Attachment #2 p.2

sebia
electrophoresis

State of West Virginia, Department of Administration, Purchasing Division

Proposal# JOL2232012

Reagent Rental Reagent And Consumable Detail

Part Number	Description	Tests/Kit	Test/Wk	Kits/Year	Price/Kit	Annual Investment	Cost/Test
Neo Natal Hemoglobin							
2006	Capillarys Neonatal Hemoglobin	835	577	39	$2,282.28	$89,009.07	$2.73
Controls & Consumables		*Packaging*					
2052	Capillarys Wash Solution	2 x 75 ml		1	$172.00	$172.00	
2058	Capillarys Capiclean	25 ml		2	$272.00	$544.00	
4777	Hgb AF Control	1 x 1 ml		33	$350.00	$11,550.00	
4792	Agarose/Capillarys Hgb AFSC Control	1 x 1ml		0	$224.00	$0.00	
9201	Microtubes	110 x 1 ml		36	$40.00	$1,458.18	
							Cost/Reportable
					Annual Reagent Total	$102,733.26	$3.42444

Proposal#: JOL2232012

State of West Virginia, Department of Administration, Purchasing Division	**Sebia, Inc.**
User's Name	Vendor Name
User's Signature	Debra Shaw **Contracts Coordinator**
Printed Name & Title	Title
Date	Date

Capillarys/ MiniCap tests per kit can vary depending upon use (days run per week, repeats and controls).

All proposals are subject to approval by Sebia, Inc. Contract Administration.
Instrumentation pricing available while supplys last.

Sebia, Inc. 400-1705 Corporate Drive, Norcross, GA 30093
Contract Fax (678) 807-2900 Reagent Order Fax (678) 405-3705 Toll Free 1-800-835-6497
www.sebia-usa.com

Attachment #3

College of American Pathology (CAP) Regulations
RE: HEMOGLOBINOPATHY TESTING

To confirm or not to confirm?

No single laboratory test has adequate sensitivity or specificity for detection of all hemoglobinopathy syndromes; therefore a group of tests or hemoglobinopathy investigations is required[1].

CAP CHM.33732[2]: Are all samples with hemoglobin variants migrating in "non-A, non-S" positions on alkaline electrophoresis, isoelectric focusing, or HPLC further defined with electrophoresis at acid pH or other acceptable methods where clinically and technically appropriate?

Electrophoresis at acid pH is useful to further characterize hemoglobin variants migrating in the Hb A2 position, if all variants are not clearly separated by the primary method. This method will differentiate the three major hemoglobins that migrate in this position, namely Hb C, Hb E, and Hb O-Arab, as well as give information on rare variants such as Hb C-Harlem. However, for hemoglobin variants that migrate in other "non-A, non-S" positions, such as fast hemoglobin variants, electrophoresis at acid pH is generally not informative. Further workup of such variants, including referral to a reference laboratory, is dependent upon the patient's overall clinical situation, such as findings of erythrocytosis or a hemolytic anemia.

CAP CHM.33748[2]: Are all samples that appear to have Hb S in the primary screening (by whatever method) further examined to confirm the presence of Hb S by solubility testing or other acceptable methods?

All samples with hemoglobins migrating in the "S" positions or peak must be tested for solubility or by other acceptable confirmatory testing for sickling hemoglobin(s). Known sickling and non-sickling controls both must be included with each run of patient specimens tested. Solubility testing alone is not sufficient for detecting or confirming the presence of sickling hemoglobins.

CAP CHM.33764[2]: Are all samples that appear to have Hb S as the predominant band by the primary screening (by whatever method) and that are confirmed as sickling by appropriate methods further examined to ascertain whether the "Hb S" band or peak contains solely Hb S or both Hb S and Hb D, Hb G or other variant hemoglobins?

When the predominant hemoglobin component appears to be Hb S, it is necessary to determine whether this represents homozygous Hb S or a heterozygous for Hb S and another variant such as Hb D, Hb G, Hb Lepore, or other hemoglobin variant(s). Given the clinical implications of homozygous Hb S (or Hb S/β-zero thalassemia) it is imperative to exclude other hemoglobin variants, however rare. Referral of these specimens to a reference laboratory for further workup is acceptable.

---

[1] Lafferty J, Wayne J, Chui D, Crawford L, Raby A, Richardson H. Good practice guidelines for laboratory investigation of hemoglobinopathies. *Laboratory Hematology.* 2003;9:237-245.

[2] College of American Pathologists: http://www.cap.org/apps/docs/laboratory_accreditation/checklists/chemistry_and_toxicology_april2006.doc

sebia electrophoresis

Attachment #4

sebia

PN 2006 Capillarys Neonatal Hemoglobin Kit - Package Insert Intended Use –

INTENDED USE

The CAPILLARYS NEONAT Hb kit is designed for the separation of the normal hemoglobins (F and A) in blood samples from human new-borns, and for the detection of the major hemoglobin variants (S, C, E, D and Bart's), by electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 System. The CAPILLARYS NEONAT Hb kit is designed for laboratory use.
The CAPILLARYS 2 is an automated analyzer which performs a complete hemoglobin profile for the qualitative analysis of hemoglobins. The assay is performed on the hemolysate of whole blood samples previously collected on filter paper.

For *In Vitro* Diagnostic Use.

Attachment #6

SEBIA-1 OP ID: AN

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 02/09/12

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Mickey Wilson & Assoc., Inc. P.O. Box 88588 Atlanta, GA 30356-8588 Michael H. Wilson 770-452-7118	CONTACT NAME: Annette Thompson PHONE (A/C, No, Ext): 770-452-7118 FAX (A/C, No): 770-454-7487 E-MAIL ADDRESS: annette@mwainsurance.com
INSURED SEBIA, INC. 400-1705 CORPORATE DRIVE NORCROSS, GA 30093	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Chubb Group of Insurance Cos. INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	GENERAL LIABILITY X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC			35852555	10/29/11	10/29/12	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Emp Ben.	$ $ $ $ $ $ $	10,000,000 1,000,000 10,000 1,000,000 2,000,000 10,000,000 1,000,000
A	AUTOMOBILE LIABILITY ANY AUTO ALL OWNED AUTOS SCHEDULED AUTOS X HIRED AUTOS X NON-OWNED AUTOS			73544473	10/29/11	10/29/12	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $ $	1,000,000
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 0			79839135	10/29/11	10/29/12	EACH OCCURRENCE AGGREGATE	$ $ $	5,000,000 5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		(13)-7172-57-04	02/10/12	02/10/13	X WC STATU-TORY LIMITS X OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, if more space is required)
O.C.G.A. INSURANCE LAWS AND CODES SHALL PREVAIL UNDER ANY CIRCUMSTANCES.

CERTIFICATE HOLDER

PROOF

PROOF OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Michael H. Wilson

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
LBS12065	1

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

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SEBIA
400-1705 CORPORATE DRIVE
NORCROSSS, GA 30093

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - LABORATORY SERVICES

167-ELEVENTH AVENUE
SOUTH CHARLESTON, WV
25303 304-558-3530

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
02/13/2012				

BID OPENING DATE: 02/23/2012 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO	ITEM NUMBER	UNIT PRICE	AMOUNT

ADDENDUM NO. 1

1. QUESTIONS AND ANSWERS ARE ATTACHED.
2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.

EXHIBIT 10

REQUISITION NO.: LBS12065

ADDENDUM ACKNOWLEDGEMENT

I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATIONS, ETC.

ADDENDUM NO.'S:

NO. 1.....

NO. 2.....

NO. 3.....

NO. 4.....

NO. 5.....

I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

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

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).

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

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02/13/2012				

BID OPENING DATE: 02/23/2012 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT

THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.

VENDOR MUST CLEARLY UNDERSTAND THAT ANY VERBAL REPRESENTATION MADE OR ASSUMED TO BE MADE DURING ANY ORAL DISCUSSION HELD BETWEEN VENDOR'S REPRESENTATIVES AND ANY STATE PERSONNEL IS NOT BINDING. ONLY THE INFORMATION ISSUED IN WRITING AND ADDED TO THE SPECIFICATIONS BY AN OFFICIAL ADDENDUM IS BINDING.

Linda Rehnberg
SIGNATURE

SEBIA, INC.
COMPANY

2-22-12
DATE

NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.

REV. 09/21/2009

END OF ADDENDUM NO. 1

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE

TITLE	FEIN	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 ____ of ____ Pages

Requisition / P.O. No.: LBS12065

File:

Acct. No.: 5163-2012-2961-099-371

Spending Unit: DHHR/OLS

Vendor: _____ P.O. Date: _____

Item No.	Quantity	Description	Unit Price	Amount
		VENDOR QUESTION #1: Given the stated specifications, Contractor would like clarification on West Virginia Department of Administration Purchasing Departments verification of Contractors' claims of FDA clearance of reagents and test protocol for use in neonatal screening. Are claims of FDA clearance verified through review of the intended use and data included in the FDA 510(k) Decision Summary, or solely through supply an FDA clearance letter, which may not include the intended use population. RESPONSE: It is a class II device, verified with 510(k) Premarket Notification. Please see attachment.		

000004

Eckerd, Barbara M

From: Eckerd, Barbara M
Sent: Friday, February 13, 2009 1:45 PM
To: Eckerd, Barbara
Subject: Fwd: RE: Primus GeneSys FDA Clearance
Attachments: TEXT.htm

«TEXT.htm»

>» "Dan Huie" <dhuie(3primusdiagnostics. com> 11/20/2008 2:59:22 PM >»

Hi Krista!
Please pass this on to the Agency for further clarification of the Primus GeneSys' FDA "approval."
Our Primus QA Manager also contacted the FDA regarding the question you had asked. Mr. Young Pak of the FDA responded with the following information.
Question from Britt Einspahr, Primus QA Manager:
Do you have a guidance document that you could point me to that discusses 510(k) clearance versus FDA approval - that the FDA does not specifically "approve" of devices? (IVD in this case)

Answer from Mr. Young Pak, FDA:
Dear Britt,

FDA approval refers to class III devices; 510(k)clearance (also refers as market clearance) refers to class I, II devices. You also see 510(k) as "substantial equivalence" determination by FDA - what this means is that the 510(k) applicant has demonstrated that their new device is substantially equivalent to other legally marketed device.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfmPfr =814.2&SearchTerm=pma - regulation re: PMA arroba

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr =807.81 - regulation re: Premarket notification (510(k))

Best Regards, Mr. Young Pak Center for Devices and Radiological Health U.S. Food and Drug.Administration

Hope that helps! Once again Primus has received 510(k) clearance from the FDA and thus has the highest level of approval from the FDA for IVD medical instruments. Dan Huie

From: Dan Huie
Sent: Wednesday, November 19, 2008 1:54 PM
To: 'krista.s.ferrell@wv.gov'
Cc: Stacey Blichar; 'Doe Randolph'
Subject: Primus GeneSys FDA Clearance

Hi Krista!

This is Dan Huie from Trinity Biotech. I am West Virginia's representative for the Primus GeneSys product. It was good speaking with you on the phone today. I am happy to provide you the information needed to show that the GeneSys is indeed FDA "approved". Please see the attached Introduction letter that explains the rest of the attached documents.

If you have any questions, please call me at 215.498.8933 or email me. I want to make sure we have answered all your questions by the end of the day.

I look forward to hearing from you soon!

Best Regards, Dan
Huie

Dan Huie | Technical Sales Representative | Primus Diagnostics |
www.primusdiagnostics.com <http://www.primusdiagnostics.com/>
Direct: 1.215.498.8933 I Main: 1.800.377.4752 I Fax: 1.816.361.1974

New Search Back To Search Results

510(k) Premarket Notification Database

Device Classification Name	Abnormal Hemoglobin Quantitation
510(k) Number	K955283
Device Name	PRIMUS VARIANT SYSTEM PVS99
Applicant	PRIMUS CORP. P.O. Box 22599 Kansas City, MO 64113
Contact	Jim Noffsinger
Regulation Number	864.7415
Classification Product Code	GKA
Date Received	11/16/1995
Decision Date	03/01/1996
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Hematology
Review Advisory Committee	Hematology
Statement/Summary/Purged Status	Statement/purged 510(k)
Type	Traditional
Reviewed By Third Party	No
Expedited Review	

Database Updated 02/06/2009

sebia®
electrophoresis

Linda Rehnberg, MT (ASCP)
Sales Administration Manager

400-1705 Corporate Drive
Norcross, GA 30093

tel 770.446.3707 x3707
fax ~~770.410.9541~~
contract fax 678.807.2900
toll free 800 835 6497 x3707
linda.rehnberg@sebia-usa.com