen® HIV controls.	4,018	\$22.40ea	\$90,003.20
TOTAL				\$989,995.70

SHIP TO INFORMATION MUST BE COMPLETE: NAME, PHONE, COMPLETE ADDRESS

CDPH Mile Square
 ATTN: Felicia Hinton/Tracy Martin
 2045 W. Washington
 Chicago, IL 60612
 Phone: 312.413.0090

DPS PROJECT CHECKLIST

For DPS Use Only	
Date Received	_____
Date Returned	_____
Date Accepted	_____
CA/CN's Name	_____

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.

GENERAL INFORMATION:

Date: 6-19-08
 REQ No.: 38986
 Specification No.: (if known): 67049
 PO No.: (if known):
 Modification No.: (if known):
 Project Description: UNI-GOLD RAPID HIV TESTING DEVICES AND CONTROLS

Contact Person: Cathy Yanda
 Tel: 7-9656 Fax: 7-9663 E-mail: yanda_cathy@cdph.org
 @cityofchicago.org
 Project Manager:
 Tel: Fax: E-mail:
 @cityofchicago.org
 Previous PO No.: (if known):

FUNDING:

City: Corporate Bond Enterprise Grant* Other
 State: IDOT/Transit IDOT/Highway Grant* Other
 Federal: FHWA FTA FAA Grant* Other

LINE	FY	FUND	DEPT	ORGN	APPR	ACTV	OBJT	PROJECT	RPTG	\$ DOLLAR AMOUNT
1	09	0100	041	3350	9129	220342				989995

Estimated Value \$989,995.70

IF GRANT FUNDED, A COPY OF THE APPROVED GRANT AND APPLICATION ARE REQUIRED and any other Terms and Conditions that may apply.

SCOPE STATEMENT:

Attached is a Detailed Scope of Services and/or Specification

IMPORTANT: THIS IS A CRITICAL PORTION OF YOUR SUBMITTAL. IN ORDER FOR DPS TO ACCEPT YOUR SUBMITTAL YOU MUST COMPLETE THE SPECIFIC SCOPE REQUIREMENTS AS SET FORTH IN THE SUPPLEMENTAL CHECKLIST FOR THAT UNIT.

The following is a general description of what should be included in a Scope of Services or Specification:
 A clear description of all anticipated services and products, including: time frame for completion, special qualifications of prospective vendors, special requirements or needs of the project, locations, anticipated participating user departments, citation of any applicable City ordinance or state/federal regulation or statute.

TYPE OF PROCUREMENT REQUESTED (check all that apply):

NEW REQUEST

Blanket Agreement
 Standard Agreement
 Small Orders

MOD/AMENDMENT

Time Extension
 Vendor Limit Increase
 Scope Change/Price Increase/Additional Line Item(s)
 Other (specify):

FORMS: Requisition Special Approvals Non-Competitive Review Board (NCRB)

CONTRACT TERM: 3 Requested Term (number of months): 36
 YEARS MONTHS

DPS PROJECT CHECKLIST

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 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:

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 No

Will services be performed on or near a waterway? Yes No

DPS PROJECT CHECKLIST

VEHICLES/HEAVY EQUIPMENT SUPPLEMENTAL CHECKLIST

Required Attachments:

- 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

Attach any documentation indicating any previous purchase activity to assist in the procurement process

TELECOMMUNICATIONS AND UTILITIES SUPPLEMENTAL CHECKLIST

Required Attachments: Detailed Scope of Services/Specification which sets forth all of the anticipated services and products the user department wants provided, including time frame for completion, special qualifications of prospective vendors, special requirements or needs of the project, locations, anticipated participating user departments, citation of any applicable City ordinance or state/federal regulation or statute.

Has the project been reviewed by BIS? Yes No

Attach copy of BIS Recommendation; Reservation(s); or participate under current contract.

Does the project include software? Yes No

If yes, is signed ITSC form attached? Yes No

Does the location involve:

A public way? Yes No

Any concession in the City's facilities? Yes No

Is it anticipated City Council approval of the project or contract will be required? Yes No

DPS PROJECT CHECKLIST

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:

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-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

- 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).
- 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.
 - 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
 - CLIA complexity;
 - Waived for whole blood fingerstick and venipuncture samples
 - Moderate complexity for serum and plasma samples
- Controls:
 - 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-Gold™ 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-Gold™ Recombigen® HIV assay.
 - Uni-Gold™ 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-Gold™ Recombigen® HIV Negative Controls have been designed to give a negative reaction when tested on the Uni-Gold™ 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



Trinity Biotech
200 Corporate Blvd
Lansdale, PA 19380, NJ
21322

Phone: 800-438-0124
Fax: 202-898-1063
www.trinitybiotech.com

QUOTATION

Account Manager: Heather Wilson Date: 6/10/08
Account Name: Chicago Dept of Public Health Account Number: US1810

Account Address: 333 S. State St., 2nd Floor
Chicago, IL 60604

Contact Name: Paul LaKosky, M.A.
Title & Department: Director of HIV Counseling & Testing Services

Telephone: 312-747-9655 Fax: 312-747-9663

Catalog #	Description	Price per Test	Total Price
1206506	Uni-Gold HIV kit	\$8.25	\$165
1206530	Uni-Gold HIV Controls		\$22.40

Quotation Valid Until: 9-10-2008 Authorized By: Heather Wilson



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-Gold™ Recombigen® HIV assay and Uni-Gold™ 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

**CITY OF CHICAGO
 PURCHASE REQUISITION**

Copy (Department)

DELIVER TO: 041- DEPAUL 2FL 333 S. STATE ST. 2ND FLOOR Chicago, IL 60604	REQUISITION: 38986 PAGE: 1 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

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
1	1934041500	109,090.00	Each	0.00	0.00

HIV TESTING KITS AND SUPPLIES - UNI-GOLD RECOMBIGEN HIV, A SINGLE USE RAPID IMMUNOASSAY, FDA APPROVED 3RD GENERATION ENZYME IMMUNOASSAY (EIA)

SUGGESTED VENDOR: TRINITY BIOTECH, INC.

REQUESTED BY: Richard W Rzeszutko

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	008	0100	0413350	9129	220340	0000	00000000	000000	00000	0000	0.00
LINE TOTAL:											0.00

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
2	1934041502	4,018.00	Each	0.00	0.00

HIV TESTING KITS AND SUPPLIES - UNI-GOLD RECOMBIGEN HIV CONTROLS FOR USE WITH UNI-GOLD RECOMBIGEN HIV TEST

SUGGESTED VENDOR: TRINITY BIOTECH, INC.

REQUESTED BY: Richard W Rzeszutko

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	008	0100	0413350	9129	220342	0000	00000000	000000	00000	0000	0.00
LINE TOTAL:											0.00

REQUISITION TOTAL: 0.00