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

## Request for p Quotation

MCH11056

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

մՈՒՆԻԱՐՈՒՈՐՈՐՈՐՈՐՈՐԻՐԻ Sacks Medical Corporation 143 Wagner Road Evans City, PA 16033

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

DATE PRINTED 1	TERMS OF SALE SHIP VIA	F.O.B. FREIGHT TERMS
08/05/2010		
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0	PEN-END BLANKET CONTRACT	\$ 45 \$ 00
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# **SMC DIRECT, LLC**

\*Formally known as Sacks Medical Corporation 143 WAGNER ROAD EVANS CITY, PA. 16033 PH# 1-800-521-1635 FX# 1-800-233-5583

# **EFFECTIVE IMMEDIATELY**

# Dear Customer – WE HAVE RECENTLY CHANGED OUR COMPANY NAME ...

I am sending you the following general vendor information that also includes my company e-mail address.

Of course, if you do have any further questions or require any additional information, please don't hesitate to call me!

Thank You: James R. Kopcie

Mailing Address;

**SMC Direct, LLC** 

143 Wagner Road

Evans City, Pa. 16033

Warehouse/Physical Address; Same as Above !!!

Phone# 800-521-1635

Fax# 800-233-5583

**NEW Fed ID#** 

27-1802742

Your Contact

James R. Kopcie – Ext# 212

E-Mail:

jim@mysmcdirect.com

**Direct Cell** 

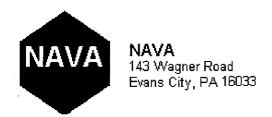
412-977-6209

# COST SHEET FOR MCH11056

29,415.	#	TOTAL COST		
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1,890.00	19.15	ONE STEP HCG URINE/SERUM PREGNANCY TEST  200 EA 25TEST/KIT *OUR PROP PREGNANCY TEST	200 EA	
<b>**</b>	*		QUANTITY	
TOTAL COST	UNIT PRICE	DESCRIPTION	Item # Apprx. Annual Usage	Item#

Award will be based on the lowest cost per line item who meets specifications.

order. Wendor must submit an original itemized invoice for order. Payment will be made in arrears after receipt of each completed



## ONE-STEP URINE/SERUM COMBO PREGNANCY DIPCARD TEST

[CLIA-WAIVED FOR URINE TEST ONLY] SMC PROD# PREG-NAVA-CB-25 & PREG-NAVA-CB-50

#### INTENDED USE

One-Step Urine/Serum Combo Pregnancy Card Test is a colloidal gold antibody complex based immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in serum or urine. This test is for professional use in obtaining a visual qualitative result for the early detection of pregnancy.

## INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. From the onset of pregnancy hCG concentrations in a woman's serum and urine increase rapidly making the hormone a good marker for pregnancy testing. Seven to ten days after conception the hCG concentration reaches 20 mIU/ml and then increases steadily to reach its maximum between the eighth and eleventh week of pregnancy<sup>1,2,3</sup>.

One-Step Urine/Serum Combo Pregnancy Test is a qualitative, sandwich dye conjugate immunoassay for the determination of human hCG in urine.4.5 The method employs a combination of monoclonal and polyclonal antibodies to selectively identify hCG in test samples with a high degree of sensitivity. In less than 5 minutes, elevated levels of hCG equal to or greater than 20 mIU/mL can be detected.

## **PRINCIPLE**

As the test sample, urine or serum, diffuses through the absorbent reaction pack, the labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the test region (T) and produces a pink-rose color band when hCG concentration is equal to or greater than 20 mIU/mL. In the absence of hCG, there is no line in the test The reaction mixture continues flowing through the absorbent device past the test region and control region (C). Unbound conjugate binds to the reagents in the control region, producing a pink-rose color band, demonstrating that the reagents and reaction pack are functioning correctly.

### MATERIALS AND REAGENTS PROVIDED

- 1. One-Step Urine/Serum Combo Pregnancy Reaction Pack: Test pack containing goat polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG (antibody) dye conjugate in protein matrix with 0.1% sodium azide. Test pack is sealed in a foil pouch containing a desiccant and sample dropper.
- Product package insert.

## MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection containers and a clock or timer.

#### STORAGE AND STABILITY

One-Step reaction pack can be stored at room temperature (18 -30°C) or refrigerated (2 - 8°C). Avoid freezing.

#### WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- WARNING: The reagents in this kit contain sodium azide that may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build up. Urine specimens should be considered hazardous and handled appropriately.

#### SPECIMEN COLLECTION

Urine (0.5ml):

The urine specimen must be collected in a clean dry container either plastic or glass, without preservative. No centrifugation or filtration of urine is required. Specimens collected at any time may be used, however the first morning urine generally contains the highest concentration of hormone.

Serum (0.5ml):

Collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to form a clot for 20 to 30 minutes at room temperature. Centrifuge to obtain clear serum and transfer the serum into a clean plastic or glass tube. The sample serum can be tested without prior treatment.

Specimens may be refrigerated (2 - 8°C) and stored up to 72 hours prior to assay. If samples are refrigerated, they must be equilibrated to room temperature (18 - 30°C) for 10 minutes before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle and clear aliquots obtained for testing.

## **PROCEDURE**

- Equilibrate all materials and reagents to room temperature before testing.
- Remove the "reaction pack" from its foil wrapper by tearing along the "splice".
- Fill the urine dropper with urine or serum and hold the dropper vertically and add three (3) to four (4) full drops approximately 160 μl, without bubbles, into the sample (S) well.
- Wait for the pink lines to appear. Positive results may be read as early as three (3) minutes. It is important that the background is clear before the results are read.

Note: Although rare, early stages of pregnancy may show positive results nearer to 10 minutes due to very low concentrations of hCG.

Do not interpret results after 10 minutes!

## INTERPRETATION OF RESULTS

Positive:

At 3 to 5 minutes, two pink colored bands appear, one in the control region (C) and one in the test region (T), indicates a positive result and that the specimen contains hCG level of 20 mIU/mL or greater.

Negative: At 3 to 5 minutes, only one pink colored band appears in the control region (C), the result is negative and that the specimen may contain hCG level of less than 20mIU/mL.

Invalid:

At 3 to 5 minutes, if no bands appear, or a test band appears without a control band, the result is invalid and the test should be repeated using a new device.



PERSON

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2019 Washington Street East
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25301 304-558-3417

TERMS OF SALE DATE PRINTED SHIP VIA FOB. FREIGHT TERMS 08/05/2010 01:30PM 09/02/2010 BID OPENING TIME LINE QUANTITY UOP AMOUNT ITEM NUMBER UNIT PRICE PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID: 800-521-1435 JAMES RO KOPCIE FAX # CONTACT PERSON: INQUIRIES VRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF 8/17/2010. QUESTIONS MAY BUSINESS ON BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER to assure no vendor receives an unfair advantage, no \$UBSTANTIVE 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 CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSIUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE GENCY AS A CONDITION OF AWARD. SEE REVERSE SIDE FOR TERMS AND CONDITIONS SIGNATURE TELEPHONE DATE

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

## STATE OF WEST VIRGINIA

# **PURCHASE CONTINUATION SHEET**

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Item No.	Quantity	Description		Unit Price	Amount				
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		TEST KIT MUST BE A ONE STEP ASSAY PROCEDURE; TEST KIT I 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.							
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File: RW22	Acct. No.: MUL MUL	
Spending Unit:	-/OMCFH/F	PP

P.O. Date: Vendor. **Unit Price Amount** Description Quantity Item No. Q. IN THE DESCRIPTION OF MCH11058 THEY USE THE BRAND NAME OF INFALAB, WHICH IS NOT EITHER OF THE TWO VENDORS THAT GOT THE BID BACK IN 2008. A. INFALAB IS INFOLAB. THE PO MCH80446B IS ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 50 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-50 AND THE ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 25 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-25 Q. I DON'T HAVE THE PRICE THEY USED TO GET THE BID. WOULD YOU PLEASE PROVIDE THE LAST BID PRICE? . A. PO FOR MCH80446A THE ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 25-TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-25 \$10.00 PER KIT. THE PO MCH80446B IS ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 50 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-60 \$19.50 PER KIT. 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 INTERNATIONAL INC FOR THE ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 25 TEST/KIT FORMAT: CASSETTE INFOLAB-CATALOG # IT FHC-202-25. THE CURRENT VENDOR FOR THE PO MCH80446B IS STANBIO LABORATORY ONE STEP HCG URINE/SERUM PREGNANCY TEST KIT OR EQUAL 50 TEST/KIT FORMAT: CASSETTE INFOLAB CATALOG # IT FHC-202-50:> Q. HOW MANY LOCATIONS WILL PRODUCT BE SHIPPED TO? PRODUCTS WILL BE SHIPPED TO ONE LOCATION DHIR MATERIALS MANAGEMENT. 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 DEAGE/NEED BY Q. HOW MANY SAMPLES ARE TO BE SENT-IN WITH THE QUOTATION? 2 samples of each. It is preferred with bid but not required.

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.

## Taken, subscribed, and sworn to before me this 25 My Commission expires **NOTARY PUBLIC** AFFIX SEAL HERE COMMONWEALTH OF PENNISYLVANIA COMMONWEALTH OF PENNSYLVANIA No area son Notarial Seal Selma Arongon, Nosaw Publik Selma Aronson, Notary Putilic City Dr. - Teb age. Alien HILV City Of Pittsburgh, Allegheny Countyly Commission Ev 2010 My Commission Expires Dec. 16, 2010 Pennsylvania Association of Notarles Member, Pennsylvania Association of Notaries Purchasing Affidavit (Revised 12/15/09)