Validity Testing Information Part I

Laboratory Name: Quest Diagnostics, Incorporated
Address: 3175 Presidential Drive
Atlanta, GA 30340
Responsible Person: Barry Sample, Ph.D. (Printed Name)

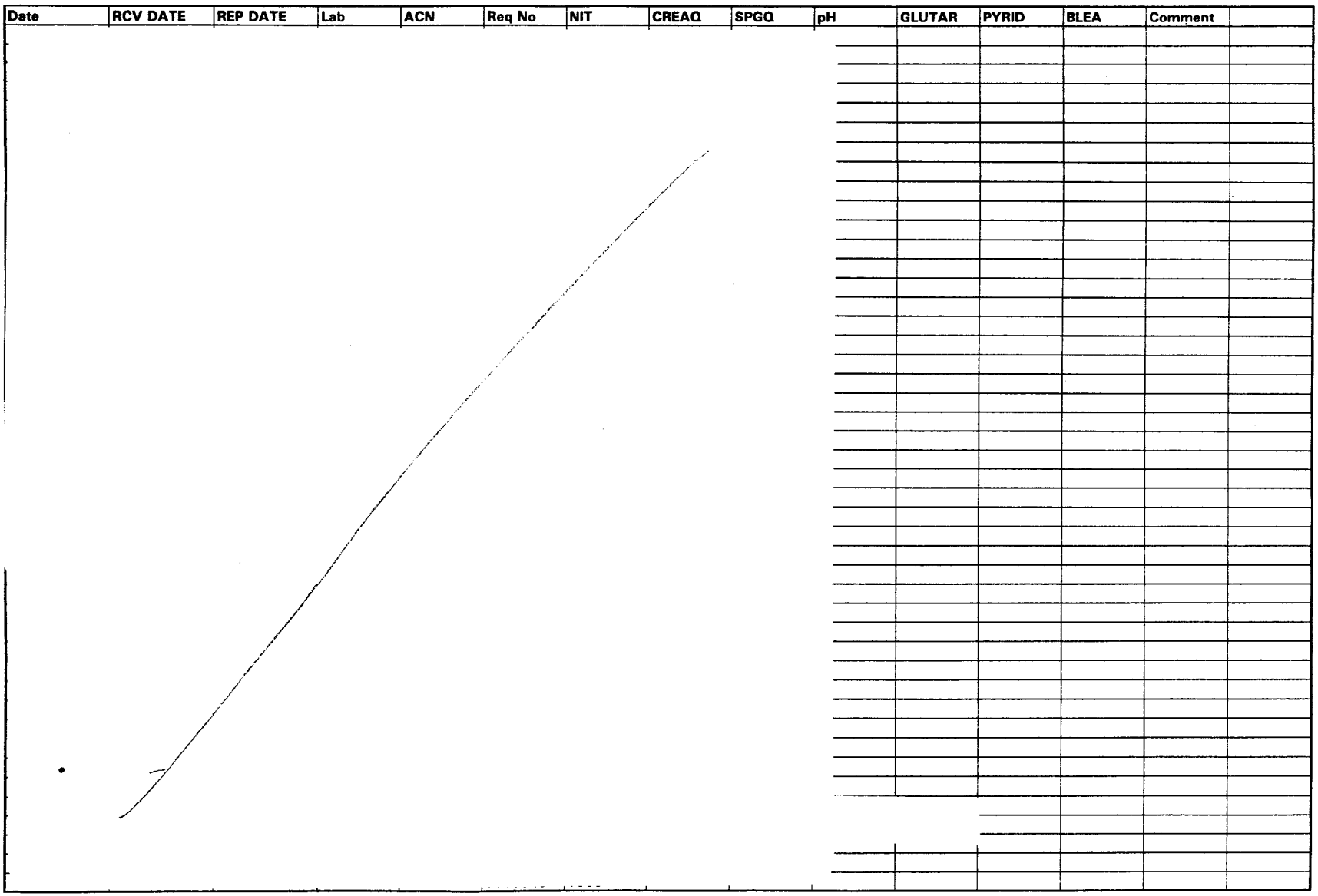
I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

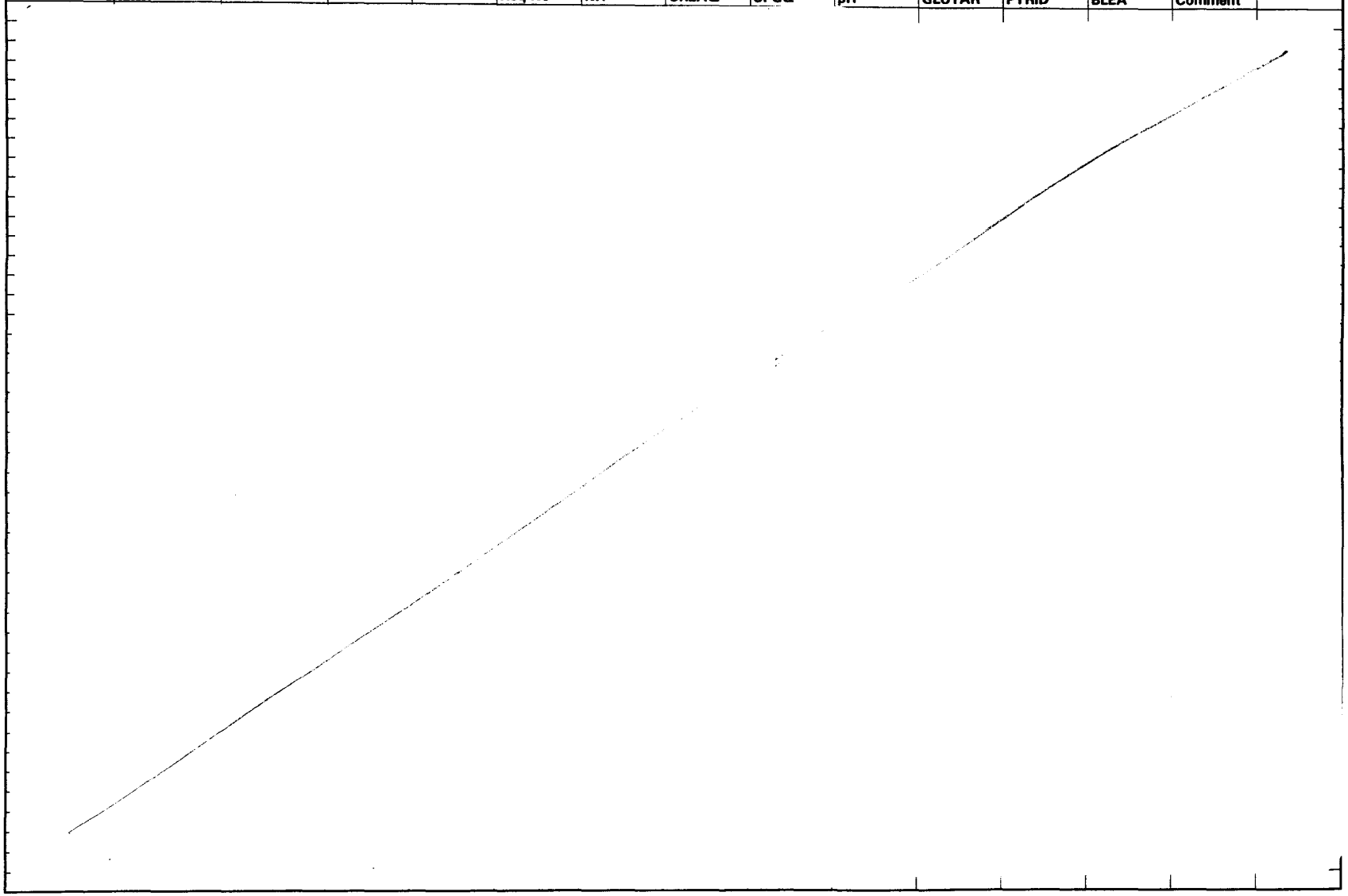
10/6/2000
Date

Barry Sample, Ph.D.
Printed Name, Responsible Person

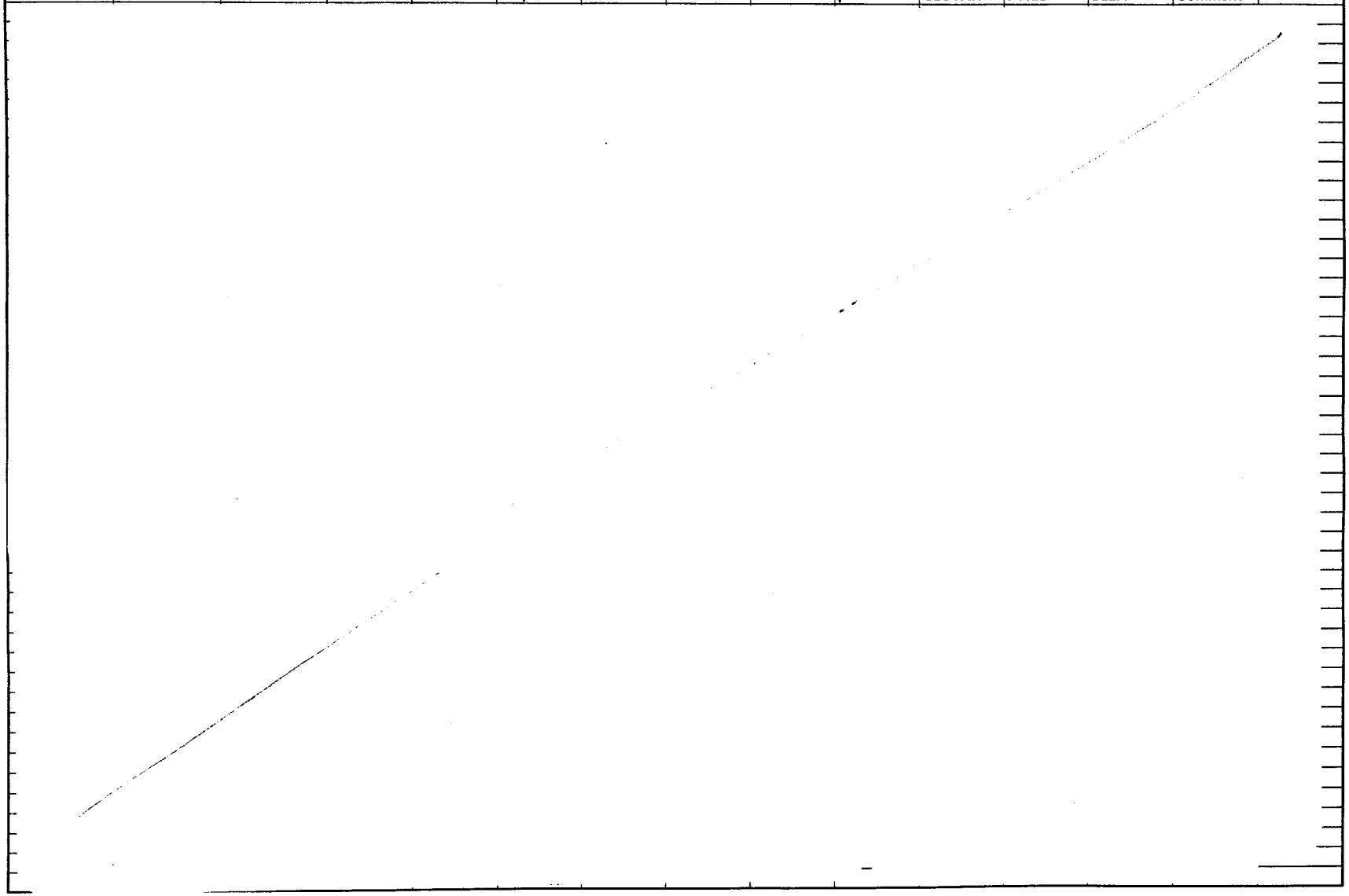
Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment	



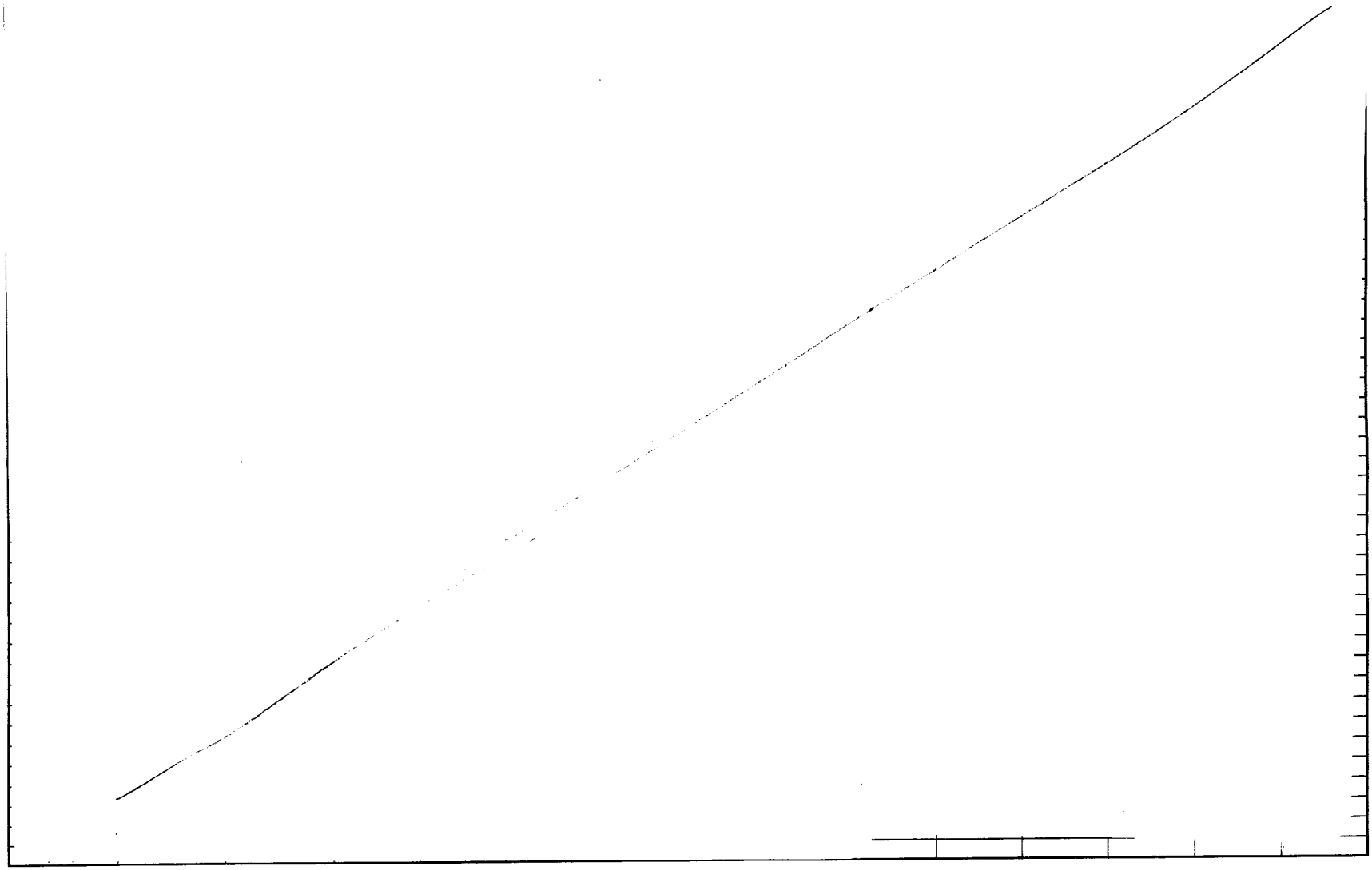
Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment



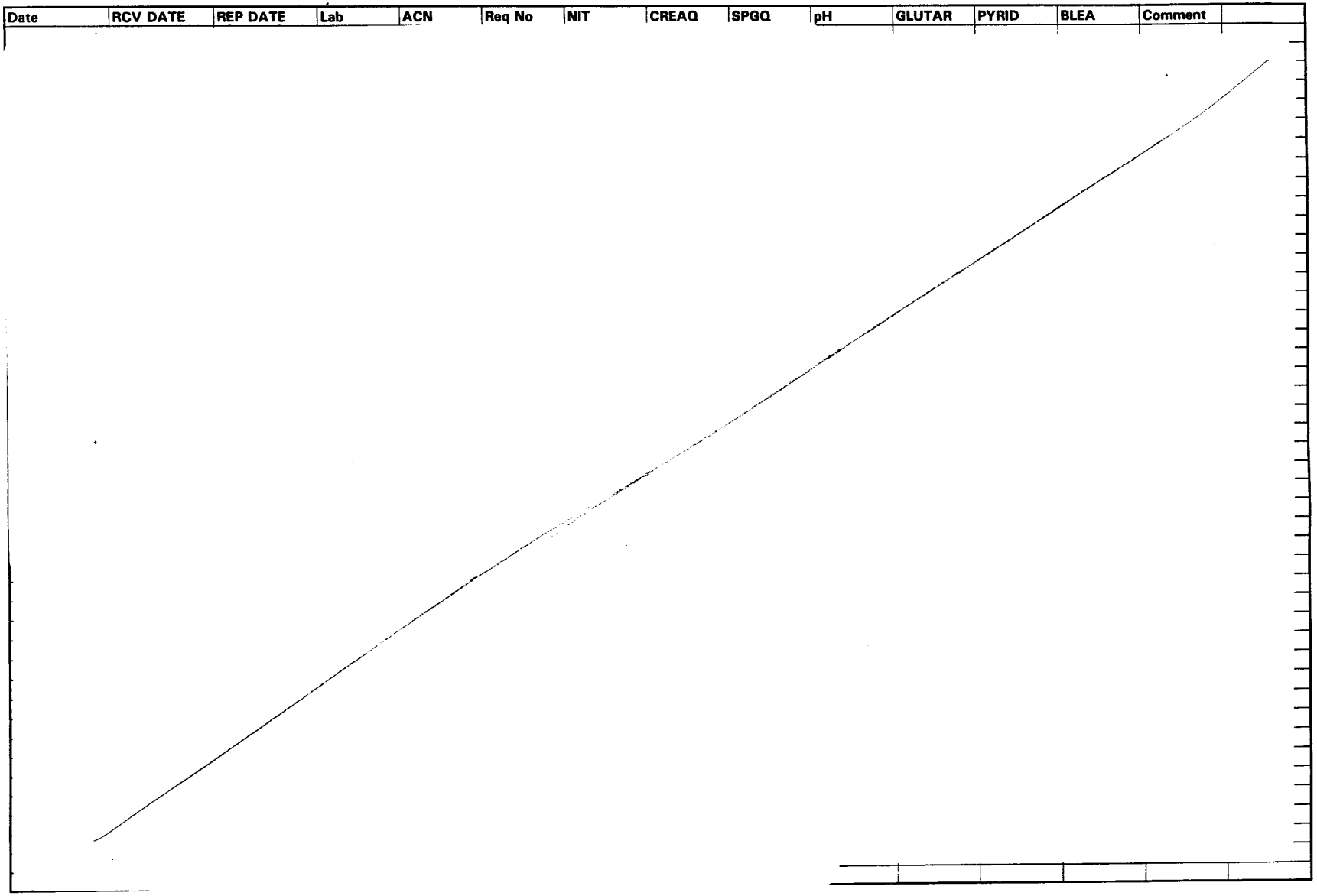
Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment



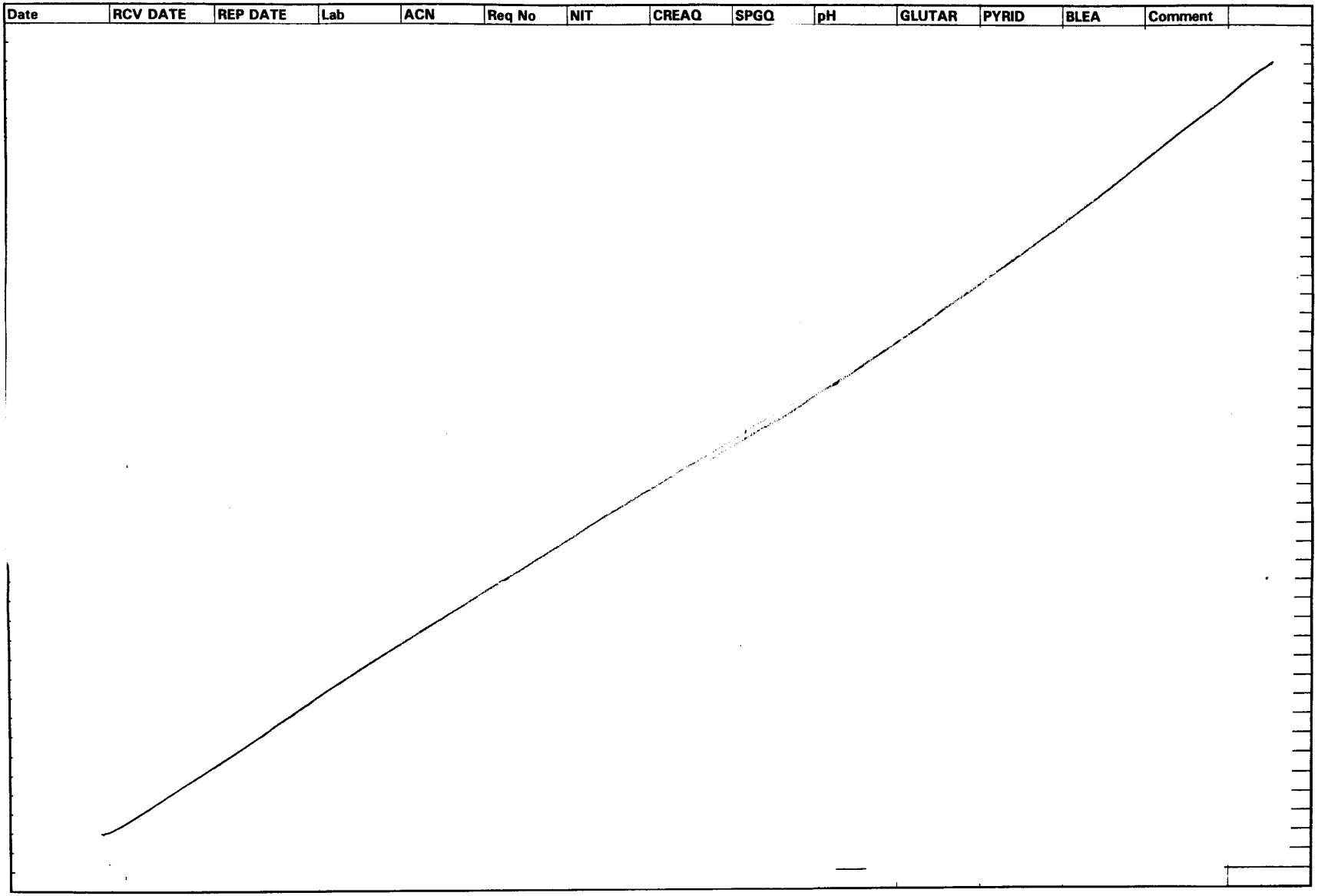
Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment



Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment



Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment



Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	Comment	

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 26, 2000

0067
Dr. R.H. Barry Sample
Quest Diagnostics Incorporated
NIDA Processing
3175 Presidential Drive
Atlanta, GA 30340

Dear Dr. Sample:

The enclosed critique was developed from the inspection report associated with the October 11-13, 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 RTI 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/svt067

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0067
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Atlanta, GA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 11 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:

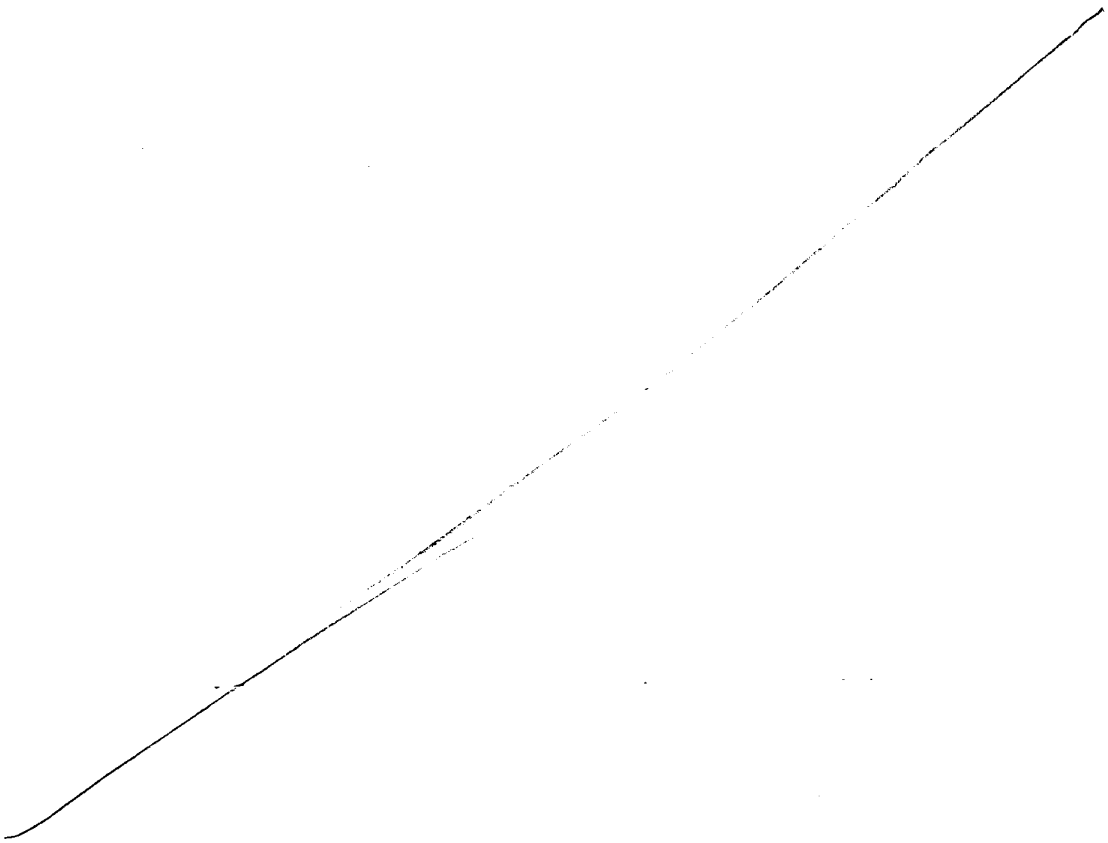
Section E. Standard Operating Procedures - Procedures Manual

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

O. General Comments

Quest Diagnostics Incorporated

3175 Presidential Drive
Atlanta, Georgia 30340
770.452.1590
800.729.6432
Fax 770.936.5012

December 4, 2000

Susan Crumpton
NLCP Technical Analyst
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

This letter is in response to the critique dated October 26, 2000 requesting corrective action for deficiencies cited during the specimen validity testing inspection of our laboratory (#0067). The laboratory's procedures have been updated to be in compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The following issues have been addressed:

If you have any questions pertaining to the laboratory corrective action plan, please contact Dr. Barry Sample at (770) 936-5024 or Brian Brunelli at (770) 936-5009.

Sincerely,

R.H. Barry Sample, Ph.D.
Responsible Person

Brian A. Brunelli
Responsible Person (in-training)

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 11, 2000

0067
Dr. R.H. Barry Sample
Quest Diagnostics Incorporated
NIDA Processing
3175 Presidential Drive
Atlanta, GA 30340

Dear Dr. Sample:

We have reviewed the material provided in your correspondence of December 4, 2000, submitted in response to issues raised during the October 11-13, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of October 26, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

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.

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/SVT067

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