Validity Testing Information Part I

Laboratory Name: Quest Diagnostics
Address: 801 E Dixie Ave, Suite 105A
Leesburg, Florida 34748

Responsible Person: ~~P.L. Hilderbrand, 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).

Maryann O'Toole (ALT-RP) — 10/4/05

Signature, Responsible Person — Date

Maryann O'Toole

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).

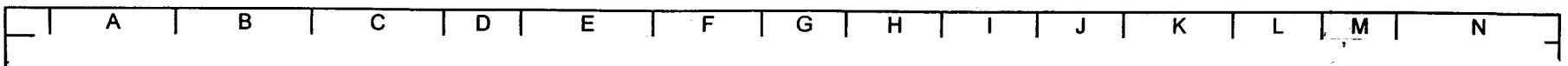
Signature, Responsible Person

OCT 17 2000
Date

R.L. Hilderbrand, Ph.D.
Printed Name, Responsible Person

N-30

Audit



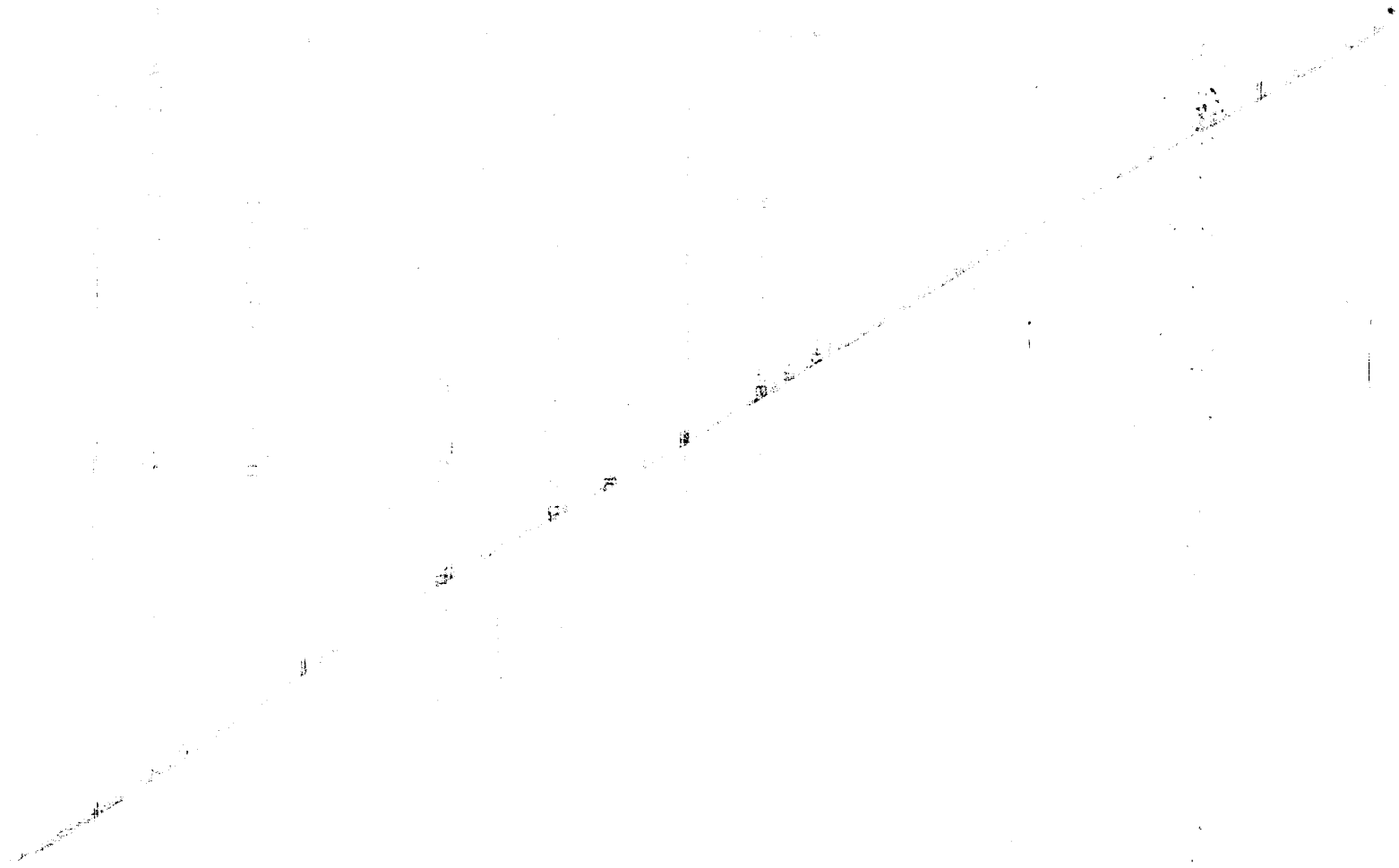
	A	B	C	D	E	F	G	H	I	J	K	L	M	N

S-10
N-24
PA-1

	A	B	C	D	E	F	G	H	I	J	K	L	M	N

Audit .

	A	B	C	D	E	F	G	H	I	J	K	L	M	N



Audit

S – 6
N – 22
Pyr - 6
Bleach 1

	A	B	C	D	E	F	G	H	I	J	K	L	M	N

	A	B	C	D	E	F	G	H	I	J	K	L	M	N

Audit

S - 2
N - 8
Pyr - 7
Bleach - 2
pH 1

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Date	RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID	BLEA	RESULT

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 31, 2000

0141
Dr. Richard Hilderbrand
Quest Diagnostics Incorporated
801 East Dixie Avenue
Leesburg, FL 34748

Dear Dr. Hilderbrand:

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 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/svt141

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0141
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Leesburg, FL

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

Section O. General Comments

Quest
Diagnostics

801 East Dixie Avenue
Leesburg, FL 34748
1(800)342-9520, FAX (352)728-0293

November 27, 2000

Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709-2194

Re: Special Inspection of Laboratory 0141

Dear Ms. Crumpton:

The following information is provided in response to your letter of October 31, 2000, which requested corrective action from the Specimen Validity Inspection of the Quest Laboratory, Leesburg:

If there are any questions, please call me at 352-728-0274.

Sincerely yours,

Richard L. Hilderbrand, PhD
RP

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 19, 2000

0141
Dr. Richard Hilderbrand
Quest Diagnostics Incorporated
801 East Dixie Avenue
Leesburg, FL 34748

Dear Dr. Hilderbrand:

We have reviewed the material provided in your correspondence of November 27, 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 31, 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. 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

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.*** 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT141

801 East Dixie Avenue
Leesburg, FL 34748
1(800)342-9520, FAX (352)728-0293

rec'd 1/5/01 SDC

January 4, 2001

Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709-2194

Re: Special Inspection of Quest Diagnostics Laboratory 0141

Dear Ms. Crumpton:

The following information is provided in response to your letter of December 19, 2000, which directed corrective action on the response to the Specimen Validity Inspection of the Quest Diagnostics Laboratory, Leesburg:

If there are any questions, please call me at 352-728-0274.

Sincerely,

Richard L. Hilderbrand, PhD
RP

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 10, 2001

0141
Dr. Richard Hilderbrand
Quest Diagnostics Incorporated
801 East Dixie Avenue
Leesburg, FL 34748

Dear Dr. Hilderbrand:

We have reviewed the material provided in your correspondence of January 4, 2001, submitted in response to remaining issues from the October 11-13, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 19, 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. ***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 during 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT141

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