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
Bio-Rad Laboratories, Inc.
6565 185th AVENUE NE
REDMOND WA, 98052

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	Net 30 ARO	Best Way	Destination	Prepaid

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..... Date 2/13/2012

NO. 2.....

NO. 3.....

NO. 4.....

NO. 5.....

I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF

RECEIVED
2012 FEB 23 A 9:37
PURCHASING DIVISION
STATE OF WV

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
[signature]	800-666-8111 x 1761	2/22/2012

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
Contract Admin Supervisor	94-1381833	

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.html** 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
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2019 Washington Street East
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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.

Janette J. Stockert
SIGNATURE

Janette J. Stockert
Bio-Rad Laboratories, Inc.
COMPANY

2/22/2012
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
Janette J. Stockert	800-666-8111 x 1761	2/22/2012
TITLE: Contract Admin Supervisor	FEIN: 94-1381833	ADDRESS CHANGES TO BE NOTED ABOVE

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

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

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

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304-558-0067

VENDOR
*709065635 01 800-666-8111
BIO RAD LABORATORIES INC
6565 185TH AVENUE NE

REDMOND WA 98052

SHIP TO
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BPH - LABORATORY SERVICES

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LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
				OPEN-END BLANKET CONTRACT		
0001	30,000	EA		193-12 Bio-Rad P/N 2503000 VARIANTnbs Sickle Cell Program Reorder Pack REPORTABLE SPECIMENS TRINITY BIOTECH PART#30-01-0051	Price per Test $1.50 Price per Kit $1,500.00	Total Price for 30 Kits: $45,000.00
0002	500	EA		193-12 Bio-Rad P/N 2503000 VARIANTnbs Sickle Cell Program Reorder Pack REPORTABLE SPECIMENS TRINITY BIOTECH PART#30-01-0051	Price per Test $1.50 Price per Kit $1,500.00	Price for 500 tests: $750.00 Price per Kit $1,500.00

OPEN END CONTRACT

THE SUCESSFUL VENDOR AGREES TO ENTER WITH THE AGENCY, THE WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN SERVICES, INTO AND OPEN END CONTRACT TO PROVIDE NEWBORN SCREENING SECTION OF THE OFFICE OF LABORATORY SERVICES (OLS), 167 11TH. AVENUE, SOUTH CHARLESTON, WV 25303, FOR REAGENTS TO PERFORM HEMOGLOBINAPATHY SCREENING FOR DETECTION OF HEMOGLOBINS (HBS) A, F, S, C, E, D, O AND BART'S FROM NEONATAL DRIED BLOOD SPOT SPECIMENS. THIS COST PER REPORTABLE SPECIMEN SERVICE IS TO BE TRINITY BIOTECH

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
Janette Bracken	800-666-8111 x 1761	2/22/2012

TITLE	FEIN	
Contract Admin Supervisor	94-1381833	ADDRESS CHANGES TO BE NOTED ABOVE

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*709065635 01 800-666-8111
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REDMOND WA 98052

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PART #03-01-0051 OR EQUAL BASED ON THE ATTACHED SPECIFICATIONS AND REQUIREMENTS.

VENDOR MUST PROVIDE AN AUTOMATED PROCESSING SYSTEM AT NO ADDITIONAL CHARGE FOR USE WITH THE REQUESTED REAGENTS. THIS SYSTEM INCLUDES A COMPUTER, MONITOR, PRINTER, ETC., WHICH WILL BE RETAINED AND MAINTAINED BY THE VENDOR BUT MUST HAVE CAPABILITY OF INTERFACING WITH THE LIMS (LABORATORY INFORMATION MANAGEMENT SYSTEM).

EXHIBIT 3

LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON AWARD 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 BY THE STATE OF WEST VIRGINIA, ITS AGENCIES, OR POLITICAL SUBDIVISIONS, THE TERMS, CONDITIONS AND PRICING SET FORTH 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
[signature]	800-666-8111 x 1761	2/22/2012
TITLE: Contract Admin Supervisor	FEIN: 94-1381833	ADDRESS CHANGES TO BE NOTED ABOVE

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Department of Administration
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RFQ NUMBER	PAGE
LBS12065	4

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

VENDOR
*709065635 01 800-666-8111
BIO RAD LABORATORIES INC
6565 185TH AVENUE NE

REDMOND WA 98052

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THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT 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
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 REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER.

REV. 3/88

INQUIRIES:
WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 2/7/2012. 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 ST., EAST

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
[signature]	800-666-8111 x 1761	2/22/2012

TITLE	FEIN	
Contract Admin Supervisor	94-1381833	ADDRESS CHANGES TO BE NOTED ABOVE

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HTTP://WWW.STATE.WV.US/ADMIN/PURCHASE/VRC/VENPREF.PDF

NOTICE

A 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.

THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:

SEALED BID

BUYER:----------RW/FILE 22----------

RFQ. NO.:----------LBS12065----------

BID OPENING DATE:--------2/23/2012----------

BID OPENING TIME:------1:30 PM----------

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

425-498-1757

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
Roberta Rockell	800-666-8111 x 1761	2/22/2012

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
Contract Admin Supervisor	94-1381833	

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Volume

The estimated volume is 30,000 specimens per year for the initial screening of hemoglobinopathies. Of this amount, approximately 500 specimens will need the confirmatory assay performed for hemoglobinopathies that resulted as abnormal in the initial screening. Quantities listed are approximations only, based on estimates supplied by the 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 it be it more or less.

Cost per reportable specimen must be Trinity Biotech Part # 03-01-0051, or equal. The cost per specimen for the reagent rental of the system must include reagents, calibrators, columns, consumables, installation, training and regularly scheduled maintenance. Vendors bidding other testing methods that provide the same end result, must clearly state their testing methods.

Selected vendor must provide an automated processing system at no additional charge for use with the requested reagents. This system includes a computer, monitor, printer, software program and manuals which will be retained and maintained by the vendor. It must have capability of interfacing with the Laboratory Information Management System (LIMS).

Reagent Specifications & Requirements

1. The reagents and test protocol must be FDA cleared for use in neonatal screening.

2. The reagents must have a shelf life of 90 days or more beyond date of receipt.

3. Reagents and columns must NOT be lot specific.

4. The column must allow for 500 injections.

* 5. The column and reagents must be the same for the screen and confirmatory high resolution assay.

B22-12 *Bio-Rad does not perform both screen and confirmatory on same reagents

6. The column must be composed of PolyCAT A weak cation exchange material, or equal.

- Must have Fast Ethernet 100 BT or greater connectivity

- Must be capable of interfacing with WVDHHR network domain to allow automatic data transfer to a designated folder to merge data into the Neometrics laboratory information management system (LIMS)

- Must have Windows XP

11. Vendor must allow all WVDHHR network security and management configurations required by established policy to maintain network security and restriction access as necessary.

12. Must have electronic chromatogram storage and retrieval.

14 Must provide a printed data record.

Installation and Training Requirements

1. Delivery and installation of equipment must be within 90 days of the approved purchase order.

2. Vendor must provide a company representative for installation and training. Subcontracting of these services shall not be acceptable.

   a. Vendor must show proof of Worker's compensation and general liability insurance. The minimum amount of insurance coverage required is $1,000,000.00.

3. Training of OLS personnel either off site or on site must be provided within four weeks after installation of the equipment at the expense of the vendor.

Maintenance Specifications

1. Vendor will be responsible for all shipping charges incurred by shipping of the equipment to and from the laboratory.

RFQ Cost Sheet

Bidders shall provide a cost for the following:

Cost per Reportable Specimen: Trinity Biotech Part #30-01-0051, or equal:

Bio-Rad Laboratories Cat. 250300

$ 1.50 each quick screen — $ 45,000.00 Total

Cost per specimen (approximately 30,000 reportable specimens per year)

This is the initial screening test of all specimens received in the Newborn Screening Section analyzed for hemoglobinopathies. — $750- for 500 tests

Bio-Rad Laboratories Cat. 250300

$ 1.50 each reflex high resolution — $ $1,500.00 kit of 1000 tests Total

Cost per specimen (approximately 500 reportable specimens per year)

This is the confirmatory assay of specimens analyzed for hemoglobinopathies that resulted as abnormal in the initial screening.

GRAND TOTAL: $ 46,500.00

2/22/12 * See Price Exhibit

The award will be made to vendor with the lowest overall grand total cost of all tests which meets all the requested specifications and requirements.

Janette J. Stockert — 2/22/2012

Vendor Signature — Date

Janette J. Stockert
Government Contract Admin Supervisor/Paralegal

WV-96
Rev. 10/07

AGREEMENT ADDENDUM

In the event of conflict between this addendum and the agreement, this addendum shall control:

1. **DISPUTES** - Any references in the agreement to arbitration or to the jurisdiction of any court are hereby deleted. Disputes arising out of the agreement shall be presented to the West Virginia Court of Claims.

2. **HOLD HARMLESS** - Any clause requiring the Agency to indemnify or hold harmless any party is hereby deleted in its entirety.

3. **GOVERNING LAW** - The agreement shall be governed by the laws of the State of West Virginia. This provision replaces any references to any other State's governing law.

4. **TAXES** - Provisions in the agreement requiring the Agency to pay taxes are deleted. As a State entity, the Agency is exempt from Federal, State, and local taxes and will not pay taxes for any Vendor including individuals, nor will the Agency file any tax returns or reports on behalf of Vendor or any other party.

5. **PAYMENT** - Any references to prepayment are deleted. Payment will be in arrears.

6. **INTEREST** - Should the agreement include a provision for interest on late payments, the Agency agrees to pay the maximum legal rate under West Virginia law. All other references to interest or late charges are deleted.

7. **RECOUPMENT** - Any language in the agreement waiving the Agency's right to set-off, counterclaim, recoupment, or other defense is hereby deleted.

8. **FISCAL YEAR FUNDING** - Service performed under the agreement may be continued in succeeding fiscal years for the term of the agreement, contingent upon funds being appropriated by the Legislature or otherwise being available for this service. In the event funds are not appropriated or otherwise available for this service, the agreement shall terminate without penalty on June 30. After that date, the agreement becomes of no effect and is null and void. However, the Agency agrees to use its best efforts to have the amounts contemplated under the agreement included in its budget. Non-appropriation or non-funding shall not be considered an event of default.

9. **STATUTE OF LIMITATION** - Any clauses limiting the time in which the Agency may bring suit against the Vendor, lessor, individual, or any other party are deleted.

10. **SIMILAR SERVICES** - Any provisions limiting the Agency's right to obtain similar services or equipment in the event of default or non-funding during the term of the agreement are hereby deleted.

11. **ATTORNEY FEES** - The Agency recognizes an obligation to pay attorney's fees or costs only when assessed by a court of competent jurisdiction. Any other provision is invalid and considered null and void.

12. **ASSIGNMENT** - Notwithstanding any clause to the contrary, the Agency reserves the right to assign the agreement to another State of West Virginia agency, board or commission upon thirty (30) days written notice to the Vendor and Vendor shall obtain the written consent of Agency prior to assigning the agreement.

13. **LIMITATION OF LIABILITY** - The Agency, as a State entity, cannot agree to assume the potential liability of a Vendor. Accordingly, any provision limiting the Vendor's liability for direct damages to a certain dollar amount or to the amount of the agreement is hereby deleted. Limitations on special, incidental or consequential damages are acceptable. In addition, any limitation is null and void to the extent that it precludes any action for injury to persons or for damages to personal property.

14. **RIGHT TO TERMINATE** - Agency shall have the right to terminate the agreement upon thirty (30) days written notice to Vendor. Agency agrees to pay Vendor for services rendered or goods received prior to the effective date of termination.

15. **TERMINATION CHARGES** - Any provision requiring the Agency to pay a fixed amount or liquidated damages upon termination of the agreement is hereby deleted. The Agency may only agree to reimburse a Vendor for actual costs incurred or losses sustained during the current fiscal year due to wrongful termination by the Agency prior to the end of any current agreement term.

16. **RENEWAL** - Any reference to automatic renewal is hereby deleted. The agreement may be renewed only upon mutual written agreement of the parties.

17. **INSURANCE** - Any provision requiring the Agency to insure equipment or property of any kind and name the Vendor as beneficiary or as an additional insured is hereby deleted.

18. **RIGHT TO NOTICE** - Any provision for repossession of equipment without notice is hereby deleted. However, the Agency does recognize a right of repossession with notice.

19. **ACCELERATION** - Any reference to acceleration of payments in the event of default or non-funding is hereby deleted.

20. **CONFIDENTIALITY:** -Any provision regarding confidentiality of the terms and conditions of the agreement is hereby deleted. State contracts are public records under the West Virginia Freedom of Information Act.

21. **AMENDMENTS** - All amendments, modifications, alterations or changes to the agreement shall be in writing and signed by both parties. No amendment, modification, alteration or change may be made to this addendum without the express written approval of the Purchasing Division and the Attorney General.

ACCEPTED BY:

STATE OF WEST VIRGINIA	**VENDOR**
Spending Unit: _____	Company Name: Bio-Rad Laboratories, Inc.
Signed: _____	Signed: [signature]
Title: _____	Title: Janette J. Stockert Government Contract Admin Supervisor/ParaLEGAL
Date: _____	Date: 2/22/2012

RFQ No. LBS12065

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: Bio-Rad Laboratories, Inc.

Authorized Signature: [signature] Date: 2/22/2012

State of Washington

County of King, to-wit:

Taken, subscribed, and sworn to before me this 22 day of February, 2012.

My Commission expires March 08, 2013.

AFFIX SEAL HERE

Notary Public
State of Washington
BRIAN J FREY
MY COMMISSION EXPIRES
March 08, 2013

NOTARY PUBLIC [signature]

BIO-RAD

Bio-Rad Laboratories, Inc.

Clinical Diagnostics Group
6565 185th Avenue NE
Redmond, Washington 98052
Phone: 425-881-8300
Fax: 425-498-1650

February 22, 2012

Roberta Wagner
Department of Administration
Purchasing Division
2019 Washington Street, East
Charleston, WV 25311

Dear Ms. Wagner:

GENERAL TERMS AND CONDITIONS

Please revise clause #13 to read as follows: HIPPA BUSINESS ASSOCIATE ADDENDUM: The West Virginia State Government HIPPA Business 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.

Per the Confidentiality clause #14, please change to read: "For the purpose of this Agreement, confidential information ("Confidential Information") shall be labeled "Confidential" and shall mean all proprietary, secret or confidential information or data relating to State of West Virginia or Bio-Rad Laboratories and their respective operations, employees, services or customers. Each party agrees to: (i) maintain the confidentiality of the other's Confidential Information, (ii) not–disclose Confidential Information to third parties without the express written permission of the disclosing party, and (iii) use Confidential Information solely to advance the purpose of this Agreement. Confidential Information does not include: information that, a) was in the receiving party's possession before receipt from the disclosing party; b) is or becomes available to the public through no fault of the receiving party; c) is received in good faith by the receiving party from a third party and is not subject to an obligation of confidentiality owed to the third party; or d) is independently developed by the receiving party without reference to information received under this Agreement."

Agreed to and accepted this _22_ day of Februaury, 2012.

Bio-Rad Laboratories, Inc.	State of West Virginia
By: _____	By: _____
Name: Janette J. Stockert	Name: _____
Title: Contract Administration Supervisor	Title: _____

Bio-Rad Laboratories, Inc.

JJS:CH

Bio-Rad Laboratories, Inc.

Clinical Diagnostics Group
6565 185th Avenue NE
Redmond, Washington 98052
Phone: 425-881-8300
Fax: 425-498-1650

Price Exhibit

Date: 2/22/2012

CONFIDENTIAL

INSTRUMENTATION USE AGREEMENT

USER
Department of Administration
Purchasing Division
2019 Washington Street, East
Charleston, WV 25311
Attention: Roberta Wagner

SUPPLIER OF INSTRUMENTATION

Bio-Rad Laboratories, Inc
4000 Alfred Nobel Drive
Hercules, CA 94547
Attention: Janette J. Stockert

INSTRUMENTATION SUPPLIED

Cat. #	Description	Quantity
2503010	Variant NBS New Born Screening System	1

LOCATION OF INSTRUMENTATION
(IF OTHER THAN ABOVE ADDRESS OF CUSTOMER)

Department_____

No. & Street_____

City_____

State & Zip_____

TERMS AND CONDITIONS

Bio-Rad Laboratories grants to the User possession of the instrumentation listed above and on any attached schedule, together with any replacements, duplicate parts, repairs, additions, devices, and accessories incorporated therein and/or affixed thereto, hereinafter referred to as the Instrumentation, to be used by the user at the specific location recited above subject to the following terms and conditions.

1. The Instrumentation shall at all times remain the property of Bio-Rad and the User shall have no right or property interest therein but only the right to use the Instrumentation. Bio-Rad shall have the right to display notice of ownership by affixing to the Instrumentation an identifying plate, stencil or other indication of ownership.

2. There will be no charges for the use of the equipment, and this agreement does not require the State of West Virginia Health and Human Resources to purchase any supplies or services whatsoever from Bio-Rad for the use of this equipment.

3. For each VARIANT™nbs Newborn Screening System, Bio-Rad will provide one-time training, at no additional charge, for one technologist at Bio-Rad's Benicia, CA facility (includes airfare, lodging and meals, which shall be arranged by Bio-Rad according to its corporate travel policies).

4. The Customer shall not permit or allow any attachment, lien, security interest, or other encumbrance to be filed against the Instrumentation by any individual, company, corporation, or other form of business organization with the exception of Bio-Rad or its assigns.

5. The User shall take proper care of the Instrumentation and shall not make any alterations, additions, or improvements to the Instrumentation without the prior written consent of Bio-Rad. The User shall not permit anyone other than a Bio-Rad Representative to service or repair the Instrumentation without the prior written consent of Bio-Rad.

6. Service Coverage

   6.1 At no additional cost to Customer, Bio-Rad will provide telephone assistance 24 hours per day, 365 days per year.

   6.2 As part of this Agreement, Bio–Rad or Bio-Rad appointed personnel will provide on-site or depot (returned to Bio-Rad) service, as needed, to keep the Equipment in good working order. On-site or depot service will be provided, at no cost to customer, Monday through Friday, 8:00 a.m. to 5:00 p.m. (local time), excluding national holidays. On-site extended service coverage (Saturday, Sunday, and/or holidays) is available, but is not included in this Agreement. See Signature Service Agreement Rate Schedule currently effective for "Extended Reagent Rental Service Coverage" charges.

   6.3 Bio-Rad will not be required to pay the cost of any damage to the Equipment caused by Customer's negligence, abuse, or alteration of the Equipment, or by any service performed by unauthorized personnel.

   6.4 Customer agrees that only Bio-Rad appointed personnel are to service the Equipment.

   6.5 Customer agrees to utilize only Bio-Rad approved reagents, calibrators, and disposables on the Equipment.

   6.6 Bio-Rad shall not be responsible for the moving (de-installation and re-installation) of equipment from one lab to another, additional operator training, and/or any other extra services not specified in this Agreement. Bio-Rad will make a good faith effort to repair any equipment covered under this Service Agreement. Repairs required by any of these things or extra services provided by Bio-Rad (moving equipment, additional operator training, etc) will be performed at Customer's expense at the prevailing Time & Materials rates in effect at the time.

7. Either party upon giving 60 days written notice to the other party can terminate this agreement at any time. After such termination, Bio-Rad may enter upon the User's premises and without any court order or other process of law, repossess and remove the Instrumentation with or without notice to the User.

8. Transportation charges to (and where applicable from) the place of business of the customer for the Equipment shall be borne by Bio-Rad.

AGREED TO AND ACCEPTED BY:

State of West Virginia Health and Human Resources	Bio-Rad Laboratories, Inc.
_____	_____
Authorized Representative	Janette J. Stockert
_____	Government Contracts Administration Supervisor/Paralegal
Title	Title
_____	2/22/2012
Date	Date
_____	
Purchase Order No.	

Bio-Rad Laboratories, Inc.

Clinical Diagnostics Group
6565 185th Avenue NE
Redmond, Washington 98052
Phone: 425-881-8300
Fax: 425-498-1650

PRICE AGREEMENT – No. BT 7749

CONFIDENTIAL

Department of Administration
Purchasing Division
2019 Washington Street, East
Charleston, WV 25311
Attention: Roberta Wagner

Date: 2/22/2012

F.O.B.: Destination

Route: Best Way

Terms: Net 30 days from date of invoice

Any terms and conditions contained in Customer's purchase order form shall be null and void unless specifically agreed to in writing by Bio-Rad.

Your Reference: LBS12065

Our Reference: BT 7749

Shipment can be made 60 - 90 days for instrument and 3 - 5 days for reagents after receipt of order.

NOTE: Bio-Rad will only ship to end-user. Pricing quoted to United States and its possessions only

ANNUAL QUANTITY	DESCRIPTION	UNIT PRICE
31	**VNBS SCP Reorder Pack** Cat. # 2503000	**$1,500.00 / Kit**

Bio-Rad agrees to hold firm quoted prices for 36 months.

(Note: Please fax any correspondence to 1-425-498-1757
Or email to bid_coordination@bio-rad.com)

This quotation is good for thirty (30) days from date of issue.

Quotation submitted by:

Janette J. Stockert
Government Contracts Administration
Supervisor/Paralegal

JJS / CH

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 02/22/2012

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
Aon Risk Insurance Services West, Inc.
San Francisco CA Office
199 Fremont Street
Suite 1500
San Francisco CA 94105 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (415) 486-7000 **FAX (A/C. No.):** (415) 486-7029
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	The Travelers Indemnity Co.	25658
INSURER B:	Travelers Property Cas Co of America	25674
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Bio Rad Laboratories, Inc
1000 Alfred Nobel Drive
Hercules CA 94547 USA

COVERAGES **CERTIFICATE NUMBER:** 570045321194 **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. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	**GENERAL LIABILITY** X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC			HC2JGLSA117D7817	10/01/2011	10/01/2012	EACH OCCURRENCE	$1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
							GENERAL AGGREGATE	$2,000,000
							PRODUCTS - COMP/OP AGG	$2,000,000
B	**AUTOMOBILE LIABILITY** X ANY AUTO X ALL OWNED AUTOS X HIRED AUTOS SCHEDULED AUTOS X NON-OWNED AUTOS			HC2J-CAP-117D7805	10/01/2011	10/01/2012	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
B	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED RETENTION			HSMJCUP162D8682	10/01/2011	10/01/2012	EACH OCCURRENCE	$5,000,000
							AGGREGATE	$5,000,000
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			TC2JUB6A04782811 AOS	10/01/2011	10/01/2012	X WC STATU-TORY LIMITS OTH-ER	
A		N/A		TRKUB6A04783A11 AZ, MA,WI	10/01/2011	10/01/2012	E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, if more space is required)
RE: Account #57811-001

CERTIFICATE HOLDER

State of West Virginia
Health and Human Rescources
BPH Laboratory Service
167 Eleventh Avenue
Charleston WV 25303 USA

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

Aon Risk Insurance Services West Inc.

Holder Identifier :

Certificate No : 570045321194

BIO-RAD

L50031607

REF 250-3000

VARIANT™nbs Sickle Cell Program

Instruction Manual

VARIANT™nbs Sickle Cell Program Reorder Pack

1000

IVD

CE

***UNITED STATES**, Bio-Rad Laboratories, Inc., 4000 Alfred Nobel Drive, Hercules, CA 94547*

EC REP ***UK**, Bio-Rad Laboratories Europe, Ltd., 3 Riverview Business Park, Friarton, Perth PH2 8DF, Scotland*

In Vitro Diagnostic Directive (IVDD, 98/79/EC) Symbols

ANLT CRTR • Analytical Cartridge • Analytische Kartusche • Cartouche analytique • Cartucho de análisis • Cartuccia analitica • Coluna analítica • Αναλυτική μικροστήλη	**CD** • CD-ROM • CD-ROM • CD-ROM • CD-ROM • CD-ROM • CD-ROM • CD-ROM	**BUF 1** • Elution Buffer 1 • Elutionspuffer 1 • Tampon d'élution 1 • Tampón de elución 1 • Tampone di eluizione 1 • Tampão de eluição 1 • Ρυθμιστικό διάλυμα έκλουσης 1
BUF 2 • Elution Buffer 2 • Elutionspuffer 2 • Tampon d'élution 2 • Tampón de elución 2 • Tampone di eluizione 2 • Tampão de eluição 2 • Ρυθμιστικό διάλυμα έκλουσης 2	**RTN MRKR 1** • Retention Time Marker 1 • Retentionszeit-Marker 1 • Marqueur du temps de rétention 1 • Marcador de tiempo de retención 1 • Marker del tempo di ritenzione 1 • Marcador do tempo de retenção 1 • Δείκτης χρόνου κατακράτησης 1	**RTN MRKR 2** • Retention Time Marker 2 • Retentionszeit-Marker 2 • Marqueur du temps de rétention 2 • Marcador de tiempo de retención 2 • Marker del tempo di ritenzione 2 • Marcador do tempo de retenção 2 • Δείκτης χρόνου κατακράτησης 2
RTN MRKR SET • Retention Time Marker Set • Retentionszeit-Marker-Set • Jeu de marqueurs du temps de rétention • Conjunto de marcadores de tiempo de retención • Set di marker del tempo di ritenzione • Conjunto de marcadores de tempo de retenção • Σετ δεικτών χρόνου κατακράτησης	**WSH SOLN** • Wash Solution • Waschlösung • Solution de lavage • Solución de lavado • Soluzione di lavaggio • Solução de lavagem • Διάλυμα πλύσης	**WB PRM** • Whole Blood Primer • Vollblut-Primer • Sang total de conditionnement • Cebador de sangre total • Primer di sangue intero • Iniciador de sangue total • Εκκινητής ολικού αίματος

Table of Contents

KIT COMPONENTS

REF 250-3000, VARIANTnbs Sickle Cell Program Reorder Pack

The reorder pack contains supplies for 1000 tests :

REF	*Description*
250-3001	**Elution Buffer 1.** Two bottles containing 2500 mL of a sodium phosphate buffer, pH 6.5. Contains < 0.05% sodium azide as a preservative.
250-3002*	**Elution Buffer 2.** One bottle containing 2500 mL of a sodium phosphate buffer, pH 6.6. Contains < 0.05% sodium azide as a preservative.
250-3003*	**Analytical Cartridge.** Two cation-exchange analytical cartridges, 4.6 mm ID x 30 mm, capable of performing up to 500 tests each.
250-3004*	**Retention Time Marker Set.** One set consisting of five vials of Retention Time Marker 1 (FAES) and five vials of Retention Time Marker 2 (FADC). Contain lyophilized human red blood cell hemolysate with gentamicin, tobramycin, and EDTA as preservatives. Reconstituted volume is 5 mL per vial.
250-3008*	**Wash Solution.** One bottle containing 1800 mL of deionized water with < 0.05% sodium azide as a preservative.
250-3009*	**Whole Blood Primer.** Ten vials of lyophilized human red blood cell hemolysate with gentamicin, tobramycin, and EDTA as preservatives. Reconstituted volume is 0.5 mL per vial.
250-3020*	**Resin Update CD-ROM.** One CD-ROM with VARIANTnbs Sickle Cell program parameters.

** Components are not available for individual sale.*

ADDITIONAL REQUIRED ITEMS, AVAILABLE FROM BIO-RAD

REF	*Description*
250-3016	**GDM Workstation**
250-3010	**VARIANTnbs Newborn Screening System (1 VNAS + 1 VNCS)**

ADDITIONAL REQUIRED ITEMS, NOT AVAILABLE FROM BIO-RAD

Description

BD Falcon U-bottom microplate, REF 353910

DBS puncher or 1/8-inch diameter disc punch for filter paper

Validated Punchers:

- Wallac (BSD) Multi puncher, REF 1296-081

  or

- Wallac DBS puncher, REF 1296-071

Plate Shaker

Pipettes for delivering 250 µL, 0.5 mL, and 5 mL

Deionized Water

Disposable Gloves

8 1/2-inch x 11-inch Printer Paper

Disposable Towelettes

Transfer Pipettes

3. Add 250 µL deionized water to each well. Leave the microplate for elution on the bench at room temperature for 10 min.
4. Gently rotate the microplate on a plate shaker at 500 rpm for 5 min.

   NOTE: *500 rpm for 5 min is only a guideline. Due to variation in plate shakers (i.e., speed range and orbit), each lab should establish its own procedure to ensure optimal sample elution and mixing.*
5. Visually inspect each microplate to ensure all wells are thoroughly mixed; if necessary, rotate for a longer time or at a higher speed.
6. The samples are now ready for analysis.

   NOTE: *No need to remove disc.*

Specimen Shipping

All samples of human origin must be shipped in accordance with national and international transportation regulations.

PREPARATION AND STORAGE OF REAGENTS

When changing to a different lot of reagents and/or cartridge, the parameters from the matching Resin Update CD-ROM must be installed to ensure optimum performance of the program.

Elution Buffers and Wash Solution

1. The Elution Buffers and Wash Solution will be stable until the expiration date when stored unopened at 15–30 °C. After opening the bottles, these reagents are stable for 30 days when stored at 15–30 °C.
2. To install Elution Buffers and Wash Solution, follow the procedure described in the *VARIANTnbs Operation Manual, Section 4.2.2.* Initiate a system flush as described in the *VARIANTnbs Operation Manual, Section 3.10, step 3.*
3. With a new reorder pack, install one bottle of each reagent and follow the procedure for *Installing a New Reorder Pack Lot* in the *Procedure* section. After 500 injections, install a fresh bottle of Elution Buffer 1.

Whole Blood Primer

Inject Whole Blood Primer once before the first run of each day to condition the cartridge for analysis. When installing a new cartridge, inject Whole Blood Primer twice before the first run.

1. The Whole Blood Primer will be stable until the expiration date when stored unopened at 2–8 °C.
2. Prepare the Whole Blood Primer by adding 0.5 mL of deionized water to the vial.
3. Allow to stand for 10 minutes at 15–30 °C.
4. Swirl gently to dissolve and ensure complete mixing.
5. Write the reconstitution date on the label. The reconstituted Whole Blood Primer is stable for 21 days when stored at 2–8 °C.

The primer can either be included in the plate template or run manually via the Inject Primer procedure (as described in the *GDM 3.1 Software Operation Manual, Section 5.3*). If the primer is included in the plate template, it should be followed by at least 3 Blank wells of deionized water to ensure adequate flushing. You may see peaks in the chromatography for the first 2 wells of deionized water. If any peaks appear in the chromatography for the last deionized water injection, contact your local Bio-Rad technical support office.

NOTE: *If you are still using GDM 3.0 software, continue to include at least 5 Blank wells of deionized water after the primer to ensure adequate flushing.*

Pre-Run Checklist

For Pre-Run Checklist, see *VARIANTnbs Operation Manual, Section 4.2.*

Run Setup

1. Refer to *GDM 3.1 Software Operation Manual, Section 5.1, Creating a Worklist.*
2. Pipette 250 µL of the reconstituted Whole Blood Primer and reconstituted Retention Time Markers into the applicable microplate wells according to the GDM worklist.

Data Review

Refer to *GDM 3.1 Software Operation Manual, Section 6, Data Management.*

Repeat Testing

Refer to *GDM 3.1 Software Operation Manual, Section 5.4.6, Repeating a Plate or Several Samples.*

QC Requirements

1. Reconstituted Retention Time Markers 1 (FAES) and 2 (FADC) are quality control samples.
2. Reconstituted Retention Time Markers 1 (FAES) and 2 (FADC) should be run with each group of patient samples.
3. All analytes for quality control samples (FAES and FADC) must be correctly detected and identified.
4. Total Area of quality control samples (FAES and FADC) should be greater than 750,000 microvolt•second.

NOTE: *If the retention time windows for the respective analytes are not correct, refer to the VARIANTnbs Operation Manual for troubleshooting solutions.*

INTERPRETATION OF RESULTS

Guidelines for the Interpretation of Results

1. All QC requirements must be met to accept a run.
2. The VARIANTnbs identifies hemoglobins by the comparison of peak retention times with the peak retention time of a known hemoglobin analyzed on the system. Known hemoglobins elute in retention time "windows" that have been previously established. (See *Peak Name Windows* section.)
3. Each laboratory should establish its own guidelines for interpretation of the patient report, based on the hemoglobin variants present in its patient population and experience with the VARIANTnbs Sickle Cell Program.
4. Total area must be between 750,000 and 6,300,000 microvolt•second.

Peak Name Windows

Peak name "windows" are intended to assist the laboratory in the interpretation of normal and abnormal hemoglobins detected in patient samples. The windows consist of time ranges during which frequently occurring hemoglobins have been observed to elute.

Sample Chromatograms

The following chromatograms are intended to aid in the interpretation of results.

Bio-Rad VARIANTnbs System
Instrument #1

Site Number:
NeoHb

Sample ID:	C2_68	Analysis Performed:	11/11/2009 15:46:33
Run Date:	11/11/2009	Injection Number:	54
Run Number:	3	Report Generated:	11/11/2009 15:48:14
Plate Type:	Patient Plate	Operator ID:	la
Plate Position:	2		
Plate ID:	9001		
Well#:	B7		

Peak	Peak Name	Retention Time (min)	Height	Area	Area
1	FAST	0.114	15858	24566	1.3
2	F1	0.402	6199	52154	2.8
3	Unknown	0.510	11194	22844	1.2
4	F	0.623	442298	1022735	54.8
5	OTHER(1)	0.696	3358	9469	0.5
6	A	0.817	161228	444482	23.8
7	E/A2	0.965	42986	134485	7.2
8	S	1.189	44088	156229	8.4

Pattern: FASE
Total Area: 1866963

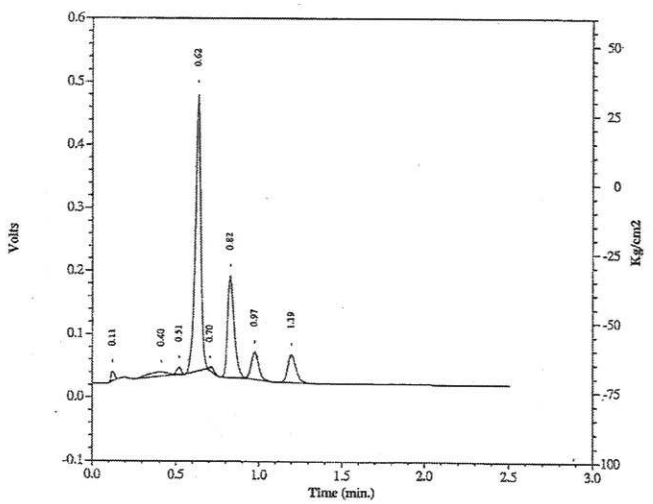


Figure 1: *Retention Time Marker 1*

Sample Chromatograms (Continued)

Bio-Rad VARIANTnbs System
Instrument #1

Site Number:

NeoHb

Sample ID:	C1_36	Analysis Performed:	11/17/2009 14:52:21
Run Date:	11/17/2009	Injection Number:	38
Run Number:	1	Report Generated:	11/17/2009 16:50:10
Plate Type:	Patient Plate	Operator ID:	LS
Plate Position:	1		
Plate ID:	9001		
Well#:	D2		

Peak	Peak Name	Retention Time (min)	Height	Area	Area%
1	FAST	0.119	35558	59297	3.6
2	Unknown	0.177	3905	7757	0.5
3	F1	0.513	46572	208136	12.7
4	F	0.633	439010	1101706	67.1
5	OTHER(1)	0.719	3943	13906	0.8
6	A	0.825	85173	250672	15.3

Pattern: FA
Total Area: 1641474

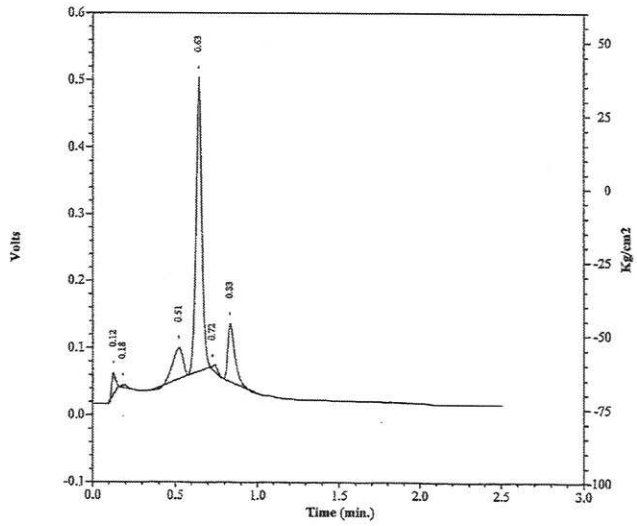


Figure 3: *Normal Pattern (FA)*

Sample Chromatograms (Continued)

Bio-Rad VARIANTnbs System
Instrument #1

Site Number:

NeoHb

Sample ID:	C1_381	Analysis Performed:	11/17/2009 15:01:47
Run Date:	11/17/2009	Injection Number:	391
Run Number:	2	Report Generated:	11/17/2009 16:59:57
Plate Type:	Patient Plate	Operator ID:	ls
Plate Position:	1		
Plate ID:	9001		
Well#:	C9		

Peak	Peak Name	Retention Time (min)	Height	Area	Area%
1	FAST	0.110	47838	76364	3.9
2	F1	0.471	27103	129305	6.7
3	F	0.608	462442	1108611	57.2
4	OTHER(1)	0.715	8581	19100	1.0
5	A	0.809	123995	326557	16.8
6	D	1.054	85071	279084	14.4

Pattern: FAD
Total Area: 1939021

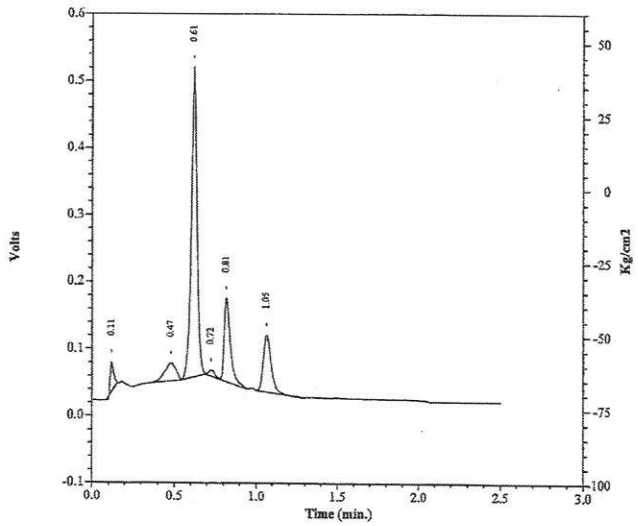


Figure 5: *Hemoglobin D Trait (FAD)*

Sample Chromatograms (Continued)

Bio-Rad VARIANTnbs System
Instrument #1

Site Number:

NeoHb

Sample ID:	C1_300	Analysis Performed:	11/17/2009 14:58:11
Run Date:	11/17/2009	Injection Number:	308
Run Number:	1	Report Generated:	11/17/2009 16:59:01
Plate Type:	Patient Plate	Operator ID:	LS
Plate Position:	4		
Plate ID:	9004		
Well#:	B8		

Peak	Peak Name	Retention Time (min)	Height	Area	Area%
1	FAST	0.110	40452	64619	3.4
2	Unknown	0.169	4228	7825	0.4
3	F1	0.479	33678	166036	8.7
4	F	0.613	521055	1268534	66.3
5	OTHER(1)	0.722	9193	16619	0.9
6	A	0.817	79782	211670	11.1
7	C	1.682	62253	178526	9.3

Pattern: FAC
Total Area: 1913829

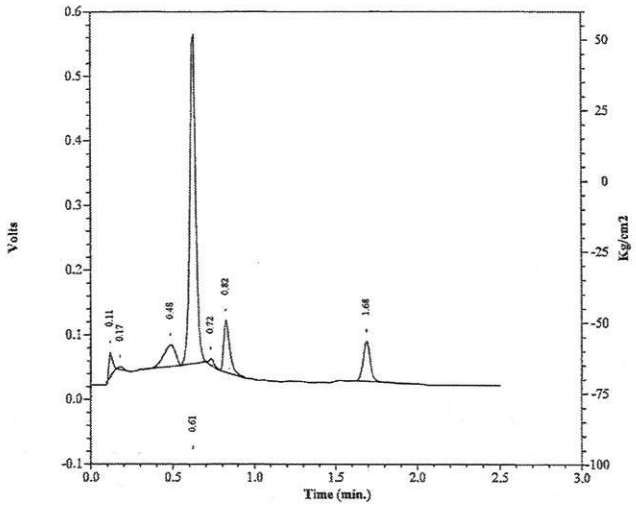


Figure 7: *Hemoglobin C Trait (FAC)*

Sample	Instrument	Retention Time Precision (%CV)					
		F	A	E	D	S	C
Retention Time Marker 1	1	0.3	0.4	0.5		0.5	
	2	0.6	0.6	0.4		0.6	
	3	0.6	0.6	0.6		0.5	
Retention Time Marker 2	1	0.3	0.4		0.4		0.2
	2	0.7	0.6		0.4		0.3
	3	0.6	0.6		0.5		0.3
Pooled Normal Sample	1	0.7	0.6				
	2	0.8	0.5				
	3	0.4	0.7				

Table 3: *Summary of Within-Device Precision (Formerly Total Precision) for 3 Systems*

Accuracy

In a 4-site correlation study of a predicate HPLC method to VARIANTnbs Sickle Cell Program, 99.8% (1023/1025) results agreed for detection of hemoglobins F, A, E, D, S, and C.

Two results did not agree:

1. A sample identified as FA with unknown peak by the predicate HPLC method was identified as FAS by this method. An independent isoelectric focusing measurement assigned FAS to this sample in agreement with this method.
2. A sample identified as FAD by the predicate HPLC method was assigned FADC with a 2.5% peak area for hemoglobin C by this method.

Number of Samples	Predicate HPLC Method	VARIANTnbs Sickle Cell Program	
	F, A, E, D, S, and/or C Peaks Detected	Agree	Disagree
591	FA	590	1 (FAS)
52	FAE	52	0
38	FAD	37	1 (FADC)
247	FAS	247	0
90	FAC	90	0
3	FSC	3	0
2	FC	2	0
1	FE	1	0
1	F	1	0
1025		1023	2

Table 4: *Correlation Study of a Predicate HPLC Method to VARIANTnbs Sickle Cell Program*

NOTES:

VARIANT™ nbs Newborn Screening System:

VARIANT™nbs Newborn Automatic Sampler (VNAS)
and
VARIANT™nbs Newborn Chromatography Station (VNCS)
REF 250-3010

VARIANT™nbs GDM Workstation
REF 250-3016

October 2011
L50030006

BIO-RAD

VARIANT™nbs Newborn Screening System

Operation Manual

CE

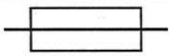
IVD

Mfd. For *USA, Bio-Rad Laboratories, Inc., 4000 Alfred Nobel Drive, Hercules, CA 94547, by OEM Systems Co. Ltd., 84 Mekawa Makishima-Cho, Uji-Shi Kyoto 6110041, Japan*

EC REP *UK, Bio-Rad Laboratories Europe, Ltd., 3 Riverview Business Park, Friarton, Perth PH2 8DF, Scotland*

- Biohazard
- Infektionsgefahr
- Risque biologique
- Peligro biológico
- Rischio biologico
- Risco biológico
- Βιολογικός κίνδυνος

- Caution
- Vorsicht
- Attention
- Precaución
- Attenzione
- Cuidado
- Προσοχή



- Fuse
- Sicherung
- Fusible
- Fusible
- Fusibile
- Fusível
- Ηλεκτρική ασφάλεια

- Protective Conductor Terminal
- Schutzleiter-Anschlusspunkt
- Borne du conducteur de terre
- Borne del conductor de tierra
- Terminale del conduttore protettivo
- Terminal do condutor protector
- Ακροδέκτης προστατευτικού αγωγού

- Humidity Range
- Feuchtigkeitsbereich
- Plage d'humidité
- Rango de humedad
- Range di umidità
- Intervalo de humidades
- Εύρος τιμών υγρασίας

- Moving Parts
- Sich bewegende Teile
- Pièces mobiles
- Piezas móviles
- Parti in movimento
- Peças em movimento
- Κινούμενα μέρη

- Ground Terminal
- Masseanschluss
- Borne de terre
- Borne de la puesta a tierra
- Terminale di terra
- Terminal de ligação à terra
- Ακροδέκτης γείωσης

- Waste from Electrical and Electronic Equipment
- Abfall von elektrischen und elektronischen Geräten
- Déchets d'équipements électriques et électroniques
- Residuos de Aparatos Eléctricos y Electrónicos
- Rifiuti da attrezzature elettriche ed elettroniche
- Resíduos de Equipamento Eléctrico e Electrónico
- Απόβλητα ηλεκτρικού και ηλεκτρονικού εξοπλισμού

- Sharp Biohazard
- Infektionsgefahr durch spitze Gegenstände
- Objets piquants/tranchants posant un risque biologique
- Peligro biológico de objetos cortantes
- Rischio biologico da oggetti appuntiti
- Perigo biológico por instrumentos afiados
- Βιολογικός κίνδυνος από αιχμηρά αντικείμενα

GENERAL SAFETY INFORMATION

- The VARIANT™nbs Newborn Screening System was designed, tested, and certified to meet various safety standards.
- This system is safe to use when operated in accordance with the instructions given in this operation manual.
- These safety certifications do not extend to other equipment or accessories not similarly certified, even when connected to the VARIANTnbs Newborn Screening System.
- Unauthorized modification or alteration of this system voids the warranty, voids the certifications, and creates a potential safety hazard for the operator.
- Read through and familiarize yourself with the contents of this operation manual before using the system for the first time.

HAZARDS

- The VARIANTnbs Newborn Screening System is designed to operate safely and effectively when used in the manner prescribed by the manufacturer.
- If the VARIANTnbs or any of its associated components are used in a manner not specified by the manufacturer, the inherent protection provided by the equipment may be impaired.
- Bio-Rad Laboratories, Inc. is not responsible for any injury or damage caused by the use of this system for purposes other than for which it is intended or by unauthorized modifications of the system.
- Service of the VARIANTnbs Newborn Screening System should be performed only by Bio-Rad personnel.
- Although the VARIANTnbs provides some inherent protection against hazards, special precautions should be taken to avoid harm to the operator or equipment.

Biohazards

The following activities may expose the operator to biohazardous conditions:

- Handling samples, retention time markers, whole blood primer, and controls
- Cleaning spills
- Handling and disposing of solid and liquid waste
- Moving or packaging the instrument
- Performing maintenance procedures
- Performing decontamination procedures
- Replacing system parts

- Treat all VARIANTnbs retention time markers, whole blood primer, and controls as potentially biohazardous materials and handle accordingly.

Disposal of Biohazardous Materials

Dispose of the following potentially contaminated materials in accordance with local, regional, and national laboratory regulations:

- Clinical samples
- Reagents
- Retention Time Markers
- Whole Blood Primer
- Controls
- Used microplates and other consumables (e.g., analytical cartridges) that may be contaminated

Sharp Biohazard

Use caution when handling the sample needle to avoid injury. The used sample needle should be considered potentially biohazardous; discard according to the laboratory standard operating procedures for biohazardous sharps.

Chemical Hazards

VARIANTnbs reorder pack components may contain potentially harmful chemical materials. Follow all instructions for handling, storage, and disposal as described in the appropriate method instruction manual.

- Consult the Material Safety Data Sheets (MSDS) for specific safety information.
- Do not smoke, eat, or drink in areas where reagents are handled.
- Wear personal protective equipment while handling all reagents.
- Chemical reagents should be handled in accordance with Good Laboratory Practices.

Electrical Hazards

Do not remove instrument covers. There are no user-serviceable parts inside. Refer all servicing to Bio-Rad service personnel.

Always follow basic safety precautions when using this instrument to reduce the risk of injury, fire, or electrical shock.

NOTE: *The main power cords at the rear of the VARIANTnbs VNAS and VNCS serve as the primary power disconnects. Do not position the system where it is difficult to disconnect the main power cords.*

Electrical and Electronic Waste Hazards

The Waste Electrical and Electronic Equipment (WEEE) Regulations implement provisions of the European Parliament and Council Directive 2002/96/EC aimed at reducing the amount of EEE waste going for final disposal. As the producer, Bio-Rad Laboratories, Inc. has specific instructions for the recovery of this instrument at the time of end of use. Please go to www.bio-rad.com for the process applicable to your region.

Contents

1 Introduction

The VARIANTnbs is a next generation Newborn Screening System with added front end automation and Genetic Data Management capabilities. The VARIANTnbs provides an integrated method for sample preparation, separation and determination of the relative percent of specific hemoglobins in eluted blood spots. The VARIANTnbs is a fully automated, high-throughput hemoglobin analyzer. It consists of 2 modules: the Newborn Chromatography Station (VNCS) and the Newborn Automatic Sampler (VNAS). In addition, a computer workstation is used to control the VARIANTnbs using the Genetic Data Management (GDM) software.

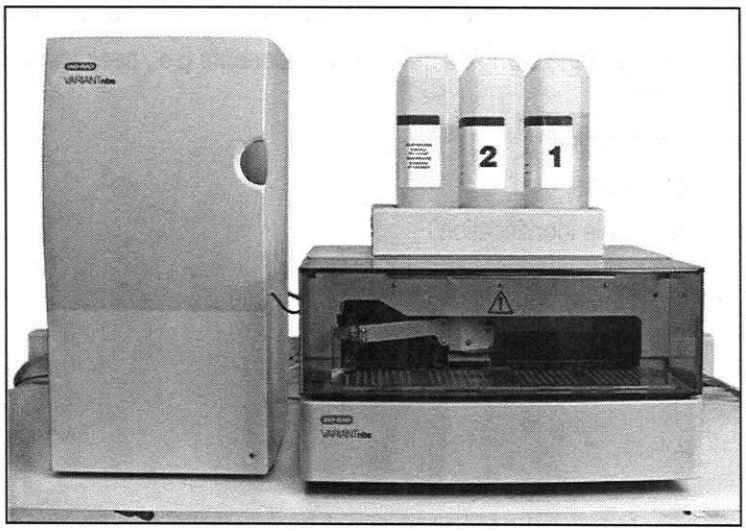


Figure 1-1: *The VARIANTnbs*

2 System Description

The VARIANTnbs is a fully automated, high-throughput hemoglobin analyzer. It consists of 2 modules: the Newborn Chromatography Station (VNCS) and the Newborn Automatic Sampler (VNAS). The VNCS houses the degasser, 2 pumps, injection valve, switching valve, static mixer, syringe pump, cartridge block, and hemoglobin detector. The VNAS consists of a microplate tray/cooling plate, plate cover, sampling arm, built-in barcode scanner, and reagent reservoir with built-in level sensors.

The proprietary cartridge is disposable and easy to change. The total number of analyses which can be performed on a single cartridge is 500; the number of analyses is tracked by a counter. All consumable items, including reagents and cartridges, are available from Bio-Rad.

The VARIANTnbs is controlled by Bio-Rad Genetic Data Management (GDM) software. The software supports import of a sample worklist. The software allows for updating the method parameters from a CD. Modifications to the existing method may also be made using the Edit Test function in GDM, which supports all assay-specific actions and parameters. See the *GDM Software Operation Manual* for more information.

2.1 Automatic Sampler (VNAS) Components

The main components are:

1. Sampling Arm
2. Microplate Tray/ Cooling Rack
3. Wash Station
4. Barcode Reader
5. Main Cover

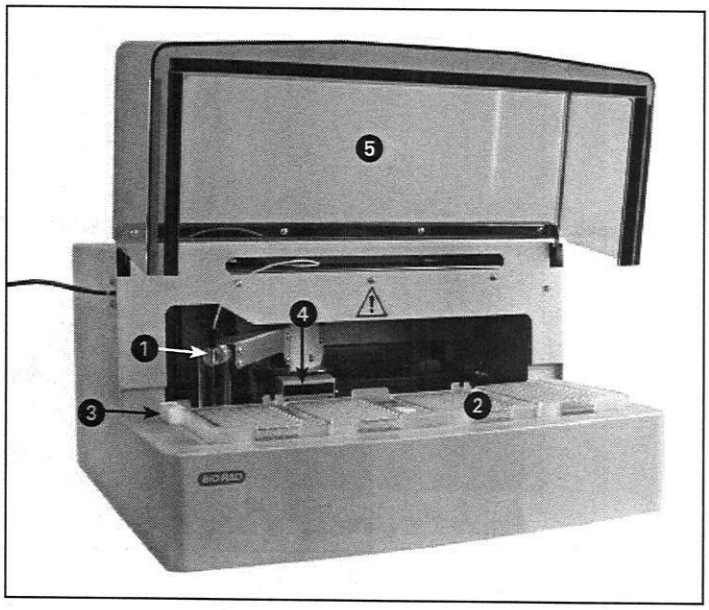


Figure 2-1: *The Newborn Automatic Sampler (VNAS) with Cover Open*

2.3 Automatic Sampler (VNAS), Rear Components/Functions

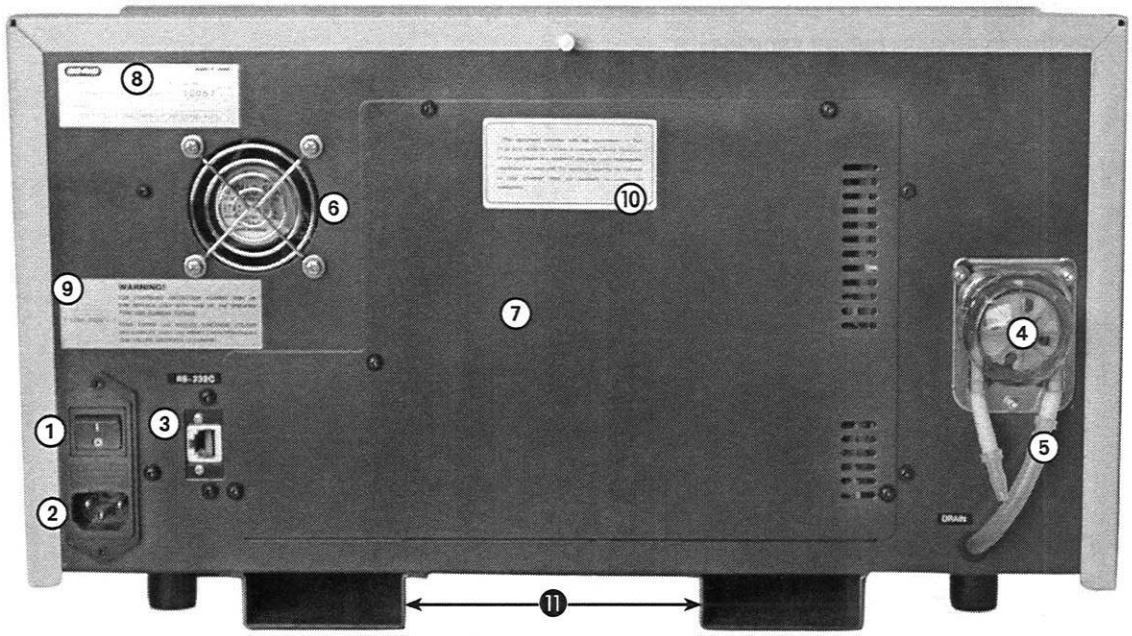


Figure 2-4: *Automatic Sampler (VNAS), Rear View*

No.	Name	Function
❶	Power Switch	The power switch controls power to all system components in the Automatic Sampler (VNAS).
❷	AC Power Input	The power input allows connection of a 3 conductor modular cord with ground to a suitable power source (110 VAC or 220 VAC).
❸	RJ-45 Serial Port	Connection to PC.
❹	Drain Pump	Pump assigned to filling and emptying wash station.
❺	Drain Tube Connector	Device connecting the drain pump to the drain tube.
❻	Main Cooling Fan	Cools instrument electronics.
❼	Rear Service Panel	Provides entry access to instrument components.
❽	Serial Number Label	Instrument ID.
❾	Fuse Warning Label	Provides voltage information.
❿	FCC Label	Instrument notification.
⓫	Cooling Fan Duct	Airflow path for sample cooling fan.

2.6 Chromatography Station (VNCS) Component Functions

No.	Name	Function
❶	Degasser	An in-line tubular Teflon® membrane within a vacuum chamber; removes dissolved gases from buffers 1 and 2.
❷ ❸	Pumps	The pump module consists of 2 dual-piston reciprocating pumps. Each pump has an optical sensor that monitors pump operation. Each pump head has one inlet and one outlet valve, which regulate the direction of buffer flow. Pump A is the left-half of the pump module and pump B is the right-half of the pump module. The pump inlet port for each pump is located directly below the pump heads; the inlet port allows for manual priming of the inlet line for buffer 1 (pump A) or buffer 2 (pump B).
❹	Injection Valve	The injection valve is connected to the switching valve, sample needle, and sample loop. The injection valve controls the release of sample into the analytical flow.
❺	Switching Valve	Automatically selects the mixer (for the analysis) or acts as purge valve for system flush.
❻	Lee Mixer	Combines the output of pump A and B to create a gradient.
❼	Syringe Pump	Moves the sample from the VNAS to the injector loop and flushes sample lines.
❽	Cartridge Block	The cartridge block contains the cartridge holder and controls the temperature at which the separation occurs.
❾	Hemoglobin Detector	The visible wavelength detector measures the absorbance of the sample constituents.

2.8 Chromatography Station (VNCS) Rear Component Functions

No.	Name	Function
❶	Communication Port	This connector allows attachment of an RJ-45 cable to communicate with the PC running the GDM software.
❷	Reagent Level Sensor Port	This connector allows attachment of an RS-232 cable for connection to the Reagent Reservoir.
❸	Waste Sensor Port	This connector is provided for the connection of the waste level sensor signal cable.
❹	External Detector Output	Two thumbscrew connectors allow an external system to monitor the analog DC voltage output signal of the detector.
❺	Wash Solution Port	This port allows connection of the tubing connected to the Wash Solution.
❻	Buffer 1 Port	This port allows connection of the tubing connected to Buffer 1.
❼	Buffer 2 Port	This port allows connection of the tubing connected to Buffer 2.
❽	Waste Port	This port is a barbed-hose connector for connection of the waste line tubing to the waste tank.
❾	Pump Waste Port	This port is a barbed-hose connector for connection of the pump waste line tubing to the waste tank.
❿	AC Power Input	The power input allows connection of a 3 conductor modular cord with ground to a suitable power source (110 VAC or 220 VAC).
⓫	Fuse Holder	The 2 main power fuses are in separate twist-lock housings. These fuses provide over current protection for the Chromatography Station (VNCS).
⓬	Power Switch	The power switch controls power to all system components in the Chromatography Station (VNCS).

2.9 Reagent Reservoir

The reagent reservoir holds 3 reagent bottles (Buffer 1, Buffer 2, and Wash Solution) and monitors liquid volume by weight. When a reagent bottle drops below the set weight, an alarm is generated by GDM.

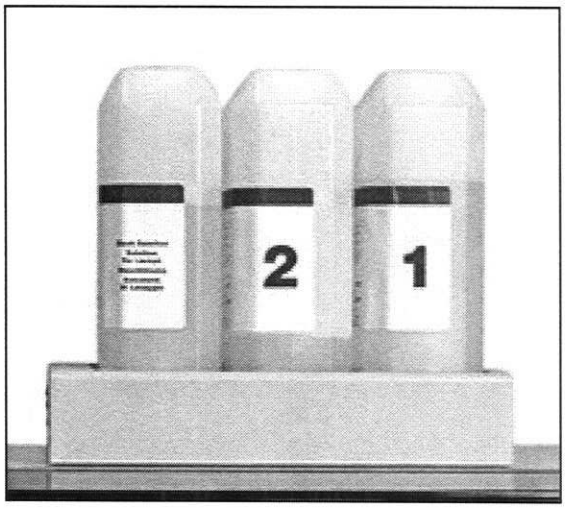


Figure 2-8: *Reagent Reservoir*

3 Installation

NOTE: *Installation of the VARIANTnbs should be performed only by an authorized Bio-Rad representative. Installation by any other person will invalidate the system warranty.*

3.1 Installation Requirements

1. Choose a location for the system that is away from direct sunlight and is relatively dust-free.
2. Room temperature should be 15–30 °C.
3. The bench or table should have a flat, level surface that is free from vibrations and is capable of supporting up to 90 kg (200 lb).
4. A grounded electrical receptacle should be within 1.8 m (6 ft) of the system. The maximum power consumption is 1750 VA (VNCS, VNAS, CPU, monitor, and printer). See Appendix B for specifications.
5. The Computer Workstation should be situated as close to the VARIANTnbs as possible, to provide adequate room for communication connections.
6. The VNCS and the VNAS should be configured as shown in Figure 1-1. No clearance is required between the modules. Ensure the VNAS and VNCS are not >11.5 cm (4.5 in.) apart to prevent sample arm movement errors.
7. Dimensions and clearance for the system are:

   Left side of VNCS: 15 cm (6 in.)
   Back: 10 cm (4 in.)
   Right side of VNAS: 15 cm (6 in.)
   Top: 5 cm above open instrument cover.

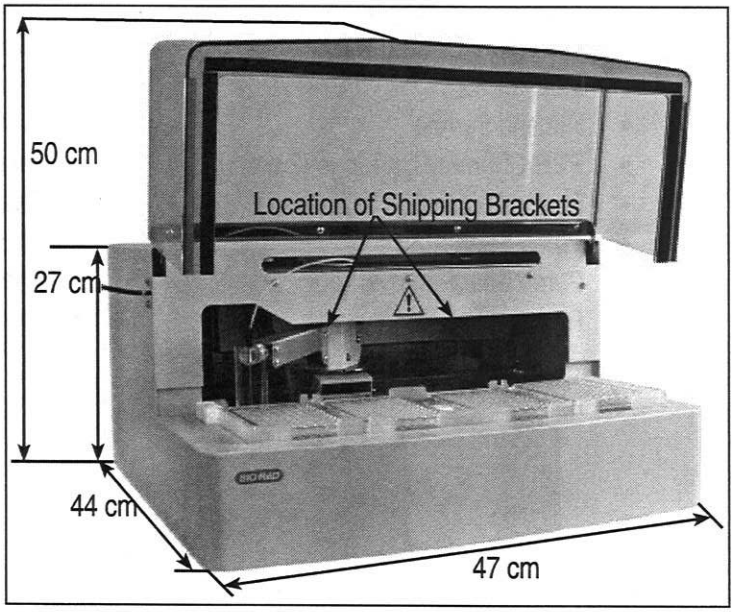


Figure 3-1: *Dimensions and Clearance*

3.4 VARIANTnbs Setup

1. Open the reagent reservoir package and place it on the VNAS. Use the attached cable to connect the VNCS to the reagent reservoir. The connection ports are on the rear of the units.
2. Connect the 9-pin serial cable for the reagent reservoir. This cable runs from the port marked "Reservoir" on the VNCS to the 9-pin connector on the reagent reservoir itself.
3. Connect all cables (i.e., printer, power) to the PC as specified in the PC Hardware Manuals.
4. Power on the PC.
5. Connect the communication cable from the rear of the VNCS to the PC. Use the RJ-45 to Dsub9P cables.
   - VNBS #1 connects to COM 1 and COM 2
   - VNBS # 2 connects to COM 5 and COM 6
   - VNBS # 3 connects to COM 7 and COM 8
   - COM 3 connects to the modem
   - COM 4 is vacant
6. Start GDM. Wait for the software to fully load. Make sure the instrument type is set to GDM in the **Setup/Configuration** screen. Enter the correct com port information in the spaces provided. See the *GDM Software Operation Manual* for more information.

   NOTE: *Do not set communication ports for instrument #2 or instrument #3 unless the instrument is present and connected to the computer.*

3.5 Electrical Connections

3.5.1 Power Cords

1. Take the power cords from the accessories box.
2. The power input for the VNAS is in the back of the module. Connect the power cord to the power input.
3. Connect the other end of the power cord to a grounded power outlet.
4. The power input for the VNCS is in the back of the module. Connect the power cord to the power input.
5. Connect the other end of the power cord to a grounded power outlet.

3.5.2 Waste Level Sensor

1. Locate the 10 L waste tank and waste level sensor in the accessories box. The tank has 2 caps: a larger main cap with a port, and a smaller secondary cap.
2. Remove the main cap and remove the inner seal.
3. Insert the terminal end of the waste tank sensor cable through the main cap.
4. Place the waste sensor into the tank and screw the main cap over the sensor until it is tight. Connect the waste tank signal cable to the terminal labeled WASTE on the rear panel of the VNCS.
5. Put a small (⅛") vent hole in the secondary cap.

3.6.3 Sample Line

1. Connect the sample tubing from the VNAS to port 5 of the 6-port injection valve on the VNCS. Be sure to use the supplied Rheodyne fittings.
2. The Sample IN port is not used.

3.7 Cartridge Installation

The VARIANTnbs system requires an analytical cartridge for sample analysis.

1. Open the cover to the VNCS. Locate the cartridge block in the center of the VNCS. Loosen the thumbscrew and open the cover to the left to a resting position.
2. Lift the cartridge holder from the cartridge block and bring it towards you. Grasp both ends of the holder; hold one end stationary and turn the other in a counterclockwise direction until the 2 ends are separated.
3. Remove the end caps from a new cartridge. Position the cartridge with the arrow pointing in the direction of flow (bottom to top), with the labeling on its side. Push the cartridge firmly into one end of the holder until it is fully seated; be careful not to bend the inlet line while inserting the cartridge. Place the remaining end of the holder over the cartridge. See Figure 3-4. Secure the holder, keeping one end stationary while turning the other end clockwise until finger-tight.
4. Place the cartridge holder inside the cartridge block, taking care to rest the solvent lines in the grooves. See Figure 3-5.
5. Holding the bottom solvent line in the groove, close the cartridge block cover. Turn the thumbscrew clockwise until finger-tight, clamping the cartridge block around the cartridge holder.

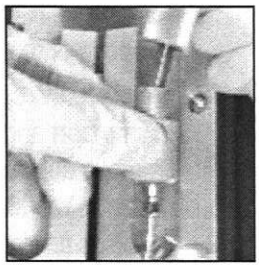


Figure 3-4: *Inserting Cartridge into Holder*

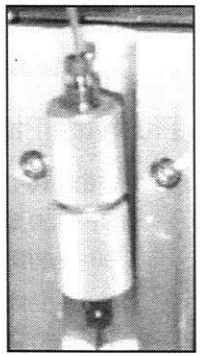


Figure 3-5: *Inserting Holder into Cartridge Block*

3.8 Prime the Lines

Use this procedure to remove any air bubbles that may be trapped in the fluid lines. Air may enter the system during initial installation, when the flow path is opened for service, or when the sinker is not positioned at the bottom of the reagent bottle.

GDM is needed to perform this procedure. See the *GDM Software Operation Manual* for more information.

1. Turn on the VNCS power switch. The system will perform a short self-check.
2. Turn on the VNAS power switch. The system will perform a short self-check.
3. From the GDM **Maintain/Instruments** screen, click **Return to Active**. In the dialog box, click **No** (do not perform automatic warm-up operations).

   NOTE: *If GDM displays a communication error message or the system stays in Startup state and does not go to Ready, the communication ports may be incorrectly configured. Verify that the ports selected in the* ***Setup/Configuration*** *screen match the ports that are actually connected to the VNCS and VNAS.*

3.10 Select a Test

The test which applies to the current configuration of cartridge and reagents must be selected in GDM. See the *GDM Software Operation Manual* for more information.

1. From GDM, go to the **Setup/Test** screen. In the Select New Test box, choose the appropriate test. If the test you select is different from the test previously selected, the screen prompts you to change the buffers and cartridge.
2. Perform the **Update Kit** procedure using the Update Kit CD-ROM provided in the test reorder pack.
3. Click **Cartridges**. Click **Start System Flush**.

   A system flush ensures that the reagent lines are filled with buffer and prepares the system for operation. The system flush lasts approximately 20 minutes.
4. After the system flush is completed, check for any leaks in the system using manual pump control:
   a. From GDM, go to the **Maintain/Instruments** screen.
   b. Set %B to 50%.
   c. Set Flow Rate to 2.0 mL/min.
   d. Set Flow Timer to 1.00 min.
   e. Click **Start Flow**.
   f. Check for any leaks, particularly at the cartridge holder. Tighten any connections that are leaking and wipe up any fluid.

3.11 Removing Air from the Pumps

Following the installation of buffers, use this procedure to remove air from the pumps in the VNCS. This procedure may also be repeated if pressure fluctuation (> ±5%) or low pressure is observed during system operation.

1. See Figure 3-8. Use an 8-mm (5/16") wrench and a 10-mm wrench to remove the outlet and inlet lines. Place the 10-mm wrench onto the check valve, and the 8-mm wrench onto the nut immediately above the check valve (outlet). While holding the check valve stationary with the 10-mm wrench, turn the 8-mm wrench counterclockwise. Once the nut is loosened sufficiently, use your fingers and completely disconnect the nut from the check valve. **Do not remove the check valve.**
2. Attach the luer fitting to the 20-mL syringe. Fasten the luer line finger-tight fitting to the first outlet check valve of pump A (far left).

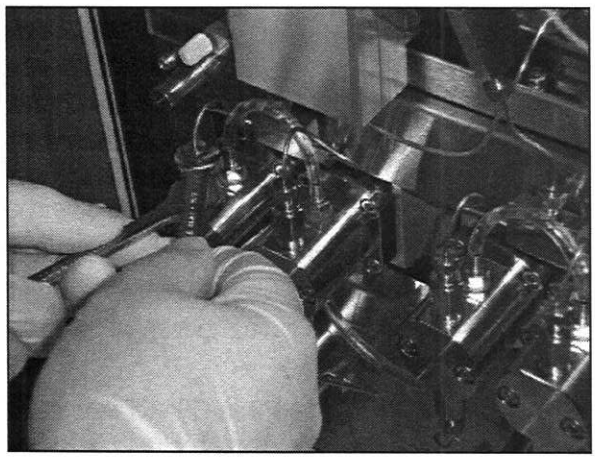


Figure 3-8: *Removing the Outlet Line, Pump A*

3.12 Microplate Barcode Labels

Barcode labels are required for the automatic identification of microplates.

Microplate barcode label requirements:

- The barcode height must be >3 mm.
- The barcode width must be ≤60 mm (narrow bar width 0.125–0.19 mm) or ≤80 mm (narrow bar width 0.19–1.0 mm).
- The barcode label should be affixed on the microplate side wall that faces the barcode reader when placed on the VNAS.
- The barcode label must be positioned so that the barcode itself is centered on the microplate side wall. See Figure 3-10 for correct label placement.

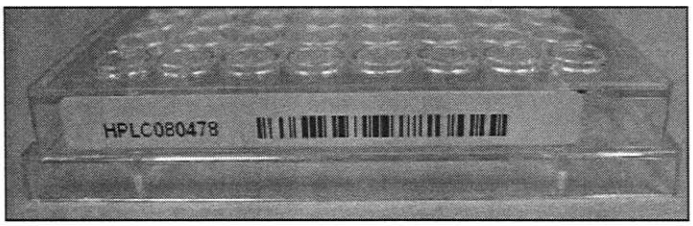


Figure 3-10: *Microplate with Barcode Label*

4 Operation

4.1 General Information

- Automatic and manual operation of the VARIANTnbs system is performed using GDM. See the *GDM Software Operation Manual* for more information. All runs are started and stopped from the **Run/Worklist** screen.
- Up to 4 microplates can be loaded on the VARIANTnbs at one time.

4.1.1 Routine for Each Sample Analysis

The following steps are completed for sample analysis:

a. The sample needle enters the microplate well.
b. The VNCS syringe withdraws eluted sample from the well.
c. Eluted sample is drawn over to the VNCS where it fills the sample loop.
d. The sample is injected into the buffer stream.
e. The sample needle and line are flushed to ensure that cross-contamination between samples does not occur.
f. The sample and buffer mixture flows through the cartridge, where the sample is separated into its constituents.
g. The sample constituents and buffer flow through the detector, where the absorbance of each sample constituent is measured.
h. The resulting chromatogram is shown on GDM.
i. A system flush removes any residual sample components.

4.2 Pre-Run Checklist

Prior to beginning daily operation of the VARIANTnbs, complete the Pre-Run Checklist section of the Daily Maintenance Log provided in Appendix C. Consult the Daily Maintenance Log when preparing the system for an unattended, overnight run.

BIOHAZARD: Performing daily maintenance procedures may expose you to biohazardous conditions. To safely perform the maintenance procedures described in this manual, always wear laboratory gloves, coat, and goggles or safety glasses with side shields.

4.2.6 Check the Level of the Waste Tank

Ensure the waste tank has sufficient room to accommodate waste from the next run. To empty the waste tank:

1. Unscrew the main cap from the waste tank. Lift the cap and waste sensor up and out of the tank. Place the cap and sensor on an absorbent towel.
2. Dispose of the waste properly (contact your laboratory safety officer).
3. Place the sensor back into the waste tank; secure the main cap.

WARNING: Some reagents used with the VARIANTnbs contain sodium azide as a preservative (see labels). Azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of reagents containing sodium azide, always flush with large volumes of water to prevent metal azide buildup. For further information, consult the manual, Safety Management, No. CDC-22, "Decontamination of Laboratory Sink Drains to Remove Azide Salts" (Centers for Disease Control and Prevention, Atlanta, GA, April 30, 1976).

4.2.7 Pressure Check Pump A and Pump B

See Section 3.11, step 10.

4.2.8 Clean the Sample Needle

WARNING: Use caution when handling the sample needle to avoid injury. Do not attempt to replace a broken needle that has detached from its base. Contact your local Bio-Rad office for technical assistance.

1. Prepare approximately 30 mL of a diluted bleach solution (1:10 dilution of 5% sodium hypochlorite in water) in a 50 mL beaker to clean the sample needle.
2. From GDM, go to the **Maintain/Instruments** screen.
3. Under NAS Sampler, click **Go To Base**. The sample needle will move from the wash station to the base position (i.e., front right corner of the sampler).
4. Unscrew the tube fitting from the sampling arm.

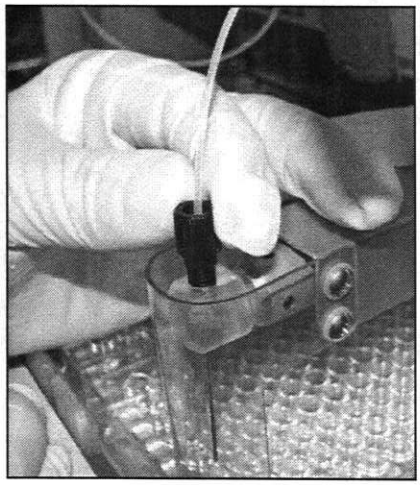


Figure 4-1: *Unscrewing Tube Fitting*

4.2.9 Clean the Wash Station

1. From GDM, go to the **Maintain/Instruments** screen.
2. Under NAS Sampler, click **Go To Base**. The sample needle will move from the wash station to the base position (i.e., front right corner of the sampler).
3. Using a cotton swab soaked with the same diluted bleach solution (1:10 dilution of 5% sodium hypochlorite in water) that is used to clean the sample needle, wipe the wash station until no visible blood remains.

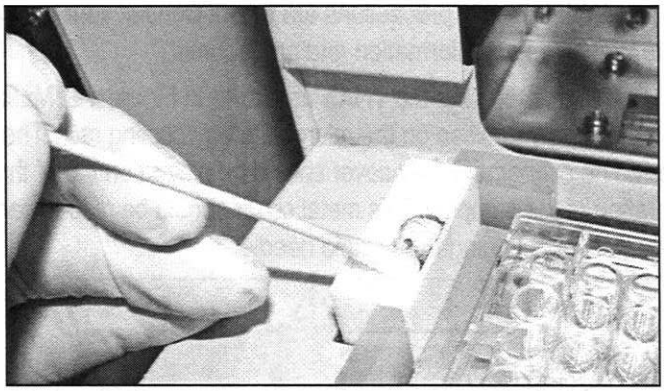


Figure 4-5: *Wiping Wash Station with Cotton Swab*

4. Using a transfer pipette, flush the station with excessive amounts of deionized water to remove any remaining bleach.
5. To return to Ready state after completing manual operations, click **Return to READY state**.

4.2.10 Flush the Piston/Seal Wash Port

See Section 3.9.

4.5 Long-Term System Shutdown

If the VARIANTnbs is to be shut down for more than 2 weeks, follow the procedures below to ensure that the system remains in optimal operating condition.

1. Remove the inlet lines and sinkers from the buffer and wash bottles. Cap the reagent bottles.
2. Place the sinkers, at the ends of the lines, into a beaker of deionized water.
3. Perform a system flush. See Section 3.10, step 3.
4. Remove inlet lines from the deionized water and place sinker ends into a plastic bag to keep clean.
5. Remove the cartridge and cap the ends. See the instruction manual for storage recommendations. Place a dummy cartridge in the cartridge holder.
6. Turn off the main power switches for the VNAS and the VNCS.

5 Maintenance

Routine maintenance for the VARIANTnbs is performed at 4 intervals:

- Daily (pre-run and post-run)
- Weekly
- Twice-monthly
- Monthly

These maintenance intervals are suitable for a workload of approximately 4000 samples per month. All maintenance procedures are necessary to maintain optimum operation of your system.

See the Maintenance Log Sheets in Appendix C.

The instructions for daily maintenance are in Section 4.

WARNING: All maintenance procedures described in this manual can be safely performed by qualified personnel. Maintenance not covered in this manual should be performed only by a Bio-Rad representative.

CAUTION: Turn the power switch off and disconnect the power cord from the main power source before performing any maintenance procedure that requires removal of any panel or disassembly of any interior instrument component.

BIOHAZARD: Performing maintenance procedures may expose you to biohazardous conditions. To safely perform the maintenance procedures described in this manual, always wear laboratory gloves, coat, and goggles or safety glasses with side shields.

5.1 Daily Maintenance Checklist

Pre-Run:

- ❑ Warm-up Procedure (Section 4.2.1)
- ❑ Check Buffer and Wash Levels (Section 4.2.2)
- ❑ Cartridge Injection Count (Section 4.2.5)
- ❑ Check Waste Level (Section 4.2.6)
- ❑ Pressure Check Pump A (Section 3.11, step 10)
- ❑ Pressure Check Pump B (Section 3.11, step 10)
- ❑ Check for Leaks
- ❑ Clean Sample Needle (Section 4.2.8)
- ❑ Clean Wash Station (Section 4.2.9)
- ❑ Flush Piston/Seal Wash Port (Section 3.9)
- ❑ Check Paper Supply

Post-Run:

- ❑ Remove Samples (Section 4.4.1)
- ❑ Wipe Spills (Section 4.4.2)

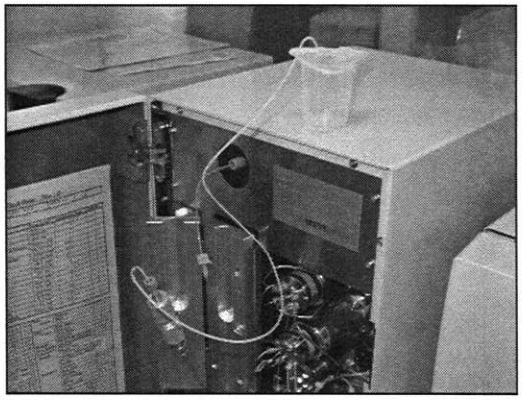


Figure 5-1: *Decon Tubing Installed*

6. From GDM, go to the **Setup/Test/Cartridges** screen.
7. Change the **In Use** column to **No** for the current analytical cartridge.
8. In the new cartridge line, enter the following information.

Lot #	Injection Limit
Dummy	1000

9. Change the **In Use** column to **Yes** for the dummy cartridge.
10. Place a microplate in position 1 on the VARIANTnbs. Fill wells 1–5 with undiluted bleach (5% sodium hypochlorite).
11. Fill wells 6–25 with DI water.
12. Go to the **Run/Worklist** screen.
13. Create a worklist for the 25 "samples" using the "Decon Run Template".
14. Start the run.
15. When the status returns to Ready, remove the PEEK dummy cartridge, rinse the cartridge holder again with DI water, and reinstall the analytical cartridge.
16. Remove the microplate.
17. Go to the **Setup/Test/Cartridges** screen. Change the **In Use** column to **Yes** for the current analytical cartridge.

5.8 Clean the Barcode Reader (if needed)

Inspect the barcode reader face twice per month.

If necessary, clean using a soft cotton cloth dampened with DI water, gently wiping the barcode reader face. Do not use alcohol or any other solvent, as this will damage the reader. Be careful not to scratch the barcode reader face.

5.9 Exterior Surface Cleaning

Use a cloth or sponge dampened with water to wipe the exterior surface of the system. Do not use abrasive cleaners. If required, use a mild soap solution diluted with water to clean the surface, then wipe with a damp cloth or sponge to remove any soap residue.

6 Troubleshooting

The problems that you may encounter while using the VARIANTnbs are divided into different categories.

- Common GDM Alarms: see Table 6-1.
- Hardware Problems: see Table 6-2A and Table 6-2B.
- General Operation Problems: see Table 6-3.

The tables in this section provide abbreviated procedures; see the appropriate section for an explanation of these procedures. If a remedy for your particular problem cannot be found in this operation manual, or if the recommended solution does not fix the problem, contact Bio-Rad Technical Service.

6.1 Common GDM Alarms

Table 6-1: *Troubleshooting GDM Alarms*

Error Message	Probable Cause	Recommended Solution
Communication Error	1) Either the VNCS or the VNAS is not turned on.	1) Turn on the units.
	2) Loose connection between GDM and VNCS and/or the VNAS.	2) Check that the communication cables are attached snugly and there are no breaks.
	3) **Return to Active** was clicked on the **Maintain/Instruments** screen for an instrument that is not in use.	3) Verify that any instrument not in use is in Inactive state. Place the instrument in Inactive state by clicking **Make Inactive** on the **Maintain/Instruments** screen.
	4) Incorrect Instrument Type specified in **Setup/Configuration** screen.	4) Check instrument type. Verify current instrument is set for the VARIANTnbs.
	5) Incorrect Port selected for VNCS or VNAS.	5) Change port number on the **Setup/ Configuration** screen.
Buffer Level Low	Weight level in one or more of the reagent bottles is too low.	Replace appropriate reagent bottle(s).
Waste Level High	Fluid level in the waste tank is too high.	Empty waste tank following appropriate guidelines for disposal.
Pump Overpressure	The pressure in the liquid lines has exceeded the high pressure limit.	Check for blockages in the cartridge or liquid lines (see Section 6.1.1); replace components as needed. Check for overtightened fittings.
Pump Underpressure	The pressure in the liquid lines has dropped below the low pressure limit.	Check for loose or open connections, leaks (see Section 6.1.1), open purge valve, reagent sinkers above the liquid level, or air in the pumps. Tighten loose or open connections, reposition sinkers to the bottom of the bottles, and/or prime the pumps.

6.2 Troubleshooting Hardware Problems

See Table 6-2A, Table 6-2B, and Table 6-3 for troubleshooting recommendations.

6.2.1 Chromatography Station (VNCS) Problems

Table 6-2A: *Troubleshooting VNCS Hardware Problems*

Error Message	Recommended Solution
Sampler syringe home position error	Turn main power switch to the VNCS off and then on again. If error does not clear, remove the sample needle and repeat. If error clears with needle removed, replace the sample needle. If error does not clear, call Technical Service.
Sampler injection valve does not move to load/inject position	Turn main power switch to the VNCS off and then on again; if error does not clear, call Technical Service.
Cartridge thermomodule temperature is out of limits	Allowable range is ±2 °C of setpoint; check setting on **Setup/Test/ Cartridges** screen to ensure it has not been changed.
Degasser chamber vacuum level is out of limits	Turn main power off for 10–15 minutes and then on again. If error does not clear, call Technical Service.
Buffer reservoir is low	Replace with full bottle (see Section 4.2.2).
Wash reservoir is low	Replace with full bottle (see Section 4.2.2).
Pump A error	Call Technical Service.
Pump B error	Call Technical Service.
Pump A and B errors	Call Technical Service.
System pressure is above high pressure limit	Check for blockages (see Section 6.1.1): plugged cartridge, plugged lines to cartridge, or plugged lines to detector. If blockage found, replace cartridge (see Section 3.7) or line (see Section 6.1.2). Check for overtightened fittings.
System pressure is below low pressure limit	Check for the following—open connections or breaks in the lines (leaks): reattach or replace line; purge valve position open: close valve; inlet lines not primed: prime lines (see Section 3.8); sinkers not at bottom of reagent bottles: push to the bottom and prime pumps; air in the pumps: prime pumps (see Section 3.11).
Waste tank is full	Empty the waste tank (see Section 4.2.6).
Detector lamp failure	Call Technical Service.
Sampler 7 port valve movement error	Turn main power switch to the VNCS off and then on again; if error does not clear, call Technical Service.
Fan moving error	Turn main power switch to the VNCS off and then on again; if error does not clear, call Technical Service.
Internal data error	Turn main power switch to the VNCS off and then on again; if error does not clear, call Technical Service.

Table 6-3: *General Troubleshooting*

Problem	Probable Cause	Recommended Solution
Early retention times	1) Buffer contamination (i.e., Buffer 2 was added to Buffer 1)	1) Replace buffers; do not pool buffers.
	2) Buffer evaporation	2) Replace buffer; keep buffers capped.
	3) Cartridge not primed	3) Prime cartridge per instruction manual.
	4) Wrong test parameters	4) Load correct Resin Update CD.
	5) Cartridge temperature too high	5) Verify temperature setting; check cartridge thermomodule.
	6) Defective cartridge	6) Replace cartridge.
Noise spikes appear on chromatogram/ drifting baseline	1) Air bubble in detector and/or pump system	1) Flush system (see Section 3.10, step 3).
	2) Dirty flow cell	2) Call Technical Service.
	3) Detector board fault	3) Call Technical Service.
Late retention times	1) Leak in flow path	1) Check for leaks (including cartridge holder) and correct.
	2) Air in pump(s)	2) Purge pump(s) (see Section 3.11); flush system (see Section 3.10, step 3).
	3) Cartridge temperature too low	3) Verify temperature setting; check cartridge thermomodule.
	4) Clogged reagent sinker	4) Check/replace sinker.
	5) Bad pump seal	5) Call Technical Service.
	6) Defective buffer(s)	6) Replace buffer(s).
	7) Defective cartridge	7) Replace cartridge.
Module does not turn on when main power switch is pressed, or loses power	1) Power outage at the source	1) Check main incoming power circuit breaker.
	2) Module main power fuse(s) blown	2) Replace one or both module main power fuse(s) (see Section 6.4). If repeated failure, call Technical Service.
	3) Main power switch failure	3) Call Technical Service.
No GDM response	Computer has locked up	Wait several seconds; if problem persists: • Press CTRL+ALT+DELETE. • Click **Task Manager**. • Select **End Task** for GDM. • Restart GDM.

Appendix A: Parts List

A.1 Required Items, Supplied by Bio-Rad

The following items are supplied with each VARIANTnbs system. Items are shipped in a large accessories box which accompanies the VARIANTnbs wooden crate. Some items are packaged together in plastic bags and/or small boxes; check the contents carefully to assure completeness of the order.

NOTE: *Quantities denote a single unit of measurement, unless otherwise noted.*

Description	Quantity	Supplied?
VARIANTnbs Operation Manual	1	❑ YES ❑ NO
VARIANTnbs GDM Software Operation Manual	1	❑ YES ❑ NO
Bio-Rad System Warranty Card	1	❑ YES ❑ NO
Bio-Rad Customer Acceptance Form	1	❑ YES ❑ NO
Waste Tank (10 L polyethylene)	1	❑ YES ❑ NO
Waste Level Sensor Assembly, with 2.5 m cable	1	❑ YES ❑ NO
Waste Tube for VNCS, PVC (11 mm OD, 6 mm ID, 2.5 m length)	1	❑ YES ❑ NO
Waste Tube for VNAS, Silicone (8 mm OD, 5 mm ID, 2.5 m length)	1	❑ YES ❑ NO
Waste Tube for VNCS, Silicone (8 mm OD, 5 mm ID, 2.5 m length)	1	❑ YES ❑ NO
VNCS Reagent Reservoir	1	❑ YES ❑ NO
Reagent Reservoir Communication Cable	1	❑ YES ❑ NO
Reagent Reservoir Tubing Assembly. Each tubing assembly consists of:	1	❑ YES ❑ NO
a. Labeled bottle caps	3	❑ YES ❑ NO
b. Teflon sinkers	4	❑ YES ❑ NO
c. Teflon tubing, 3.18 mm OD, 1.58 mm ID, 1.4 m length	4	❑ YES ❑ NO
d. Flangeless fittings	4	❑ YES ❑ NO
RJ-45 to RJ-45 RS232C Communication Cable	3	❑ YES ❑ NO
RJ-45 to Dsub9P RS232C Communication Cable	3	❑ YES ❑ NO
Sample Tubing, Teflon (1.58 mm OD, 0.5 mm ID, 80 cm length)	1	❑ YES ❑ NO
Plastic Syringe, 20 mL	1	❑ YES ❑ NO
Plastic Syringe, 10 mL	1	❑ YES ❑ NO
Power Cord, 110 V	2	❑ YES ❑ NO

A.4 Replacement Items, Available from Bio-Rad

Contact your Bio-Rad representative for additional information.

REF	Description
	Manuals
250-3023	VARIANTnbs Operation Manual
	Reagent Tubing
270-2133	Buffer Tubing Set (Wash, Buffers 1 & 2)
270-2383	Buffer Tubing Sinkers (4/pkg)
250-0259	Waste Tubing
	Miscellaneous Items
270-0022	Waste Tank
250-3039	Vnbs Side Port Sample Needle
270-2078	Power Cord 220V
250-0319	Spare Fuses (250V - 3.15A, qty 2, VNAS)
250-0258	Plastic Needle Cover
270-2318	Decon Tubing

Appendix B: Specifications

B.1 Chromatography Station (VNCS) Specifications

1.	Detector	Visible wavelength detector, 415/690 nm
2.	Power Requirements, input voltage	AC 100–120 V/200–240 V, 50/60 Hz automatically selectable
3.	Power Consumption	180 VA maximum (2 A maximum)
4.	Operating Environment:	
	• Ambient temperature	15–35 °C
	• Humidity	10–90%, non-condensing
5.	Storage Conditions:	
	• Ambient temperature	20–50 °C
	• Humidity	10–95%
6.	Dimensions (H x W x D):	
	• VNCS Instrument	52.4 x 27.3 x 37.0 cm (20.6 x 10.7 x 14.6 in.)
	• Waste Tank	33.0 x 30.5 x 15.2 cm (13 x 12 x 6 in.)
7.	Weight (uncrated)	≤ 35 kg (77 lb)

B.2 Visible Wavelength Detector Specifications

1.	Wavelength:	
	• Sample setting	415 nm
	• Reference setting	690 nm
2.	Linearity	± 1% of Theoretical Absorbance at 0.8 AU (based on extrapolation from lower concentration)
3.	Baseline Noise	≤ 200 µV peak to peak (10 min test period, after 30 min warm-up)
4.	Baseline Drift	≤ 1.0 mV per hour (1 hour test period, after 30 min warm-up)

B.3 Pump Module Specifications

Maximum Pressure	280 kg/cm^2 (4000 psi)

B.4 Gradient System Specifications

Accuracy of Gradient	± 0.5% B

Appendix C: Maintenance Log Sheets

Weekly Maintenance Log

Instrument No.: _____ **Year:** _____

Weekly	Week #	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
Flush Injector	1												
	2												
	3												
	4												
	5*												

**for applicable months*

(Record date and initials after activity is completed)

Appendix D: Glossary

NOTE: *The definitions in this glossary pertain only to their usage in this manual.*

AU
Absorbance Units

Chromatogram
The graph of detector output vs time.

Error Message
A message that appears on the computer screen when a condition exists that prevents normal operation of the VARIANTnbs System.

GDM
Genetic Data Management (the software program used to run the VARIANTnbs)

hPa
Hectopascal

HPLC
High Performance Liquid Chromatography

Hz
Hertz

ID
Inner diameter

Injection
The term used to describe the movement of sample through the hemoglobin detector.

mV
Millivolt

µV
Microvolt

nm
Nanometer

OD
Outer diameter

PC
Personal Computer

Run
A sequence of high-performance liquid chromatography analyses or separations.

Sample
A material to be analyzed (i.e., patient sample, calibrator, or control).

Test
A diagnostic application performed by GDM to detect and/or quantify expected analytes in a patient sample or standard solution.

VA
Volt-ampere

VAC
Volts Alternating Current

VNAS
VARIANTnbs Newborn Automatic Sampler

VNCS
VARIANTnbs Newborn Chromatography Station

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