Validity Testing Information Part I

Laboratory Name: Quest Diagnostics Inc
Address: 4770 Regent Blvd, Irving, Texas 75063

Responsible Person: H. H. Miller (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

10/3/00
Date

Harold H. Miller, Ph.D.
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).

H. H. Miller
Signature, Responsible Person

10/17/00
Date

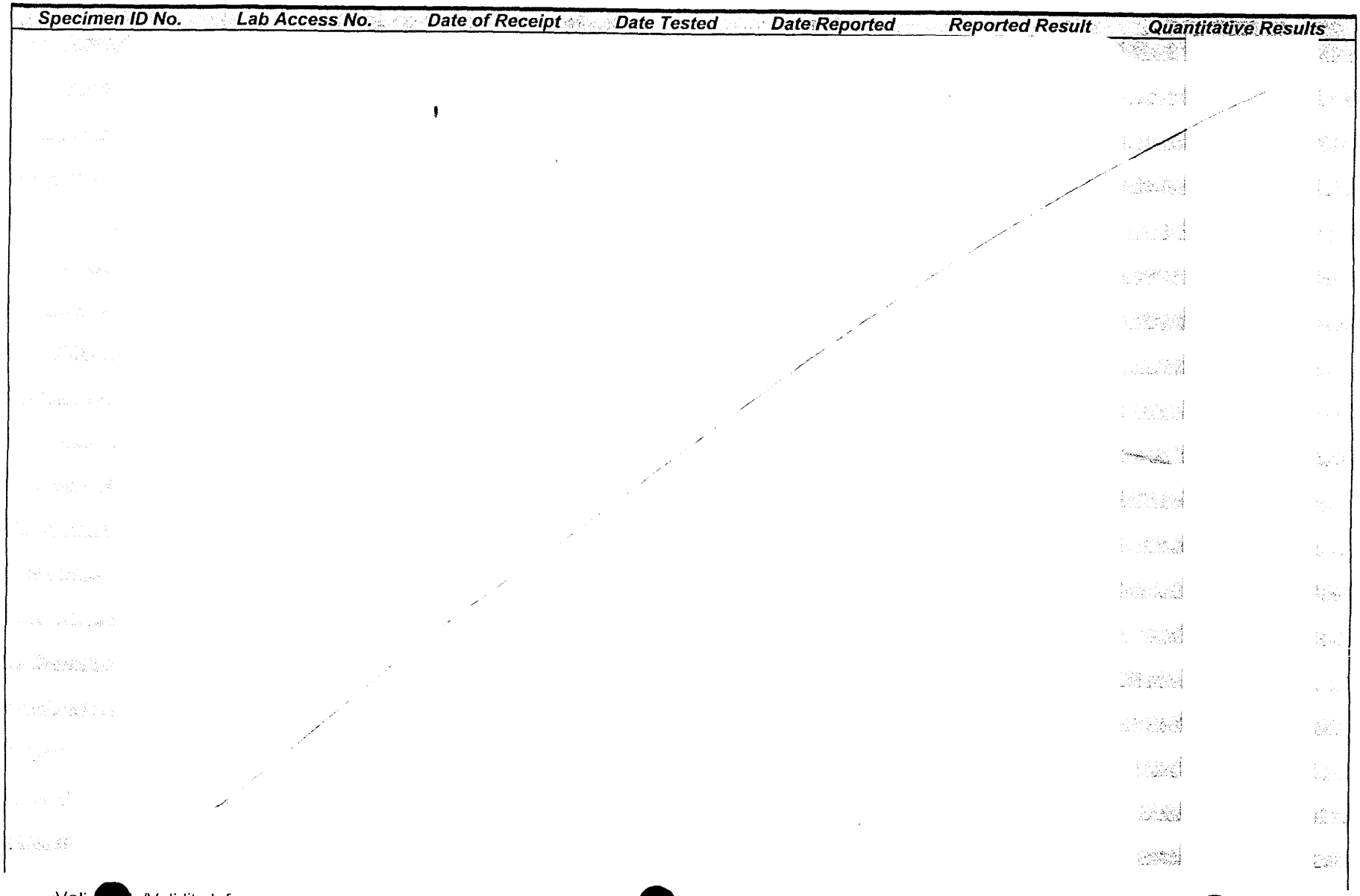
H. H. Miller
Printed Name, Responsible Person

10/17/00

SPECIMEN VALIDITY STUDY

Quest Diagnostics, Inc. Irving, Texas Lab #0336

Specimen ID No.	Lab Access No.	Date of Receipt	Date Tested	Date Reported	Reported Result	Quantitative Results

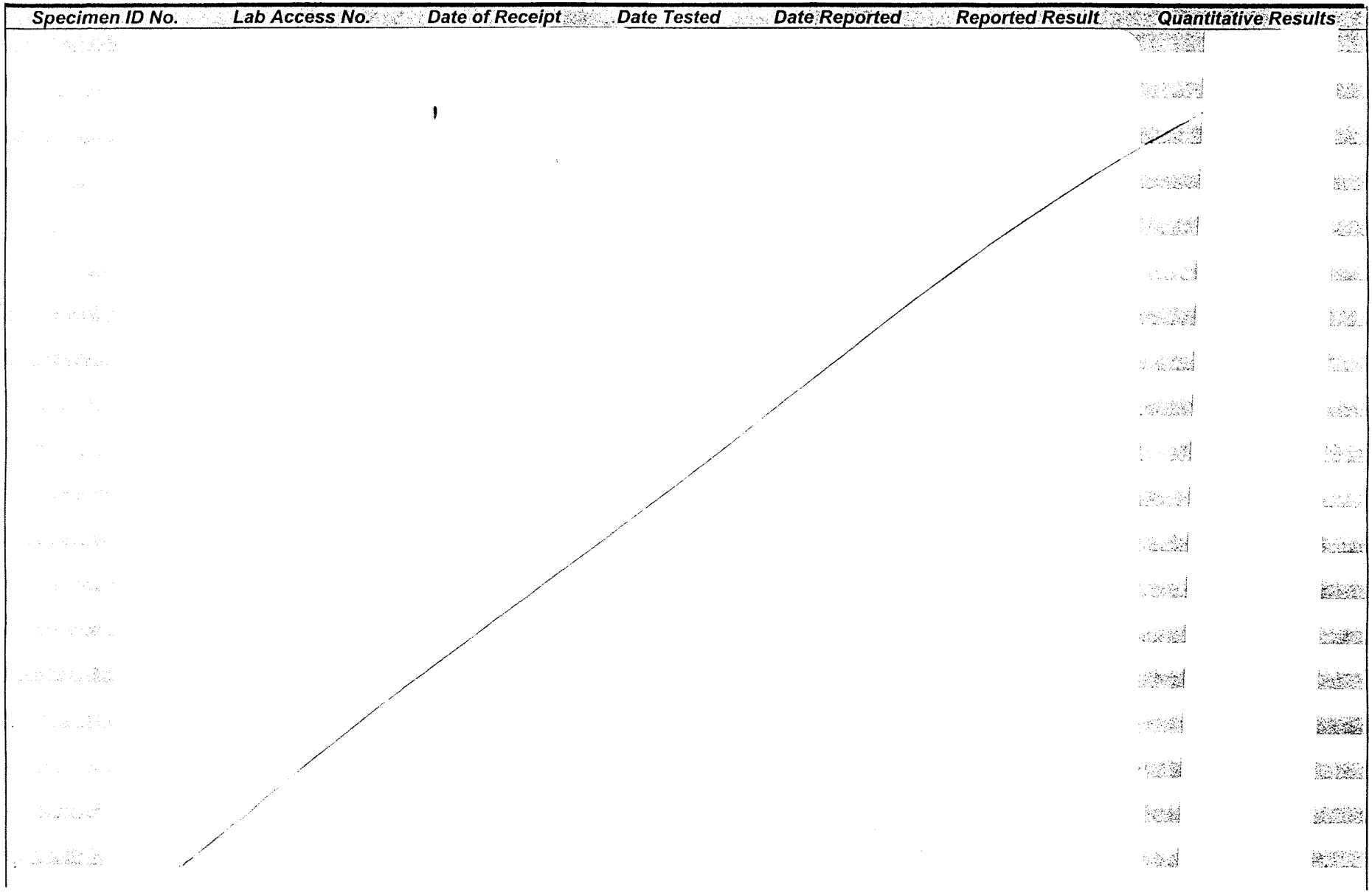


Valid[redacted]s/Validity Info

SPECIMEN VALIDITY STUDY

Quest Diagnostics, Inc. Irving, Texas Lab #0336

Specimen ID No.	Lab Access No.	Date of Receipt	Date Tested	Date Reported	Reported Result	Quantitative Results
[redacted]						



SPECIMEN VALIDITY STUDY

Quest Diagnostics, Inc. Irving, Texas Lab #0336

Specimen ID No.	Lab Access No.	Date of Receipt	Date Tested	Date Reported	Reported Result	Quantitative Results

SPECIMEN VALIDITY STUDY

Quest Diagnostics, Inc. Irving, Texas Lab #0336

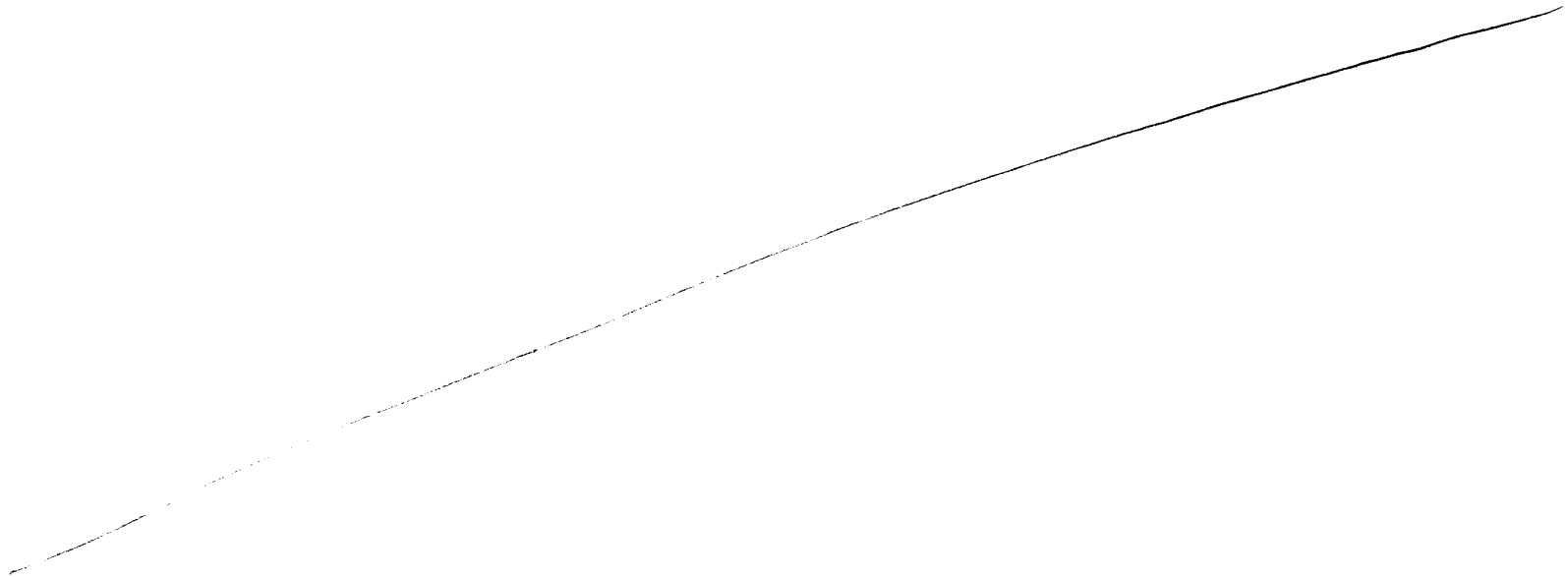
Specimen ID No.	Lab Access No.	Date of Receipt	Date Tested	Date Reported	Reported Result	Quantitative Results

Valid[redacted]s/Validity Info

SPECIMEN VALIDITY STUDY

Quest Diagnostics, Inc. Irving, Texas Lab #0336

Specimen ID No.	Lab Access No.	Date of Receipt	Date Tested	Date Reported	Reported Result	Quantitative Results



Quest Diagnostics Incorporated

4770 Regent Blvd.
Irving, TX 75063-2263
972.916.3200
800.824.6152
972.916.3379 FAX

October 26, 2000

Kenneth H. Davis
NLCP/Program Director
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ken:

In the course of preparing materials for our special validity inspection, we discovered additional information regarding those specimens reported by the Quest Diagnostics

This information is also being sent to you today via e-mail. You should receive it prior to your receipt of this letter. Thank you for your help with this project.

Sincerely,

H. H. Miller, M.T.(ASCP), Ph.D.
Responsible Person, SAMHSA Laboratory

Davis102500.doc

SPECIMEN VALIDITY STUDY

Corrections-Additions

Quest Diagnostics, Inc. Irving, Texas Lab #0336

Specimen ID No.	*Lab Access No.*	*Date of Receipt*	*Date Tested*	*Date Reported*	*Reported Result*	*Quantitative Results*

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 27, 2000

0336
Dr. Harold Miller
Quest Diagnostics Incorporated
4770 Regent Blvd.
Irving, TX 75063

Dear Dr. Miller:

The enclosed critique was developed from the inspection report associated with the November 1-3, 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 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 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. ***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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt336

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0336
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Irving, TX

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 1 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

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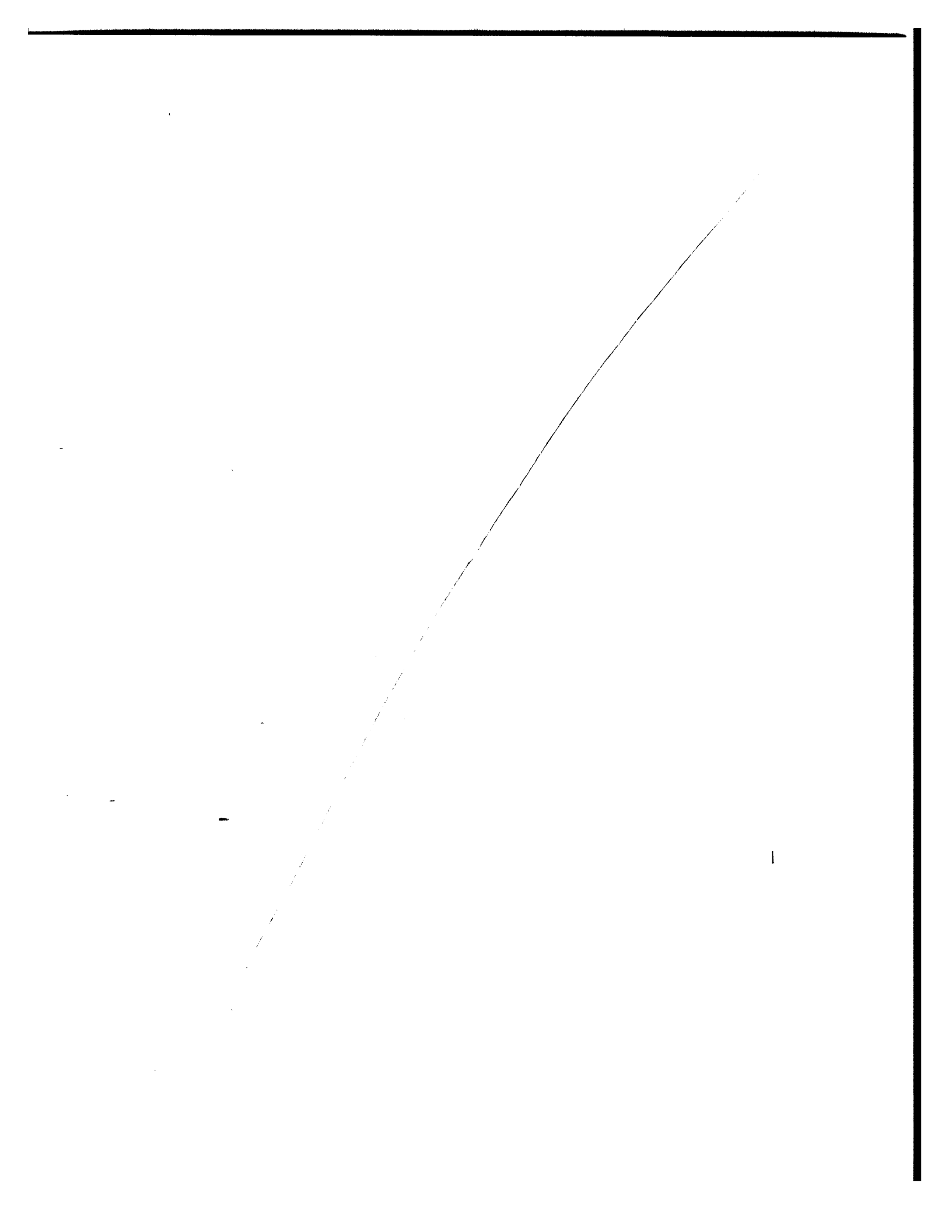
972.916.3379 FAX

December 20, 2000

Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Ms. Crumpton:

This letter is in response to the specimen validity inspection critique of the Quest Diagnostics Incorporated forensic toxicology laboratory in Irving, Texas (#0336). The response to each item is keyed to the item number as shown in the detailed critique by the inspection team. A series of attachments are also enclosed as documentation of the corrective action planned or taken.



I hope that you find these corrective actions acceptable to address the issues raised. Thank you for you assistance.

Sincerely,

H. H. Miller, M.T.(ASCP), Ph.D.
Director, Laboratory Operations and Responsible Person
Forensic Toxicology

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RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 8, 2001

0336
Dr. Harold Miller
Quest Diagnostics Incorporated
4770 Regent Blvd.
Irving, TX 75063

Dear Dr. Miller:

We have reviewed the material provided in your correspondence of December 20, 2000, submitted in response to issues raised during the November 1-3, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 27, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. However, the following issues require additional clarification and corrective action:

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 10 calendar days of receipt of this letter, information to clarify the issues listed in this correspondence. 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.***

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/SVT336

Quest Diagnostics Incorporated

4770 Regent Blvd.
Irving, TX 75063-2201
972.916.3200
800.824.6152
972.916.3379 FAX

January 17, 2001

Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

Ms. Crumpton:

I received your recent correspondence regarding my response to the findings of the special validity inspection of Quest Diagnostics Incorporated, Irving, Texas forensic toxicology laboratory (Crumpton to Miller, 1/8/01). In this letter I wish to provide a plan for implementation of the changes requested.

When all of these changes are proven to work correctly and the SOP has been revised formally and implemented, I will provide a follow-up communication to your office with copies of the SOP for your review.

Sincerely,

H. H. Miller, M.T.(ASCP), Ph.D.
Responsible Person, SAMHSA Lab

Crumpton011701.doc

Quest Diagnostics Incorporated

4770 Regent Blvd.
Irving, TX 75063-2201
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800.824.6152
972.916.3879 FAX

February 7, 2001

Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

Ms. Crumpton:

In recent correspondence to me regarding the special validity inspection of Quest Diagnostics Incorporated Irving, Texas location (#0336; Crumpton to Miller, 1/8/01) you listed several items requiring additional clarification and corrective actions. The purpose of this letter is to provide you with the additional information to address the issues raised. The numbers of the cited items below correspond to the numbers in your correspondence referenced above. I have also referenced attached documents taken from the SOP in support of the changes made.

The resolution of the above issues should complete the outstanding corrective actions with regard to the SVT inspection critique. Thank you for your comments and help with this process.

Sincerely,

H. H. Miller, M.T.(ASCP), Ph.D.
Director, Laboratory Operations and Responsible Person
Forensic Toxicology

Crumpton020701.doc

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

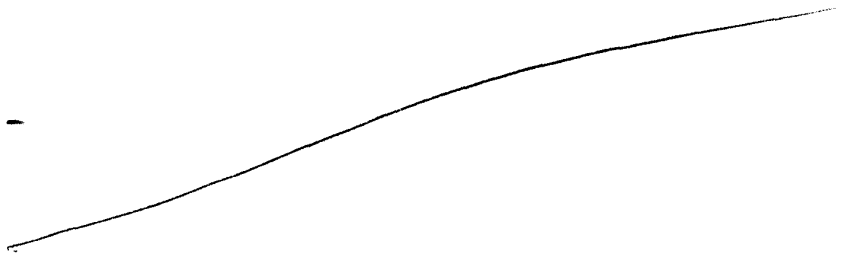
February 13, 2001

0336
Dr. Harold Miller
Quest Diagnostics Incorporated
4770 Regent Blvd.
Irving, TX 75063

Dear Dr. Miller:

We have reviewed the material provided in your correspondence of January 17 and February 7, 2001, submitted in response to issues raised during the November 1, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 27, 2000, and January 8, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. However, the laboratory must address the following issue raised during our review of submitted standard operating procedures (SOPs):

•



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 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 or referral to the Department of Transportation for Public Interest Exclusion action.***

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

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/SVT0336