RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 17, 2000

0138
Mr. M. P. George
Ms. Carole Trojan
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George and Ms. Trojan:

The enclosed critique was developed from the inspection report associated with the October 18, 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:

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.

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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt138

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0138
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Schaumburg, IL

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

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section K. Records Audit

Section L. Certification and Reporting

Quest Diagnostics Incorporated

506 East State Parkway
Schaumburg, IL 60173

December 2, 2000

Deborah Denson
Research Triangle Institute
3040 Cornwallis Rd
Research Triangle Institute, NC 27709

Dear Ms. Denson:

The following corrective actions have been implemented in response to the Specimen Validity Inspection.

Attached our copies of the revised procedure from our SOP.

Please call if you have any questions, 1-800-669-6995.

Sincerely,

M.P. George
Carole Trojan

RESEARCH TRIANGLE INSTITUTE

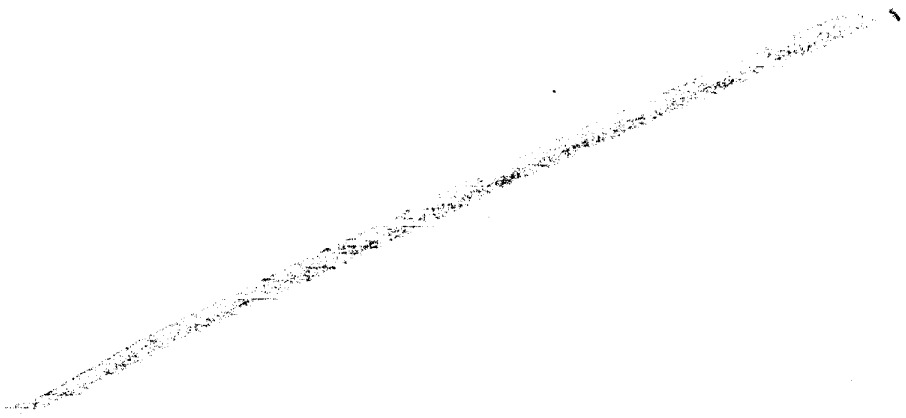
National Laboratory Certification Program

December 15, 2000

0138
Mr. M. P. George
Ms. Carole Trojan
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George and Ms. Trojan:

We have reviewed the material provided in your correspondence of December 2, 2000 submitted in response to issues raised during the October 18, 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 corrective actions have been completed to address the issues raised. The following is a review of the material submitted:



Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure 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.

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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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT138

Validity Testing Information Part I

Laboratory Name: Quest Diagnostics Inc
Address: ~~506 E. State Parkway~~ Schaumburg, IL 60173
Responsible Person: ~~M. P. Gerogl~~ Carole Tagsan (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).

Carole Trogan — 10-4-2000

Signature, Responsible Person — Date

M. P. GEORGE / CAROLE TROGAN

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).

Carole Teagan — 10/16/00

Signature, Responsible Person — Date

M.P. LABORATORY CAROLE TEAGAN

Printed Name, Responsible Person

Quest Diagnostics Incorporated

506 East State Parkway
Schaumburg, IL 60173

October 19, 2000

Research Triangle Institute
Suzanne P. Clark
NLCP Program
3040 Cornwallis Rd
Research Triangle Pk, NC

Dear Ms. Clark:

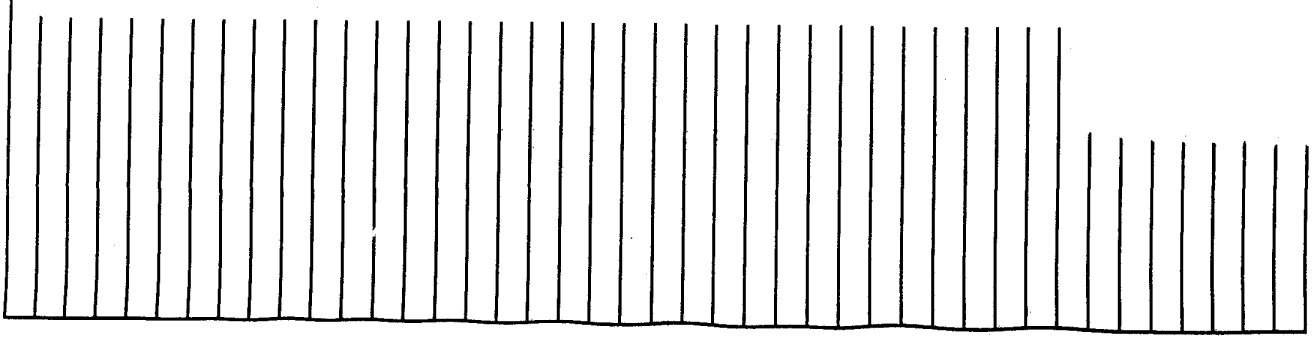
During a 2nd review of records

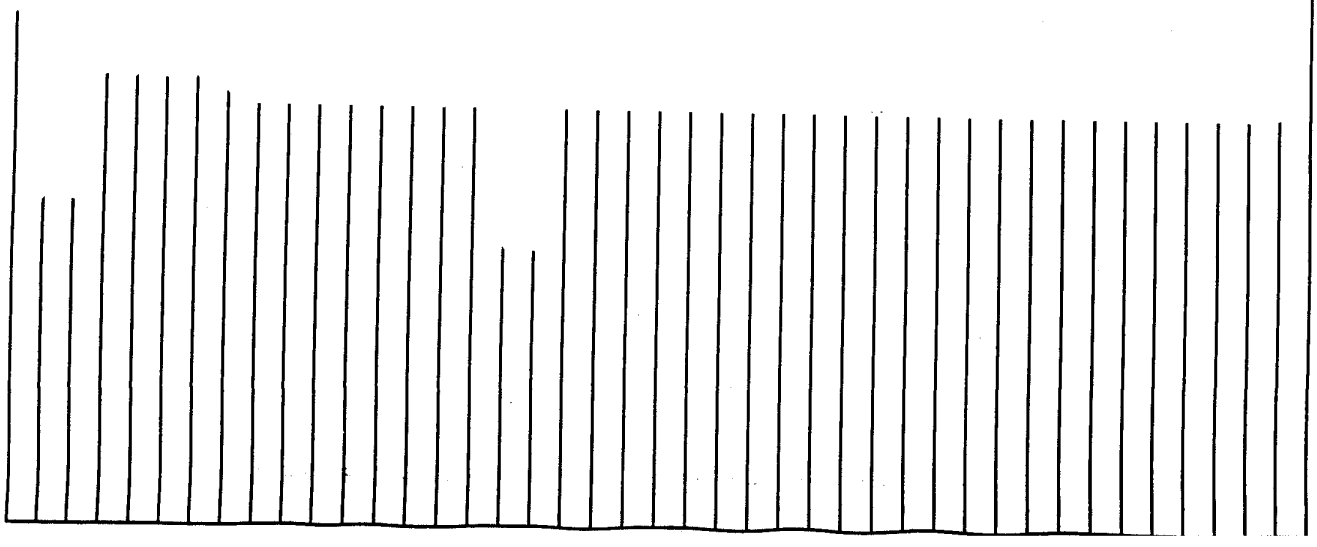
Sincerely,

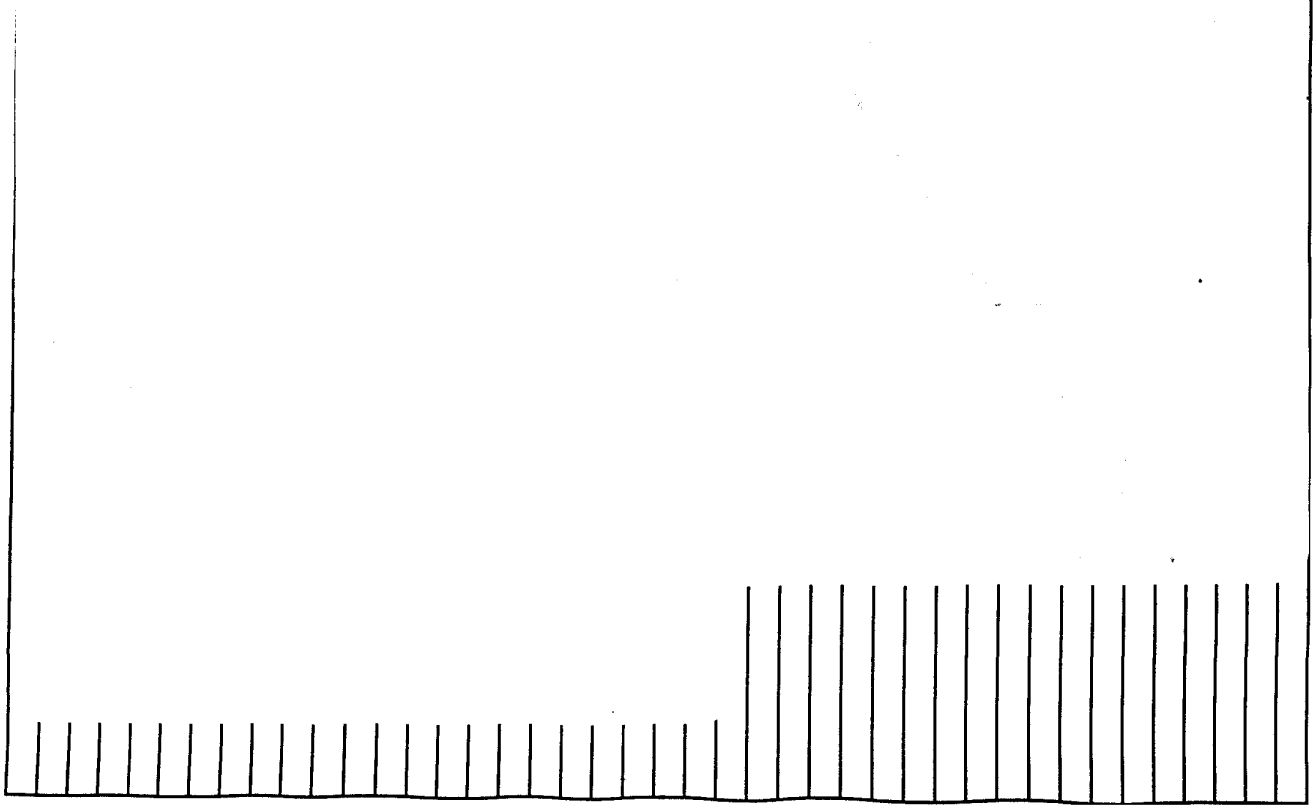
Carole Trojan

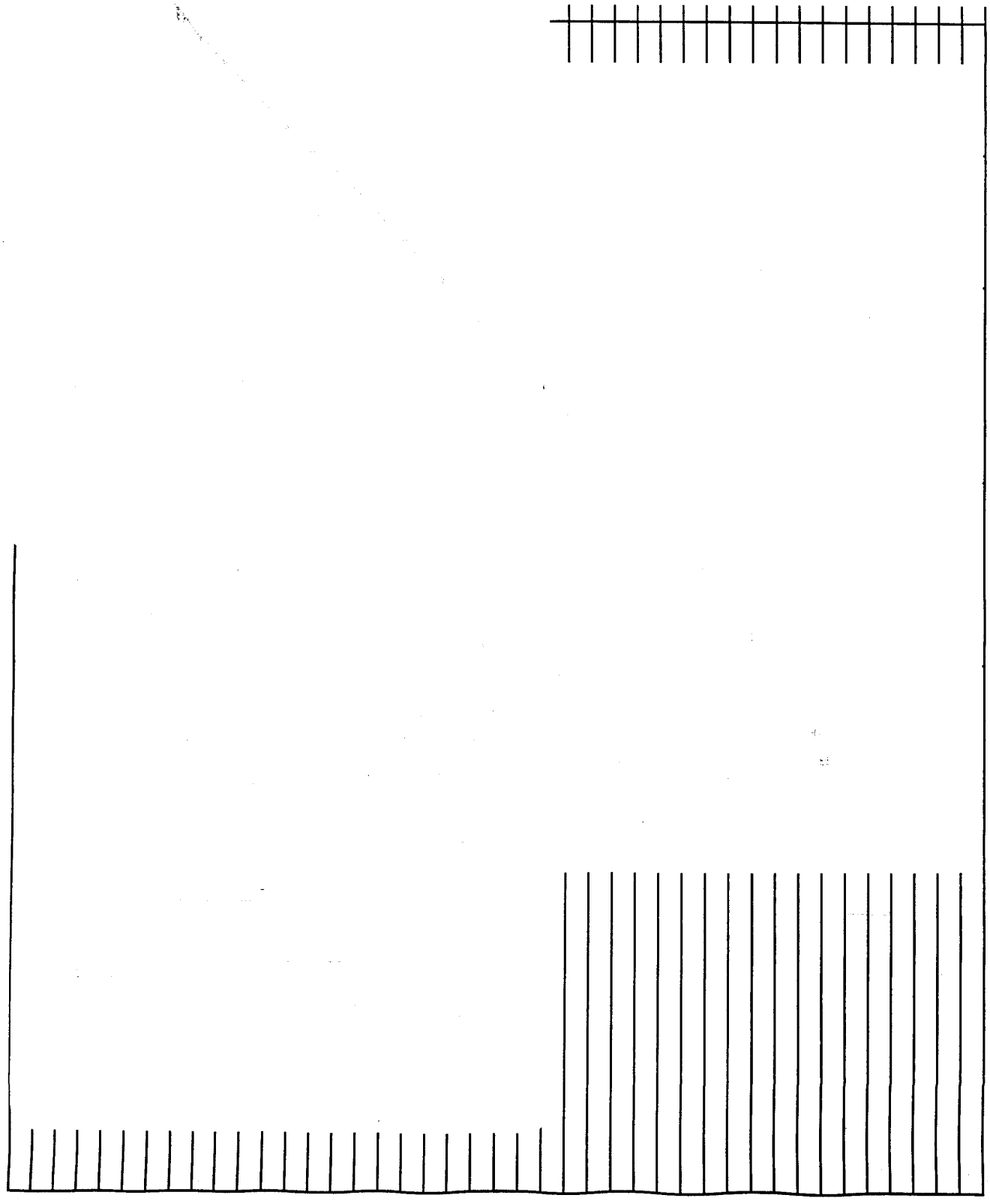
Revised
10-23-00 FW

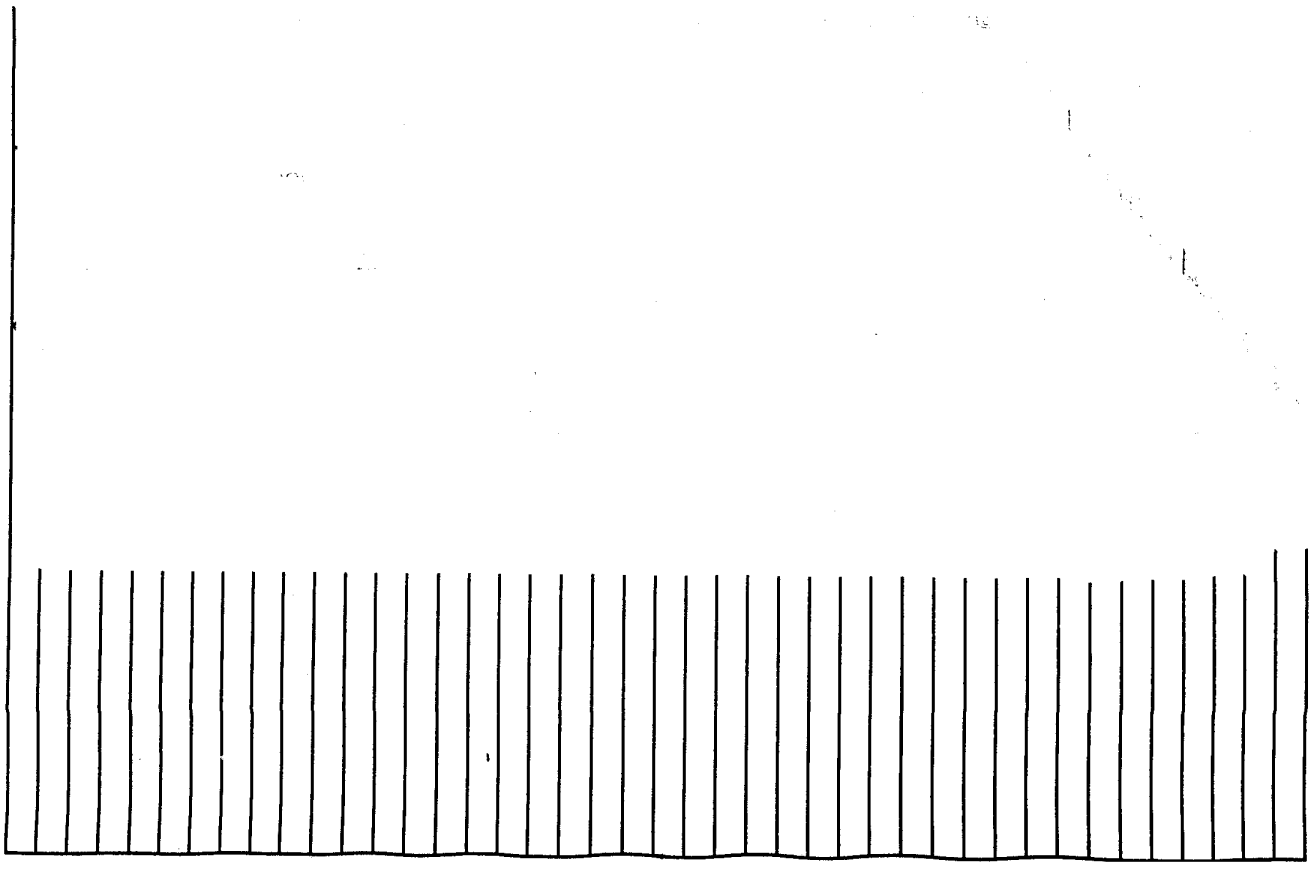
SPECIMEN ID	ACCESSION #	DATE RCVD	DATE REPORTED	REPORTED RESULT	QUANTITATIVE RESULTS	COMMENTS

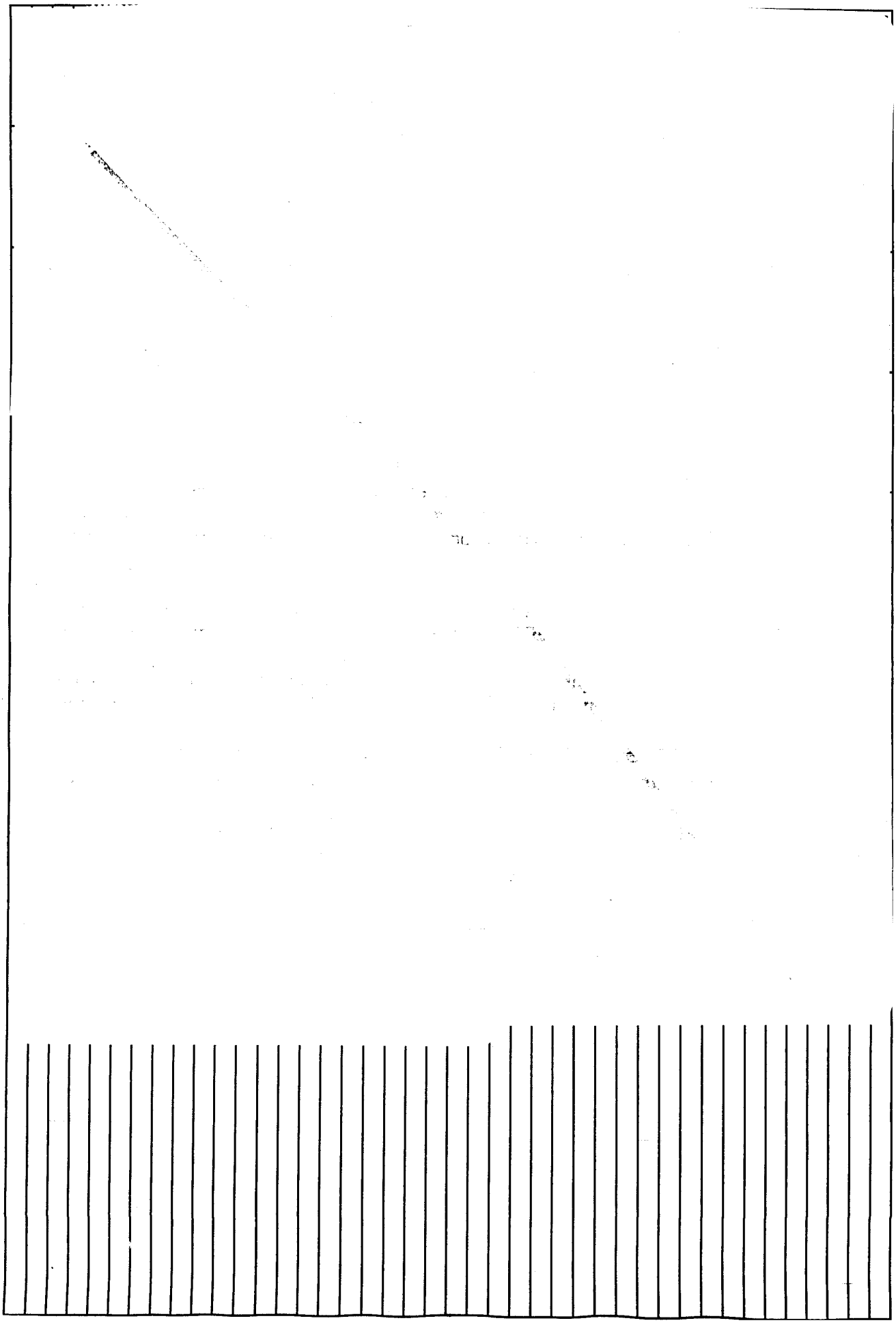


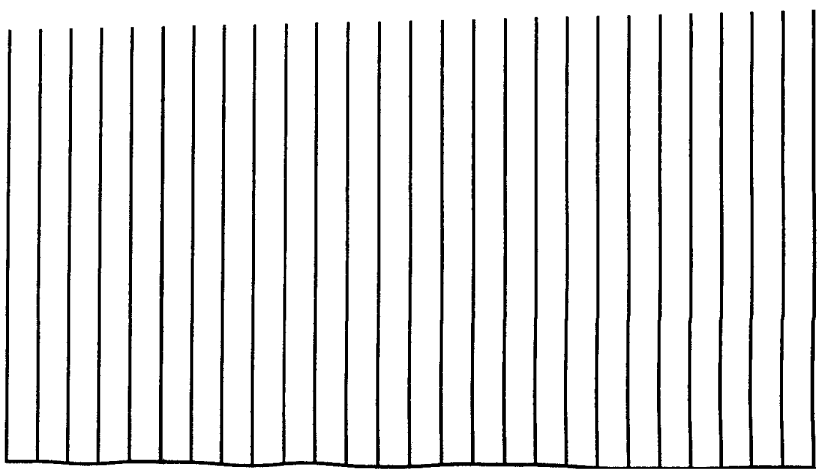












DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

*U.S. GPO: 1989-624-403

Validity Testing Information Part I

Laboratory Name: QUEST DIAGNOSTICS
Address: 1355 Mittel Blvd. Wood Dale, IL 60191
(Alternate)
Responsible Person: PORFIRIA MONJE (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).

P Monte — 10/19/00

Signature, Responsible Person (Alternate) — Date

PORFIRIA MONTE

Printed Name, Responsible Person (Alternate)

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:

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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).

P Monje — 10/19/00

Signature, Responsible Person (Alternate) — Date

PORFIRIA MONJE

Printed Name, Responsible Person (Alternate)

.CH TRIANGLE INSTITUTE

National Laboratory Certification Program

September 29, 2000

TO: All NLCP Certified Laboratories

The National Laboratory Certification Program (NLCP) staff at SAMHSA and RTI have been requested by the Department of Transportation to obtain information from each NLCP certified laboratory regarding its validity testing procedures and reported results.

***Each laboratory must complete and provide the Validity Testing Information Part I to RTI by close of business (COB) on* October 5, 2000.**

Each laboratory must complete and provide the Validity Testing Information Part II to RTI by close of business (COB) on October 17, 2000.

Do not discard or destroy any DOT/HHS regulated specimens that are adulterated and/or substituted until further notification.

If you have any questions, please contact Dr. John Mitchell (919 541-6778), Dr. Michael Baylor (919 541-7043), or me (919 541-6709).

Sincerely,

Kenneth H. Davis, Jr.
NLCP/RTI Program Director

Enclosure

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