


**Validity Testing Information Part I**

Laboratory Name: Quest Diagnostics Inc  
Address: 7470 Mission Valley Road San Diego, CA 92108  
Responsible Person: DAddario / Callies (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

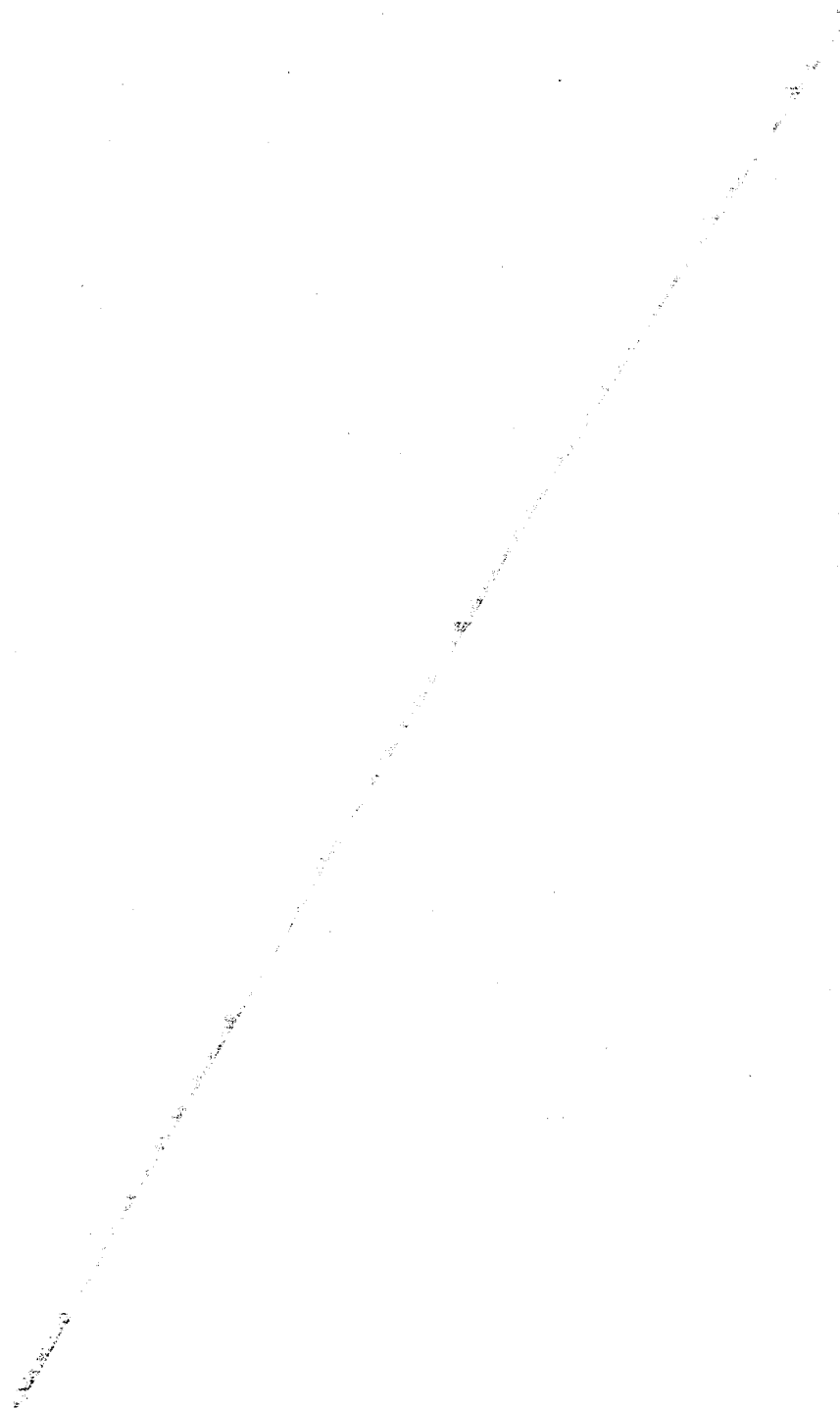
10/5/00  
Date

Anthony P. D'Addario  
Printed Name, Responsible Person

QUEST DIAGNOSTICS INC (SAN DIEGO)  
LABORATORY 0101

receipt reported accession # specimen ID Nitrite pH Cr SG result

















QUEST DIAGNOSTICS INC (SAN DIEGO)  
LABORATORY 0101



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 4, 2000

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

The enclosed critique was developed from the inspection report associated with the November 1-3, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). [



Mr. Callies  
Dr. D'Addario  
Page 2 of 5  
12/04/00

Mr. Callies  
Dr. D'Addario  
Page 3 of 5  
12/04/00

Mr. Callies  
Dr. D'Addario  
Page 4 of 5  
12/04/00



Mr. Callies  
Dr. D'Addario  
Page 5 of 5  
12/04/00

The laboratory must take corrective action to address the issues outlined above and provide documentation to RTI or the inspectors at the next specimen validity testing inspection as described. Please organize the material for the inspectors 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.***

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/svt101

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0101  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: San Diego, CA

Document Reviewed:  Specimen Validity Testing Inspection Report

Date: 1 November 2000

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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

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-8000  
800-848-4225 Toll Free

received  
12/11/00 STK



December 8, 2000

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter is in response to your correspondence of December 4, 2000 regarding the specimen validity testing inspection of this laboratory.

Please contact me if additional information is needed.

Sincerely,

*James A. Callies*  
James A. Callies  
Scientific Director

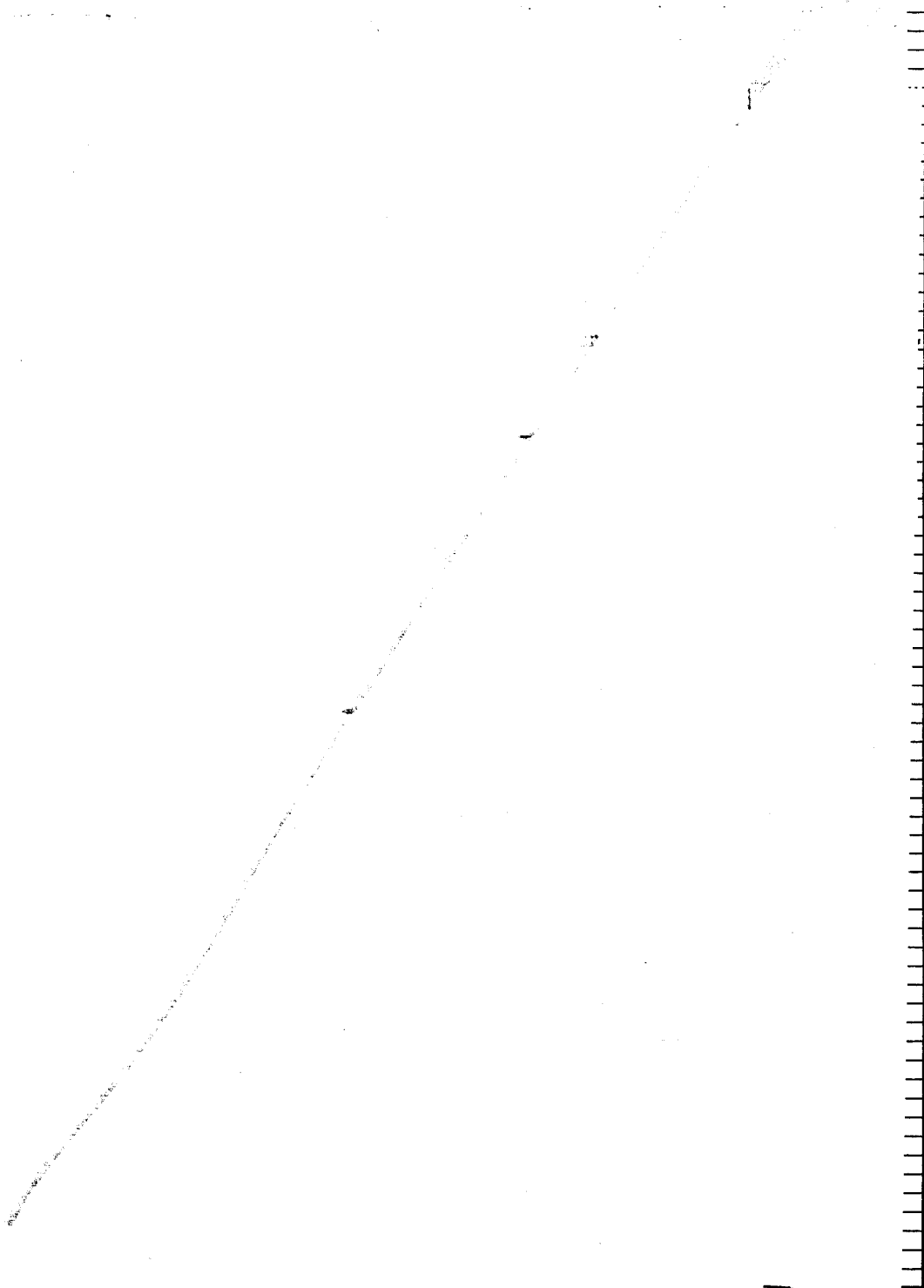


receipt	reported	accession #	specimen ID	Nitrite	pH	Cr	SG	result	load number

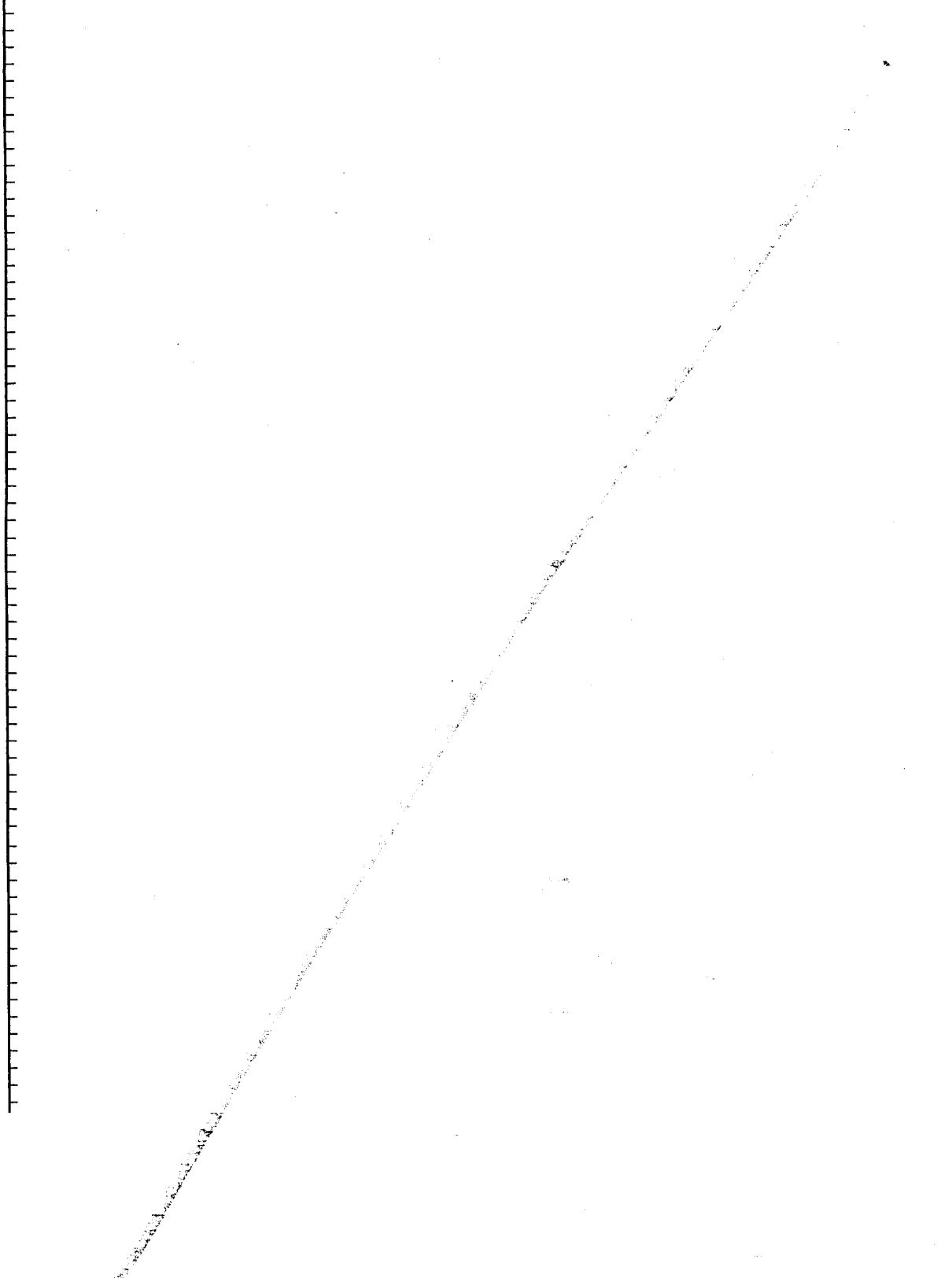




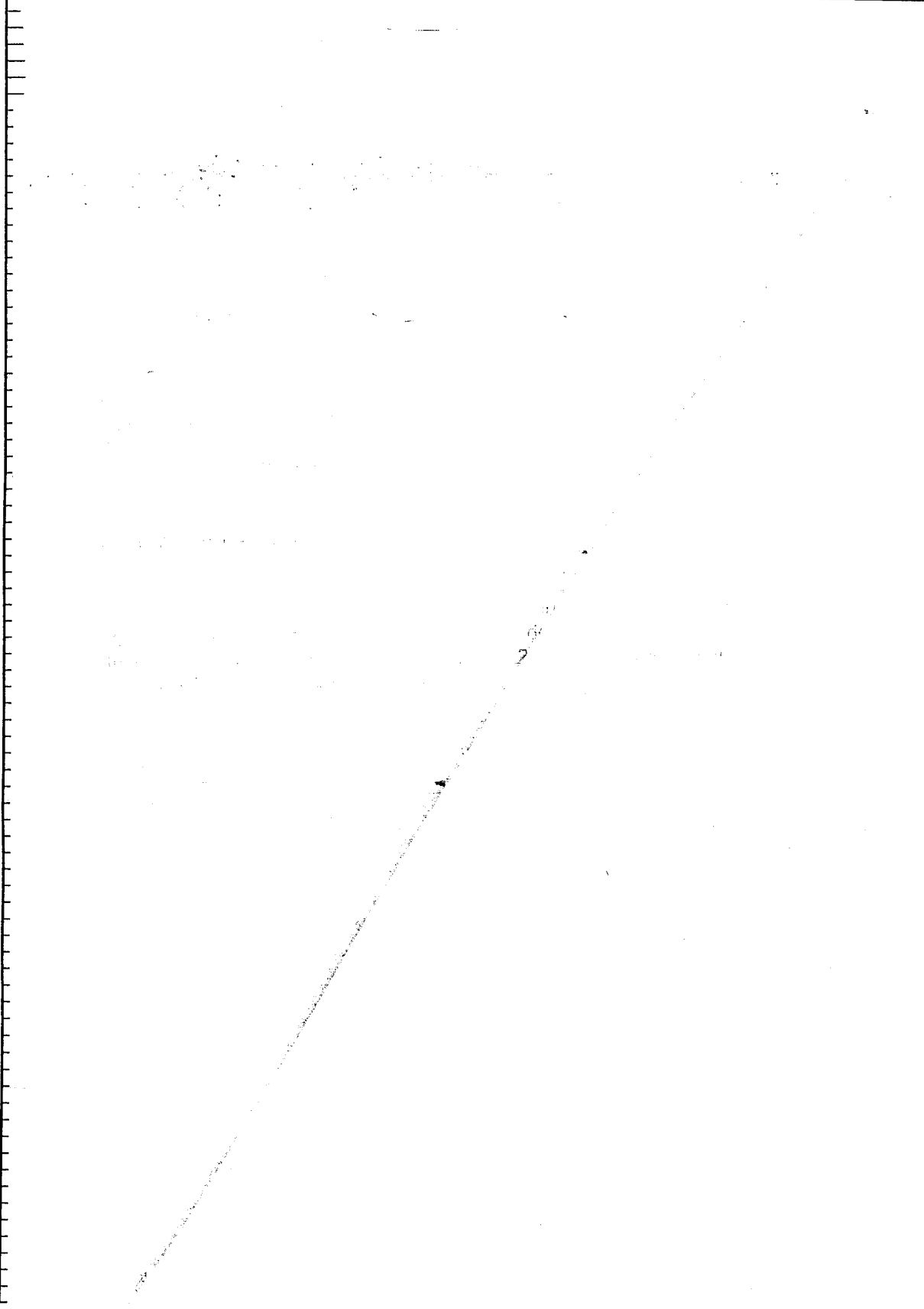
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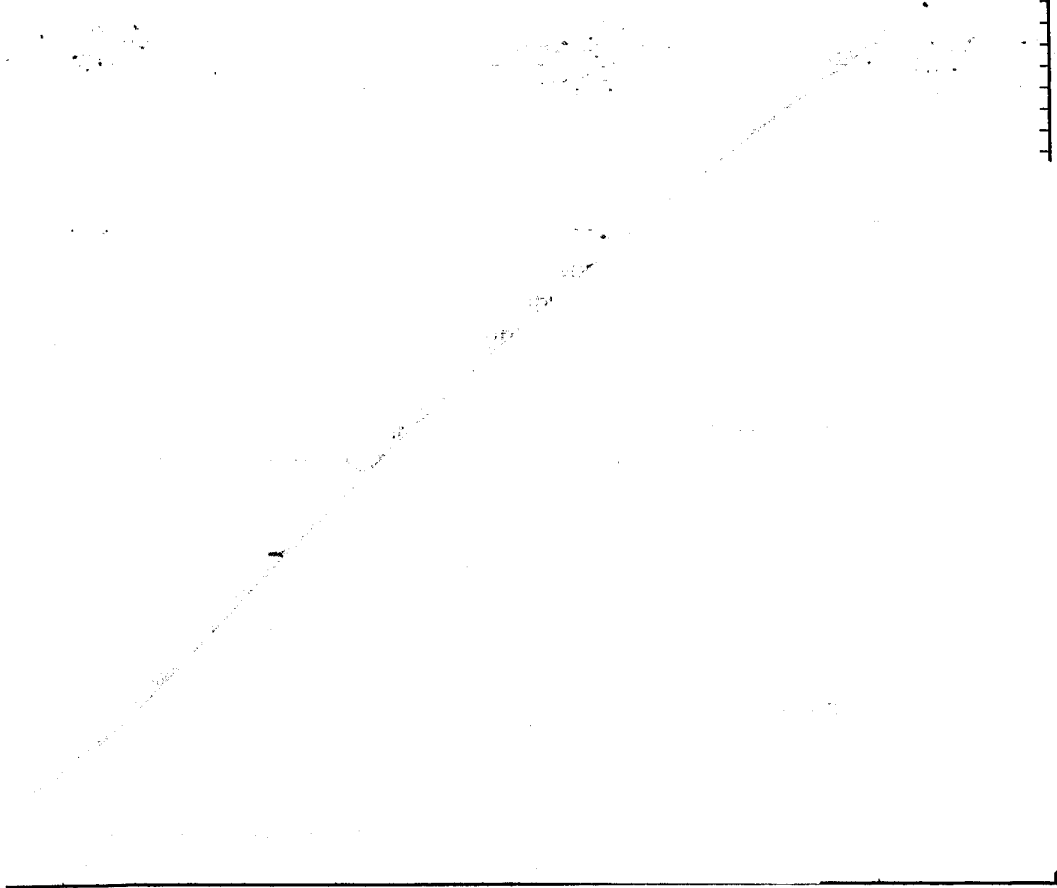
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receipt	reported	accession #	specimen ID	Nitrite	pH	Cr	SG	result	load number
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receipt	reported	accession #	specimen ID	N#rite	pH	Cr	SG	result	load number
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RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 13, 2000

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the material provided in your correspondence of December 8, 2000, submitted in response to our correspondence of December 4, 2000, concerning deficiencies cited during your November 1-3, 2000, specimen validity testing inspection. The following is a summary of our review:





Mr. Callies  
Dr. D'Addario  
Page 2 of 2  
12/13/00

The laboratory must submit, within 5 working days of receipt of this letter, information to address the issue described in this correspondence. ***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/SVT101

Quest Diagnostics Incorporated

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-3000  
800-848-4225 Toll Free

received  
12/18/00 SDC



December 12, 2000

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter is an additional response to your correspondence of December 4, 2000. Our original response was forwarded December 8, 2000.

Please contact me if additional information is needed.

Sincerely,

*James A. Callies*  
James A. Callies  
Scientific Director

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 13, 2000

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the material provided in your correspondence of December 8, 2000, submitted in response to our correspondence of December 4, 2000, concerning deficiencies cited during your November 1-3, 2000, specimen validity testing inspection. The following is a summary of our review:

Mr. Callies  
Dr. D'Addario  
Page 2 of 2  
12/13/00

The laboratory must submit, within 5 working days of receipt of this letter, information to address the issue described in this correspondence. ***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/SVT101

Quest Diagnostics Incorporated

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-3000  
800-848-4225 Toll Free

received  
12/18/00 SDC



December 12, 2000

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter is an additional response to your correspondence of December 4, 2000. Our original response was forwarded December 8, 2000

Please contact me if additional information is needed.

Sincerely,

*James A. Callies*  
James A. Callies  
Scientific Director

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 18, 2000

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed your December 12, 2000, correspondence, submitted in response to our letter of December 4, 2000. The laboratory has submitted information to address issues raised during the November 1-3, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The following is a summary of our review:

The laboratory must submit the final response addressing other issues outlined in our December 4, 2000, letter and critique within 30 calendar days of receipt of that correspondence. 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,

A handwritten signature in cursive script that reads "Susan Crumpton".

Susan Crumpton  
NLCP Technical Analyst

cc: Project Files/svt101



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 13, 2000

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the material provided in your correspondence of December 8, 2000, submitted in response to our correspondence of December 4, 2000, concerning deficiencies cited during your November 1-3, 2000, specimen validity testing inspection. The following is a summary of our review:

Mr. Callies  
Dr. D'Addario  
Page 2 of 2  
12/13/00

The laboratory must submit, within 5 working days of receipt of this letter, information to address the issue described in this correspondence. ***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/SVT101

Quest Diagnostics Incorporated

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-3000  
800-848-4225 Toll Free

received  
12/18/00 SDC



December 12, 2000

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter is an additional response to your correspondence of December 4, 2000. Our original response was forwarded December 8, 2000

Please contact me if additional information is needed.

Sincerely,

*James A. Callies*  
James A. Callies  
Scientific Director

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 18, 2000

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed your December 12, 2000, correspondence, submitted in response to our letter of December 4, 2000. The laboratory has submitted information to address issues raised during the November 1-3, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The following is a summary of our review:

The laboratory must submit the final response addressing other issues outlined in our December 4, 2000, letter and critique within 30 calendar days of receipt of that correspondence. 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,

A handwritten signature in cursive script that reads "Susan Crumpton".

Susan Crumpton  
NLCP Technical Analyst

cc: Project Files/svt101



Quest Diagnostics Incorporated

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-3000  
800-848-4225 Toll Free

received  
1/3/01 SOC



December 19, 2000

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter is in response to your correspondence of December 13, 2000 ;

Sincerely,

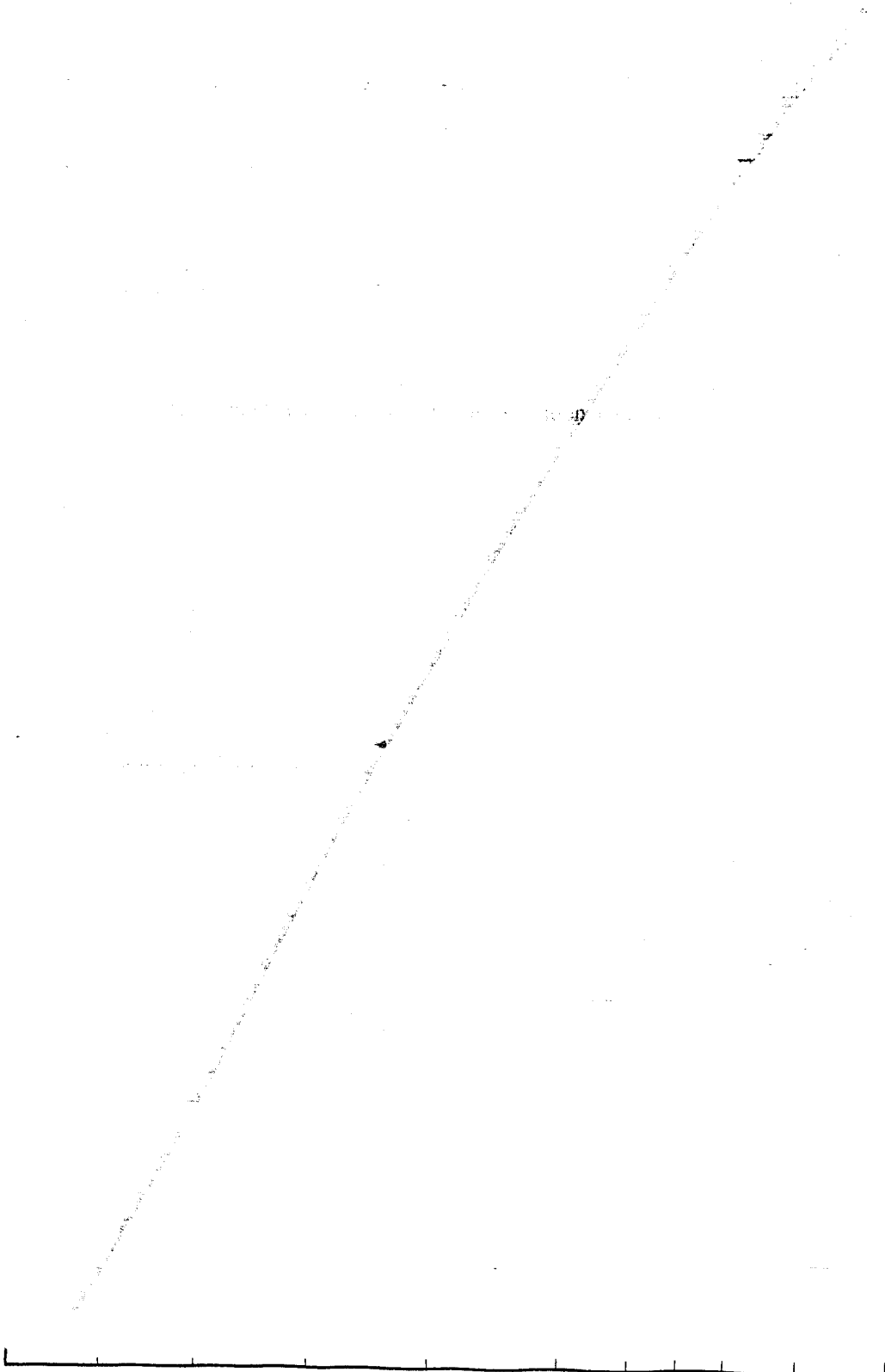
Handwritten signature of Anthony P. D'Addario in cursive.

Anthony P. D'Addario, Ph.D.  
Technical Director

Handwritten signature of James A. Callies in cursive.

James A. Callies  
Scientific Director

number	receipt	reported	accession #	specimen ID	Nitrite	pH	Cr	SG	result
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number	receipt	reported	accession #	specimen ID	Nitrite	pH	Cr	SG	result
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Quest Diagnostics Incorporated

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-3000  
800-848-4225 Toll Free

received  
1/4/01 SDU



January 2, 2001

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

As promised in our letter dated December 19, 2000, this is follow-up correspondence providing data:

Sincerely,

Handwritten signature of Anthony P. D'Addario in cursive.

Anthony P. D'Addario, Ph.D.  
Technical Director

Handwritten signature of James A. Callies in cursive.

James A. Callies  
Scientific Director

	receipt	reported	accession #	specimen ID	Nitrite	pH	Cr	SG	result
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RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 5, 2001

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Dr. D'Addario and Mr. Callies:

We have reviewed the material provided in your correspondence of December 19, 2000, and January 2, 2001, submitted in response to issues raised during the November 1-3, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 13, 2000.

Dr. D'Addario and Mr. Callies  
Page 2 of 2  
01/05/01

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/SVT101

Quest Diagnostics Incorporated

7470 Mission Valley Road  
San Diego, CA 92108  
619 686-3000  
800-848-4225 Toll Free

received  
1/18/01 SDC



January 17, 2001

Susan Crumpton  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This letter is in response to your correspondence dated January 5, 2001

Sincerely,

*James A. Callies*  
James A. Callies, FTCB  
Scientific Director

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 8, 2001

0101  
Mr. James A. Callies  
Dr. Anthony P. D'Addario  
Quest Diagnostics Incorporated  
7470 Mission Valley Road  
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the inspectors' report from the January 24, 2001, specimen validity testing inspection of your laboratory. The information submitted by the inspectors appears to demonstrate that appropriate corrective actions have been completed to address the issues raised in the laboratory's November 1, 2000, specimen validity testing inspection. The laboratory must take steps to address the following issues raised:

Callies and D'Addario  
Page 2 of 2  
02/08/01

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. The laboratory must take corrective actions to address the issues outlined above. 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/SVT2\_101