Validity Testing Information Part I

Laboratory Name: Address:

PATHOLOGY ASSOCIATES MEDICAL LAB 11604 É Indiana, Spokare, WA 99206

Responsible Person: H. DAUID MICHARUSEN (Printed Name)

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

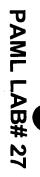
Signature, Responsible Person

/0 . 4 . 00

Date

Printed Name, Responsible Person

Validity Testing Information Part II



		Spec ID# Lab Acc# Receipt
7		pt Reported Result
		Quant
		Comment

Validity Testing Information Part II

PAML LAB# 27

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RESEARCH TRIANGLE INSTITUTE

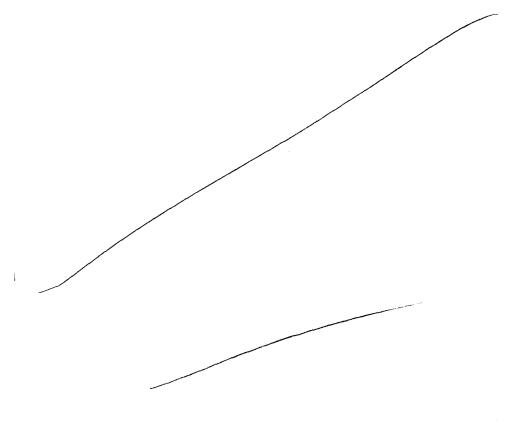
National Laboratory Certification Program

January 30, 2001

0027 Mr. H. David Michaelsen Pathology Associates Medical Labs 11604 East Indiana Avenue Spokane, WA 99206

Dear Dr. Michaelsen:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory appeared to meet a number of the minimum technical criteria. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.





Mr. Michaelsen January 30, 2001 Page 2 of 6 Mr. Michaelsen January 30, 2001 Page 3 of 6

Mr. Michaelsen January 30, 2001 Page 4 of 6 Mr. Michaelsen January 30, 2001 Page 5 of 6 Mr. Michaelsen January 30, 2001 Page 6 of 6

If you have any questions or if we can be of further assistance, please call me at $(919)\ 541-7265$ or Dr. Michael Baylor at $(919)\ 541-7043$.

Sincerely,

Deborah J. Denson NLCP Technical Analyst

Enclosure

Project Files/M19 CC:

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0027

Document No. Final

Laboratory:

Pathology Associates Medical Laboratories

Location:

Spokane, WA

Document Reviewed:

] Application Form

[XX] Inspection Report #M19

Date: 9 November 2000

] Other _

Status:

1 Appeared to meet most of the minimum technical criteria [XX] Appeared to meet a number of the minimum technical criteria

Failed to meet a number of the minimum technical criteria

Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet a number of the minimum technical criteria required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before the next inspection.

The following deficiencies were identified, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

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Lab ID# 0027

Section H. Initial Tests

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section K. Records Audit

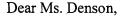
Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

Ver. Final Lab ID# 0027





Enclosed is our response to your critique of Maintenance Inspection #19. Even though we have already started to address and resolve all listed issues, my following response is limited to those issues you requested information to be submitted or addressed.



11604 E. Indiana Avenue Spokane, WA 99206

509.926.2400 800.541.7891 509.924.0002 Fax

Partnerships:

PACLAB

NETWORK
LABORATORIES
Scattle, Washington

ALPHA

ALPHA MEDICAL LABORATORY Coeur d'Alene, Idaho

TCL

TRI-CITIES
LABORATORY
Tri-Cities, Washington

TVL

TREASURE VALLEY
LABORATORY
Boise, Idaho

Chief Executive Officer

Thomas O. Tiffany, Ph.D.

Medical Director

T.J. Allerding, M.D., Ph.D.

Technical Directors

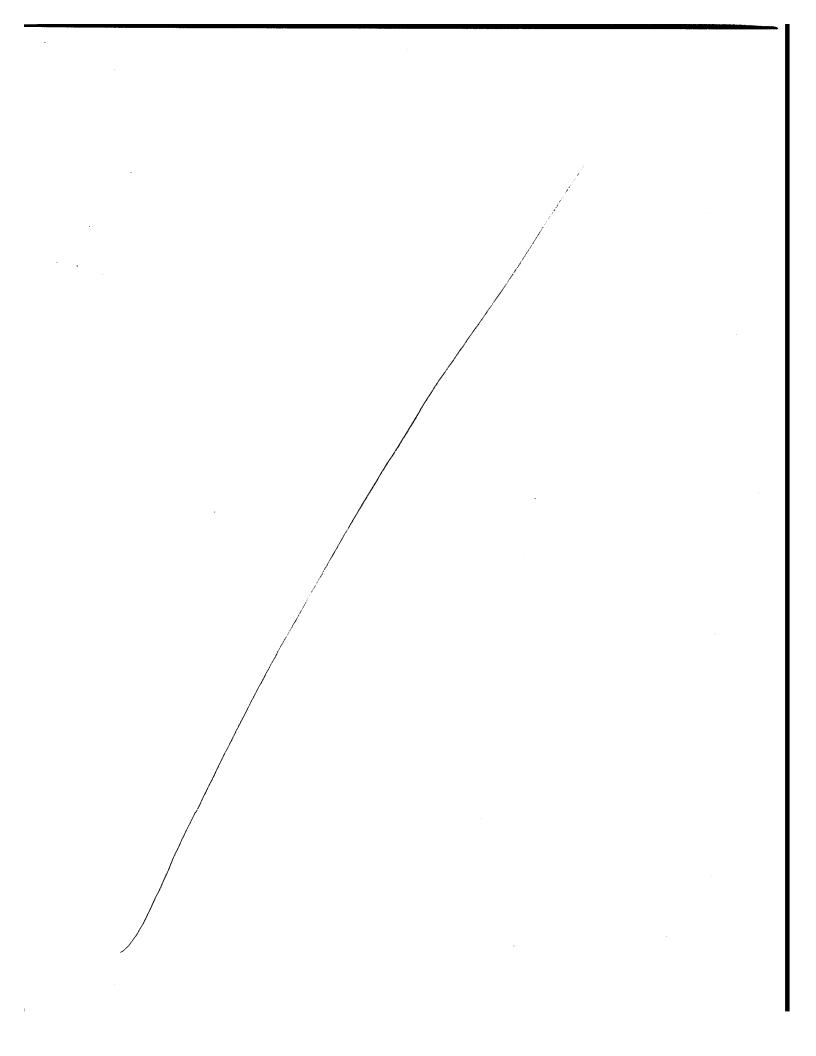
Richard D. Barclay, Ph.D.,
Toxicology

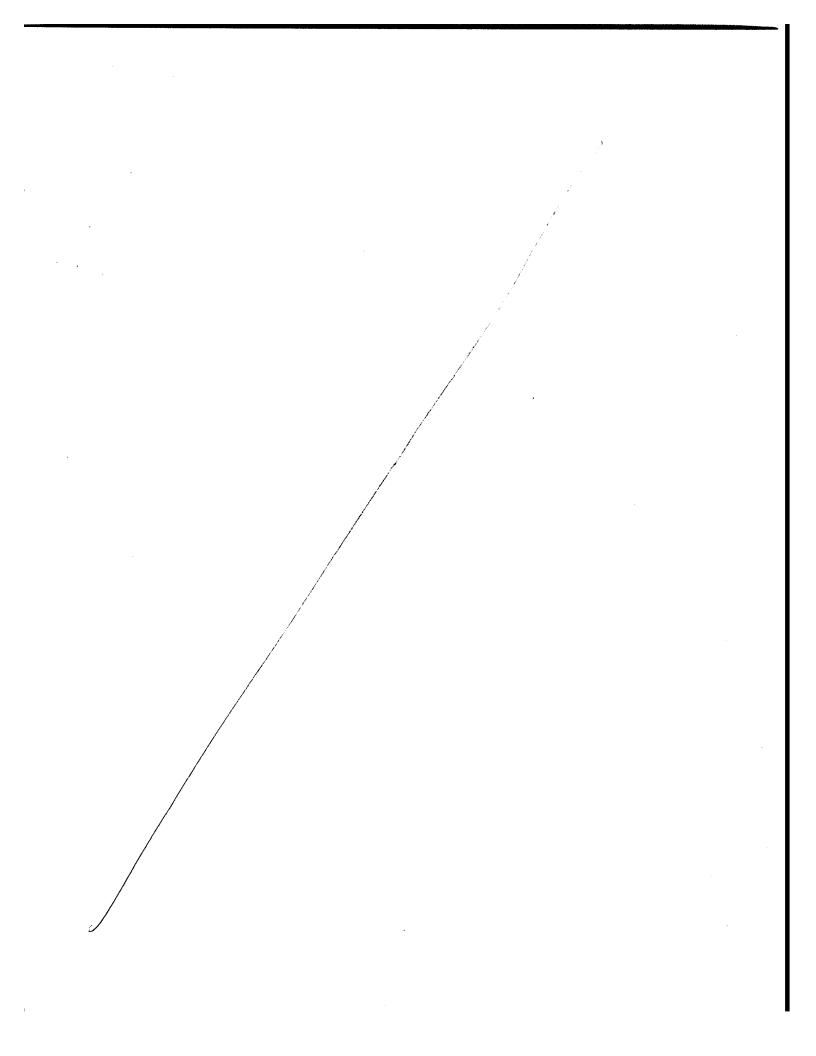
William A. Dittman, M.D., Hematology

Julie S. Hanna, Ph.D., Marilyn A. Lloyd, Ph.D., Cytogenetics

L.M. Killingsworth, Ph.D., Chemistry

Ann Robinson, Ph.D., Microbiology





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See response above along with documentation submitted regarding this issue.

Respectfully,

H. David Michaelsen (RP) General Manager of Toxicology