Master Agreement - E194 - 295 – 08

Renewal

Document Id: 295
Document Name: E194-714-1TMM
Procurement Folder: 555
Procurement Type: IFB
Original Effective Begin Date: **2/9/2006**
Original Expiration Date: **1/31/2008**
Current Effective Date: 2/1/2008
Current Expiration Date: 1/31/2009
Document Description: Test, Pregnancy, Urine

Contact Information

Tina M. Mizelle
Phone: (804) 786-1603
Email: tina.mizelle@dgs.virginia.gov
Fax: (804) 786-5413

Thresholds

Minimum Order Amount: $100.00
Minimum Order Value: Yes
Maximum Order Amount: $0.00
Maximum Order Value: No
Not to Exceed Amount: $0.00
Not to Exceed: No

Authorized Departments

Department: A601 - Health, Dept. of and State Agencies/Local
Spending Limit: $0.00

Vendor

Legal Name: Stanbio Laboratory
Vendor Contact Name: Customer Service
Location Legal Name: same
Vendor Contact Email: stanbio@stanbio.com
Vendor Contact Phone: (800) 531-5535
Vendor Type: Primary
MA Number: E194 - 295

Renewal Periods

~~**Line Number: 1**~~
~~Renewal Period Length: 1~~
~~Renewal Period Unit: Years~~
~~Effective Date: 2/1/2008~~
~~Expiration Date: 1/31/2009~~
~~Notification Days Prior to Expiration: 90~~

Line Number: 2
Renewal Period Length: 1
Renewal Period Unit: Years

Effective Date: 2/2/2008 Expiration Date: 2/1/2009
Notification Days Prior to Expiration: 90

Line Number: 3
Renewal Period Length: 1 Renewal Period Unit: Years
Effective Date: 2/2/2009 Expiration Date: 2/1/2010
Notification Days Prior to Expiration: 90

Terms And Conditions

This Master Agreement shall include all General and Special Terms and Conditions Per the Original Invitation For Bids Document.

Contract Term
THE INITIAL TERM OF THIS CONTRACT WILL BE FOR TWO YEARS BEGINING APPROXIMATELY February 1, 2006 through January 31, 2008.

Renewal of Contract
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 day) prior to expiration.

Price Changes (Price Escalation/De-escalation)
Price adjustments may be permitted only for changes in the Contractor's cost of materials. Consumers Price Indices, Producers Price Indices or other appropriate indices 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.

Contract Cancellation

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.

Purchase Report

The Contractor shall furnish the Division of Purchases and Supply reports of the total dollar volume of purchases made under this contract and the total number of each contract item ordered under this contract in accordance with the following schedule: 1. The first report shall include purchases made in the first six months of the contract. 2. For contracts of one year, the Contractor shall furnish a second report listing the purchases made in the first nine months of the contract. In addition, for contracts exceeding one year, the Contractor shall furnish reports at the end of each consecutive twelve month period and 90 calendar days prior to the expiration date of the contract. All reports shall be delivered to the Division of Purchases and Supply no later than 14 calendar days after the request has been made by the Division. Reports shall be sent to the attention of the appropriate contract officer. Failure to submit this information in the required time may result in disqualification from bidding on the next solicitation for this contract. Each report shall be in two segments: (1) One to report the total dollar volume of purchases and the total number of each item ordered by State agencies, institutions and departments; (2) One to report the total dollar volume of purchases and number of each item ordered by all other Commonwealth public bodies (e.g. cities, towns, counties, schools and authorities, etc.), if authorized users of this contract

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 know 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.

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. Using ETF via

eVA will generally get you a lower transaction cost and save you money compared to payment via the purchasing card. Standard payment terms are net 30 days from products delivery or properly executed invoice receipt, whichever is later.

Minimum Order

Orders will be F. O. B. delivery to ordering agency within the Commonwealth of Virginia. For orders of less then $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. Destination with no transportation chares added. If at the agency's request shipments are below the minimum order value, the contractor may add actual transportation to invoice for payment.

Return

Exchange for credit may be accomplished by ordering agencies consistent with the contractor's published return goods policy. A copy of bidder's published return goods policy should accompany the bid. Failure to submit the policy may be cause for rejection of the bid.

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.

Quality Standards

A. TESTS: All products covered by this invitation 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. B. 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 that 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 manufacture's lot or control number and expiration date for dated products. C. 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. D. GUARANTEE: The bidder's signature on this proposal 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 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 E. RECALL: In submitting this bid, bidder expressly assumes full responsibility for prompt notification of any drug recall. F. 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.

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.

Delivery

All orders shall be shipped directly to the agency or department within 5 days after receipt of purchase order. 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. 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.

Specifications

A. The urine pregnancy test kit shall utilize the monoclonal and/or polyclonal antibody technology as the primary method of detecting HCG in the urine. B. The test shall have a sensitivity of 20 mIU/ml or greater for urine in accordance with the WHO 3rd I.S. C. 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 D. 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 shall 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. E. 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. F. 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. G. The test shall be equally reliable when used for early pregnancy and family planning (6 week postpartum check-up). H. 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. I. The kits shall contain all supplies necessary to perform the tests with the exception of specimen collection devices. J. Negative and positive controls shall be provided with each kit. These controls may be liquid controls or embedded with the test device. K The kit shall contain a minimum of 20 tests and no more than 40 tests. Each individual test kit shall be individually packaged. L.. 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. M. Kit shall be standardized in accordance with WHO 3rd for Human Chorionic Gonadotropin (hcg).

Commodity Information

Line: 1

Commodity: 19340

Description: Diagnostic Reagents And Tests (For Diseases, Pregnancy, Etc.): Cards, Slides, Spot Tests, Strips, Tablets, Etc., **QuPID Pregnancy Test, Catalog 1220-025 (see attachment for product information).**

Commodity Specs:

Extended Description: Test, Pregnancy, Urine One Step Method in Accordance with the Accompanying Specifications.

Unit Price: **$0.67000 each**

Box Price: **$16.75/Box**

Catalog: **1220-025**

Packing: **25 Tests Per Box**

Delivery: 10 days ARO

Free On Board Name: FOB Destination-Freight Prepaid

Line: 2

Commodity: 19340

Description: Diagnostic Reagents And Tests (For Diseases, Pregnancy, Etc.): Cards, Slides, Spot Tests, Strips, Tablets, Etc., **True 20 Pregnancy Test, Catalog 1430-050 (see attachment for product information).**

Commodity Specs:

Extended Description: Test, Pregnancy, Urine One Step Method in Accordance with the Accompanying Specifications.

Unit Price: **$0.58000 each**

Box Price: **$29.00/Box**

Catalog: **1430-050**

Packing: **50 Tests Per Box**

Delivery: 10 days ARO

Free On Board Name: FOB Destination-Freight Prepaid

Line: 3

Commodity: 19340

Description: Diagnostic Reagents And Tests (For Diseases, Pregnancy, Etc.): Cards, Slides, Spot Tests, Strips, Tablets, Etc., **Pregnancy Test Controls, Catalog 1225-205**

Commodity Specs:

Extended Description: Controls pregnancy, for above pregnancy test kits. hCG Bi-Level Urine Pregnancy Controls.

Unit Price: **$0.00000 each**

Catalog: **1225-205**

Delivery: **10 days ARO**

Box Price: **$0.00/Kit**

Packing: **2 vials/Kit at 5ml each vial**

Free On Board Name: FOB Destination-Freight Prepaid

Attachment A

Stanbio QuPID®
One-Step Pregnancy Test
Procedure No. 1220

CLIA Complexity: Waived

Intended Use: For the qualitative determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

Summary and Principle[1,2]

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During normal pregnancy, hCG can be detected as early as 6 days following conception, doubling every 1.3 to 2 days. The detection of hCG is an excellent marker for confirming pregnancy.

HCG consists of an alpha and a beta sub-unit. The alpha sub-unit is shared by other glycoprotein hormones, e.g., luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH). The beta sub-units of these molecules differ and confer biological specificity to each. The Stanbio QuPID® test detects the intact hCG molecule in urine.

The Stanbio QuPID® test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG in urine. The assay is conducted by the addition of urine specimen into the sample well and observing for the formation of colored lines in the result area. The urine specimen migrates via capillary action along the membrane and reacts with the antibody-dye conjugate. Positive hCG specimens react with the specific antibody-hCG-colored conjugate and form a colored line in the Specimen Zone (S) portion of the membrane. Absence of this colored line suggests a negative result. To serve as a positive procedural control, a colored line in the Control Zone (C) will always appear regardless of the presence or absence of hCG.

Reagents

QuPID® One-Step Pregnancy Test, Ref. No. 1221

Sealed foil pouch containing: One (1) Test Device, comprised of colored dye coated with polyclonal antibodies specific for hCG, immobilized antibodies against hCG and monoclonal anti-mouse IgG antibodies.

Precautions: *For In Vitro Diagnostic Use.*

Do not use beyond the expiration date printed on the kit or foil pouch. Use appropriate precautions for collection, handling, and storage of specimens. Do not remove the Test Device from the pouch until needed.

Reagent Storage and Stability: Each QuPID® test is stable until the expiration date on the foil pouch when stored at room temperature 59-86°F (15-30°C). **Do Not Freeze!**

Material Provided

QuPID® Test; Disposable Specimen Dropper

Materials Required But Not Provided

Specimen collection container; Interval Timer

Specimen Collection and Preparation[3]

The urine specimen must be collected in a clean, dry container, either plastic or glass, without preservatives. Specimens collected at any time may be used, however, the first morning urine generally contains the highest concentration of hCG and is therefore the most suitable. This test is for urine only. Do not use on serum or plasma specimens. Dispose of all used test devices, disposable droppers and specimens in suitable biohazardous waste containers.

Sample Stability: If testing is to be delayed more than a few hours, the urine can be stored at 2-8°C for up to 72 hours or frozen (-20°C) for 3 months, but must be brought to room temperature prior to testing.

Interfering Substances: High hCG levels may occur in patients suffering from chorionic epithelioma or hydatid mole. In these cases, a false positive may occur. Excretion of hCG is often decreased in extra uterine pregnancy, toxemia of pregnancy or threatened abortion. Such circumstances can yield false negative results.

Potentially interfering substances were added to urine which had hCG levels of 0 and 20 mIU/mL. In all cases, no interference with the expected results were observed.

Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Benzolecgonine	10 mg/dL
Bilirubin	1 mg/dL
Caffeine	20 mg/dL
Cannabidiol	10 mg/dL
Cannabinol	10 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2 gm/dL
Hemoglobin	1 mg/dL
Tetracycline	20 mg/dL
Uric Acid	20 mg/dL

Homologous Hormones:

hTSH	1000 µIU/mL	• WHO 68/38
hLH	500 mIU/mL	• WHO 2nd IRP HMG
hFSH	1000 mIU/mL	• WHO 2nd IRP HMG

Test Procedure

Note: Several tests may be run at a time. A new disposable dropper must be used for each specimen.

1. Bring urine specimen to room temperature before use.
2. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
3. Holding the disposable dropper vertically, dispense **2 FULL DROPS** (approximately 0.120 mL) of specimen into the round sample well. (see illustration).
4. Read result at **3 MINUTES**.

Quality Control

A positive procedural control (Control Zone "C") is built into the QuPID® test device. This control line will always appear if the test is performed correctly and if the device is working properly. An absence of this control line indicates incorrect procedure or deterioration of reagents. The absence of interfering background is a negative procedural control. If background color appears in the result area which interferes with the ability to read the test results, the result may be invalid.

If the control line fails to appear with a repeat assay, do not report patient result. **Contact Stanbio Technical Service: 1-800-531-5535, (830) 249-0772 or Fax (830) 249-0851.**

External Quality Control

Good Laboratory Practice recommends the use of external controls to assure that the reagents and assay are performing correctly. For this purpose, we recommend the Stanbio Bi-level hCG Urine Controls, Cat. No. 1225-205. **CAUTION:** Water (deionized, distilled or tap) should NOT be used as a negative control. Normal physiological urine contains the proper amounts of electrolytes and proteins needed to produce the correct result. External controls should be tested with each new lot or shipment of test materials once for each test kit, or as otherwise required by your laboratory's standard GLP quality control procedures.

Process the controls as you would a patient specimen. A positive result is indicated by the appearance of a colored line in the Specimen Zone (S), along with a colored line at the Control Zone (C) in the result area. A negative result is indicated by the appearance of **only** a colored line at the Control Zone (C) in the result area.

Results

Negative Results: The test is negative if only a line appears at the Control Zone (C) in the result area.

Negative Result

Positive Results: The test is positive if two (2) colored lines appear. One (1) colored line will appear at the Specimen Zone (S) and one (1) at the Control Zone (C). The appearance of any pink to red colored line in the Specimen Zone (S) along with a line in the Control Zone (C) should be considered positive. Intensity of colored lines is not an indication of the concentration of hCG in the sample.

Positive Result

Invalid Results: The test is invalid if no line appears at the Control Zone (C) even if a colored line appears at the Specimen Zone (S). In this case, the test should be repeated.

Invalid Results

Limitations[4,5,6,7]

A specimen with a low level of hCG may show color development over time.

The contents of this kit are for use in the qualitative detection of hCG. A number of conditions (see Interfering Substances section) other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, cause elevated levels of hCG. These diagnoses should be confirmed by other test methods.

Normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Spontaneous miscarriage may also cause confusion in interpreting assay results.

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). These specimens may demonstrate either false positive or false negative results when tested with assays which employ mouse monoclonal antibodies.

HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion, therapeutic abortion or hCG injections.

Positive results from early pregnancy may later prove negative due to natural termination of the pregnancy. This is estimated to occur in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall. A faint colored line in the Specimen Zone indicates a positive result, however, the result should be interpreted in the context of possible clinical or physiological conditions cause slightly elevated hCG levels. If such conditions exist or are suspected, it is good laboratory practice to resample and test 48-72 hours later.

If a urine specimen is too dilute (i.e. low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained 48-72 hours later and retested.

As with all pregnancy tests, the final diagnosis should be based on a correlation of test results with typical clinical signs and symptoms.

Expected Values[8]

Healthy men and non-pregnant women do not have hCG levels detectable by the Stanbio QuPID® Test. In normal pregnancy, levels of 20 mIU/mL hCG can be reached 2 to 3 days before the first missed menstrual period. HCG levels peak about 8 weeks after the last menstrual period and then decline to lower values during the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal within days after parturition.

Performance Characteristics

Accuracy by Comparison: A study was performed using a total of (150) positive and (150) negative urine specimens. These specimens were assayed with the Stanbio QuPID® Test and the Abbott TestPack™ Plus urine test according to their package inserts, and yielded the following results:

	Abbott TestPack™ Plus			
		(+)	(-)	
Stanbio QuPID®	(+)	150	0	Sensitivity: ~99%
	(-)	0	150	Specificity: ~99%
				Accuracy: ~99%

The accuracy study was also performed by determining the qualitative recovery of known amounts of hCG added to a negative urine pool.

	Conc. hCG Added (mIU/mL)	Expected	Observed
Urine Pool	0	Negative	Negative
	20	Positive	Positive
	50	Positive	Positive
	100	Positive	Positive

Specificity: A study was performed using positive and negative urine specimens spiked with 500 mIU/mL hLH, 1000 µIU/mL hTSH, and 1000 mIU/mL hFSH. No cross-reactivity was observed.

Standardization: The Stanbio QuPID® Pregnancy Test is standardized in accordance with the WHO 3rd I.S. for human chorionic gonadotropin.

Clinical Studies: An evaluation of the QuPID® test was conducted at three clinics using patient samples. Testing was performed by clinic personnel with diverse educational backgrounds and work experience. The results obtained at each site had 100% agreement with the expected results.

Precision: Within run precision was determined by using 12 replicates of three specimens containing 0, 20 and 100 mIU/mL of hCG. The negative and positive values were correctly identified 100% of the time. Between run precision was determined by using the same three specimens, 0, 20 and 100 mIU/mL of hCG, in 11 different assays, using three different lots of test devices over a two (2) month period. Again, the negative and positive values were correctly identified 100% of the time.

Sensitivity: The Stanbio QuPID® Test for Pregnancy detects hCG concentrations of 20 mIU/mL and greater in urine specimens in accordance with the WHO 3rd I.S. Specimens containing high levels of hCG (1,000,000 mIU/mL) when tested consistently gave positive results.

References

1. Braunstein, G.D., Rasor, J., Alder, D., Danzer H.,Wade, M.E. Am. J. Obstet.Gynecol.,Vol. 126,678-681,1976.
2. Braunstein, G.D., Vaitukaitis, J.L., Carbone, P.P., and Ross, G.T., Ann. Inter. Med. 78, 39-45 (1973)
3. Morgan, F.J., Canfield, R.E., Vaitukatis, J.L., and Ross, G.T., Endocrinology, 94, 1601-1606 (1974).
4. Kohr, G. and Milstein, C., Nature, 256, 495-497 (1975)
5. Thompson, R.J., Jackson, A.P., and Langlois, N., Clin. Chem., 32, 476-481 (1982)
6. Engavall, E. Methods in Enzymology, 70, 419-439 (1980)
7. Rasor, J.L., and Braunstein, G.D., Obstet. Gynecol., 50, 553-558 (1977).
8. Lenton, E.A., Neal, L.M., and Sulaiman, R., fertility and sterility, 37, 773-778 (1982)

For Technical Service call:
800-531-5535
(830) 249-0772 •Fax (830) 249-0851
e-mail: stanbio@stanbio.com
http:\\www.stanbio.com

Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006 U.S.A.

DN: RBR.1220CE.01
Last revision: 03/2004
Procedure: 1220

STANBIO LABORATORY

Attachment B

Stanbio True® 20 One-Step Pregnancy Test Procedure No. 1430

CE

A Qualitative Immunoassay for the Detection of Human Chorionic Gonadotropin (hCG) in Urine.

Summary and Principle [1, 2]

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During normal pregnancy, hCG can be detected as early as 6 days following conception, doubling every 1.3 to 2 days. The detection of hCG is an excellent marker for confirming pregnancy.

HCG consists of an alpha and a beta sub-unit. The alpha sub-unit is shared by other glycoprotein hormones, e.g., luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH). The beta sub-units of these molecules differ and confer biological specificity to each. The Stanbio True® 20 hCG test detects the intact hCG molecule in urine.

The Stanbio True® 20 hCG test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG. The assay is conducted by the addition of specimen into the sample well and observing for the formation of colored lines in the result area. The specimen migrates via capillary action along the membrane and reacts with the antibody-dye conjugate. Positive hCG specimens react with the specific antibody-hCG-colored conjugate and form a colored line in the Test Zone (T) portion of the membrane. Absence of this colored line suggests a negative result. To serve as a positive procedural control, a colored line in the Control Zone (C) will always appear regardless of the presence or absence of hCG.

Reagents

True® 20 Urine hCG Test Device

Sealed foil pouch containing: One (1) Test Device, comprised of colored dye coated with polyclonal antibodies specific for hCG, immobilized antibodies against hCG and monoclonal anti-mouse IgG antibodies.

Precautions: *For In Vitro Diagnostic Use.*
Do not use beyond the expiration date printed on the kit or foil pouch. Use appropriate precautions for collection, handling, and storage of specimens. Do not remove the Test Device from the pouch until needed.

Reagent Storage and Stability: Each True® 20 hCG test is stable until the expiration date on the foil pouch when stored at room temperature 59-86°F (15-30°C).

Do Not Freeze!

Material Provided

True® 20 hCG Test Device; Disposable Specimen Dropper

Materials Required But Not Provided

Specimen collection container; Interval Timer

Specimen Collection and Preparation[3]

Urine specimens must be collected in a clean, dry container, either plastic or glass, without preservatives. Specimens collected at any time may be used, however, the first morning urine generally contains the highest concentration of hCG and is therefore the most suitable. If testing is to be delayed more than a few hours, the urine can be stored at 2-8°C for up to 72 hours or frozen (-20°C) for 3 months, but must be brought to room temperature prior to testing. Do not use serum !

Interfering Substances: High urine hCG levels may occur in patients suffering from chorionic epithelioma or hydatid mole. In these cases a false positive may occur. Excretion of hCG is often decreased in extra uterine pregnancy, toxemia of pregnancy or threatened abortion. Such circumstances can yield false negative results.

Potentially interfering substances were added to urine which had hCG levels of 0 and 20 mIU/mL. In all cases, no interference with the expected results were observed.

Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Benzolecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabidiol	10 mg/dL
Cannabinol	10 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2 gm/dL
Hemoglobin	1 mg/dL
Tetracycline	20 mg/dL
Uric Acid	20 mg/dL

Homologous Hormones:

hTSH	1000 µIU/mL	• WHO 68/38
hLH	500 mIU/mL	• WHO 2nd IRP HMG
hFSH	1000 mIU/mL	• WHO 2nd IRP HMG

Test Procedure

Note: Several tests may be run at a time. A new disposable dropper must be used for each specimen.

1. Bring specimen to room temperature before use.
2. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
3. Holding the disposable dropper vertically, dispense **2 DROPS** (approximately 0.12 mL) of urine into the round sample well (see illustration).
4. Read at **3 MINUTES**.

Quality Control

A positive procedural control (Control Zone "C") is built into the True® 20 hCG test device. This control line will always appear if the test is performed correctly and if the device is working properly. An absence of this control line indicates incorrect procedure or deterioration of reagents. The absence of interfering background is a negative procedural control. If background color appears in the result area which interferes with the ability to read the test results, the result may be invalid.

If the control line fails to appear with a repeat assay, do not report patient result. **Contact Stanbio Technical Service: 1-800-531-5535, (830) 249-0772 or Fax (830) 249-0851.**

External Quality Control

Good Laboratory Practice recommends the use of external controls to assure that the reagents and assay are performing correctly. For this purpose, we recommend the Stanbio Bi-level hCG Urine Controls, Cat. No. 1225-205. **CAUTION:** Water (deionized, distilled or tap) should NOT be used as a negative control. Normal physiological specimens contain the proper amounts of electrolytes and proteins needed to produce the correct result.External controls should be tested with each new lot or shipment of test materials once for each test kit, and as otherwise required by your laboratory's standard GLP quality control procedures.

Process the controls as you would a patient specimen. A positive result is indicated by the appearance of a colored line in the Test Zone (T), along with a colored line at the Control Zone (C) in the result area. A negative result is indicated by the appearance of <u>only</u> a colored line at the Control Zone (C) in the result area.

Results

Negative Results: The test is negative if only a line appears a the Control Zone (C) in the result area.

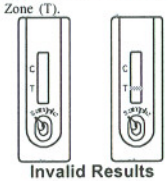
Negative Result

Positive Results: The test is positive if two (2) colored lines appear. One (1) colored line will appear at the Test Zone (T) and one (1) at the Control Zone (C). Weak positive results may show a lighter colored line in the Test Zone than the Control Zone.

Positive Result

Invalid Results: The test is invalid if no line appears at the Control Zone (C) even if a colored line appears at the Test Zone (T).

In this case, the test should be repeated.



Invalid Results

Limitations[4,5,6,7]

A specimen with a low level hCG may show color development over time. The contents of this kit are for use in the qualitative detection of hCG.

A number of conditions (see Interfering Substances section) other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, cause elevated levels of hCG. These diagnoses should be considered if appropriate to clinical evidence.

Normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Spontaneous miscarriage may also cause confusion in interpreting assay results.

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). These specimens may demonstrate either false positive or false negative results when tested with assays which employ mouse monoclonal antibodies.

HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion, therapeutic abortion or hCG injections.

Do not use test devices which have become wet or which have been left out of the foil pouch for more than 24 hours.

Positive results from early pregnancy may later prove negative due to natural termination of the pregnancy. This is estimated to occur in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall. It is therefore recommended when using a sensitive hCG assay such as the True® 20 hCG test, that weak positive results be re-tested 48-72 hours later.

If a urine specimen is too dilute (i.e. low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained 48-72 hours later and retested.

As with all pregnancy tests, the final diagnosis should be based on a correlation of test results with typical clinical signs and symptoms.

Expected Values[8]

Healthy men and non-pregnant women do not have hCG levels detectable by the Stanbio True® 20 hCG Test. In normal pregnancy, levels of 20 mIU/mL hCG can be reached 2 to 3 days before the first missed menstrual period. HCG levels peak about 8 weeks after the last menstrual period and then decline to lower values during the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal within days after parturition.

Performance Characteristics

Accuracy by Comparison: A study was performed using a total of (150) positive and (150) negative urine specimens. These specimens were assayed with the True® 20 Plus hCG Test and the Abbott TestPack™ Plus urine test according to their package inserts, and yielded the following results:

		Abbott TestPack™ Plus	
		(+)	(-)
Stanbio True® 20 hCG Test	(+)	150	0
	(-)	0	150

The accuracy study was also performed by determining the qualitative recovery of known amounts of hCG added to negative urine pools.

	Conc. hCG Added (mIU/mL)	Expected	Observed
Urine Pool	0	Negative	Negative
	20	Positive	Positive
	50	Positive	Positive
	100	Positive	Positive

Specificity: A study was performed using positive and negative urine specimens spiked with 500 mIU/mL hLH, 1000 µIU/mL hTSH, and 1000 mIU/mL hFSH. No cross-reactivity was observed.

Standardization: The True® 20 hCG Test is standardized in accordance with the WHO 3rd I.S. for human chorionic gonadotropin.

Clinical Studies: An evaluation of the True® 20 hCG test was conducted at four clinics using patient urine samples. Testing was performed by clinic personnel with diverse educational backgrounds and work experience. The results obtained at each site had 100% agreement with the expected results.

Precision: Within run precision was determined by using 12 replicates of four specimens containing 0, 20, 50, and 100 mIU/mL of hCG. The negative and positive values were correctly identified 100% of the time. Between run precision was determined by using the same four specimens containing 0, 20, 50, and 100 mIU/mL of hCG, in 11 different assays, using three different lots of test devices. Again, the negative and positive values were correctly identified 100% of the time.

Sensitivity: The Stanbio True® 20 hCG Test for Pregnancy detects hCG concentrations of 20 mIU/mL and greater in urine specimens in accordance with the WHO 3rd I.S. Specimens containing high levels of hCG (1,000,000 mIU/mL), when tested, consistently gave positive results.

References

1. Braustein, G.D., Rasor, J., Alder, D., Danzer H.,Wade, M.E. Am. J. Obstet.Gynecol.,Vol., 126,678-681,1976
2. Braunstein, G.D., Vaitukaitis, J.L., Carbone, P.P., and Ross, G.T., Ann. Inter. Med., 78, 39-45 (1973).
3. Morgan, F.J., Canfield, R.E., Vaitukatis, J.L., and Ross, G.T., Endocrinology, 94, 1601-1606 (1974).
4. Koher, G. and Milstein, C., Nature, 256, 495-497 (1975)
5. Thompson, R.J., Jackson, A.P., and Langlois, N., Clin. Chem., 32, 476-481 (1982)
6. Engavall, E., Methods in Enzymology, 70, 419-439 (1980)
7. Rasor, J.L., and Braunstein, G.D., Obstet. Gynecol., 50, 553-558 (1977).
8. Lenton, E.A., Neal, L.M., and Sulaiman, R., fertility and sterility, 37, 773-778 (1982).

STANBIO LABORATORY, LP DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES OF THE MERCHANTABILITY AND FITNESS PERTAINING TO THIS PRODUCT WHICH ARE NOT EXPRESSLY DETAILED IN THIS PACKAGING INFORMATION OR A WRITTEN AGREEMENT BETWEEN THE BUYER AND SELLER OF THIS PRODUCT.

STANBIO LABORATORY, LP MAINTAINS THAT THIS PRODUCT CONFORMS TO THE INFORMATION CONTAINED IN THIS INSERT. PURCHASER MUST DETERMINE THE SUITABILITY OF THE PRODUCT FOR ITS PARTICULAR USE. USE ONLY IN ACCORDANCE WITH LABELING INSTRUCTIONS.

For Technical Service call:
800-531-5535
(830) 249-0772 •Fax (830) 249-0851
e-mail: stanbio@stanbio.com
http:\\www.stanbio.com

Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006 U.S.A

DN: RBR.1430.CE.EN.01-M
Last revision: 06/05
Procedure: 1430

Attachment C

Stanbio hCG Bi-Level Control Set, Procedure No. 1225

For Use as hCG Pregnancy Controls in Qualitative Urine hCG Pregnancy Procedures

Summary and Principle

Controls, when assayed with actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision.

Stanbio's hCG Bi-Level Urine Control Set contains one positive control and one negative control (No detectable hCG) prepared in human urine with added preservatives and stabilizers.

Reagents

Positive hCG Urine Control (Red Cap), Ref. No. 1222
@ 250 mIU/mL hCG in urine with added preservatives.

Negative hCG Urine Control (Green Cap), Ref. No. 1223
Urine containing no detectable level of hCG with added preservatives.

Precautions: For In Vitro Diagnostic Use.

Reagent Preparation: HCG Bi-Level Urine Controls are supplied ready-to-use.

Reagent Storage and Stability: hCG Bi-Level Urine Controls are stable until expiration dates on respective labels when properly stored at 2-30°C. Once opened, controls are stable for 90 days when properly stored at 2-30°C and kept tightly capped after each use.

DO NOT USE IF CONTAMINATION IS EVIDENT.

Procedure

1. Remove hCG Bi-Level Urine Control Set from storage and allow to reach room temperature prior to use.
2. Follow the test procedure located in manufacturer's package insert for performing each test.
   DO NOT MIX CAPS FROM DIFFERENT VIALS!
3. After use, replace cap tightly on control vial and return to test box for storage.

Results

The hCG Bi-Level Urine Controls are quantitated by an EIA hCG assay and tested against each of Stanbio's hCG immunoassay products. See appropriate package insert for interpretation of test results.

For Technical Service call:
(800) 531-5535
(830) 249-0772
http://www.stanbio.com

Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

DN: RBR.1225CE.00
Last Revision: 02/04
Procedure No. 1225

STANBIO™

Stanbio hCG Bi-Level Control Set, Procedure No. 1225

For Use as hCG Pregnancy Controls in Qualitative Urine hCG Pregnancy Procedures

Summary and Principle

Controls, when assayed with actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision.

Stanbio's hCG Bi-Level Urine Control Set contains one positive control and one negative control (No detectable hCG) prepared in human urine with added preservatives and stabilizers.

Reagents

Positive hCG Urine Control (Red Cap), Ref. No. 1222
@ 250 mIU/mL hCG in urine with added preservatives.

Negative hCG Urine Control (Green Cap), Ref. No. 1223
Urine containing no detectable level of hCG with added preservatives.

Precautions: For In Vitro Diagnostic Use.

Reagent Preparation: HCG Bi-Level Urine Controls are supplied ready-to-use.

Reagent Storage and Stability: HCG Bi-Level Urine Controls are stable until expiration dates on respective labels when properly stored at 2-30°C. Once opened, controls are stable for 90 days when properly stored at 2-30°C and kept tightly capped after each use.

DO NOT USE IF CONTAMINATION IS EVIDENT.

Procedure

1. Remove hCG Bi-Level Urine Control Set from storage and allow to reach room temperature prior to use.
2. Follow the test procedure located in manufacturer's package insert for performing each test.
   DO NOT MIX CAPS FROM DIFFERENT VIALS!
3. After use, replace cap tightly on control vial and return to test box for storage.

Results

The hCG Bi-Level Urine Controls are quantitated by an EIA hCG assay and tested against each of Stanbio's hCG immunoassay products. See appropriate package insert for interpretation of test results.

For Technical Service call:
(800) 531-5535
(830) 249-0772
http://www.stanbio.com

Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

DN: RBR.1225CE.00
Last Revision: 02/04
Procedure No. 1225

STANBIO™

Stanbio hCG Bi-Level Control Set, Procedure No. 1225

For Use as hCG Pregnancy Controls in Qualitative Urine hCG Pregnancy Procedures

Summary and Principle

Controls, when assayed with actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision.

Stanbio's hCG Bi-Level Urine Control Set contains one positive control and one negative control (No detectable hCG) prepared in human urine with added preservatives and stabilizers.

Reagents

Positive hCG Urine Control (Red Cap), Ref. No. 1222
@ 250 mIU/mL hCG in urine with added preservatives.

Negative hCG Urine Control (Green Cap), Ref. No. 1223
Urine containing no detectable level of hCG with added preservatives.

Precautions: For In Vitro Diagnostic Use.

Reagent Preparation: HCG Bi-Level Urine Controls are supplied ready-to-use.

Reagent Storage and Stability: HCG Bi-Level Urine Controls are stable until expiration dates on respective labels when properly stored at 2-30°C. Once opened, controls are stable for 90 days when properly stored at 2-30 and kept tightly capped after each use.

DO NOT USE IF CONTAMINATION IS EVIDENT.

Procedure

1. Remove hCG Bi-Level Urine Control Set from storage and allow to reach room temperature prior to use.
2. Follow the test procedure located in manufacturer's package insert for performing each test.
   DO NOT MIX CAPS FROM DIFFERENT VIALS!
3. After use, replace cap tightly on control vial and return to test box for storage.

Results

The hCG Bi-Level Urine Controls are quantitated by an EIA hCG assay and tested against each of Stanbio's hCG immunoassay products. See appropriate package insert for interpretation of test results.

For Technical Service call:
(800) 531-5535
(830) 249-0772
http://www.stanbio.com

Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

DN: RBR.1225CE.00
Last Revision: 02/04
Procedure No. 1225

STANBIO™