FLORIDA
DEPARTMENT OF HEALTH (DOH)
DOH 16-026

10-2016

INVITATION TO BID (ITB)
FOR
Rapid HIV Antibody Test Kits

TABLE OF CONTENTS

SECTION 1.0: INTRODUCTORY MATERIALS

1.1 Statement of Purpose

The purpose of this Invitation to Bid (ITB) is for the Department of Health to obtain competitive prices for n United States Food and Drug Administration (FDA) approved rapid HIV antibody testing device that does not require blood to be drawn, but instead uses a finger stick to provide the specimen for testing. This device is used in testing settings where blood draw methods of sampling are not allowed. This device also provides a testing method for clients who have an aversion to having blood drawn from their bodies.

1.2 Specifications

Detailed specifications for this solicitation are provided as **Attachment A** in this ITB.

1.3 Definitions

Bid: The complete written response of the Provider to this ITB, including properly completed forms, supporting documents, and attachments.

Business days: Monday through Friday, excluding state holidays.

Business hours: 8 a.m. to 5 p.m., Eastern Time on all business days.

Calendar days: All days, including weekends and holidays.

Clinical Laboratory Improvement Amendments (CLIA): of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. .

Contract: The formal agreement or order that will be awarded to the successful Provider under this ITB, unless indicated otherwise.

Department: The Department of Health; may be used interchangeably with DOH.

Minor Irregularity: As used in the context of this solicitation, indicates a variation from the ITB terms and conditions which does not affect the price of the Bid, or give the Provider an advantage or benefit not enjoyed by other Providers, or does not adversely impact the interests of the Department.

Order: As used in the context of this solicitation refers to a Purchase Order or a Direct Order.

Provider: The business entity that submits a Bid. This term also may refer to the entity awarded a contract by the Department in accordance with the terms of this ITB.

Quality Control Reagents: Human plasma-based reagents specifically formulated and manufactured to ensure performance of the test, and used to verify the user's ability to properly perform the test and interpret the results.

Sensitivity: The probability that a test will produce a positive result in a specimen that is positive for HIV antibodies.

Specificity: The probability that a test will produce a negative result in a specimen that is negative for HIV antibodies.

Vendor Bid System (VBS): Refers to the State of Florida internet-based vendor information system at: http://myflorida.com/apps/vbs/vbs_www.main_menu.

SECTION 2.0: PROCUREMENT PROCESS, SCHEDULE & CONSTRAINTS

2.1 Procurement Officer

The Procurement Officer assigned to this solicitation is:

Florida Department of Health
Attention: **Diana K. Trahan**
4052 Bald Cypress Way, Bin B07
Tallahassee, FL 32399-1749
Email: Diana.Trahan@flhealth.gov

2.2 Restriction on Communications

Respondents to this solicitation or persons acting on their behalf may not contact, between the release of the solicitation and the end of the 72-hour period following the agency posting the notice of intended award, excluding Saturdays, Sundays, and state holidays, any employee or officer of the executive or legislative branch concerning any aspect of this solicitation, except in writing to the procurement officer as provided in the solicitation documents. Violation of this provision may be grounds for rejecting a response. Section 287.057(23), Florida Statutes.

2.3 Term

It is anticipated that the Contract resulting from this ITB will be for one year beginning December 7, 2016 or the Contract execution date whichever is later, subject to renewal as identified in Section 4.2. The Contract resulting from this ITB is contingent upon availability of funds

2.4 Timeline

EVENT	DUE DATE	LOCATION
ITB Advertised / Released	**November 10, 2016**	**Posted to the Vendor Bid System at:** http://vbs.dms.state.fl.us/vbs/main_menu
Questions Submitted in Writing	**Must be received PRIOR TO: November 16, 2016 5:00 P.M.**	**Submit to:** Florida Department of Health Central Purchasing Office **Attention: Diana K. Trahan** Suite 310 4052 Bald Cypress Way, Bin B07 Tallahassee, FL 32399-1749 E-mail: **Diana.Trahan@flhealth.gov**

Answers to Questions (Anticipated Date)	**November 17, 2016**	**Posted to Vendor Bid System at:** http://vbs.dms.state.fl.us/vbs/main_menu
Sealed Bids Due and Opened	**Must be received PRIOR TO:** **November 29, 2016 3:00 P.M.**	**PUBLIC MEETING** **Submit to:** Florida Department of Health Central Purchasing Office **Attention: Diana K. Trahan** Suite 310 4052 Bald Cypress Way, Bin B07 Tallahassee, FL 32399-1749
Anticipated Posting of Intent to Award	**November 30, 2016**	**Posted to the Vendor Bid System at:** http://vbs.dms.state.fl.us/vbs/main_menu

2.5 Addenda

If the Department finds it necessary to supplement, modify or interpret any portion of the specifications or documents during the solicitation period a written addendum will be posted on the MyFlorida.com Vendor Bid System, http://vbs.dms.state.fl.us/vbs/main_menu. It is the responsibility of the Provider to be aware of any addenda that might affect their Bid.

2.6 Questions

This provision takes precedence over General Instruction #5 in PUR1001.

Questions related to this solicitation must be received, in writing (either via U.S. Mail, courier, e-mail, fax, or hand-delivery), by the Procurement Officer identified in **Section 2.4**, within the time indicated in the Timeline. Verbal questions or those submitted after the period specified in the Timeline will not be addressed.

2.7 Basis of Award

A single award will be made to the responsive, responsible Provider offering the lowest grand total price for Rapid HIV Antibody Test Kits, to include quality control reagents, package inserts, training, and delivery, FOB destination. In case of conflict, the “per unit” price will control.

2.8 Identical Tie Bids

Where there is identical pricing from multiple Providers, the Department will determine the order of award in accordance with Florida Administrative Code, Rule 60A-1.011.

2.9 Federal Excluded Parties List

A Provider or subcontractor(s) that, at the time of submitting a Bid for a new Contract or renewal of an existing Contract is on the Federal Excluded Parties List, is ineligible for, may not submit a Bid for, or enter into or renew a Contract with an agency for goods or services, if any federal funds are being utilized.

SECTION 3.0: INSTRUCTIONS FOR BID SUBMITTAL

3.1 General Instructions to Respondents (PUR 1001)

This section explains the General Instructions to Providers (PUR 1001) of the solicitation process, and is a downloadable document incorporated into this solicitation by reference. This document should not be returned with the Bid. http://dms.myflorida.com/content/download/2934/11780

The terms of this solicitation will control over any conflicting terms of the PUR1001.

3.2 Instructions for Submittal

1. Providers are required to complete, sign, and return the "Price Page" with the Bid submittal. (Mandatory Requirement)

2. Providers must submit all technical and pricing data in the formats specified in the ITB.

3. Submit one original Bid and one electronic copy of the Bid on CD or thumb drive. The electronic copy should contain the entire Bid as submitted, including all supporting and signed documents. Refer to **Section 3.4** for information on redacting confidential information, if applicable.

4. Bids may be sent by U.S. Mail, Courier, or Hand Delivered to the location indicated in the Timeline.

5. Bids submitted electronically will **not** be considered.

6. Bids must be submitted in a sealed envelope/package with the solicitation number and the date and time of the Bid opening clearly marked on the outside.

7. The Department is not responsible for improperly marked Bids.

8. It is the Provider's responsibility to ensure its Bid is submitted at the proper place and time indicated in the ITB Timeline.

9. The Department's clocks will provide the official time for Bid receipt.

   Materials submitted will become the property of the State of Florida and accordingly, the State reserves the right to use any concepts or ideas contained in the response.

3.3 Cost of Preparation

Neither the Department of Health nor the State is liable for any costs incurred by a Provider in responding to this solicitation.

3.4 Public Records and Trade Secrets

Notwithstanding any provisions to the contrary, public records must be made available pursuant to the provisions of the Public Records Act. If the Provider considers any portion

of its Bid to this solicitation to be confidential, exempt, trade secret or otherwise not subject to disclosure pursuant to Chapter 119, Florida Statutes, the Florida Constitution or other authority, the Provider must segregate and clearly mark the document(s) as "**CONFIDENTIAL**".

Simultaneously, the Provider will provide the Department with a separate redacted paper and electronic copy of its Bid and briefly describe in writing the grounds for claiming exemption from the public records law, including the specific statutory citation for such exemption. This redacted copy must contain the solicitation name, number, and the name of the Provider on the cover, and must be clearly titled "**REDACTED COPY**".

The redacted copy must be provided to the Department at the same time the Provider submits its Bid and must only exclude or obliterate those exact portions which are claimed confidential, proprietary, or trade secret. The Provider will be responsible for defending its determination that the redacted portions of its Bid are confidential, trade secret or otherwise not subject to disclosure. Further, the Provider must protect, defend, and indemnify the Department for any and all claims arising from or relating to the determination that the redacted portions of its Bid are confidential, proprietary, trade secret or otherwise not subject to disclosure. If the Provider fails to submit a redacted copy with its Bid, the Department is authorized to produce the entire documents, data or records submitted by the Provider in answer to a public records request for these records.

3.5 Price Page (Mandatory Requirement)

The Price Page is **Attachment B** of this ITB. Providers must fill out the Price Page as indicated, sign it, and return it with their Bid.

Providers must also complete and submit the renewal pricing section of the Price Page, Attachment B.

3.6 Documentation

Providers must complete and submit the following information or documentation as part of their Bid:

3.6.1 Statement of Non-Collusion

Providers must sign and return with their Bid the **Statement of Non-Collusion** form, **Attachment C.**

3.7 Special Accommodations

Any person requiring special accommodations at DOH Purchasing because of a disability should call DOH Purchasing at (850) 245-4199 at least five (5) work days prior to any pre-Bid conference, Bid opening, or meeting. If hearing or speech impaired, please contact Purchasing by using the Florida Relay Service, at 1-800-955-8771 (TDD).

3.8 Responsive and Responsible (Mandatory Requirements)

Providers must complete and submit the following mandatory information or documentation as part of their Bid. Any Bid which does not contain the information below will be deemed non-responsive.

- Bids must be received by the time specified (**Section 2.4**).
- **Attachment B**: Price Page (as specified in **Section 3.5**)

3.9 Late Bids

The Procurement Officer must receive Bids pursuant to this ITB no later than the date and time shown in the Timeline (Refer to **Section 2.4**). Bids that are not received by the time specified will not be considered.

SECTION 4.0: SPECIAL CONDITIONS

4.1 General Contract Conditions (PUR 1000)

The General Contract Conditions (PUR 1000) form is a downloadable document incorporated in this solicitation by reference, that contains general Contract terms and conditions that will apply to any Contract resulting from this ITB, to the extent they are not otherwise modified. This document should not be returned with the Bid. http://dms.myflorida.com/content/download/2933/11777

The terms of this solicitation will control over any conflicting terms of the PUR1000. Paragraph 31 of PUR 1000 does NOT apply to this solicitation or any resulting contract.

4.2. Renewal

The Contract resulting from this solicitation may be renewed. Renewals may be made on a yearly basis or for a period that may not exceed three years or the term of the original Contract, whichever is longer. Renewals must be in writing, subject to the same terms and conditions set forth in the initial Contract and any written amendments signed by the parties. Renewals are contingent upon satisfactory fiscal and programmatic performance evaluations as determined by the Department and are subject to the availability of funds.

4.3 Conflict of Interest

Section 287.057(17)(c), Florida Statutes, provides "A person who receives a Contract that has not been procured pursuant to subsections (1)-(3) to perform a feasibility study of the potential implementation of a subsequent Contract, who participates in the drafting of a solicitation or who develops a program for future implementation, is not eligible to Contract with the agency for any other contracts dealing with that specific subject matter, and any firm in which such person has any interest is not eligible to receive such Contract. However, this prohibition does not prevent a vendor who responds to a request for information from being eligible to Contract with an agency."

The Department of Health considers participation through decision, approval, disapproval, recommendation, preparation of any part of a purchase request, influencing the content of any specification or procurement standard, rendering of advice, investigation, or auditing or any other advisory capacity to constitute participation in drafting of the solicitation.

Refer to Section #3.6.2 Statement of Non-Collusion**, Attachment D.**

4.4 Certificate of Authority

All limited liability companies, corporations, corporations not for profit, and partnerships seeking to do business with the State must be registered with the Florida Department of State in accordance with the provisions of Chapters 605, 607, 617, and 620, Florida Statutes, respectively prior to Contract execution. The Department retains the right to ask for verification of compliance before Contract execution. Failure of the selected contractor to have appropriate registration may result in withdrawal of Contract award.

4.5 Provider Registration

Each provider doing business with the State of Florida for the sale of commodities or contractual services as defined in section 287.012, Florida Statutes must register in the MyFloridaMarketPlace system, unless exempted under Florida Administrative Code Rule 60A-1.030. State agencies must not enter into an agreement for the sale of commodities or contractual services as defined in section 287.012, Florida Statutes, with any provider not registered in the MyFloridaMarketPlace system, unless exempted by rule. The successful provider must be registered in the MyFloridaMarketPlace system within 5 days after posting of intent to award.

Registration may be completed at:
https://vendor.myfloridamarketplace.com/vms-web/spring/login?execution=e2s1
Those lacking internet access may request assistance from MyFloridaMarketPlace Customer Service at 866-352-3776 or from State Purchasing, 4050 Esplanade Drive, Suite 300, Tallahassee, FL 32399.

4.6 Minority and Service-Disabled Veteran Business-Participation

The Department encourages Minority, Women, Service-Disabled Veteran, and Veteran-Owned Business Enterprise participation in all its solicitations.

4.7 Subcontractors

The Department will not authorize the use of subcontractors in the Contract resulting from this ITB.

4.8 Order

Providers must become familiar with the Department's Order which contains administrative, financial and non-programmatic terms and conditions mandated by federal laws, state statutes, administrative code rules, and directive of the Chief Financial Officer.

Use of the Order is mandatory for Department Direct Orders issued in MFMP as they contain the basic clauses required by law. The terms and conditions contained in the Order Terms and Conditions are non-negotiable. The State of Florida, Department of Health, Order Terms and Conditions are located at: http://www.floridahealth.gov/about-the-department-of-health/about-us/administrative-functions/purchasing/_documents/DOH-Terms-and-Conditions.pdf

4.9 Conflict of Law and Controlling Provisions

Any Contract resulting from this ITB, and any conflict of law issue, will be governed by the laws of the state of Florida. Venue must be Leon County, Florida.

4.10 Agency Inspectors General

It is the duty of every state officer, employee, agency, special district, board, commission, contractor, and subcontractor to cooperate with the inspector general in any investigation, audit, inspection, review, or hearing pursuant to section 20.055,

Florida Statutes.

4.11 Records and Documentation

To the extent that information is utilized in the performance of the resulting Contract or generated as a result of it, and to the extent that information meets the definition of "public record" as defined in section 119.011(12), Florida Statutes, said information is hereby declared to be and is hereby recognized by the parties to be a public record and absent a provision of law or administrative rule or regulation requiring otherwise, must be made available for inspection and copying by any interested person upon request as provided in Chapter 119, Florida Statutes, or otherwise. It is expressly understood that the successful Provider's refusal to comply with Chapter 119, Florida Statutes, will constitute an immediate breach of the Contract resulting from this ITB and entitles the Department to unilaterally cancel the Contract agreement. The successful Provider will be required to promptly notify the Department of any requests made for public records.

Unless a greater retention period is required by state or federal law, all documents pertaining to the program contemplated by this ITB must be retained by the successful Provider for a period of six years after the termination of the resulting Contract or longer as may be required by any renewal or extension of the Contract. During the records retention period, the successful Provider agrees to furnish, when requested to do so, all documents required to be retained. Submission of such documents must be in the Department's standard word processing format (currently Microsoft Word 6.0). If this standard should change, it will be at no cost incurred to the Department. Data files will be provided in a format readable by the Department.

The successful Provider must maintain all records required to be maintained pursuant to the resulting Contract in such manner as to be accessible by the Department upon demand. Where permitted under applicable law, access by the public must be permitted without delay.

4.12 Protests

Failure to file a protest within the time prescribed in section 120.57(3), Florida Statutes, or failure to post a bond or other security required by law within the time allowed for filing a bond shall constitute a waiver of proceedings under Chapter 120, Florida Statutes.

Only documents delivered by the U.S. Postal Service, a private delivery service, in person, or by facsimile during Business hours (Monday-Friday, 8:00 a.m. - 5:00 p.m., Eastern Standard Time) will be accepted. Documents received after hours will be filed the following business day.

No filings may be made by email or any other electronic means. All filings must be made with the Agency Clerk ONLY and are only considered "filed" when stamped by the official stamp of the Agency Clerk. It is the responsibility of the filing party to meet all filing deadlines.

Do not send Bids to the Agency Clerk's Office. Send all Bids to the Procurement Officer and address listed in the Timeline.

The Agency Clerk's mailing address is:

Agency Clerk
Florida Department of Health
4052 Bald Cypress Way, BIN A-02
Tallahassee, Florida 32399-1703
Telephone No. (850) 245-4005

The Agency Clerk's physical address for hand deliveries is:

Agency Clerk, Department of Health
2585 Merchants Row Blvd.
Tallahassee, Florida 32399
Fax No. (850) 410-1448

ATTACHMENT A
Specifications

A. Statement of Purpose

The Florida Department of Health's Division of Disease Control and Health Protection, Bureau of Communicable Diseases, (Department), is seeking to purchase (an estimated amount of 200,000) rapid HIV antibody tests, quality control reagents, training and delivery, FOB destination. The Department provides rapid HIV testing devices, quality control reagents (controls), and medical supplies to more than 1,500 registered HIV testing locations within the state, and performs more than 200,000 rapid HIV tests per year. These tests are given to residents or visitors to the state of Florida who are interested in being aware of their HIV status. Awareness of one's HIV status is the first step in accessing life-saving medicine and medical treatments that can and will help ensure that an individual's HIV infection is kept in check and does not progress to AIDS. **Product Specifications**

Rapid HIV antibody tests must:

- Be FDA approved for the detection of HIV-1 and HIV-2 antibodies using, finger stick whole blood and venipuncture whole blood;
- Be a CLIA waived complexity (CLIA waived);
- Have a demonstrated sensitivity of at least 99.7 percent for whole blood specimens as defined in the product's package insert;
- Have a demonstrated specificity of at least 99.9 percent for whole blood specimens as defined in the product's package insert ;
- Have a processing time of no more than 15 minutes for whole blood specimens;
- Have a finger stick blood collection unit of no more than 5µl;
- Have an expiration date of no less than 20 months from the date of delivery to the Department; and,
- Quality control reagents (controls) and accessory kits must be included with the purchase of the rapid HIV tests and made available throughout the duration of the shelf-life of the product. Controls must include one HIV-1 reactive control, one HIV-2 reactive control, and one HIV non-reactive control, and must be manufactured for use specifically with the rapid HIV antibody test submitted.

B. Literature

Technical documentation is required to be provided with Bid submissions to demonstrate compliance of the product Bid with applicable technical requirements of this ITB. All Bids must meet or exceed all conditions and specifications of this ITB.

The Department, in its sole discretion and in the best interest of the State, may determine the acceptability of the Bid through technical documentation made available to the Department as of the date and time of Bid opening. Such authority of the Department shall in no way relieve the Provider from the ultimate responsibility of submitting the required technical documentation, nor shall any Provider assume that such documentation is otherwise available to the Department. The Department shall not be responsible for the accuracy of the technical documentation in its possession.

C. Training

The Provider shall provide training for sites throughout the state, as requested by the Department, for the duration of the shelf-life of the product. The Department will work with the Provider to identify training needs and locations.

D. Warranty

A warranty against defective material, workmanship and failure to perform is required for all Rapid HIV Antibody Tests and equipment for the duration of the product's shelf life. Replacement of all defective parts found within the warranty period shall be made without cost to the Department.

E. Delivery

- The Provider shall be responsible for properly packing shipments. Packing materials consist of items used to securely and properly pack tangible products for shipment, storage and stocking.
- The Provider shall notify the Department's Contract Manager within five days of purchase order issuance of any potential delays.
- Any or all items delivered to the Department not meeting the specifications of this ITB and Contract, or that are found to be defective, will not be accepted. Such items will be returned to the Provider at the Provider's expense for refund or replacement. Since it is impossible for the Department to inspect all items upon arrival, the Provider shall afford a reasonable opportunity for inspection and returning of defective items.
- Deliveries shall be made between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding state holidays, unless otherwise stated on the Contract.
- Inside warehouse door delivery is required for all shipments.
- Provider must include the cost of shipping, i.e., free on board (FOB) destination / inside delivery. The Department will not pay freight charges.

All items requested in this ITB must be delivered, FOB destination to the address listed below no later than t30 days from the date of order**.**

The Storage Center
3110 Apalachee Parkway
Tallahassee, FL 32311

ATTACHMENT B
Price Page

A single award will be made to the responsive, responsible Provider offering the lowest grand total price for all items described in this ITB including delivery, FOB destination. In the event there is a discrepancy between the unit price, the total price or the grand total price listed, the unit price will control. Providers must insert a price for each line indicated below.

Initial One Year Term

Description	Estimated Amount of Units	Unit Price	Total Price
Rapid HIV Antibody Test Kits, to include quality control reagents, package inserts, training, and delivery, FOB destination.	**200,000**	**$**_____	**$**_____

Renewal Pricing

Description	Estimated Amount of Units	Unit Price	Total Price
1 Year Renewal Rapid HIV Antibody Test Kits, to include quality control reagents, package inserts, training, and delivery, FOB destination.	**200,000**	**$**_____	**$**_____

GRAND TOTAL (Initial Term & Renewal Year): $ _____

Provider Name: _____

Provider Mailing Address: _____

City-State-Zip: _____

Telephone Number: _____

Email Address: _____

Federal Employer Identification Number (FEID): _____

BY AFFIXING MY SIGNATURE ON THIS BID, I HEREBY STATE THAT I HAVE READ THE ENTIRE ITB TERMS, CONDITIONS, PROVISIONS AND SPECIFICATIONS AND ALL ITS ATTACHMENTS, INCLUDING THE REFERENCED PUR 1000 AND PUR 1001. I hereby certify that my company, its employees, and its principals agree to abide to all of the terms, conditions, provisions and specifications during the competitive solicitation and any resulting Contract including those contained in the Order.

ATTACHMENT B
Price Page

Signature of Authorized Representative*: _____

Printed (Typed) Name and Title: _____

*An authorized representative is an officer of the Provider's organization who has legal authority to bind the organization to the provisions of the Bids. This usually is the President, Chairman of the Board, or owner of the entity. A document establishing delegated authority must be included with the Bid if signed by other than the President, Chairman or owner.

ATTACHMENT C
STATEMENT OF NON-COLLUSION

I hereby certify that my company, its employees, and its principals, had no involvement in performing a feasibility study of the implementation of the subject Contract, in the drafting of this solicitation document, or in developing the subject program. Further, my company, its employees, and principals, engaged in no collusion in the development of the instant Bid, proposal or reply. This Bid, proposal or reply is made in good faith and there has been no violation of the provisions of Chapter 287, Florida Statutes, the Administrative Code Rules promulgated pursuant thereto, or any procurement policy of the Department of Health. I certify I have full authority to legally bind the Provider, Respondent, or Vendor to the provisions of this Bid, proposal or reply.

_____ _____

Signature of Authorized Representative* Date

*An authorized representative is an officer of the Provider's organization who has legal authority to bind the organization to the provisions of the Bids. This usually is the President, Chairman of the Board, or owner of the entity. A document establishing delegated authority must be included with the Bid if signed by other than the President, Chairman or owner.