Validity Testing Information Part I

Laboratory Name: Quest Diagnostics Inc.
Address: 4444 Giddings Rd
Auburn Hills MI 48326

Responsible Person: Marvin Gu (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

OCT 0 5 2000

Date

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

OCT 1 6 2000

Date

MANOK KIM
PH.D., DABCC

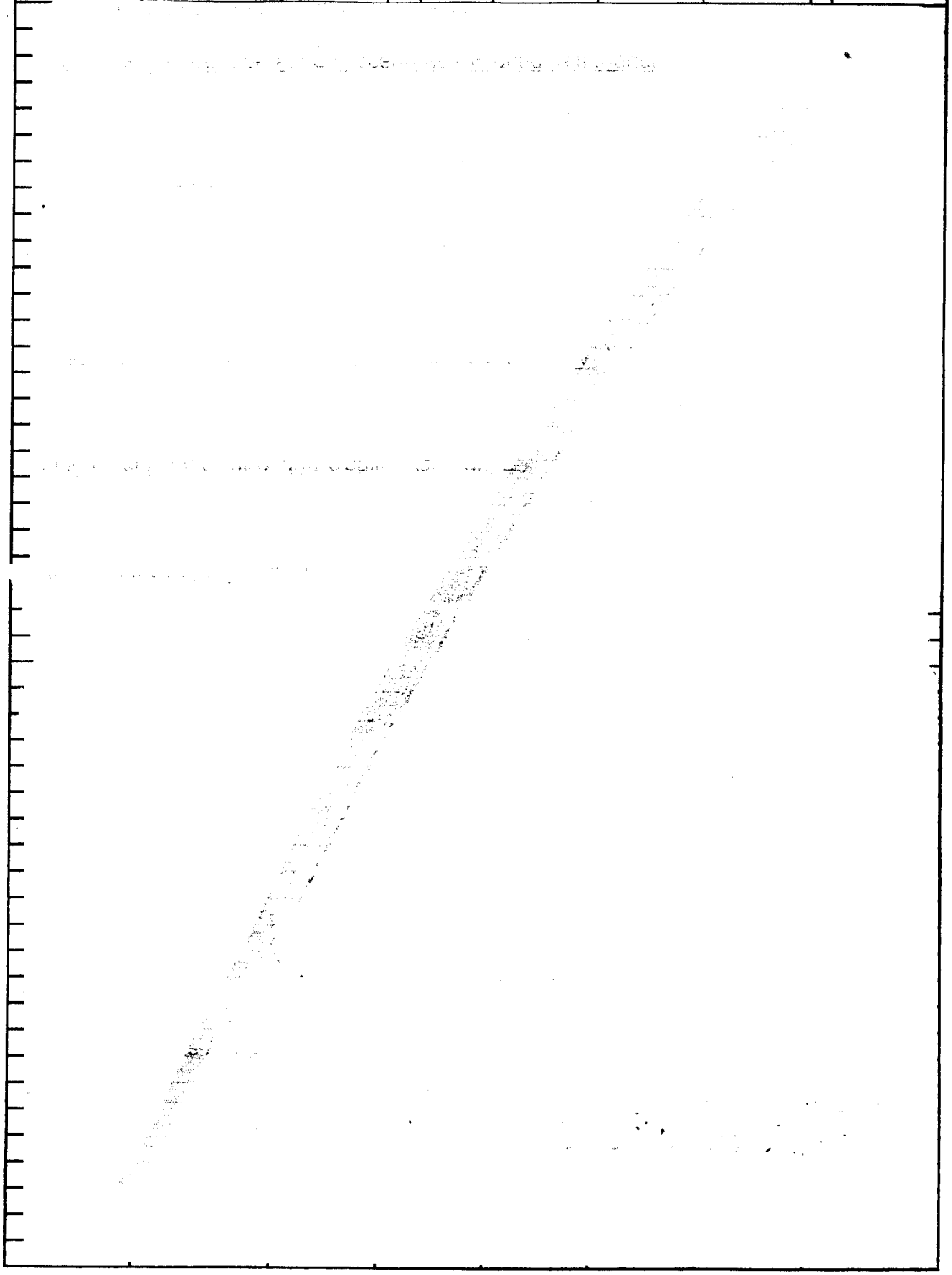
Printed Name, Responsible Person

Quest Diagnostics Inc.
4444 Giddings Rd
Auburn Hills MI 48326

Quest Diagnostics Inc.
4444 Giddings Rd
Auburn Hills MI 48326

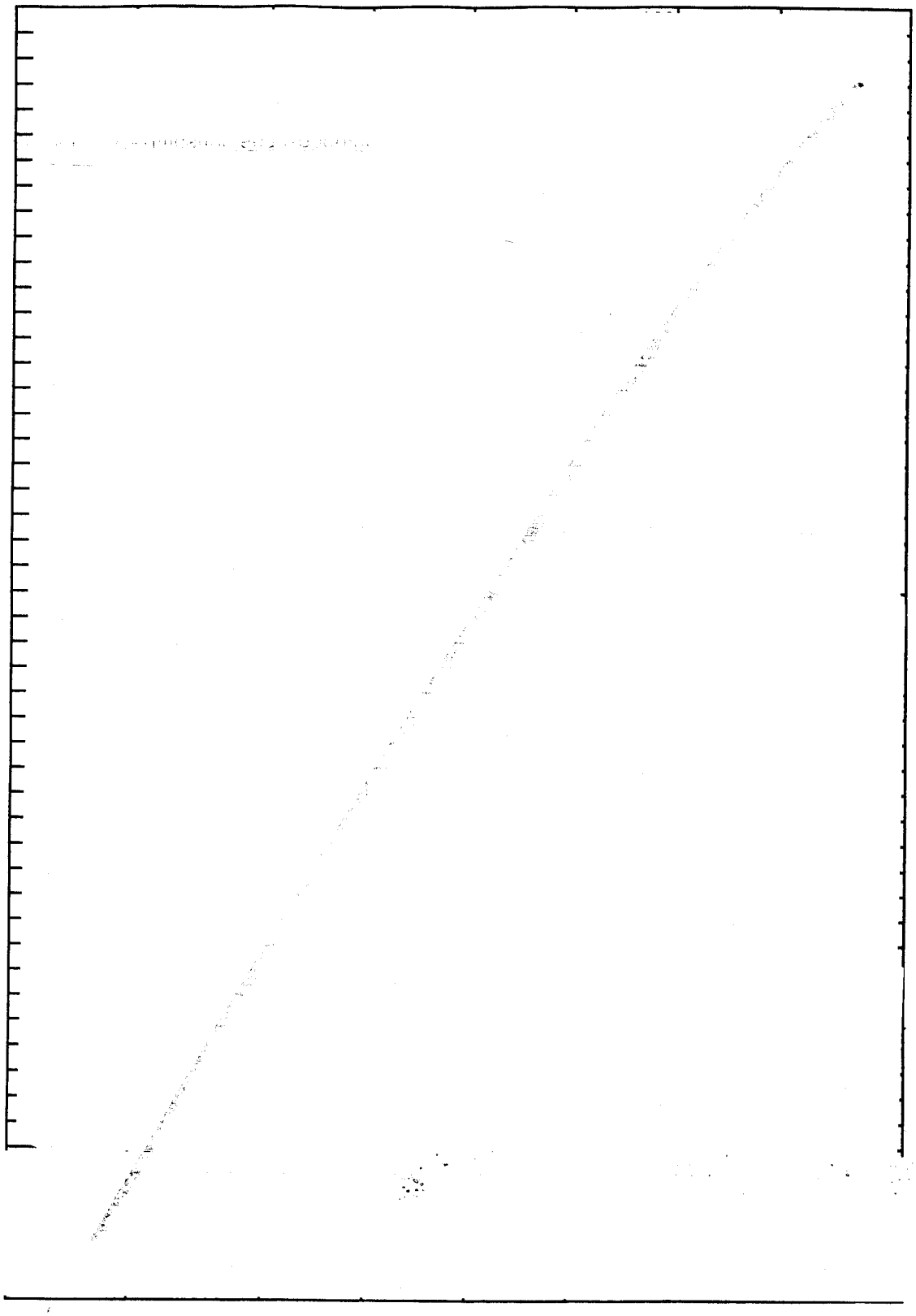
Lab # 0140, 444 Gidding Rd, Auburn Hills, MI

ID #	Accession#	Received	Reported	Adul/Sub	Nitrite	Creat	Sp.Gr.

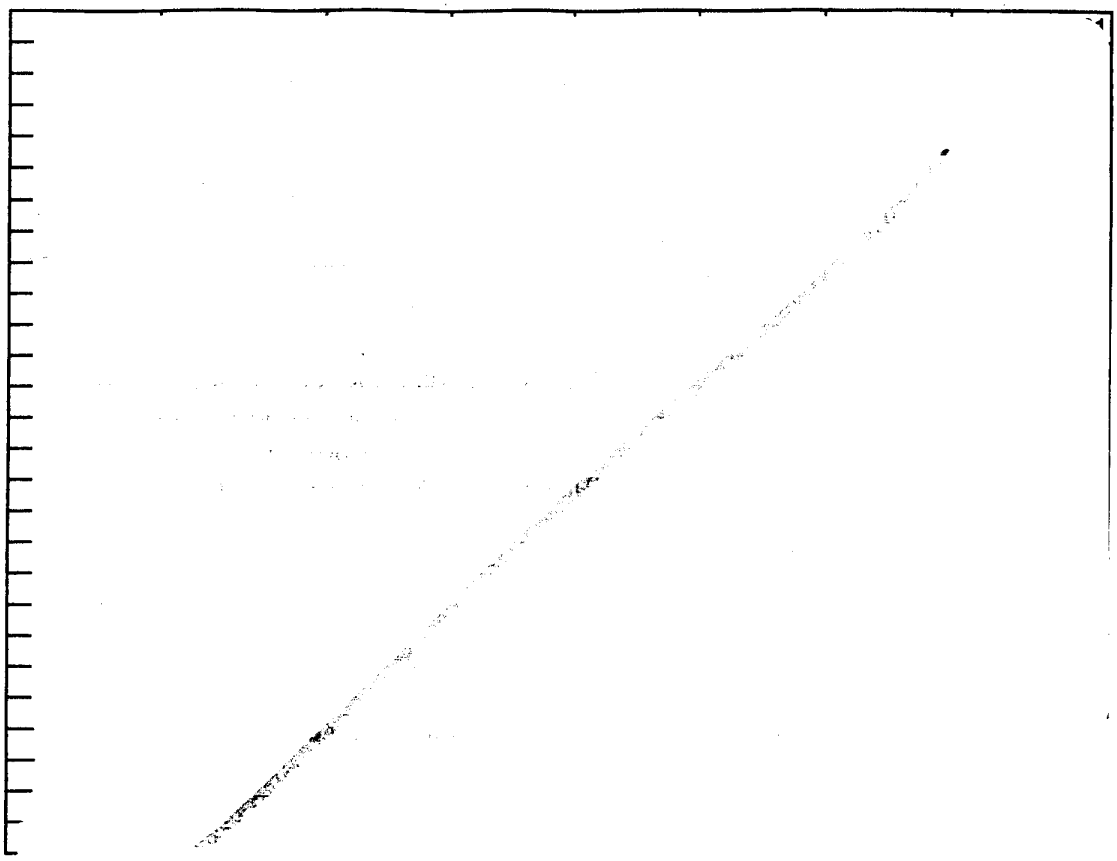


140 SV7 audit.xls

Quest Diagnostics Inc.
4444 Giddings Rd
Auburn Hills MI 48326



Quest Diagnostics Inc.
4444 Giddings Rd
Auburn Hills MI 48326



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 13, 2000

0140
Dr. Manok Kim
Quest Diagnostics Incorporated
4444 Giddings Road
Auburn Hills, MI 48326

Dear Dr. Kim:

The enclosed critique was developed from the inspection report associated with the November 8, 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. ***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 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

Enclosure

cc: Project Files/svt140

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0140
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Auburn Hills, MI

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

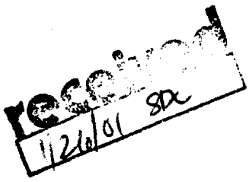
Section I. Specimen Validity Tests

Section K. Records Audit

Section L. Certification and Reporting

Quest Diagnostics Incorporated

4444 Giddings Rd.
Auburn Hills, MI 48326
248.373.9120



Jan 25,2001

Susan Crumpton
National laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton,

I am responding to your letter dated December 15, 2000.

Please let me know if you have any questions.

Sincerely,

Manok Kim, RP

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 29, 2001

0140
Dr. Manok Kim
Quest Diagnostics Incorporated
4444 Giddings Road
Auburn Hills, MI 48326

Dear Dr. Kim:

We have reviewed the material provided in your correspondence of January 25, 2001, submitted in response to issues raised during the November 8, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 13, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following issues were raised during our review of the laboratory's submission:

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, documentation of corrective actions addressing 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 or referral to the Department of Transportation for Public Interest Exclusion action.***

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/SVT140

Quest Diagnostics Incorporated

4444 Giddings Rd.
Auburn Hills, MI 48326
248.373.9120

February 10,2001

Susan Crumpton
NLCP Technical Analyst
3040 Cornwallis Road
Research Triangle Park, NC 27709

Ms. Susan Crumpton

This is reply the letter of January 29,2001 regarding specimen validity testing inspection.

If you have any questions, please call me at 800-444-0106 Ext 1670

Manok Kim

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 15, 2001

0140
Dr. Manok Kim
Quest Diagnostics Incorporated
4444 Giddings Road
Auburn Hills, MI 48326

Dear Dr. Kim:

We have reviewed the material provided in your correspondence of February 10, 2001, submitted in response to remaining issues from the November 8, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of January 29, 2001. The information submitted by the laboratory appears to demonstrate that the laboratory is taking appropriate corrective actions 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 comply with program guidance on specimen validity testing. 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.***

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/SVT0140