



**COMMONWEALTH OF VIRGINIA
DIVISION OF PURCHASES AND SUPPLY
PO Box 1199
RICHMOND, VA 23218-1199**

Notice of Contract Renewal

CONTRACT# 194-71803

Contract Title: Pregnancy Tests, Urine, One-Step Method

(Changes noted in red)

1	DATE:	8/31/13
2	CONTRACT PERIOD:	9/1/13 TO 8/31/14 <i>with two one-year optional renewals remaining</i>
3	SUPERCEDES:	#194-1284
4	AUTHORIZED USERS:	Virginia Agencies and Public Bodies
5	CONTRACTOR'S eVA VENDOR ID#:	E2383
6	CONTRACTOR / VENDOR	Stanbio Laboratory
7	CONTRACTOR CONTACT	<i>Courtney Davis</i>
8	TERMS	Net 30 Days
9	DELIVERY	5 Business Days ARO
10	F.O.B.	Destination
11	CONTRACT PRICES	See Pages 5 and 6
12	DPS CONTRACT OFFICER	Name: Nan Rowe, VCO Phone: 804-786-3854 Email: nancy.rowe@dgs.virginia.gov

ADDITIONAL COPIES OF CONTRACTS AND ANY ASSOCIATED CONTRACT CHANGES ARE AVAILABLE ON THE DPS WEBSITE: www.eva.virginia.gov under the State Contracts webpage

AUTHORIZED USERS: This contract is the result of a competitive bid program and its use is optional for all STATE AGENCIES. Optional Use for other public bodies and entities authorized to use the contract by the *Code of Virginia* § 2.2-1120(D), to include private institutions of higher education chartered in Virginia **and** granted tax-exempt status under §501(c)(3) of the Internal Revenue Code, in the purchase of any commodity listed herein.

NOTE: This public body does not discriminate against faith-based organizations in accordance with the Code of Virginia, §2.2-4343, or against a bidder or offeror because of race, religion, color, sex national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment.

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1. CONTRACTOR / VENDOR INFORMATION

Contractor Name	eVA Vendor ID#	Location Address(es)	Contact Information (Name, Phone, Fax and Email)
Stanbio Laboratory Ph. 830-249-0772 Fx. 830-249-0851		1261 N. Main St. Boerne, TX 78006	<p>S. Courtney Davis Regional Sales Associate 866-782-6246 Ext 120 cdavis@stanbio.com</p> <p>Technical Service Department Phone 800-531-5535</p> <p>Customer Service Department Phone 800-531-5355 Fax 830-249-0851</p> <p>Email orders to: orders@stanbio.com</p>

2. GENERAL INSTRUCTIONS

1. Ordering Method: Unless otherwise instructed or exempted by DPS, all departments, institutions and agencies of the Commonwealth of Virginia using this contract must order items by issuing purchase orders through eVA. The orders will be governed by this agreement and the terms and conditions contained in the separate agreement for participation in eVA executed by the contractor. If this contract is authorized for use by localities, Virginia cities, counties, town and political subdivisions, they should place all purchase orders through eVA or eVA Lite.
2. Purchase Order Information: When placing an eVA non-catalog order, each line of the requisition must be identified with the correct Contractor Name and Location (eVA Vendor ID#), contract item number, full item description and the contract unit price. The exact Contract Number, as shown on page 1, **must** be inserted in the Contract Number field for each line item of the eVA requisition. Purchase orders not bearing the correct contract number in the appropriate location will be non-compliant and may not be considered a purchase against this contract.
3. Ordering Entity Acceptance: Inspection and acceptance upon delivery and approval of vendor's invoice is the responsibility of the receiving entity.
4. Complaints: Any complaint that is due to a violation or breach of the Contract provisions, shall be reported on an official DPS "PROCUREMENT COMPLAINT FORM" (Form # DGS-41-024). To facilitate notification, this form shall be completed by the ordering entity and sent to the contract vendor, with a copy sent to DPS to the address shown on the form. Contract vendors shall also use this form to initiate complaints concerning entities. Contract vendors shall also use this form to initiate complaints concerning entities. This form may be downloaded from the internet at www.eva.virginia.gov (Click on the Buyer tab, then on "Procurement Complaint Form").
5. Changes: Any changes whether for increases or decreases in pricing, delivery terms or additional options must be approved by the Division of Purchases and Supply in advance of issuance of the purchase order. Disputes between the ordering agency and the vendor will be resolved in accordance with the terms of the contract and any change orders/renewals unless prior approval was granted by DPS.

3. ADDITIONAL INFORMATION & PRICING

See Below for Product Descriptions.

Return Policy: Stanbio Laboratory guarantees all of its products to perform according to the parameters found in their respective package inserts, until the expiration date. Any product found not to perform up to these standards will be replaced without charge. Stanbio Laboratory is not responsible for products that are held past the expiration date or not stored properly. A “Return Goods Authorization” (RGA Number) MUST be obtained from Stanbio’s Quality Department before any product can be returned for non-performance. Any product received due to error on the part of Stanbio Laboratory may be returned for replacement or credit immediately after receiving authorization from Stanbio’s Customer Service Department. **Report any item / quantity discrepancies to the Customer Service Department within 5 business days from receipt of product.** Due to FDA compliance issues and GMP controls, any item(s) shipped as a result of customer error may not be returned for credit. Goods determined returnable by Stanbio Laboratory will be subject to a **15% restocking fee** to partially cover the cost of the Quality Assurance procedures Stanbio Laboratory must perform on all returned products.

Shipping and Billing Information

Shipping Location: Multiple, will vary by Purchase Order.

Billing Address: Bill to address on purchase order

Free On Board Name: FOB Destination-Freight Prepaid

Commodity Information

NIGP Commodity Code: 19340

Line: 1

Pregnancy Test, Urine, One Step Method in accordance with specifications, terms and conditions in IFB Attachment A

Unit: Each

Contractor Item No.: 1430-050

Unit Price: \$27.00 per box of 50 (\$0.54 per test)

Estimated Delivery Days: 5 Business Days

Product Name: True 20 Pregnancy Test

Packing Instructions: Packaged 50 tests per box.

Detailed Instructions: Order by the box.

Special Handling: See Package Insert

Line: 2

Bi-Level Urine HCG controls for above pregnancy test kits in accordance with specifications, terms and conditions in IFB Attachment A

Unit: Each

Contractor Item No.: 1225-205

Unit Price: \$0.00

Estimated Delivery Days: 5 Business Days

Product Name: Bi-Level Urine HCG Controls

Packing Instructions: Packaged 2 bottles per box.

Detailed Instructions: Order by the box.

4. SCOPE OF WORK / GENERAL & TECHNICAL SPECIFICATIONS

General

1. The initial term of this contract will be for two (2) years. This contract may be renewed by the Commonwealth upon written agreement of both parties for three (3) additional successive one year periods under the terms and conditions of the current contract, and at a reasonable time (approximately 90 days) prior to the expiration.
2. The specifications contained herein and in all other IFB attachments describe the minimum requirements for a term contract for a one-step pregnancy test for the Commonwealth of Virginia, its Agencies and Public Bodies.

Scope

The estimated quantity for one calendar year is approximately 40,000 pregnancy tests and 200 pregnancy test controls. Quantities set forth are estimates only, and the Contractor shall supply at bid prices actual quantities as ordered, regardless of whether such total quantities are more or less than those shown. The contract shall contain no minimum purchase volumes.

Delivery:

1. All orders shall be shipped directly to the agency or department within five (5) business days after receipt of purchase order.
2. Contractor shall communicate to the ordering agency by telephone any situation which will delay delivery beyond 10 days from receipt of order, indicating which items are back-ordered and when delivery will be completed.
3. Repetitive back orders will not be tolerated; if notification is not received within 10 days from receipt of purchase order regarding completion of back orders within 30 days, the contract may be regarded as being in default. Two such defaults during the period of the contract may be cause for removal from the Commonwealth's bidders list for those items or similar products the following contract year for drugs and cancellation of the items and award to other parties.
4. Materials must be packaged and shipped as defined by product manufacturer.
5. The Contractor shall pay all shipping and handling charges, unless otherwise specified.
6. Responsibility and liability for loss or damage shall remain with vendor until delivery is complete.

Training:

Upon request, successful bidder shall be required to conduct on site training classes in each of the 35 State Health Districts and/or other Contract user sites within 90 days of the contract award.

Dating:

All products bearing expiration dates shall be delivered with as long a shelf life as possible. Repeated incidence of delivery of short-dated products will be considered as grounds for default of contract. Any product received bearing less than a three-month dating, without prior approval of ordering agency, may be returned at contractor's expense for full credit.

Pregnancy Test:

The urine of pregnant women contains high concentrations of human chorionic gonadotropin (HCG). This provides the basis for the laboratory tests that diagnose pregnancy.

Quality Standards:

1. **Tests:** All products covered by this solicitation shall be manufactured or compounded, packaged and handled in accordance with the provisions of the current Federal Foods, Drug and Cosmetic Act regulations. Finished products shall conform, as a minimum, to applicable current USP/NF tests and standards set forth by the National Institute of Health, the U.S. Food and Drug Administration and any other applicable regulatory agency. Bidders shall have readily available evidence to support this claim.
2. **Packing and Packaging:** All products covered herein shall be labeled in accordance with the Federal Foods, Drug and Cosmetic Act. Each test shall be individually packed. More than one test may be included in a box or package. Only standard commercial packages will be accepted and each unit (bottles, vial, ampule, tube, unit dose, etc.) shall bear the manufacturer's lot or control number and expiration date for dated products.
3. **Substitution:** The substitution of brand or manufacturer after award of contract is expressly prohibited unless previously approved in writing by the Division of Purchases and Supply.
4. **Guarantee:** The bidder's signature on this bid is his guarantee that the methods used in the facilities used for the manufacture, processing, packaging, and holding of all products listed herein conform to and are operated and administered in conformity with current good manufacturing practice as required by Section 501 (a) (2) of the Federal Foods, Drug and Cosmetic Act. Bidder hereby agrees to indemnify and to hold harmless and free the Commonwealth of Virginia or any institution, agency, department, or division thereof or any of its officers, employees, or agents from and against any and all liability or damages imposed on it or them by reason of any defects in any of said products, which defects results from bidder's or manufacturer's negligence or by reason of his adulteration, misbranding, or mislabeling of said products, or by reason of patent infringement.
5. **Recall:** In submitting this bid, bidder expressly assumes full responsibility for prompt notification of any drug recall.
6. **Suitability:** The test must be capable of being performed by laboratory and non-laboratory (nurses aide, nurses, clinicians) personal in a clinic and/or lab environment.

Test Specifications:

1. The urine pregnancy test kit shall utilize the monoclonal and/or polyclonal antibody technology as the primary method of detecting HCG in the urine.
2. The test shall have a minimum sensitivity value of 20 mIU/ml for urine in accordance with the WHO 3rd I.S.
3. There shall be no cross reactivity with the following hormone concentrations: LH at 500 mIU/ml in accordance with WHO 2nd IRPHMG FSH at 1000 IU/ml in accordance with WHO 2nd IRPHMG TSH at 1000 mIU/ml in accordance with WHO 68/38
4. The test procedure shall be a one-step method. "One step" is defined as placing the specimen in or on the testing device and being able to walk away. It shall not be necessary for the user to watch the reaction. After a time interval, the user will return to read the test. The test shall be easy to read with a minimum on background color. Results shall be detectable within 4 minutes or sooner.
5. The test kits shall be capable of being stored room temperature 59-86 f (15-30 c) with a minimum shelf life of at least 3months. Kit shall be able to be shipped at ambient Temperatures without changing their expiration dates.

6. The test must be FDA approved for marketing the U.S. The test must be classified as waived by the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) test complexity listing for urine testing.
7. The test shall be equally reliable when used for early pregnancy and family planning (6-week postpartum check-up).
8. The kits shall have instructions in non-technical language with procedure illustrations. There should be example illustrations of positive, negative, and invalid or questionable results.
9. The kits shall contain all supplies necessary to perform the tests with the exception of specimen collection devices.
10. Negative and positive controls shall be provided with each kit. These controls may be liquid controls or embedded with the test device.
11. The kit shall contain a minimum of 20 tests and no more than 50 tests. Each individual test kit shall be individually packaged
12. Kit failure, as indicated by the positive control being negative or failure of the sample to migrate properly shall not be over 1% of the product shipped.
13. Kit shall be standardized in accordance with WHO 3rd for Human Chorionic Gonadotropin (hcg).

5. SPECIAL TERMS AND CONDITIONS

- A. **ADVERTISING**: In the event a contract is awarded for supplies, equipment, or services resulting from this bid, no indication of such sales or services to the Virginia Department of Health will be used in product literature or advertising. The Contractor shall not state in any of its advertising or product literature that the Virginia Department of Health has purchased or uses any of its products or services, and the Contractor shall not include the Virginia Department of Health in any client list in advertising and promotional materials.
- B. **AUDIT**: The Contractor shall retain all books, records, and other documents relative to this contract for five (5) years after final payment, or until audited by the Commonwealth of Virginia, whichever is sooner. The agency, its authorized agents, and/or state auditors shall have full access to and the right to examine any of said materials during said period.
- C. **CANCELLATION OF CONTRACT**: The purchasing agency reserves the right to cancel and terminate any resulting contract, in part or in whole, without penalty, upon 60 days written notice to the contractor. In the event the initial contract period is for more than 12 months, the resulting contract may be terminated by either party, without penalty, after the initial 12 months of the contract period upon 60 days written notice to the other party. Any contract cancellation notice shall not relieve the contractor of the obligation to deliver and/or perform on all outstanding orders issued prior to the effective date of cancellation.
- D. **CONTRACT TERM**: The initial term of this contract was two (2) years.
- E. **CONTRACT RENEWAL**: This contract may be renewed by the Commonwealth upon written agreement of both parties for two (2) additional successive one (1) year periods, under the terms and conditions of the current contract, and at a reasonable time (approximately 90 days) prior to the expiration.
- F. **eVA BUSINESS-TO-GOVERNMENT CONTRACTS AND ORDERS**: The solicitation/contract will result in approximately twenty (20) purchase order(s) per year with the eVA transaction fee specified below assessed for each order. The Vendor Transaction Fee is:
- (i) DMBE-certified Small Businesses: .75%, Capped at \$500 per order.
 - (ii) Businesses that are not DMBE-certified Small Businesses: .75%, Capped at \$1,500 per order.

The eVA transaction fee will be assessed approximately 30 days after each purchase order is issued. Any adjustments (increases/decreases) will be handled through eVA change orders.

Internet electronic procurement solution, website portal www.eva.virginia.gov, streamlines and automates government purchasing activities in the Commonwealth. The portal is the gateway for vendors to conduct business with state agencies and public bodies.

Vendors desiring to provide goods and/or services to the Commonwealth shall participate in the eVA Internet e-procurement solution and agree to comply with the following:

If this solicitation is for a term contract, failure to provide an electronic catalog (price list) or index page catalog for items awarded will be just cause for the Commonwealth to reject your bid or terminate this contract for default. The format of this electronic catalog shall conform to the eVA Catalog Interchange Format (CIF) Specification that can be accessed and downloaded from www.eVA.virginia.gov. Contractors should email Catalog or Index Page information to eVA-catalog-manager@dgs.virginia.gov.

- G. MINIMUM ORDER:** Minimum Orders are set at \$100.00. Orders will be F.O.B. Destination to ordering agency within the Commonwealth of Virginia. For orders of less than \$100.00 the Contractor will be permitted to add actual transportation cost (prepaid) to invoice for payment, or the agency may purchase such orders off contract from other sources. Partial shipments of less than minimum order value which are made at the option of the Contractor shall be made F.O.B. Destinations with no transportation charges added. If at the agency's request shipments are below the minimum order value, the Contractor may add actual transportation to invoice for payment.
- H. ORDER PLACEMENT/METHOD:** To the maximum extent possible, purchase orders shall be submitted to the Contractor via the Commonwealth of Virginia's electronic procurement system, also known as eVA. The orders will be governed by this agreement and the terms and conditions contained in the separate agreement for participation in eVA executed by the Contractor. The Commonwealth requires Contractor(s) to accept orders via the eVA ordering system.
- I. PAYMENT TERMS/OPTIONS:** Contract Users pay by check, electronic funds transfer (ETF), or with the Commonwealth's authorized procurement card. Contractor should be able to accept the Commonwealth's card for invoices under \$5,000 per transaction. The Commonwealth does not mandate the use of the charge card for invoices under \$5,000. Standard payment terms are net 30 days from products delivery or properly executed invoice receipt.
- J. PRICE ESCALATION / DEESCALATION:** The Contract pricing is fixed unit pricing. Price adjustments may be permitted only for changes in the Contractor's cost of materials based on the current market for this or similar products. Consumers Price Indices, Producers Price Indices, other appropriate indices or other supporting documentation as approved by the Division of Purchases and Supply, will be used as a guide to determine price increases or decreases. No price increases will be authorized for **365** calendar days after the effective date of the contract. Price escalation may be permitted only at the end of this period and each **365** days thereafter and only where verified to the satisfaction of the purchasing office. However, "across the board" price decreases are subject to implementation at any time and shall be immediately conveyed to the Commonwealth. **Contractor shall give not less than 30 days advance notice of any price increase to the purchasing office. Any approved price changes will be effective only at the beginning of the calendar month following the end of the full 30 day notification period.** The Contractor shall document the amount and proposed effective date of any general change in the price of materials. Documentation shall be supplied with the Contractor's request for increase which will: (1) verify that the requested price increase is general in scope and not applicable just to the Commonwealth of Virginia; and (2) verify the amount or percentage of increase which is being passed on to the Contractor by the Contractor's suppliers. The purchasing office will notify the using agencies and Contractor in writing of the effective date of any increase which it approves. However, the Contractor shall fill all purchase orders received prior to the effective date of the price adjustment at the old contract prices. The Contractor is further advised that decreases which affect the cost of materials are required to be communicated immediately to the purchasing office.
- K. PRODUCT AVAILABILITY/SUBSTITUTION:** Substitution of a product, brand or manufacturer after the award of contract is expressly prohibited unless approved in advance in writing by the Contact Officer. The Agency may, at its discretion, require the contractor to provide a substitute item of equivalent or better quality subject to the approval of the Contract Officer, for a price no greater than the contract price, if the product for which the contract was awarded becomes unavailable to the contractor.

In the event any item on the contract is to be discontinued and/or replaced by a new item, the Contractor must notify the Contract Officer in writing in advance of the product discontinuance/replacement. A formal contract modification will be processed by the Contract Officer to reflect these types of changes.

- L. PURCHASE VOLUME REPORT:** The Contractor shall furnish an annual volume report within 15 days of the end of the expiration date of the contract term. Report shall list item(s) and or services performed during the previous year. These reports shall include: item purchased, date purchased, agency, quantity, each price, extended price, and eVA purchase order number.
- M. QUANTITIES:** Quantities set forth in this solicitation are estimates only, and the contractor shall supply at bid prices actual quantities as ordered, regardless of whether such total quantities are more or less than those shown.
- N. RETURN:** Exchange for credit may be accomplished by ordering agencies consistent with the Contractor's published return goods policy.
- O. STANDARD ITEMS:** No standard items shall be deleted. Standard items shall be those listed in the manufacturers most recent published literature for the item(s) offered.
- P. WARRANTY (COMMERCIAL):** The contractor agrees that the supplies or services furnished under any award resulting from this solicitation shall be covered by the most favorable commercial warranties the manufacturer and contractor gives any customer for such supplies or services and that the rights and remedies provided therein are in addition to and do not limit those available to the Commonwealth by any other clause of this solicitation. Copies of these warranties shall be furnished with the bid.
- Q. FINANCIAL WARRANTY:**

Contractor shall ensure that the prices, discounts, incentives, and other financial terms (collectively, the "financial deal") applicable to purchases under this Contract is always at least as favorable to the purchaser as the financial deal that the Contractor or its affiliates make available to any public body in Virginia for the same good(s)/service(s) outside this Contract. Throughout the term of this Contract, if Contractor (or any affiliate) makes a better financial deal available to a public body in Virginia for any good(s)/service(s) available under this Contract, Contractor shall immediately notify DGS of the details and, at DGS's option, sign an amendment to this Contract, so that an equivalent financial deal for the affected good(s)/service(s) is also available as an option under this Contract. Contractor may request exemption if the better financial deal was for a spot purchase, and DGS shall grant such request if DGS in good faith finds that the spot purchase involved special circumstances affecting cost that would make it unfair to apply an equivalent financial deal outside of that spot purchase. Upon DGS's request (and annually on August 1), Contractor shall submit to DGS an affidavit certifying full compliance with this Section. The Contractor (and any affiliate) shall waive any contractual or other right that inhibits any public body in Virginia from disclosing to DGS or others the financial terms made available to the public body, and upon request from DGS, Contractor shall ensure that a signed confirmation of the waiver is provided to the public body and DGS. As used in this Section, an affiliate is any entity that controls, is controlled by, or is under common control with, the Contractor.