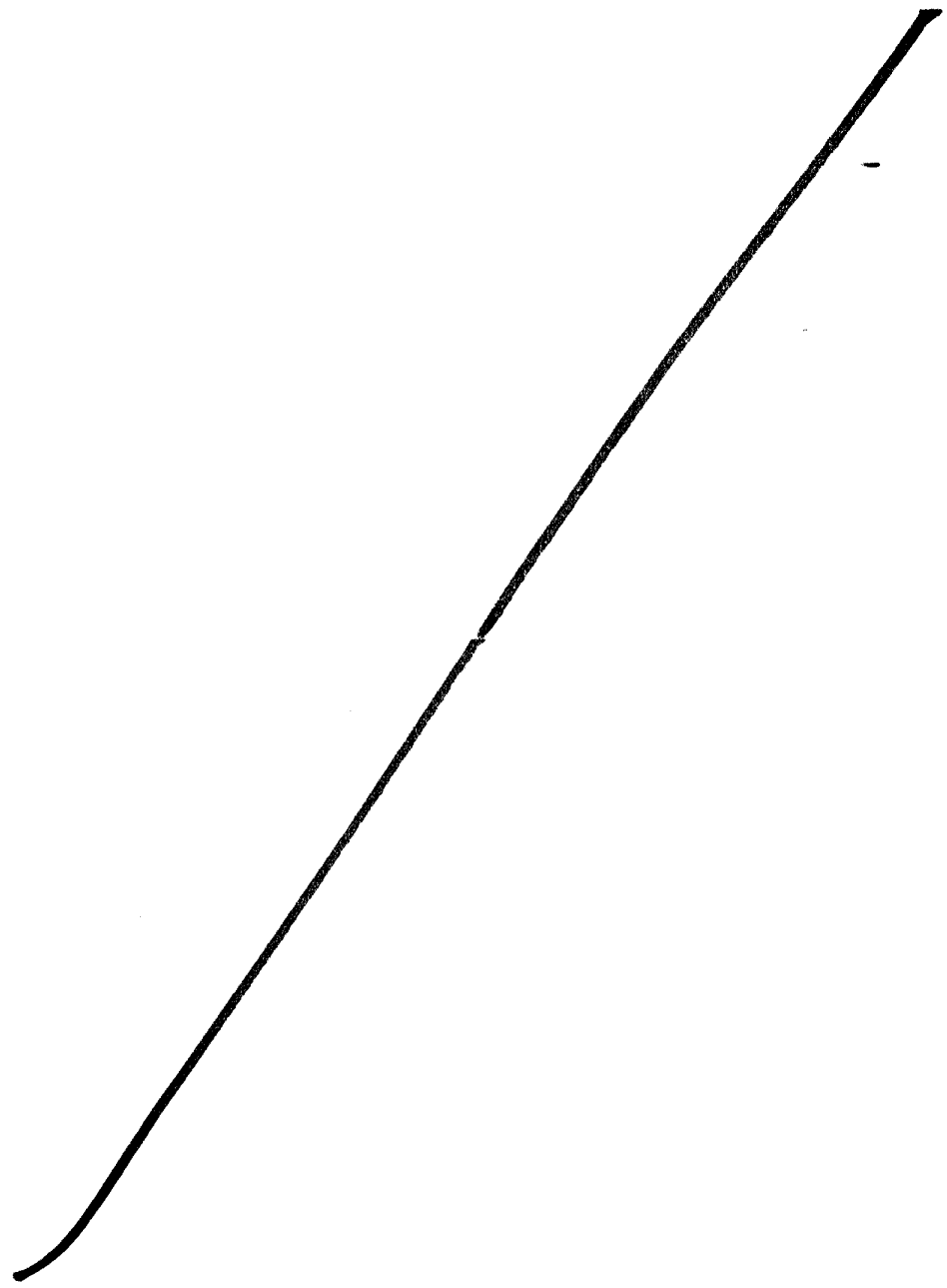
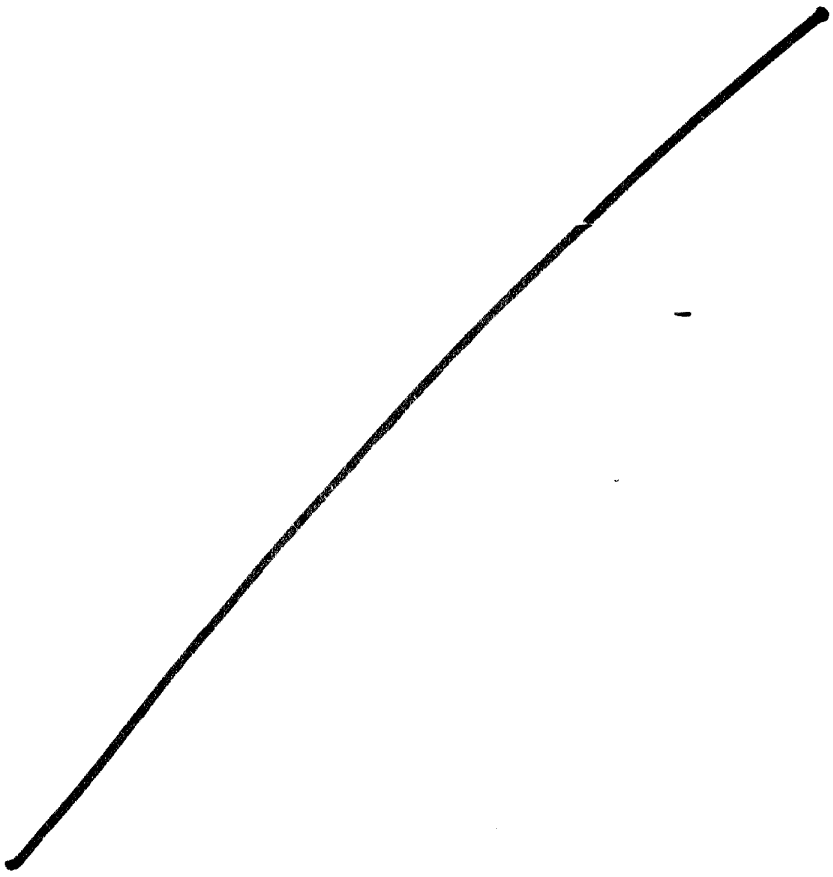


Validity Testing Information Part I

Laboratory Name: Dynacare Kasper Medical Laboratories
Address: 14940 123 Ave. Edmonton Alberta, Canada T5V 1B4.
Responsible Person: Dr. David W. Kinniburgh (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).

DW Kinniburgh
Signature, Responsible Person

Oct 4, 2000
Date

DW KINNIBURGH
Printed Name, Responsible Person


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:

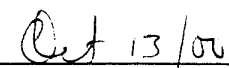
- Specimen ID number
- Laboratory Accession Number
- Date of receipt
- Date reported
- Reported result (i.e., adulterated or substituted)
- Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)

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

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).



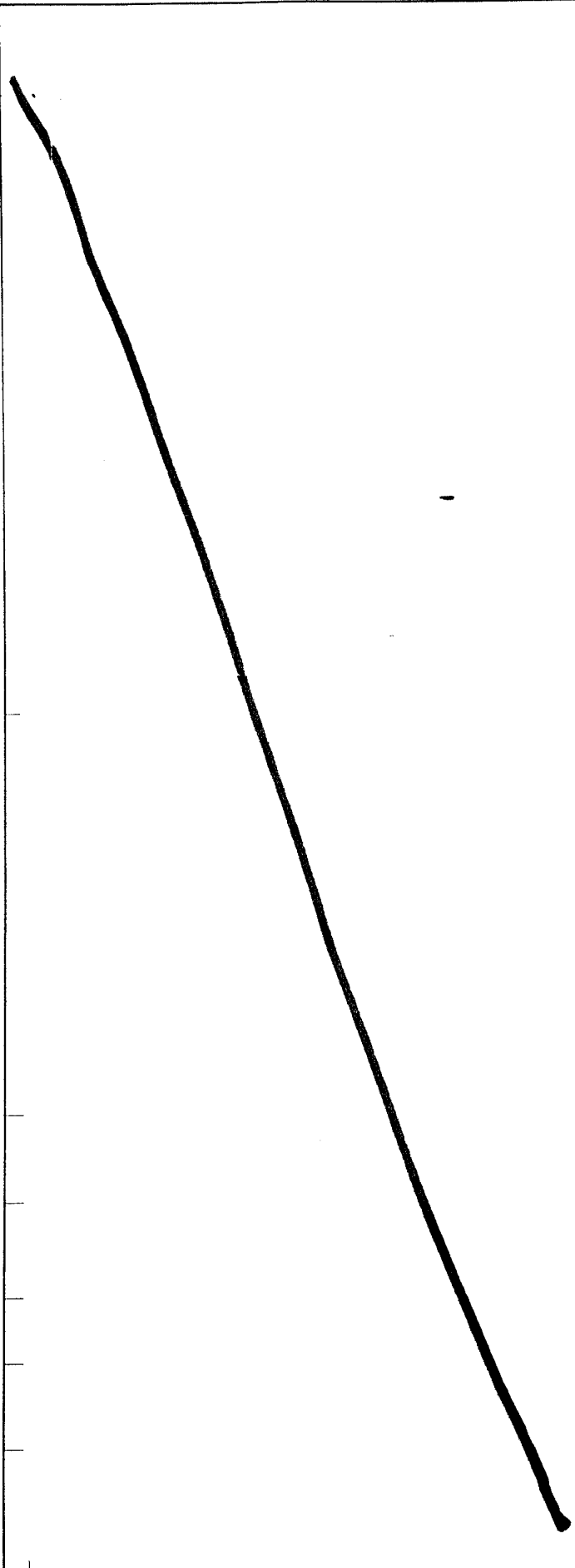
Signature, Responsible Person



Date

DW KINNIBURGH
Printed Name, Responsible Person

Sample Source	Name	ID Number	Accn #	Date Received	Date Reported	Integrity Result	Creat (mg/dl)	Specific Gravity	pH	Nitrites (ug/ml)	Chromium (ug/l)
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December 19, 2000

0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, CAN T5V1B4

Dear Dr. Kinniburgh:

The enclosed critique was developed from the inspection report associated with the November 29, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in 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 address the following issues raised:



Dr. Kinniburgh
December 19, 2000
Page 2 of 2

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 listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. 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. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.***

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

cc: Project Files/svt798


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0798
Document No. Final

Laboratory: Dynacare Kasper Medical Laboratories

Location: Edmonton, Alberta

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 29 November 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

[Redacted]

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

[Redacted]

Section G. Quality Control and Quality Assurance

[Redacted]

Section I. Specimen Validity Tests

[Large redacted area]

[Redacted]

Section K. Records Audit

[Redacted]

Section L. Certification and Reporting

[Redacted]

received
11/30/01 DD

DYNACARE



KASPER
MEDICAL LABORATORIES

*Partners in Quality,
Service and Innovation*

January 29, 2001.

0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 - 123 Avenue
Edmonton, Alberta, Canada
T5V 1B4.

Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, North Carolina, USA
27709-2194

Dear Ms. Denson,

Enclosed is our response to the critique resulting from the November 29, 2000 specimen validity testing inspection. Please do not hesitate to contact myself,

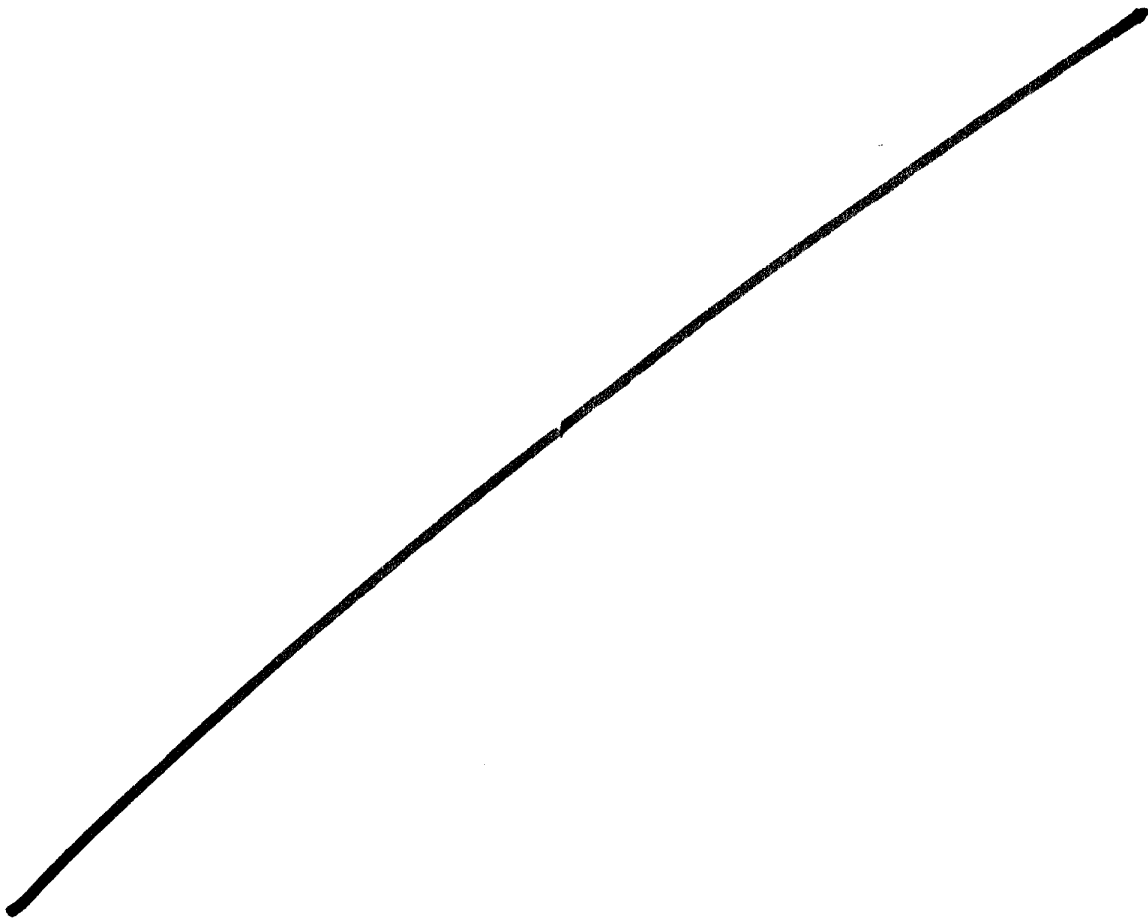
Yours sincerely,

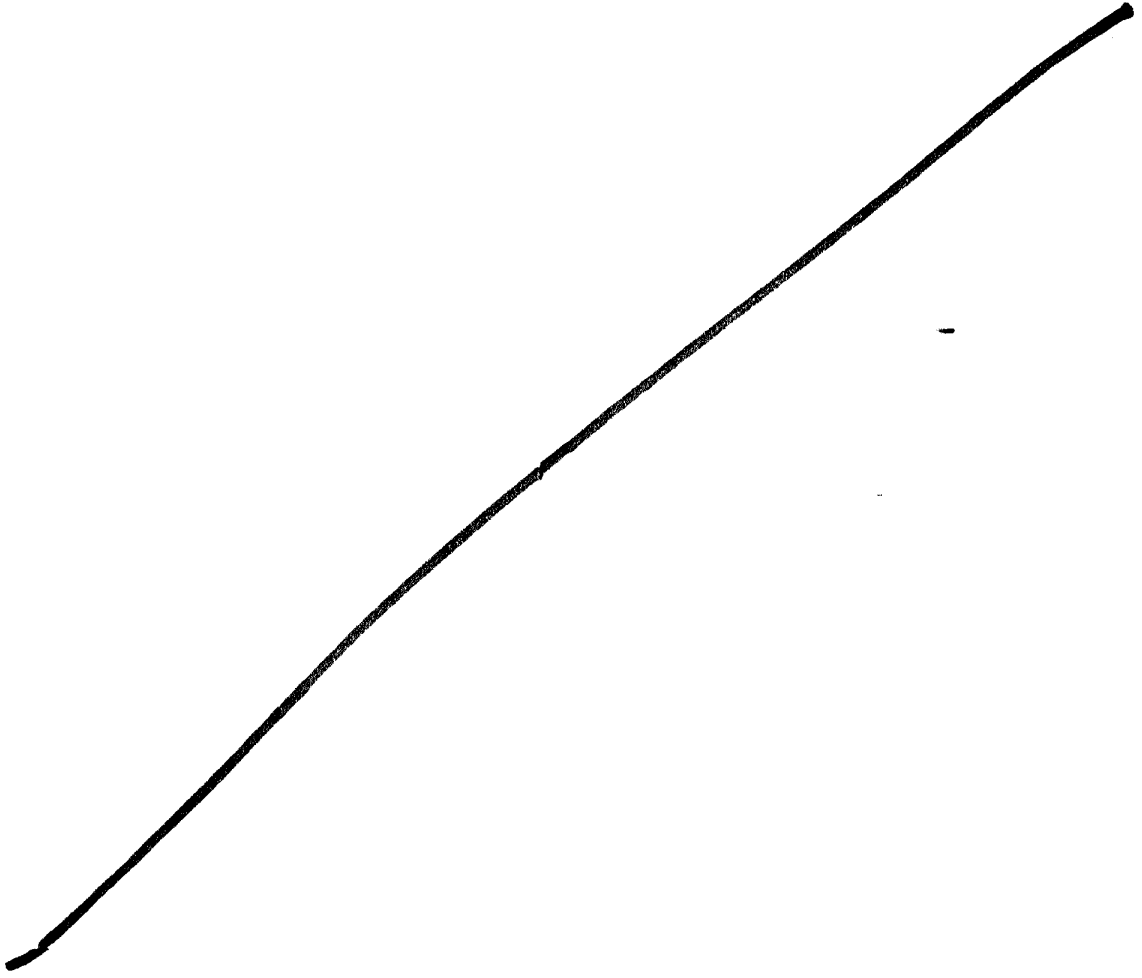
Dr. David W. Kinniburgh

Section G.



Section I





RESEARCH TRIANGLE INSTITUTE



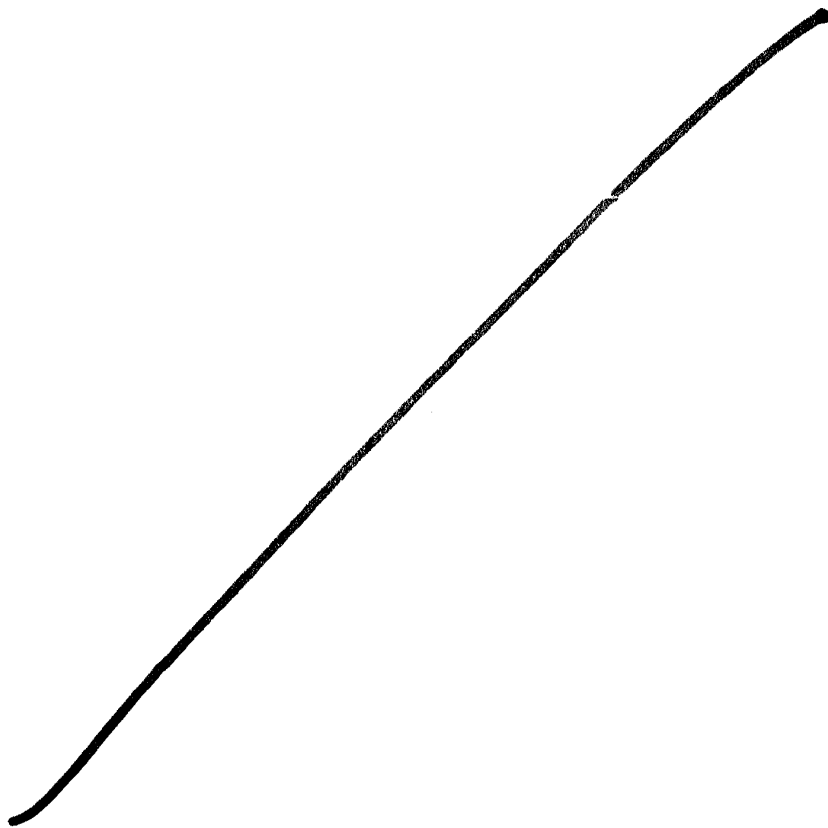
National Laboratory Certification Program

February 6, 2001


0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, CAN T5V1B4

Dear Dr. Kinnebrugh:

We have reviewed the material provided in your correspondence of January 29, 2001 submitted in response to issues raised during the November 29, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 19, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:



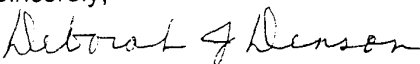
Dr. Kinniburgh
February 6, 2001
Page 2 of 2



Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its 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 and will be reviewed during the next inspection. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.

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

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT798