EALED BID PROPOSAL

PAT PHAMATECH Laboratories & Diagnostics

10151 Barnes €anyon k San Diego, CA 92121

888.635.5840

www.phamatech.com

State of West Virginia

Department of Administration Purchasing Division Building 15 2019 Washington Street, East Charleston, WV 25305-0130

Pregnancy Test Kits

RFQ Number: MCH11056

RECEIVED

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10151 Barnes Canyon R San Diego, CA 92121

888.635.5840

www.phamatech.com

Table of Contents

State of West Virginia Pregnancy Test Kits RFQ Number: MCH11056

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TYPE NAME/ADDRESS HERE

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

Request for Quotation

MCH11056

PAG	3 E :::
	1

ADDRESS CORRESPONDENCE TO ATTENTION OF ROBERTA WAGNER

304-558-0067

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT

Phamatech Inc.

10151 Barnes Canyon Rd
San Diego CA 92121

DATE PRINTED

Phamatech Inc.

MATERIALS MANAGEMENT
900 BULLITT STREET
CHARLESTON, WV
25301

304-558-3417

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Contra	acts Admin.	330836229)	ADDRESS CHANGES	S TO BE NOTED ABOVE

GENERAL TERMS & CONDITIONS REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

- 1. Awards will be made in the best interest of the State of West Virginia.
- 2. The State may accept or reject in part, or in whole, any bid.
- 3. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125 fee.
- 4. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods this Purchase Order/Contract becomes void and of no effect after June 30.
- 5. Payment may only be made after the delivery and acceptance of goods or services.
- 6. Interest may be paid for late payment in accordance with the West Virginia Code.
- 7. Vendor preference will be granted upon written request in accordance with the West Virginia Code.
- 8. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
- 9. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
- 10. The laws of the State of West Virginia and the Legislative Rules of the Purchasing Division shall govern the purchasing process.
- 11. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.
- 12. BANKRUPTCY: in the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order.
- 13. HIPAA BUSINESS ASSOCIATE ADDENDUM: The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, is available online at www.state.wv.us/admin/purchase/vrc/hipaa.htm and is hereby made part of the agreement. Provided that the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
- 14. CONFIDENTIALITY: The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/noticeConfidentiality.pdf.
- 15. LICENSING: Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, and the West Virginia Insurance Commission. The vendor must provide all necessary releases to obtain information to enable the director or spending unit to verify that the vendor is licensed and in good standing with the above entities.
- 16. ANTITRUST: In submitting a bid to any agency for the State of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will convey, sell, assign or transfer to the State of West Virginia all rights, title and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to the bidder.

I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, or person or entity submitting a bid for the same material, supplies, equipment or services and is in all respects fair and without collusion or Fraud. I further certify that I am authorized to sign the certification on behalf of the bidder or this bid.

INSTRUCTIONS TO BIDDERS

- 1. Use the quotation forms provided by the Purchasing Division. Complete all sections of the quotation form.
- 2. Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as EQUAL to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.
- 3. Unit prices shall prevail in case of discrepancy. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.
- 4. All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130
- 5. Communication during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited (W.Va. C.S.R. §148-1-6.6).



VENDOR

RFQ COPY

Phamatech Inc.

TYPE NAME/ADDRESS HERE

10151 Barnes Canyon Rd

San Diego CA 92121

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

Request for **Quotation**

MCH11056

PAGE 2

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER

HEALTH AND HUMAN RESOURCES

H BPH - OMCFH MATERIALS MANAGEMENT

I 900 BULLITT STREET

CHARLESTON, WV

25301 304-558-3417

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H BPH - OMCFH
MATERIALS MANAGEMENT

900 BULLITT STREET CHARLESTON, WV

25301

304-558-3417

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Phamatech Inc.

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State of West Virginia
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Request for Quotation

MCH11056

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ADDRESS CORRESPONDENCE TO ATTENTION OF:

ROBERTA WAGNER 304-558-0067

304-558-0067

HEALTH AND HUMAN RESOURCES
BPH - OMCFH

MATERIALS MANAGEMENT
900 BULLITT STREET
CHARLESTON, WV

25301 304-558-3417

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Phamatech Inc.

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10151 Barnes Canyon Rd San Diego CA 92121

State of West Virginia
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Request for Quotation

MCH11056

PAGE 5

ADDRESSICCARESPONDENCERION HENTION OF

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES BPH - OMCFH

P MATERIALS MANAGEMENT 900 BULLITT STREET

CHARLESTON, WV

25301 304-558-3417

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2019 WASHINGTON STREET EAST	
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*AX: 304-558-4115	
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RFQ COPY

Phamatech Inc.

TYPE NAME/ADDRESS HERE

10151 Barnes Canyon Rd San Diego CA 92121

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

Request for Quotation MCH1105

MCH11056

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 804-558-0067

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET

CHARLESTON, WV 25301

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Requisition / P.O. No.: MCH11056

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

STATE OF WEST VIRGINIA **PURCHASE CONTINUATION SHEE**

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Page 2 of 2 Pages

Vendor: Phamatech Inc. P.O. Date: 8/31/

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:		
		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	DESCRIPTION	UNIT PRICE	TOTAL COST
	QUANTITY			
ę-d	200 EA	ONE STEP HCG URINE/SERUM PREGNANCY TEST 200 EA 25TEST/KIT	\$ 8.00	\$ 1,600
2	1500 EA	ONE STEP HCG URINE/SERUM PREGNANCY TEST 1500 EA 50TEST/KIT	\$16.00	\$24,000
		TOTAL COST		\$25,600

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

Statement of Alternate Product

As part of Phamatech Inc.'s proposal for RFQ MCH11056 Pregnancy Test Kits we are submitting our own Pregnancy Test Kit. The product is manufactured by Phamatech and holds the same standards as the product currently being used. On the subsequent pages is the product insert for the Phamatech QuickCard. Also attached are samples of the product for your appraisal.

QuickCardTM HCG Combo Test

Catalog # 9014-25 / Test Instructions

Intended Use

ickCardTM HCG Combo Test is an in vitro diagnostic test for the qualitative detection of numan chorionic gonadotropin (hCG) in urine or serum. The test is a two-site immunoassay employing monoclonal and polyclonal antibodies, and is designed to reliably produce a visually detectable colored Test Band in the presence of hCG at a concentration of 25 miU/mL or greater (WHO 3rd IRP, 75/537) within five (5) minutes of sample application. This assay is intended for professional use.

Summary & Explanation

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In a normal pregnancy, hCG can be detected in serum as early as 7 days following conception and doubles every 1.3 to 2 days. At the time of the first missed menstrual period, hCG concentrations are about 100 mIU/mL. Peak hCG-levels (from 100,000 to 250,000 mIU/mL) are seen at the end of the first trimester, though higher concentrations have been observed. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy.

Elevated hCG levels comparable to those observed in early pregnancy may also be associated with trophoblastic or non trophoblastic neoplasms such as hydatidiform mole and choriocarcinoma, therefor, the possibility of such diseases should be ruled out before a positive hCG result is considered diagnostic for pregnancy.

The Pharnatech QuickCard™ HCG Combo Test is a rapid, visual, and easily read test to qualitatively detect the presence of hCG in urine or serum specimens at concentrations as low as 25 mIU/mL. The immunological specificity of the test kit virtually eliminates cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at physiological levels.

Principles of the Procedure

The QuickCardTM HCG Combo Test employs the basic immunochemical sandwich assay principle, relying on the recognition and formation of specific antibody / hCG / antibody-dye complexes. The membrane is coated with goat anti-hCG in the Test Band region and goat anti-mouse in the Control Band region, and a monoclonal anti-hCG / colloidal gold conjugate ted in the sample patch.

the aid of a plastic transfer pipette. The sample migrates by capillary action from the sample pad through the label pad, mixing with the colored anti-hCG / colloidal gold conjugate. The sample then migrates across the pre-coated membrane, carrying the colored conjugate with it. If the sample's hCG concentration is greater than or equal to 25 mIU/mL (the sensitivity of the test), a specific antibody / hCG / antibody-dye complex is formed in the Test Band region. A visually detectable line will appear in the Test Band region, indicating a positive result.

If there is no hCG in the sample, or the sample's hCG concentration is below 25 ng/mL, no line will appear in the Test Band region. The absence of a visually detectable Test Band indicates a negative result.

In either case, a visually distinct colored band is produced in the Control Region (C) by a nonspecific, antibody / dye conjugate reaction. This band serves as a built-in quality control device that demonstrates antibody recognition and reactivity as well as confirmation that the test is complete.

Reagents & Materials Provided

1. 25 individually pouched test devices

2. Test instructions

Materials Required, But Not Provided

1. Clock or timer

2. Sample containers

Warnings & Precautions

- 1. This test is for in vitro diagnostic use only.
- 2. This test is for testing human urine or serum only
- Specimens may be potentially infectious. Properly handle and dispose of all specimens and used reaction devices according to Universal Precautions for biohazardous materials.
- 4. Do not use kit beyond the stated expiration date.
- 5. Do not attempt to reuse the test device.

Storage

e the kit between 15 - 28 °C until the expiration date on the pouch or kit box.

Sample Collection & Preparation

Collect a urine sample in clean, dry container, either plastic or glass, without any preservatives. Samples may be refrigerated $(2-8 \, ^{\circ}\text{C})$ and stored up to 48 hours. For longer storage, freeze samples at $\leq -20 \, ^{\circ}\text{C}$. Serum specimens should be obtained following established laboratory collection procedures.

Procedural Notes

Read the following procedure carefully to ensure the best results with QuickCard™ HCG Combo Test.

Transfer of Specimens - A clean pipette should be used to transfer the specimen.

Incubation Time & Temperature — The QuickCardTM HCG Combo assay performs with the stated sensitivity and specificity at room temperature (15 to 28°C, 59 to 86°F). Temperatures lower than this will result in less color development at the end of the 5-minute incubation. Specimens with high hCG levels may give positive results in less than 5 minutes. For such specimens it is not necessary to wait the full 5 minutes to obtain a valid result.

Batch Processing – If several specimens are to be analyzed at one time, perform each test step for all specimens at timed intervals before proceeding to the next test step. It is recommended that no more than five (5) devices be run in any one batch.

Turbid Specimens – Turbidity and particulates in urine or serum will slow the rate of phoresis, the speed that liquid passes across the membrane. In certain cases, an extremely turbid specimen may cause the liquid transfer to stop. In such cases, centrifuge the sample and retest using a fresh device.

Assay Procedure

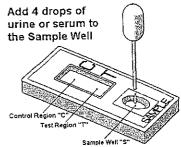
The test procedure for QuickCardTM HCG Combo is performed at room temperature. Before performing the test, read the section entitled "Procedural Notes." The assay procedure is as follows:

Preparation

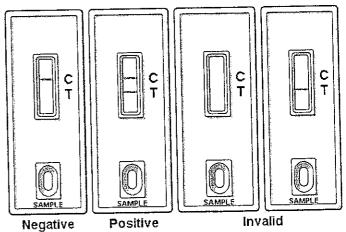
- 1. Bring the test device and sample to room temperature (15 28 °C) before testing.
- 2. Do not break the seal on the foil pouch until ready to perform the test.

Testin:

- Remove a QuickCardTM HCG Combo Test from its protective pouch. Verify that the test device is within its expiration dating.
- Lay the test device on a clean, level surface. Using the sample pipette provided with the test, add four (4) drops of sample to the Sample Well "S". Allow each drop to be absorbed before adding the next.
- Within 5 minutes a colored band will appear at the top of the test area to show that the test is complete.
- Read test results immediately at 5 minutes. Results read after 10 minutes have elapsed should be considered invalid.



Interpretation of Results



Negative – A rose-pink colored band appears in the Control Reaction Zone "C" but not in the Test Reaction Zone "T". This is a negative result and indicates the hCG level is below the detection sensitivity of 25 mIU/mL.

Positive — Two horizontal rose-pink color bands appear, one in the Control Reaction Zone "C" and one in the Test Reaction Zone "T". This is a positive result and indicates the hCG level is at or above the detection sensitivity of 25 mlU/mL.

Invalid – If no bands appear, or a Test Band appears without a Control Band, the device reagents may have deteriorated or the test may not have been performed properly. The presence of a Control Band is necessary to validate test performance. Retest the sample with a new test device

Quality Control

An internal procedural control has been incorporated into the test to ensure proper kit performance and reliability. The development of the rose-pink Control Band demonstrates antibody recognition, verifies that the reagents are chemically active, and confirms that the test

The use of external controls is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing facility. Assay controls in same method as urine specimens.

Limitations of the Procedure

- This method has been tested using urine and serum only. Other fluids have not been evaluated.
- Positive results, as evidenced by the appearance of rose-pink Test and Control oands, may
 be apparent in as little as 1 minute. However, to confirm negative results the full 5 minute
 assay time should be allowed to elapse.
- 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 specimen should be obtained from the patient and tested.
- Occasionally, samples containing hCG levels below the cutoff sensitivity for the test may produce positive results.
- A number of conditions other than pregnancy, including trophoblastic disease and certain non trophoblastic neoplasms, cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.
- 6. The test is a qualitative screening assay and is not for determining quantitative concentra-
- 7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings are evaluated.

Expected Values

Healthy males and healthy non-pregnant females do not have detectable hCG with the Pharmatech QuickCardTM HCG Combo Test. In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations approximately doubling every 38 hours. HCG levels peak in excess of 150,000 mlU/mL in approximately 10 to 12 weeks and then "ne to lower values for the remainder of the pregnancy. Following delivery, hCG levels if y decrease and usually return to normal soon after parturition.

Performance Characteristics

Sensitivity – Pharnatech's QuickCardTM Combo hCG detects urine and serum concentrations of 25 mIU/mL or greater (WHO 3rd IS, 75/537). Occasionally samples with hCG levels below 25 mIU/mL may test positive. Low hCG levels should be interpreted in the context of physiological conditions of the individual patient. Weak positive results should be confirmed with a second sample and test after an additional 48 hours. This assay consistently yields positive results with samples containing 600,000 mIU/mL.

Specificity - 300 mIU/mL i.H, 1000 mIU/mL FSH and 1000 μ IU/mL TSH were added to urine and serum samples containing 0, 25 and 100 mIU/mL hCG. In >99% of all determinations, the 0 mIU/mL sample tested negative and the 25 and 100 mIU/mL samples tested positive. The results demonstrate that the QuickCardTM HCG Combo Test has no cross-reactivity with hLH, hTSH or hFSH.

Accuracy – More than 100 urine and serum samples were collected at clinical sites from normal females who suspected they were pregnant. Testing was performed at Pharmatech. Immediately upon completion of the assays, results were visually scored as "negative" (absence of hCG) or "positive" (presence of hCG) by the technician. Quality Assurance personnel then verified all results.

When results obtained using the QuickCardTM HCG Combo Test were compared to the *QuickVue*TM, the *Test Pack Plus*TM Pregnancy Test, and the QuickCardTM One Step hCG Pregnancy Test (9008), an overall agreement of >99.0% (201/203) was observed. The QuickCardTM test correctly detected >99.9% (86/86) positive samples and 98.3% (115/117) negative samples. The results are presented below.

QuickCard™ HCG Combo vs Commercially Available HCG Combo Tests

	Observed vs. Expected Results	Agreement
Sensitivity	86/86	>99.9%
Specificity	115/117	98.3%
Ассигасу	201 / 203	>99%

Interference – The following substances were added to hCG-free and 25 mlU/rnL hCG-spiked urine and serum samples were tested with the QuickCard™ HCG Combo Test. No interference with the expected results was observed from any of the substances at the indicated concentrations.

Urine Analytes	Concentration
Albumin (serum)	2000 mg/dL
Bilirubin	1000 µg/dL
Glucose	2000 mg/dL
Chemical Analytes	Concentration
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Acetyisalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
DMSO	5.0%
EDTA	80 mg/dL
Hormone	Concentration
Estriol 17-beta	1400 µg/mL
FSH	1000 mIU/mL
LH	300 mlU/mL

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Urine Analytes	Concentration
Hemoglobin	1000 µg/dL
Uric Acid	20 mg/dL
pН	5 to 9
Chemical Analytes	Concentration
Ephedrine	20 mg/dL
Ethanol	1.0%
Gentisic Acid	20 mg/dL
β-Hydroxybutyrate	2000 mg/dL
Methadone	10 mg/dL
	10.0%
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic Acid	20 mg/dL
YY	Concentration
Hormone	
Pregnanediol	1500 µg/mL
TSH	1000 µIU/mL

Bibliography

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- Catt, K.J., Dufan, M.L., and Vaitukaitis, J.L., Journal of Clinical Endocrinology and Metabolism, 40:537 (1975)
- Braunstein, G.D., Rasor, J., Adler, D., Danzer, H., Wade, M.E., American Journal of Obstetrics and Gynecology, 126:678 (1976)
- 4. Lenton, E.A., Neal, L.M., Salaiman, R., Fertility and Sterility, 37:773 (1982)
- 5. Braunstein, G.D., et al, Annals of Internal Medicine, 78:39 (1973)
- 6. Engvall, E., Methods in Enzymology, 70:419 (1980)
- 7. Uotila, M., Ruoslahti, E., Engvall, E., Journal of Immunological Methods, 42:11 (1981)

QuickCardTM HCG Combo Test

Catalog # 9014-25



Phamatech, Inc.

10151 Barnes Canyon Road San Diego, CA 92121, USA Tel: (858) 643-5555 Fax: (858) 635-5843

Website: www.phamatech.com



Cavendish Scott Limited

SG5 1FW, England Tel: +44 (0)1462 420 226

P.O. Box 107

Fax: +44 (0)1462 420 226

9014-DI, Doc. # 100094, Rev. G, Eff. 2005-01-31



Phamatech Inc.

TYPE NAME/ADDRESS HERE

10151 Barnes Canyon Rd

San Diego CA 92121

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

Request for |

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ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET CHARLESTON, WV

25301 304-558-3417

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GENERAL TERMS & CONDITIONS REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

- 1. Awards will be made in the best interest of the State of West Virginia.
- 2. The State may accept or reject in part, or in whole, any bid.

3. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division

and have paid the required \$125 fee.

- 4. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods this Purchase Order/Contract becomes void and of no effect after June 30.
- 5. Payment may only be made after the delivery and acceptance of goods or services.
- 6. Interest may be paid for late payment in accordance with the West Virginia Code.
- 7. Vendor preference will be granted upon written request in accordance with the West Virginia Code.
- 8. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
- 9. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
- 10. The laws of the State of West Virginia and the Legislative Rules of the Purchasing Division shall govern the purchasing process.
- 11. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.
- 12. BANKRUPTCY: In the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order.
- 13. HIPAA BUSINESS ASSOCIATE ADDENDUM: The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, is available online at www.state.wv.us/admin/purchase/vrc/hipaa.htm and is hereby made part of the agreement. Provided that the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
- 14. CONFIDENTIALITY: The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/noticeConfidentiality.pdf.
- 15. LICENSING: Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, and the West Virginia Insurance Commission. The vendor must provide all necessary releases to obtain information to enable the director or spending unit to verify that the vendor is licensed and in good standing with the above entities.
- 16. ANTITRUST: In submitting a bid to any agency for the State of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will convey, sell, assign or transfer to the State of West Virginia all rights, title and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to the bidder.

I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, or person or entity submitting a bid for the same material, supplies, equipment or services and is in all respects fair and without collusion or Fraud. I further certify that I am authorized to sign the certification on behalf of the bidder or this bid.

INSTRUCTIONS TO BIDDERS

- 1. Use the quotation forms provided by the Purchasing Division. Complete all sections of the quotation form.
- 2. Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as EQUAL to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.

3. Unit prices shall prevail in case of discrepancy. All quotations are considered F.O.B. destination unless alternate hipping terms are clearly identified in the quotation.

4. All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130 5. Communication during the solicitation, bid, evaluation or award periods, except through the Purchasing Division,

is strictly prohibited (W.Va. C.S.R. §148-1-6.6).



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

Request for Quotation MCH1105

PAGE	80000
	2

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ROBERTA WAGNER 304-558-0067

RFQ COPY TYPE NAME/ADDRESS HERE Phamatech Inc. 10151 Barnes Canyon Rd San Diego CA 92121

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

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STATE OF WEST VIRGINIA

PURCHASE CONTINUATION SHEET

_	The selection Toron	D.O. D-4-	Ω	/21	/10	
endor:	Phamatech Inc.	P.O. Date:	<u> </u>	<u>, 3 T</u>	<u>/ 10</u>	

Page 2 of 2		Requisition / P.O. No.: MCH11056
File: RW22	Acct. No.: MUL MUL	MUL
Spending Unit:	MOMOEH/EE	op

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em No.	Quantity	Description		Amount
		Q. IN THE DESCRIPTION OF MCH11056 THEY USE THE BRAND NA INFALAB, WHICH IS NOT EITHER OF THE TWO VENDORS THAT GO BID BACK IN 2008.	AME OF THE	
		A. INFALAB IS INFOLAB. THE PO MCH80446B IS ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 50 TEST/KIT FOF CASSETTE INFOLAB CATALOG # IT FHC-202-50 AND THE ONE STE URINE/SERUM PREGNANCY TEST KIT OR EQUAL 25 TEST/KIT FOF CASSETTE INFOLAB CATALOG # IT FHC-202-25	PHCG	
		Q. I DON'T HAVE THE PRICE THEY USED TO GET THE BID. WOULD PLEASE PROVIDE THE LAST BID PRICE?. A. PO FOR MCH80446A THE ONE STEP HCG URINE/SERUM PREG TEST KIT OR EQUAL 25 TEST/KIT FORMAT: CASSETTE INFOLAB C# IT FHC-202-25 \$10.00 PER KIT. THE PO MCH80446B IS ONE STEP URINE/SERUM PREGNANCY TEST KIT OR EQUAL 50 TEST/KIT FOR CASSETTE INFOLAB CATALOG# IT FHC-202-50 \$19.50 PER KIT.	NANCY ATALOG HCG	
		Q. ON THE LAST BID. WERE THERE ANY SHIPPING CHARGES? A. THE SHIPPING CHARGES WERE INCLUDED IN THE KIT COST.		
		Q. WHO IS THE CURRENT VENDOR? A. THE CURRENT VENDOR FOR MCH80446A IS SCI INTERNATION FOR THE ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT C EQUAL 25 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-25. THE CURRENT VENDOR FOR THE PO MCH80446B IS LABORATORY ONE STEP HCG URINE/SERUM PREGNANCY TEST EQUAL 50 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-50.	R STANBIO	
		Q. HOW MANY LOCATIONS WILL PRODUCT BE SHIPPED TO? A. PRODUCTS WILL BE SHIPPED TO ONE LOCATION, DHHR MAT MANAGEMENT.	TERIALS	
		Q. WILL PRODUCT BE SHIPPED ALL AT ONCE, INCREMENTALLY THROUGHOUT THE YEAR? A. PRODUCT WILL BE REQUESTED THROUGHOUT THE YEAR, AS SUPPLY IS USED.		
		Q. IF SHIPPED INCREMENTALLY, HOW MANY TIMES? A. THE NUMBER OF SHIPMENTS DEPENDS ON THE USAGE/NEE CLINICS.	D BY	
		Q. HOW MANY SAMPLES ARE TO BE SENT IN WITH THE QUOTA: A. 2 samples of each. It is preferred with bid but no		
			ŀ	

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,
•	Application is made for 2.5% resident vendor preference for the reason checked:
2.	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.
requirer against or dedu	understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the ments for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency cted from any unpaid balance on the contract or purchase order.
authoriz	nission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and test the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid uired business taxes, provided that such information dress not contain the amounts of taxes paid nor any other information if by the Tax Commissioner to be confidential.
and ac	cenalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true curate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate as during the term of the contract, Bidder will noting the Purchasing Division in writing immediately.
Bidder:	Phamatech Inc. Signed: Niv notes
	8/31/10 Contracts Administrator
*Check a	ny combination of preference consideration(s) indicated at ave. which you are entitled to receive.

RFQ No. MCH 11056

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:

WITNESS THE FOLLOWING SIGNATURE

"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.

Vendor's Name: Phamatech Inc. Authorized Signature: //w mtw Date: 8/31/10 State of California County of San Diego , to-wit: Taken, subscribed, and sworn to before me this 3 day of My Commission expires DC 5 , 20 10. AFFIX SEAL HERE NOTARY PUBLIC Callage

JODEE CALLAGHAN
Commission # 1708934
San Diego County
MyComm Expires Dec 5, 2010

Purchasing Affidavit (Revised 12/15/09)