State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

REQ NUMBER	PAGE
MCH11056	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE
Joe Boggs & Associates, Inc.
PO Box 771
Charleston, WV 25323

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - OMCFH
MATERIALS MANAGEMENT
900 BULLITT STREET
CHARLESTON, WV
25301 304-558-3417

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
08/05/2010				

BID OPENING DATE: 09/02/2010 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
				OPEN-END BLANKET CONTRACT		
0001	200	KT		193-88-00-001	$1.75	$350.00
	ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL					
	25 TEST/KIT, FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-25 OR EQUAL				$1.75	42.75
0002	1,500	KT		193-88-00-001	$1.75	$2,625.00
	ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL					
	50 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-50 OR EQUAL PER THE ATTACHED SPECIFICATIONS.				$1.75	87.50
	PACKAGING (BULK) 20 TO 40 OR 25 TO 50 TESTS/BOX. # TESTS/BOX:				$1.75	70.00
	THE MODEL/BRAND/SPECIFICATIONS NAMED HEREIN ESTABLIS THE ACCEPTABLE LEVEL OF QUALITY ONLY AND ARE NOT INTENDED TO REFLECT A PREFERENCE OR FAVOR ANY PARTICULAR BRAND OR VENDOR. VENDORS WHO ARE BIDDING					

RECEIVED
2010 SEP -1 P 1:38
PURCHASING DIVISION
STATE OF WV

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
Joe Boggs	304 345-1396	8-31-10

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
CEO	55-066-4639	

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

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ALTERNATES SHOULD SO STATE AND INCLUDE PERTINENT LITERATURE AND SPECIFICATIONS. FAILURE TO PROVIDE INFORMATION FOR ANY ALTERNATES MAY BE GROUNDS FOR REJECTION OF THE BID. THE STATE RESERVES THE RIGHT TO WAIVE MINOR IRREGULARITIES IN BIDS OR SPECIFICATIONS IN ACCORDANCE WITH SECTION 148-1-4(F) OF THE WEST VIRGINIA LEGISLATIVE RULES AND REGULATIONS. VENDORS MAY BE REQUIRED TO SUBMIT SAMPLES PRIOR TO BID AWARD. ALTERNATE PRODUCT SAMPLES TO BE APPROVED BY PROGRAM DIRECTOR, PRIOR TO AWARD.

Freight Included

EXHIBIT 3

LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON OCTOBER 1, 2010 AND EXTENDS FOR A PERIOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE ORIGINAL CONTRACT. THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE.

UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.

RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE (1) YEAR PERIODS.

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
Joe Boggs	304-345-1396	8-31-10

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
CEO	55-066-4639	

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Joe Boggs & Associates, Inc.
PO Box 771
Charleston, WV 25323

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CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.

OPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANSPORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME OF WORK.)

QUANTITIES: QUANTITIES LISTED IN THE REQUISITION ARE APPROXIMATIONS ONLY, BASED ON ESTIMATES SUPPLIED BY THE STATE SPENDING UNIT. IT IS UNDERSTOOD AND AGREED THAT THE CONTRACT SHALL COVER THE QUANTITIES ACTUALLY ORDERED FOR DELIVERY DURING THE TERM OF THE CONTRACT, WHETHER MORE OR LESS THAN THE QUANTITIES SHOWN.

ORDERING PROCEDURE: SPENDING UNIT(S) SHALL ISSUE A WRITTEN STATE CONTRACT ORDER (FORM NUMBER WV-39) TO THE VENDOR FOR COMMODITIES COVERED BY THIS CONTRACT. THE ORIGINAL COPY OF THE WV-39 SHALL BE MAILED TO THE VENDOR AS AUTHORIZATION FOR SHIPMENT, A SECOND COPY MAILED TO THE PURCHASING DIVISION, AND A THIRD COPY RETAINED BY THE SPENDING UNIT.

BANKRUPTCY: IN THE EVENT THE VENDOR/CONTRACTOR FILES FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATICALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER.

THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
Joe Boggs	304-345-1396	8-31-10

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
CEO	55-066-4639	

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RFQ NUMBER	PAGE
MCH11056	4

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304-558-0067

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Joe Boggs & Associates, Inc.
PO Box 771
Charleston, WV 25323

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SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM.

REV. 04/11/2001

NOTICE

AN ORIGINAL, SIGNED BID MUST BE SUBMITTED TO:

DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
BUILDING 15
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25305-0130

PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED. BIDS MUST CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPES OR THE BID MAY NOT BE CONSIDERED:

SEALED BID

BUYER: RW-22
RFQ. NO.: MCH11056
BID OPENING DATE: 9/2/2010
BID OPENING TIME: 1:30 P.M.

A CONVENIENCE COPY WOULD BE APPRECIATED. $1.75 $2,975.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE Joe Boggs TELEPHONE 304 345-1396 DATE 8-31-10

TITLE CEO FEIN 55-066-4639 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
MCH11056	5

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

Joe Boggs & Associates, Inc
PO Box 771
Charleston, WV 25323

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PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:

FAX # 304-345-8907

CONTACT PERSON: Joe Boggs or Ritchie Boggs

INQUIRIES
WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 8/17/2010. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO:

ROBERTA WAGNER
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25311

FAX: 304-558-4115
E-MAIL: ROBERTA.A.WAGNER@WV.GOV

PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINIA CURRENTLY UTILIZES A VISA PURCHASING CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSFUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE AGENCY AS A CONDITION OF AWARD. $,2975.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
Joe Boggs	304 345-8907	8-31-10

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
CEO	55-066-4639	

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MCH11056	6

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LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

EXHIBIT 4

LOCAL GOVERNMENT BODIES: UNLESS THE VENDOR INDICATES IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST VIRGINIA. IF THE VENDOR DOES NOT WISH TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVISIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSA $HALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER.

REV. 3/88

$1.75

****** THIS IS THE END OF RFQ MCH11056 ****** TOTAL: $2,975.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE Joe Boggs TELEPHONE 304 345-1396 DATE 8-31-10

TITLE CEO FEIN 55-066-4639

ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

WV-36 (Rev. 01/01/07)

STATE OF WEST VIRGINIA

PURCHASE CONTINUATION SHEET

Page 2 of 2 Pages | Requisition / P.O. No.: MCH11056

File: RW22 | Acct. No.: MULTIPLE

Spending Unit: WVDHHR/BPH/OMCFH/FPP

Vendor: Joe Boggs & Assoc P.O. Date:

PO Box 771 Charleston, WV

Item No.	Quantity	Description	Unit Price	Amount
		SPECIFICATIONS FOR THE ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT 25 TEST KIT AND 50 TEST KIT:	$1.75	$2,975.00

MINIMUM SPECIFICATIONS THAT MUST BE MET:

A MONOCLONAL/POLYCLONAL ANTIBODY ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HUMANCHORIONICGONADOTROPHI (HCG) 50mMIU/ML OR LESS SENSITIVITY URINE OR SERUM.

MUST BE FDA APPROVED COMBINATION KIT FOR TESTING EITHER URINE OR SERUM.

TEST KIT MUST BE A ONE STEP ASSAY PROCEDURE; TEST KIT WILL REQUIRE NO PRETREATMENT OF SAMPLE OF REAGENTS OR RECONSTITUTION OF ANY KIT COMPONENT.

PROCESSING ITEM SHALL NOT EXCEED 5 MINUTES.

KIT MUST HAVE CONTROL/END OF ASSAY INDICATOR.

SHELF LIFE MUST BE GUARANTEED FOR 12 MONTHS; ROOM TEMPERATURE STORAGE OPTIMAL.

PACKAGING MUST BE (BULK) 20 TO 40 OR 25 TO 50.

COMPACT KIT MUST CONTAIN ALL SUPPLIES NEEDED TO RUN TEST.

EXTERNAL/QUALITY ASSURANCE CONTROLS WILL BE PROVIDED BY THE WEST VIRGINIA STATE OFFICE OF LABORATORY SERVICES.

SHIPPING AND HANDLING MUST BE INCLUDED IN COST PER TEST.

ALL ITEMS OF SPECIFICATIONS ARE MANDATORY. VENDORS BIDDING ON ALTERNATE PRODUCTS MUST SUBMIT PERTINENT LITERATURE PERTAINING TO PRODUCTS AND MAY BE REQUIRED TO SUBMIT SAMPLES PRIOR TO BID AWARD. ALTERNATE PRODUCT SAMPLES TO BE APPROVED BY PROGRAM DIRECTOR.

PROGRAM DIRECTOR TO EVALUATE BIDS PRIOR TO BID AWARD.

PRICES MUST BE FIRM 12 MONTHS FROM DATE OF CONTRACT AWARD WITH OPTION TO RENEW CONTRACT FOR TWO (2) ONE (1)YEAR PERIODS.

QUANTITIES LISTED ARE APPROXIMATES ONLY. QUANTITIES ORDERED MAY BE MORE OR LESS DURING THE CONTRACT PERIOD.

OMCFH/FAMILY PLANNING PROGRAM IS TITLE 10 PHS ELIGIBLE.

CURRENT CONTRACT EXPIRES: SEPTEMBER 30, 2010.

CONTRACT PERIOD: OCTOBER 1, 2010 - SEPTEMBER 30, 2011

ACCOUNT NUMBERS:

5360-2011-0506-099-037	5360-2011-3544-099-375
0407-2011-0506-575-037	0407-2011-3010-575-375
8750-2011-0506-096-037-16621	8750-2011-3010-096-375-16621

COST SHEET FOR MCH11056

Item #	Apprx. Annual Usage QUANTITY	DESCRIPTION	UNIT PRICE	TOTAL COST
1	200 EA	ONE STEP HCG URINE/SERUM PREGNANCY TEST 25TEST/KIT	$1.75	$350.00
2	1500 EA	ONE STEP HCG URINE/SERUM PREGNANCY TEST 50TEST/KIT	$1.75	$2,625.00
		TOTAL COST		$2,975.00

Award will be based on the lowest cost per line item who meets specifications.
Vendor must submit an original itemized invoice for order. Payment will be made in arrears after receipt of each completed order.

hCG

ıe Step Pregnancy Test Device (Urine) Package Insert

ıid, one step test for the qualitative detection of n chorionic gonadotropin (hCG) in urine.

'ofessional in vitro diagnostic use only.

Category

Waived

INTENDED USE

CG One Step Pregnancy Test Device (Urine) is a chromatographic immunoassay for the qualitative ion of human chorionic gonadotropin (hCG) in to aid in the early detection of pregnancy.

SUMMARY

n chorionic gonadotropin (hCG) is a glycoprotein ıne produced by the developing placenta shortly fertilization. In normal pregnancy, hCG can be ed in both urine and serum as early as 7 to 10 after conception.[1-4] hCG levels continue to rise very /, frequently exceeding 100 mIU/mL by the first d menstrual period,[2-4] and peaking in the 100,000-)0 mIU/mL range about 10-12 weeks into ancy. The appearance of hCG in both the urine and ı soon after conception, and its subsequent rapid ı concentration during early gestational growth, it an excellent marker for the early detection of ancy.

CG One Step Pregnancy Test Device (Urine) is a test that qualitatively detects the presence of hCG ıe specimen at the sensitivity of 25 mIU/mL. The ilizes a combination of monoclonal and polyclonal dies to selectively detect elevated levels of hCG in At the level of claimed sensitivity, the hCG One Pregnancy Test Device (Urine) shows no cross-/ity interference from the structurally related ırotein hormones hFSH, hLH and hTSH at high ılogical levels.

PRINCIPLE

CG One Step Pregnancy Test Device (Urine) is a chromatographic immunoassay for the qualitative ion of human chorionic gonadotropin (hCG) in :o aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test device contains anti-hCG particles and anti-hCG coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30℃. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

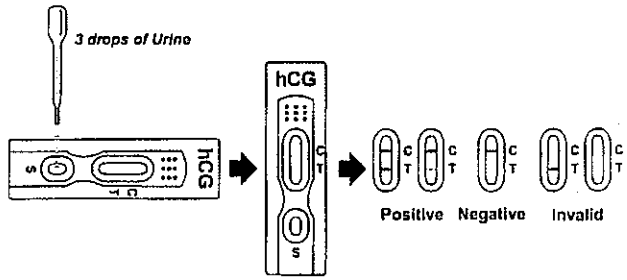
DIRECTIONS FOR USE

Allow the test device, urine specimen and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test device from the sealed pouch and use it as soon as possible.

2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.

3. Wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.



Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration.)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

;ATIVE: One red line appears in the control region No apparent red or pink line appears in the test ɔn (T).

ɅLID: Control line fails to appear. Insufficient ;imen volume or incorrect procedural techniques are nost likely reasons for control line failure. Review the edure and repeat the test with a new test device. If problem persists, discontinue using the test kit ediately and contact your local distributor.

'E: The intensity of the red color in the test line ɔn (T) will vary depending on the concentration of i present in the specimen. However, neither the ıtitative value nor the rate of increase in hCG can be rmined by this qualitative test.

QUALITY CONTROL

nal procedural controls are included in the test. A line appearing in the control region (C) is the internal edural control. It confirms sufficient specimen me and correct procedural technique. A clear ground is an internal negative background control. If est is working properly, the background in the result . should be white to light pink and not interfere with ability to read the test result.

s recommended that a positive hCG control taining ≥25 mIU/mL hCG) and a negative hCG rol (containing "0" mIU/mL hCG) be evaluated to y proper test performance. It is recommended that ral, state, and local guidelines be followed.

LIMITATIONS

Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,[5] a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.

A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.[6-7] Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

5. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The hCG One Step Pregnancy Test Device (Urine) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG One Step Pregnancy Test Device (Urine) to another commercially available urine membrane hCG test. The study included 159 urine specimens: both assays identified 88 negative and 71 positive results. The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the hCG One Step Pregnancy Test Device (Urine) when compared to the other urine membrane hCG test.

		Reference hCG Method	
		Positive	Negative
hCG One Step Pregnancy Test Device	Positive	71	0
	Negative	0	88

Sensitivity and Specificity

The hCG One Step Pregnancy Test Device (Urine) detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.
All substances listed in mg/dL unless otherwise noted.

Acetaminophen	20	Ethanol	1%
Acetone	1,000	Estriol	2
Acetylsalicylic Acid	20	Estrone 3-Sulfate	10
Acetoacetic Acid	2,000	Gentisic Acid	20
Ampicillin	20	Glucose	2,000
Ascorbic Acid	20	Hemoglobin	1,000
Atropine	20	Heroin	1
Albumin	2,000	Ibuprofen	20
β-Hydroxybutyrate salt	2,000	Methadone	10
Benzoylecgonine	10	Methamphetamine	10
Bilirubin	20	Methanol	10%
Brompheniramine	20	Morphine	0.6
Caffeine	20	Oxalic Acid	40
Cannabinol	10	Phenothiazine	20
Chlomiphene	100	Phenylpropanolamine	20
Cocaine	10	Pregnanediol	2
Codeine	10	Salicylic Acid	20
Cholesterol	500	Tetracycline	20
Creatine	20	Triglycerides	1,200
Dextromethorphan	20	Theophylline	20
DMSO	5%	Urea	2,000
EDTA	80	Uric Acid	20
Ephedrine	20		

None of the substances at the concentration tested interfered in the assay.

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3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", *Am. J. Obstet. Gynecol.* 1976; 126(6): 678-681
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DN: 1155085701
Eff. Date: 2007-09-11

Distributed by
Innovacon, Inc., San Diego, CA 92121

K041946

AUG 16 2004

XV. 510(k) Summary

Device Names:

ACON SPECTRUM Urine/Serum Pregnancy Test Device

Common Name:

Pregnancy Test Kit, Professionals

Medical Specialty:

Clinical Chemistry

Intended Use:

The ACON SPECTRUM Urine/Serum Pregnancy Test Device is for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine and serum to aid in the determination of pregnancy. It is for healthcare professionals only.

Device Description:

The test utilizes a combination of mouse monoclonal antibody conjugated with a proprietary dye-binding system and goat polyclonal antibody to qualitatively detect elevated levels of hCG in urine and serum samples. Test may be done by applying sample and observing visually for the formation of colored lines. After sample application, specimen migrates via capillary action along the components of the test. During migration, hCG molecule in the sample reacts with the monoclonal hCG antibodies-dye conjugate, and also reacts with the polyclonal hCG antibody striped down at the test region of the membrane to form an antibody-antigen-antibody-dye complex as a colored test line. Therefore, a colored line forms in the test (T) region indicates a **positive** result; while absence of this colored line indicates a **negative** result.

To serve as a procedural control, if the test has been performed properly, a RED colored zone in the control (C) region will always be cleared to expose a BLUE line, indicating adequate sample volume and proper wicking, regardless of the presence of hCG. The presence of the red dye or absence of the blue control line in the C region indicates that the test result is "**invalid**".

The ACON SPECTRUM Urine/Serum Pregnancy Test Device qualitatively detects hCG in urine or serum sample with a designated cutoff hCG concentration of 25 mIU/mL. The cutoff concentration of this test has been standardized to the World Health Organization Fourth International Standard for Chorionic Gonadotropin (NIBSC Code: 75/589). The addition of hLH (300 mIU/mL), hFSH (1,000 mIU/mL), and hTSH (1,000 μIU/mL) to negative (0 mIU/mL hCG)

and positive (25 mIU/mL hCG) urine and serum samples showed no interference in correctly read the expected test results.

Clinical Studies:

A clinical study was conducted in two sites in the U.S. by healthcare professionals with varying educational backgrounds and laboratory experience and demonstrated performance equivalency between the current and the new ACON hCG tests by professionals. A retrospective focus group study on reproducibility and precision also demonstrated high degree of correlation between the current and the new ACON hCG tests. The vast majority of the participants also found the ACON SPECTRUM Urine/Serum Pregnancy Test Device very easy to use, and that they have had no trouble understanding the labeling, reading the instructions, or interpreting the results.

Additional Laboratory Studies:

Additional laboratory study results on performance including specificity, interference substances, urinary pH, urinary specific gravity, dose hook effect, time flexibility, and volume flexibility studies are also included in this submission. These results indicate that the ACON SPECTRUM Urine/Serum Pregnancy Test Device is robust and will give accurate results under many adverse conditions.

Substantial Equivalency on Performance:

The overall performance data indicate that the ACON SPECTRUM Urine/Serum Pregnancy Test Device is safe, effective and substantially equivalent to the ACON hCG Urine/Serum One Step Pregnancy Test Device (K993065) legally sold on the U. S. market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2004

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: k041946
Trade/Device Name: ACON SPECTRUM Urine/Serum Pregnancy Test Device
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: July 16, 2004
Received: July 19, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041946

Device Name: ACON SPECTRUM Urine/Serum Pregnancy Test Device

Indications For Use: The ACON SPECTRUM Urine/Serum Pregnancy Test Device is intended for the qualitative identification the elevated level of human Chorionic Gonadotropin (hCG) in urine and serum to aid in the determination of pregnancy. It is for healthcare professionals only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041946

Rev. 09/08

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Resident Vendor Preference, if applicable.

1. **Application is made for 2.5% resident vendor preference for the reason checked:**
___ Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**
___ Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**
___ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% resident vendor preference for the reason checked:**
___ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% resident vendor preference for the reason checked:**
___ Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% resident vendor preference for the reason checked:**
___ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:**
___ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:**
___ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: Joe Boggs & Associates, LLC Signed: Joe Boggs

Date: 8-31-10 Title: CEO

*Check any combination of preference consideration(s) indicated above which you are entitled to receive.

RFQ No. MCH 110560

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

West Virginia Code §5A-3-10a states: No contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and the debt owed is an amount greater than one thousand dollars in the aggregate.

DEFINITIONS:
"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities. "Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

EXCEPTION: The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

Under penalty of law for false swearing (***West Virginia Code*** §61-5-3), it is hereby certified that the vendor affirms and acknowledges the information in this affidavit and is in compliance with the requirements as stated.

WITNESS THE FOLLOWING SIGNATURE

Vendor's Name: Joe Boggs & Associates, Inc.

Authorized Signature: Joe Boggs Date: 8-23-10

State of WV

County of KANAWHA, to-wit:

Taken, subscribed, and sworn to before me this 23 day of Aug, 2010.

My Commission expires May 8, 2020.

AFFIX SEAL HERE

NOTARY PUBLIC James Copley

OFFICIAL SEAL
JAMES COPLEY
NOTARY PUBLIC
STATE OF WEST VIRGINIA
1001 Bridge Road
Charleston, WV 25314
My Commission Expires May 8, 2020