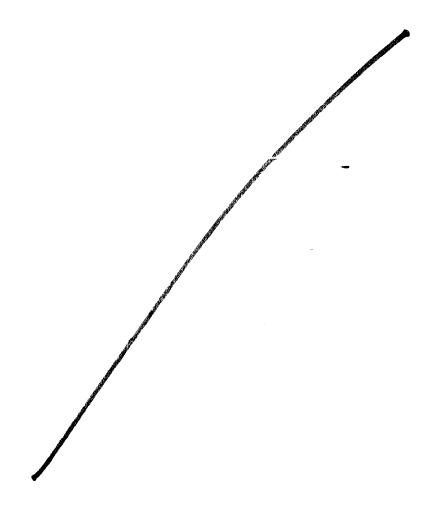
Validity Testing Information Part I

Laboratory Name: Address:

Doctors Laboratory 2906 Julia Drive, Valdasta, GA 31604

Responsible Person: D.C. Williams (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).

10 - 3 - 05 Date

David C. Williams
Printed Name, Responsible Person

DOCTORS LABORATORY, INC.

Pathologists:

YRON S. DAVIS M.D. ALBERT C. DOMM, M.D. SUSAN W. BELSON, MD. SUPRANEE DEE, M.D. RONALD R. ZIMMERMAN, D.O. P. J. RAVELO, M.D.

2906 JULIA DRIVE P.O. BOX 2658 VALDOSTA, GEORGIA 31604 (912) 244-4468

BYRON S. DAVIS, M.D. Laboratory Director

LAMAR COURSON, SC (ASCP) Director of Operations

	FAX TRANSMISSION COVER SHEET
]	Please deliver the following pages to:
1	Name: <u>Ken Davis</u> Fax Phone Number: <u>(919)541-704</u> 2
1	From: D.C.Williams Title: Director of Toxicology
I	Date: 10/5/00 Time: 730
•	You will receive pages of copy including this cover sheet. If you do not receive the pages, please call (912) 244-4468, ext 267 or 283.
ľ	Message: Accompanying find Validity Testing
-	
_	

This facsimile contains priveleged and confidential information only for the individual named above. If the reader of this fax is not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination or copying of this fax is strictly prohibited. If you have received this in error, please notify us by telephone and return the original to us at the above address. You will be reimbursed postage. Thank you.

DOCTORS LABORATORY, INC.

Pathologists:

BYRON S. DAVIS M.D. ALBERT C. DOMM, M.D. SUSAN W. BELSON, MD. SUPRANEE DEE, M.D. RONALD R. ZIMMERMAN, D.O. F. J. RAVELO, M.D. 2906 JULIA DRIVE P.O. BOX 2658 VALDOSTA, GEORGIA 31604 (912) 244-4468 BYRON S. DAVIS, M.D. Laboratory Director

LAMAR COURSON, SC (ASCP)
Director of Operations

FACSIMILE MESSAGE

229 5184 FAX:912-249-5179

FOLLOWING IS/ARE PAGE(S)
(including cover page)

ROUTE TO:

COMPANY: <u>RT 1</u>

NAME: <u>Debbie Denisou</u>

CITY:

PHONE:

FAX NO.: (919) 541 - 7457

FROM:

NAME: D.C.Williams

CONFIDENTIALITY NOTE

This facsimile (FAX) contains privileged and confidential information only for the individual name above. If the reader of this fax is not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination or copying of this fax is strictly prohibited. If you have received this in error, please notify us by telephone and return the original to us at the above address. You will be reimbursed postage. Thank you.

Validity Testing Information Part II

Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for each DOT regulated specimen that was reported either adulterated or substituted:

- Specimen ID number
- Laboratory Accession Number
- Date of receipt
- Date reported
- Reported result (i.e., adulterated or substituted)
- Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)

Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.

10/16/00 Date

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

D. C. Williams
Printed Name, Responsible Person

Doctor's Laboratory

SPECIMEN ID NO. LAB ACC. NO. DATE REC'D DATE REPORTED RESULT

QUANTITATION

10/13/10 0 Marketill



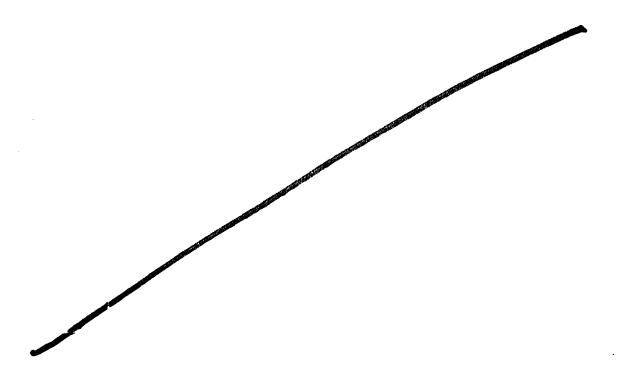
National Laboratory Certification Program

November 17, 2000

0514 Dr. David C. Williams Doctors Laboratory, Inc. 2906 Julia Drive P.O. Box 2658 Valdosta, GA 31602

Dear Dr. Williams:

The enclosed critique was developed from the inspection report associated with the October 18-20, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to correct/clarify the following issues raised:



Dr. Williams Page 2 of 3 11/17/00

Dr. Williams Page 3 of 3 11/17/00

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

NLCP Technical Analyst

Susur Crungton

Enclosure

cc: Project Files/svt514

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0514

Document No. Final

Laboratory:

Doctors Laboratory, Inc.

Location:

Valdosta, GA

Document Reviewed:

[XX] Specimen Validity Testing Inspection Report

Date: 18 October 2000

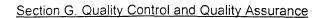
A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

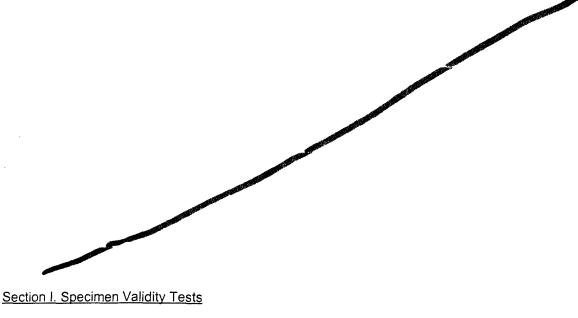
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

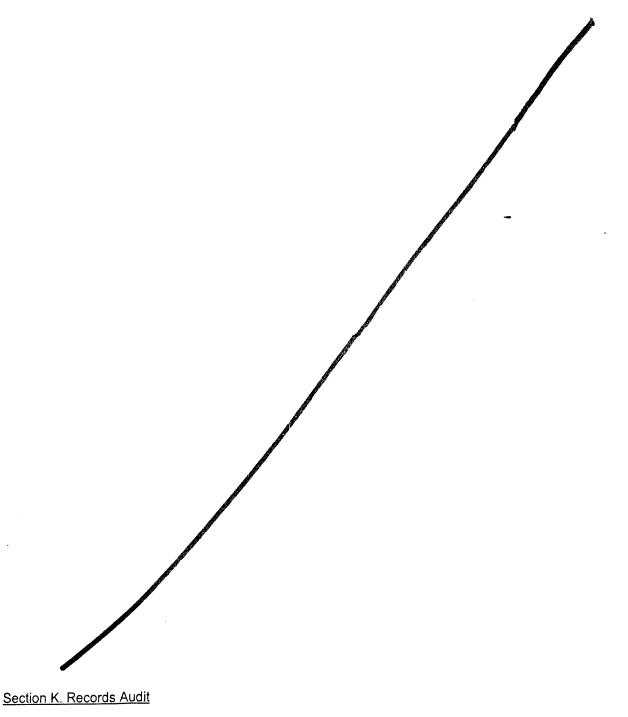






Ver. Final

Lab ID# 0514



Ver. Final Lab ID# 0514



Section L. Certification and Reporting

Section O. Overall

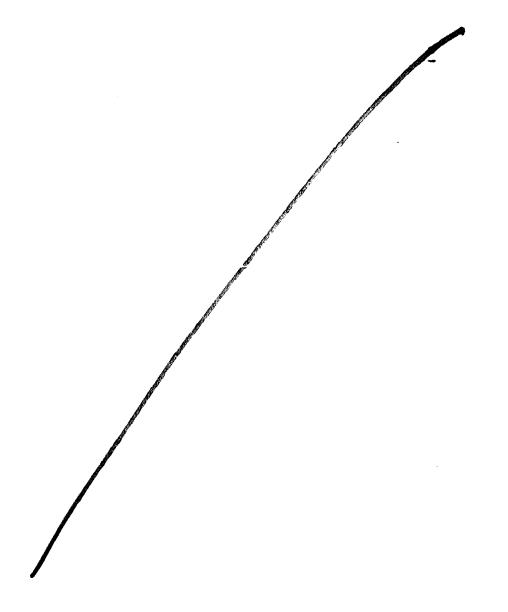


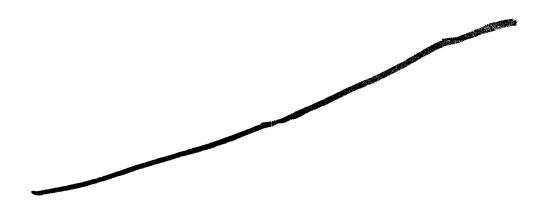
Doctors Laboratory, Inc. P. O. Box 2658 Valdosta, GA31604

December 14, 2000

Susan Crumpton Research Triangle Institute P. O. Box 12194 Research Triangle Park, NC 27709-7042

Dear Ms. Crumpton,





Sincerely,

David C. Williams, Ph. D.



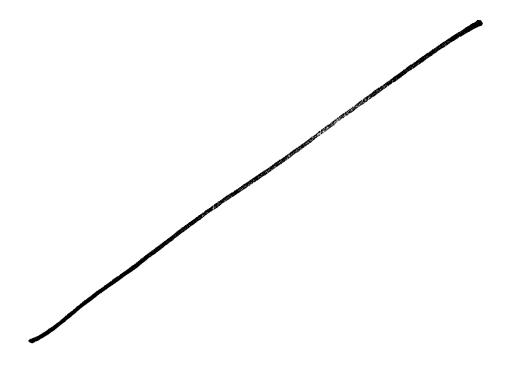
National Laboratory Certification Program

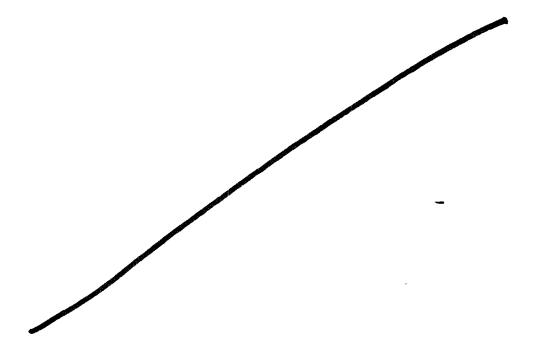
January 12, 2001

0514 Dr. David C. Williams Doctors Laboratory, Inc. 2906 Julia Drive P.O. Box 2658 Valdosta, GA 31602

Dear Dr. Williams:

We have reviewed the material provided in your correspondence of December 14, 2000, submitted in response to issues raised during the October 18-20, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 17, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. However, the following issues were raised during our review of submitted material:





Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens. All corrective actions will be reviewed during the next inspection

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

NLCP Technical Analyst

cc: Project Files/SVT514