Validity Testing Information Part I

Laboratory Name: QUEST DIAGNOSTICS
Address: 3000 SOUTHERN RD

Responsible Person: ROMEO I. SOLANO, M.D. (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).

Romeo I. Solano, PhD
Signature, Responsible Person

10/6/2000
Date

Romeo I. Solano, PhD
Printed Name, Responsible Person

Quest Diagnostics Incorporated

8000 Sovereign Row
Dallas, Texas 75247
214.638.1301

October 20, 2000

Ken H. Davis, Jr
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Dear Mr. Davis:

Enclosed please find the Validity Testing Information Part II.

Sincerely,

Romeo I Solano, Ph.D.
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

10/20/2003
Date

Romeo I. Solano, Ph.D
Printed Name, Responsible Person

Validity Testing Information Part II

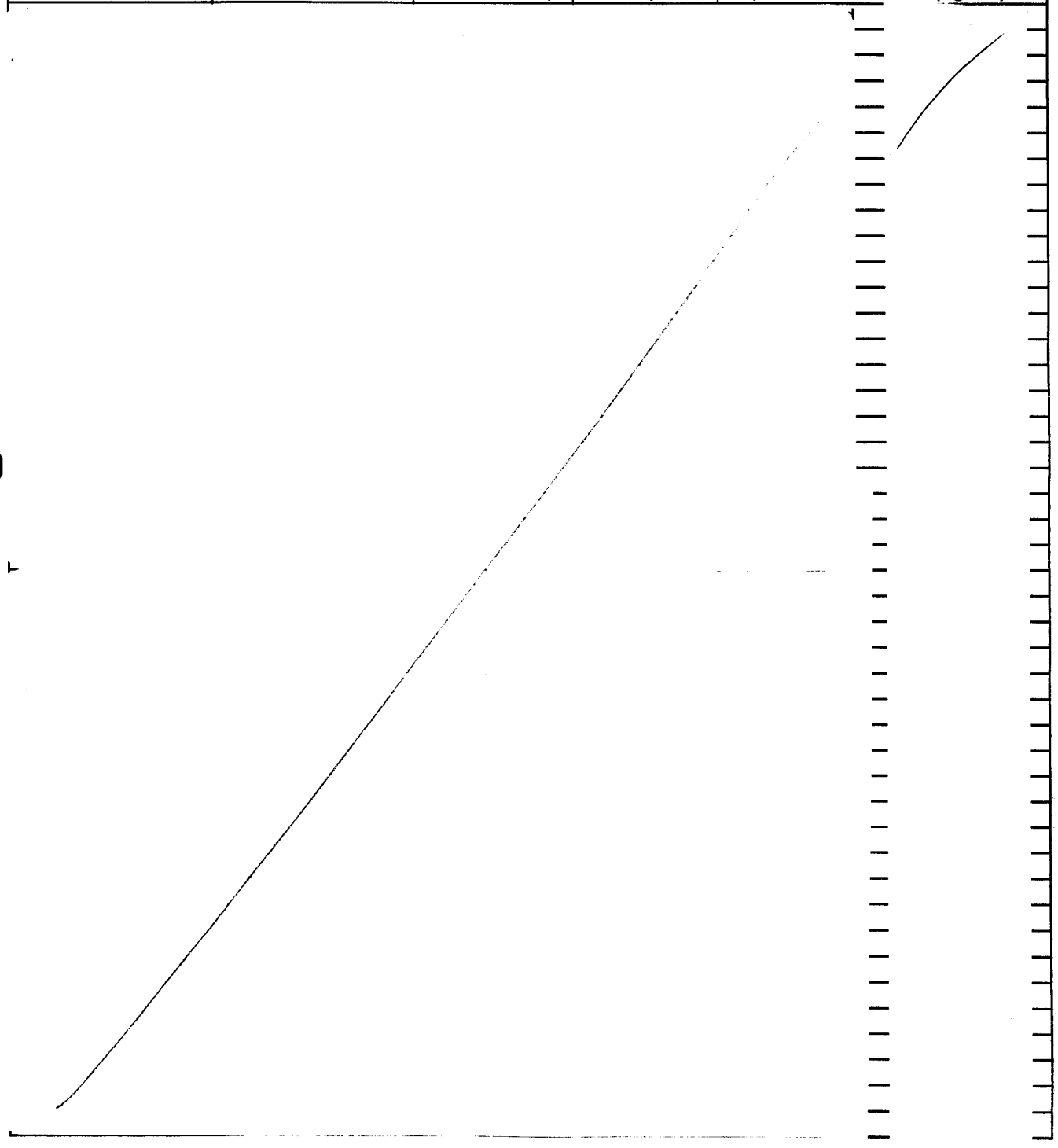
Substituted

Specimen ID Number	Laboratory Accession Number	Date of Receipt	Date reported	Reported Result	Creatinine mg/dL	Specific Gravity

Validity Testing Information Part II

Nitrite

Specimen ID Number	Laboratory Accession Number	Date of Receipt	Date reported	Reported Result	Quantitative Result NITRITE (ug/mL)



Validity Testing Information Part II

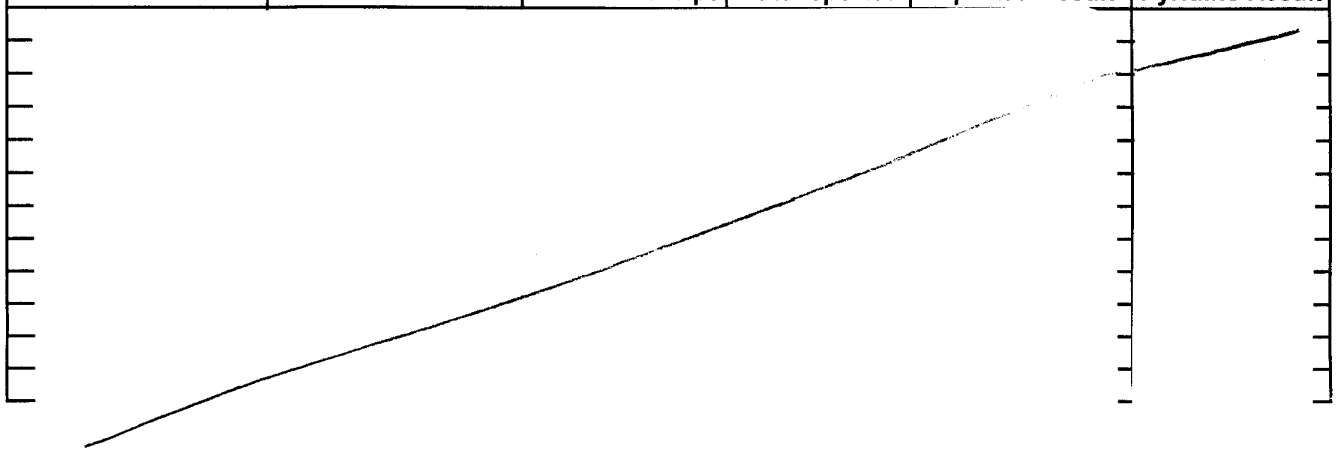
pH

Specimen ID Number	Laboratory Accession Number	Date of Receipt	Date reported	Reported Result	pH

Validity Testing Information Part II

Pyridine

Specimen ID Number	Laboratory Accession Number	Date of Receipt	Date reported	Reported Result	Pyridine Result



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 15, 2000

0035
Dr. Romeo Solano
Quest Diagnostics Incorporated
8000 Sovereign Row
Dallas, TX 75247

Dear Dr. Solano:

The enclosed critique was developed from the inspection report associated with the October 25-27, 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.

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/svt035

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0035
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Dallas, TX

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 25 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

8000 Sovereign Row
Dallas, Texas 75247
214.638.1301

received
SDC 12/19/00

December 14, 2000

Ms. Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

This letter is in response to the issues raised during the October 25-27, 2000, specimen validity testing of Quest Diagnostics Incorporated (0035). The organization of these responses parallel the issues cited in your letter dated November 15, 2000.

I believe I have addressed all concerns raised in our specimen validity testing inspection. If you need additional clarification or information, please do not hesitate to contact me at 1-214-637-7236.

Sincerely,

Romeo I. Solano, Ph.D.
Forensic Director

SVT response 1200.DOC

Encls.

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 3, 2001

0035
Dr. Romeo Solano
Quest Diagnostics Incorporated
8000 Sovereign Row
Dallas, TX 75247

Dear Dr. Solano:

We have reviewed the material provided in your correspondence of December 14, 2000, submitted in response to issues raised during the October 25-27, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 15, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address most issues raised.

The laboratory must address the following issues:

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 take corrective action to address the issues outlined in this correspondence and have documentation organized and available for review at the next specimen validity testing 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0035

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 12, 2001

0035
Dr. Romeo Solano
Quest Diagnostics Incorporated
8000 Sovereign Row
Dallas, TX 75247

Dear Dr. Solano:

We have reviewed the inspector's report from the January 29-30, 2001, specimen validity testing inspection of your laboratory. The information submitted by the inspector appears to demonstrate that appropriate corrective actions have been completed to address the issues raised in the laboratory's October 25-27, 2000, specimen validity testing inspection.

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. 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/SVT0035

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Telephone 919 541-6709 • Fax 919 541-7042