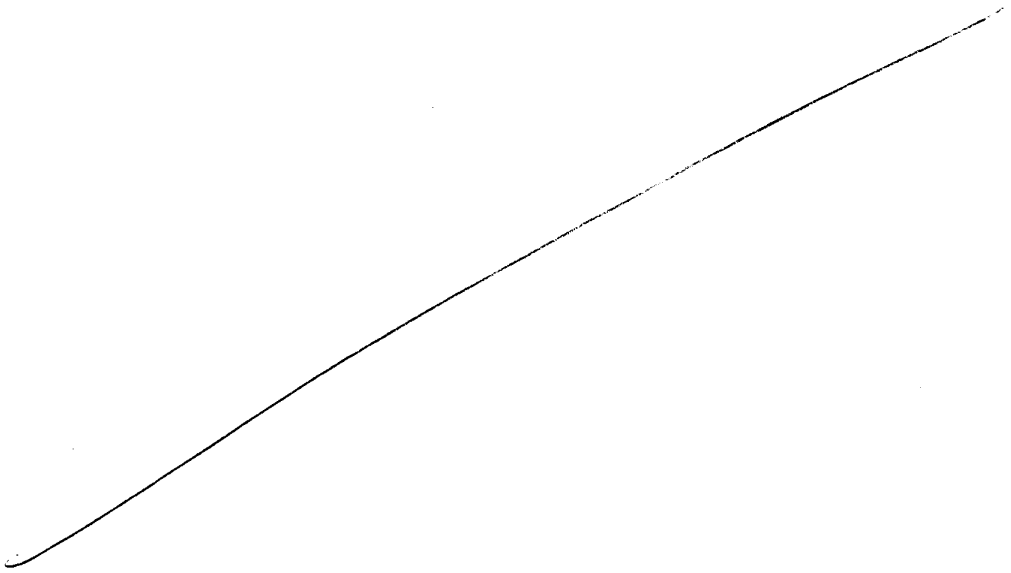
Attachment for question 4



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).

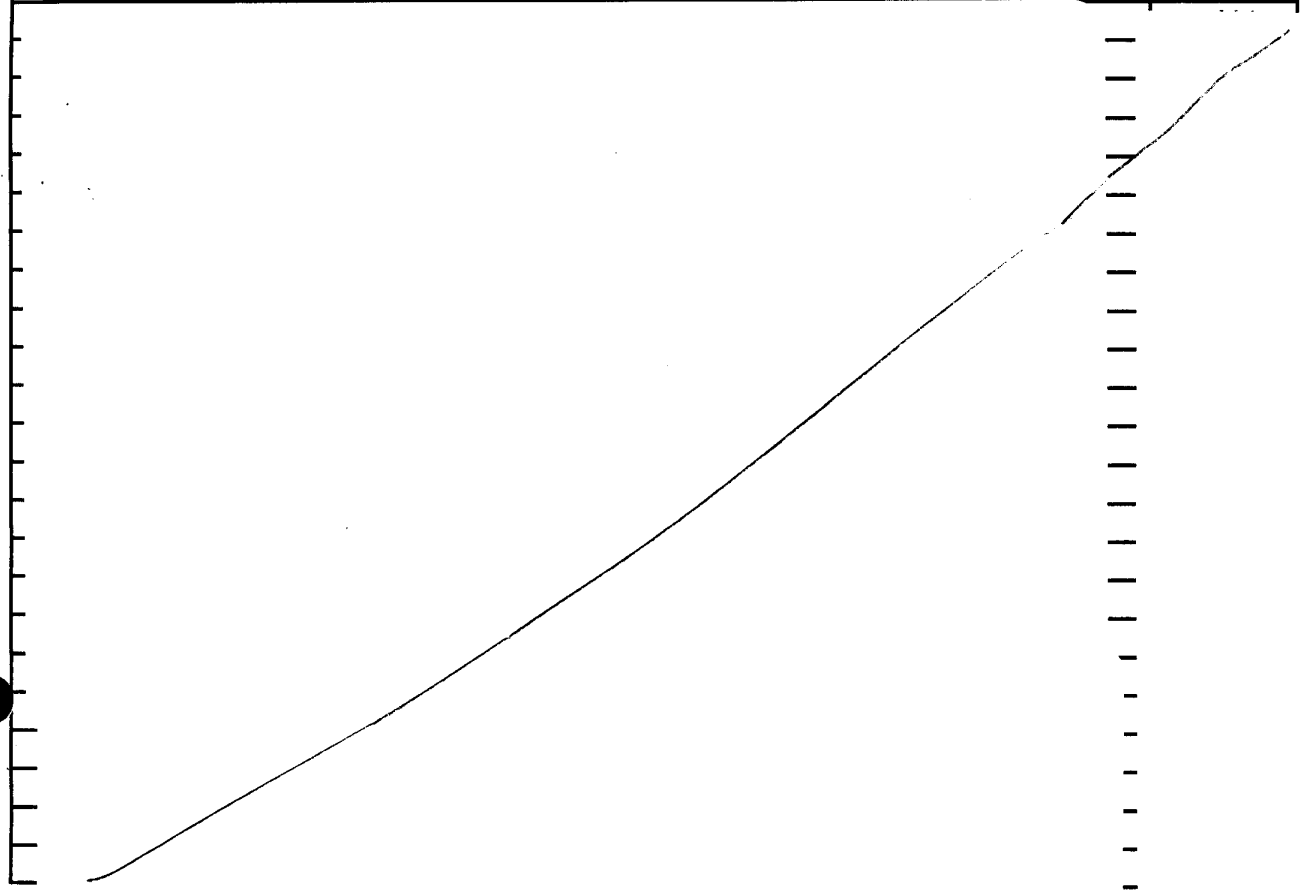
Edward Azary Ph.D. — Signature, Responsible Person

10-18-2000 — Date

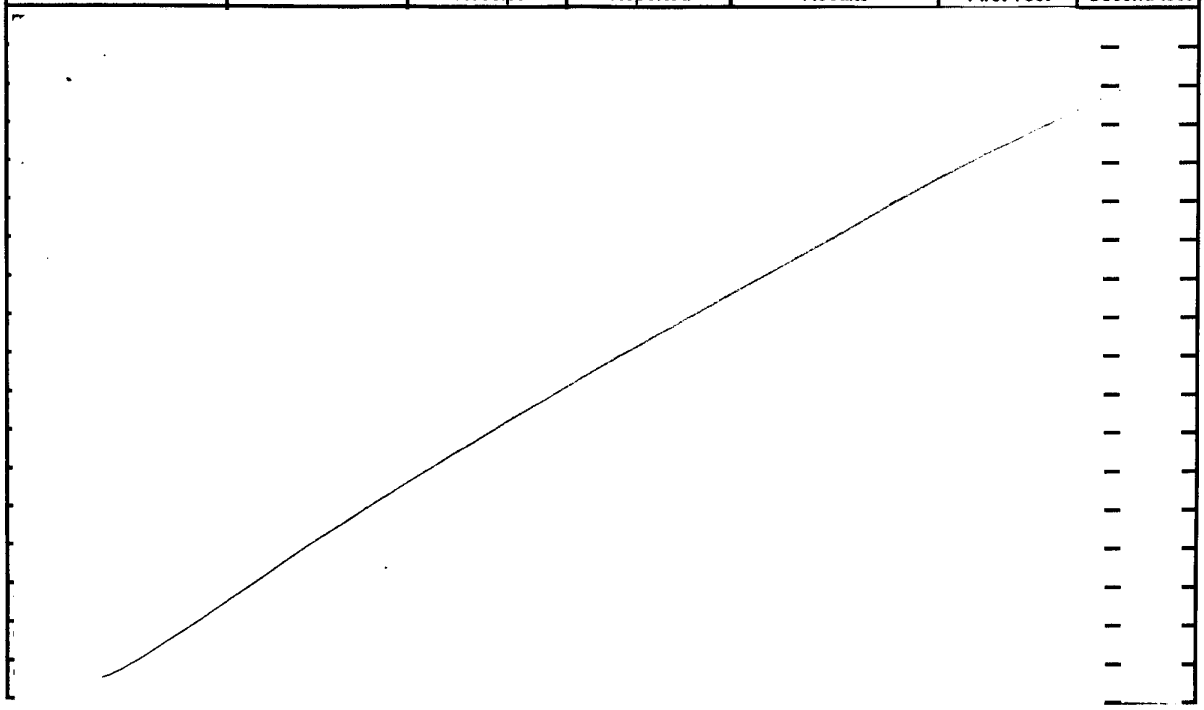
EDWARD AZARY, PH.D.

Printed Name, Responsible Person

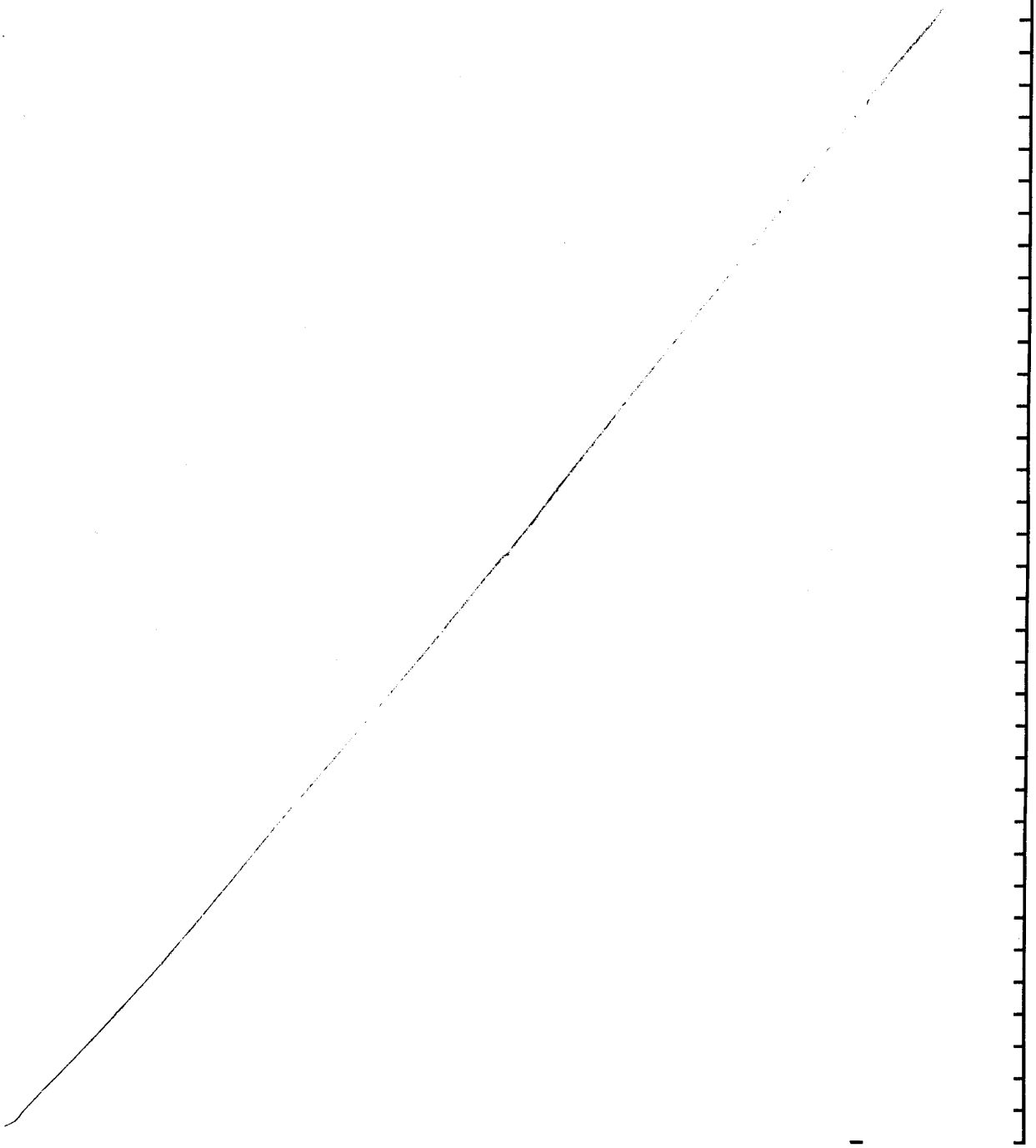
Accession #	Specimen ID #	Date of Receipt	Date Reported	Reported Results	Creatinine First Test	Creatinine Second test	Specific Gravity



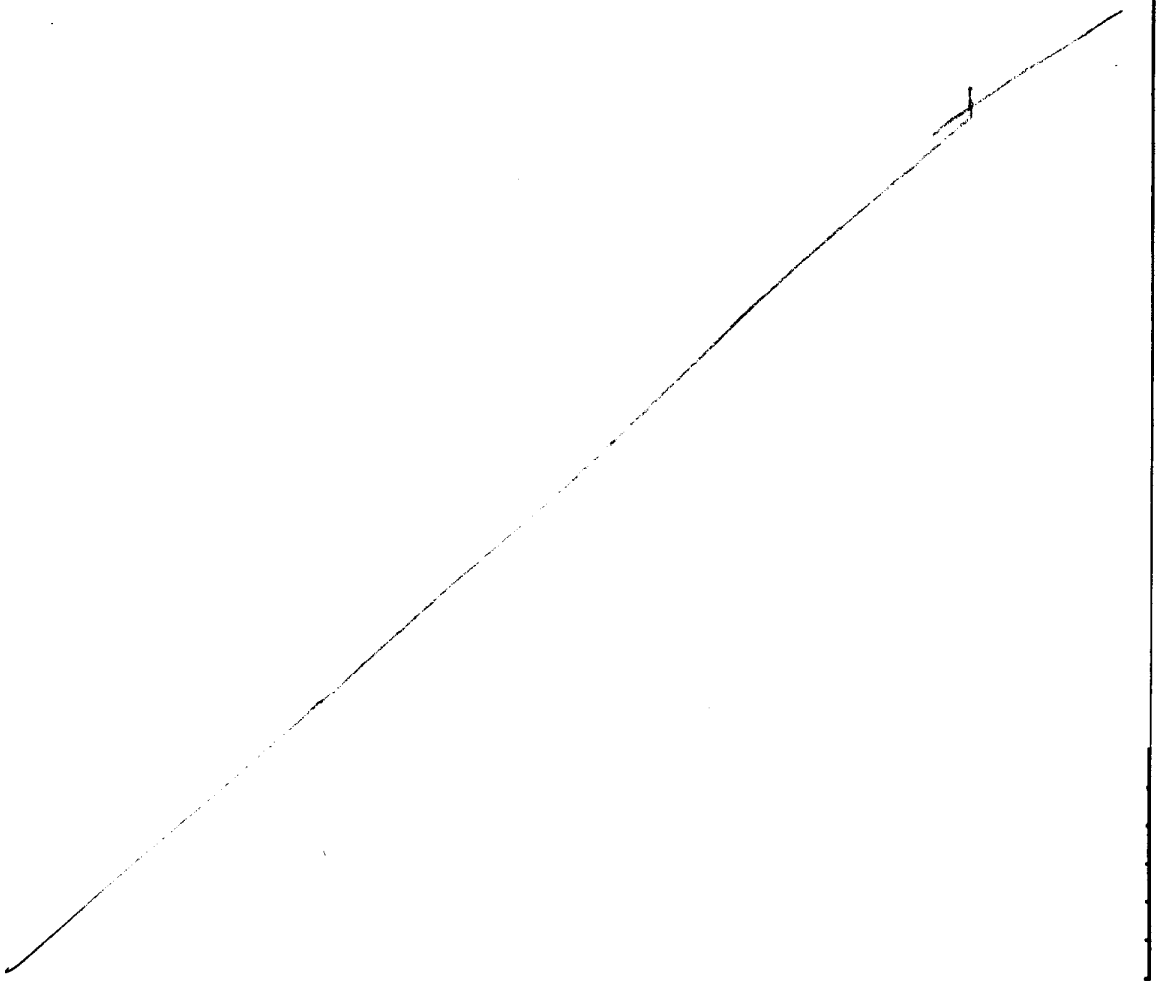
Accession #	Specimen ID #	Date of Receipt	Date Reported	Reported Results	Nitrite First Test	Nitrite Second test



Accession #	Specimen ID #	Date of Receipt	Date Reported	Reported Results	Creatinine First Test	Creatinine Second test	Specific Gravity



Accession #	Specimen ID #	Date of Receipt	Date Reported	Reported Results	Nitrite First Test	Nitrite Second test



Accession #	Specimen ID #	Date of Receipt	Date Reported	Reported Results	pH First Test	pH Second test

Accession #	Specimen ID #	Date of Receipt	Date Reported	Reported Results	pH First Test	pH Second test

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

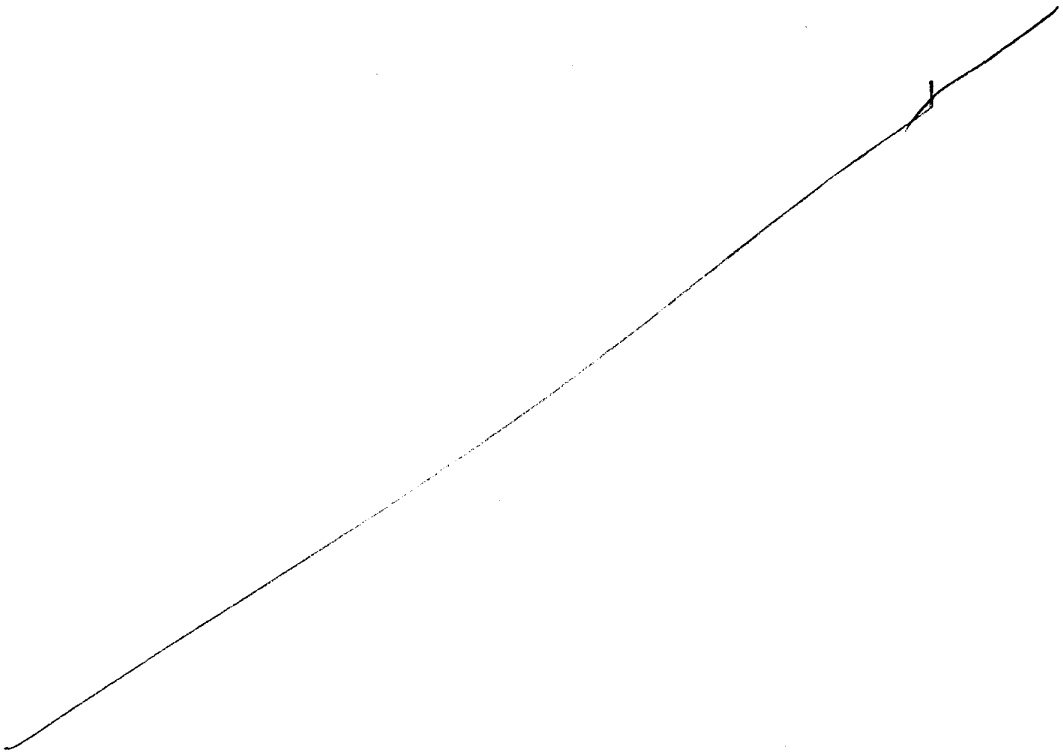
December 21, 2000

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608-1070

Dear Dr. A'Zary:

The enclosed critique was developed from the inspection report associated with the November 08, 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:

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042



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

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt055

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0055
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Teterboro, NJ

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 8 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

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

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section K. Records Audit

Section L. Certification and Reporting

Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, New Jersey 07608-1070
201.393.5000
212.736.0640

November 14, 2000

Michael Baylor, Ph.D.
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

Dear Dr. Baylor:

If you need any additional information, please feel free to contact me at 201-393-5725.

Sincerely,

Edward A'Zary Ph.D.

Edward A'Zary, Ph.D.
Director of Forensic Toxicology

Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, New Jersey 07608-1070
201.393.5000
212.736.0640

January 29, 2001

Ms. Deborah J. Denson
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road, Herman Bldg.
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

Below are the corrective actions for the RTI letter of December 21, 2000 and the comments and observations noted in the Inspection Report (Document Review and Critique) of November 8, 2000.

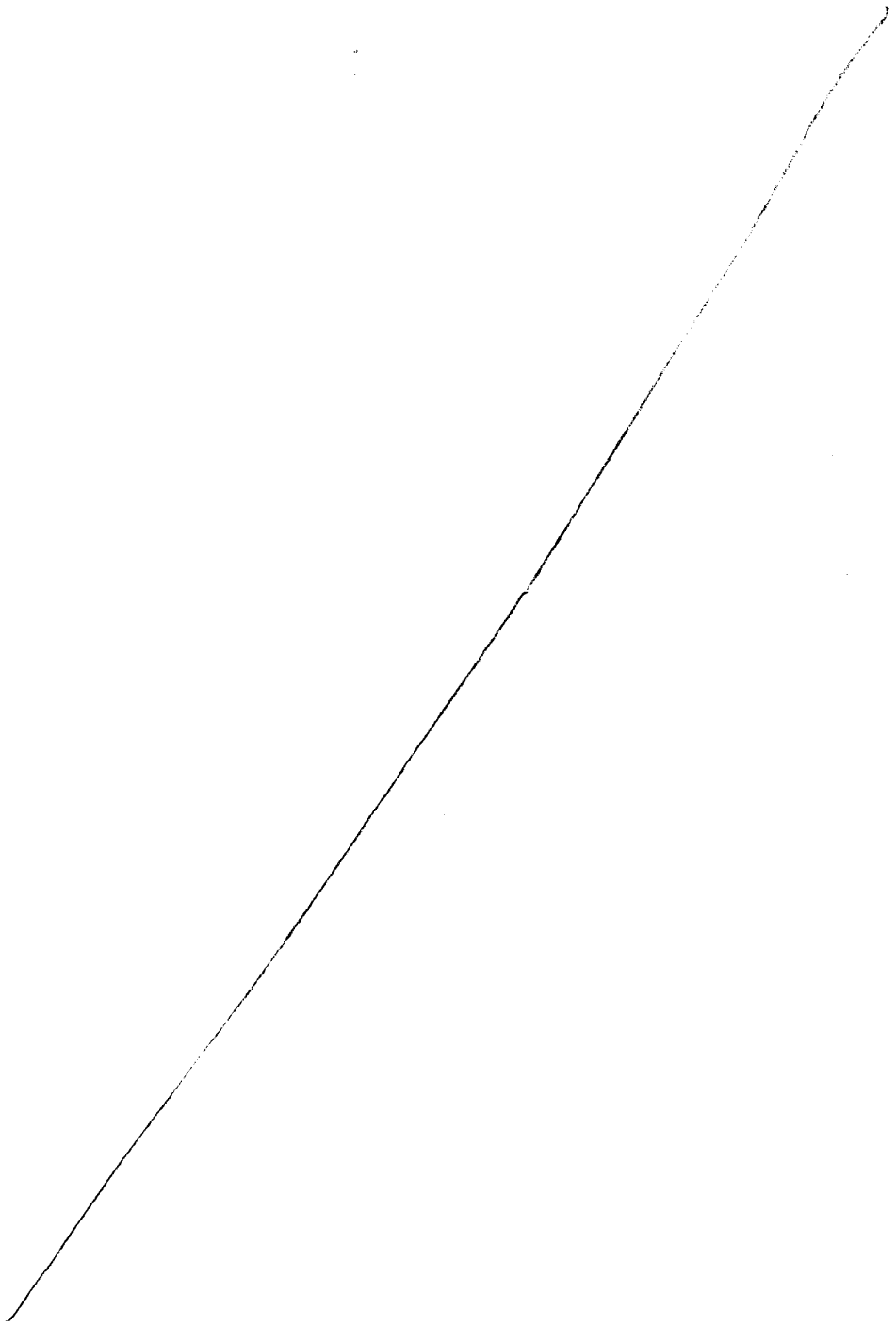
Section E. Standard Operating Procedure – Procedures Manual

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

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section K. Records Audit



Section L. Certification and Reporting

Sincerely,

Edward A'Zary, Ph.D.
Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE

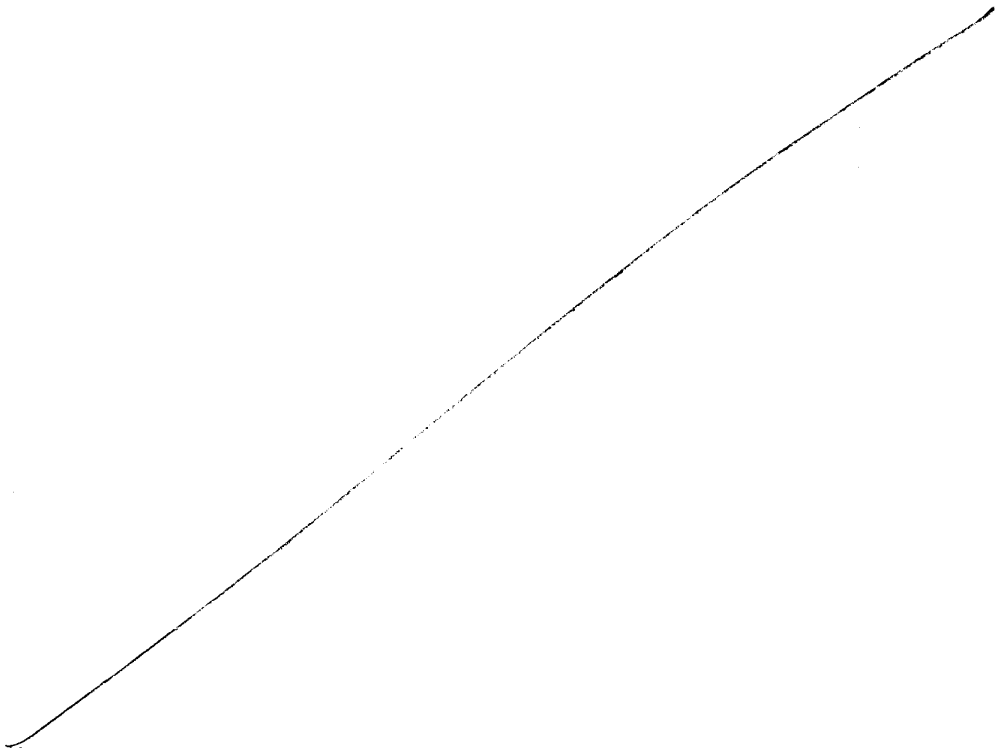
National Laboratory Certification Program

February 8, 2001

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608-1070

Dear Dr. A'Zary:

We have reviewed the material provided in your correspondence of January 29, 2001 submitted in response to issues raised during the November 08, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 21, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions are being taken to address the issues raised. The following is a review of the material submitted:



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

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/SVT055