



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 5, 1999

0073
Ms. Susan Mills
SmithKline Beecham Clinical Laboratories
400 Egypt Road
Norristown, PA 19403

Dear Ms. Mills:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following corrective actions:

F. The Chain of Custody, Accessioning, and Security section



[Redacted]

G. The Records section

[Redacted]

J. The Quality Control and Standards section

[Redacted]

M. The Immunoassay section

[Redacted]

Ms. Mills
Page 3 of 3
01/05/99

N. The Gas Chromatography/Mass Spectrometry section

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 described above. 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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of the 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 Inspection Analyst

Enclosure

cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0073
Document No. Final

Laboratory: SmithKline Beecham Clinical Laboratories

Location: Norristown, PA

Document Reviewed: Application Form
 Inspection Report #M17 Date: 12 November 1998
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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. Records Audit

Section H. Personnel

Section I. Reagents

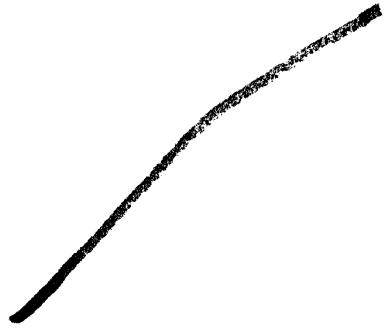
Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry



SB
SmithKline Beecham
Clinical Laboratories

received
SDC 2/3/99

February 3, 1999

Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
P. O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709


Dear Ms. Crumpton:

I am writing to respond to the critique for the seventeenth maintenance inspection report of our laboratory (#0073) under the National Laboratory Certification Program. The following items are being clarified or submitted for your review:

Page 2 of 2
Lab # 0073
2/3/99

If you require any additional information or clarification, please call me at (800) 523-0289 extension 4502.

Sincerely,



Susan Mills
Manager, Forensic Toxicology

February 9, 1999

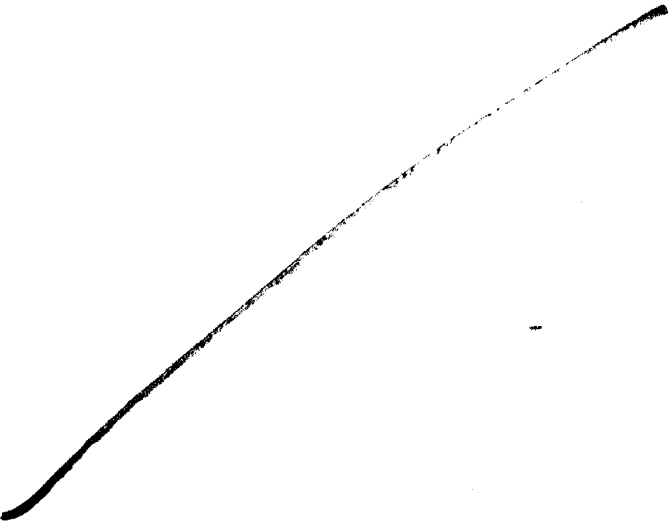
0073
Ms. Susan Mills
SmithKline Beecham Clinical Laboratories
400 Egypt Road
Norristown, PA 19403

Dear Ms. Mills:

We have reviewed the material submitted in your correspondence of February 3, 1999, provided in final response to issues raised during the seventeenth maintenance inspection of your laboratory as originally outlined in our correspondence of January 5, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following issues remain:



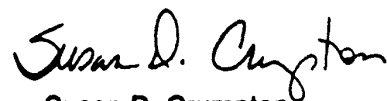
Ms. Mills
Page 2 o
02/09/99



Based upon our review of the material submitted, RTI will recommend to HHS that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP). All corrective actions must be implemented within 30 days of receipt of this correspondence and will be reviewed during the next inspection.

If you have any questions or if we can be of assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan D. Crumpton
NLCP Inspection Analyst

cc: Project Files/M17



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

May 27, 1999

0073
Ms. Susan Mills
SmithKline Beecham Clinical Laboratories
400 Egypt Road
Norristown, PA 19403

Dear Ms. Mills:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eighteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. However, the following issues were raised:

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Inspection Analyst

Ms. Mills
May 27, 1999
Page 2 of 2

Enclosure

cc: Project Files/M18

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0073
Document No. Final

Laboratory: SmithKline Beecham Clinical Laboratories

Location: Norristown, PA

Document Reviewed: Application Form
 Inspection Report #M18 Date: 13 May 1999
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

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Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 13, 2000

0073
Ms. Susan Mills
Quest Diagnostics Incorporated
400 Egypt Road
Norristown, PA 19403

Dear Ms. Mills:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

E. The Standard Operating Procedures section \

F. The Chain of Custody, Accessioning, and Security section

G. The Quality Control section
f

J. The Records Audit section
j

Ms. Mills
January 13, 2000
Page 3 of 3

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0073
Document No. Final

Laboratory: Quest Diagnostics, Inc.

Location: Norristown, PA

Document Reviewed: Application Form
 Inspection Report #M19 Date: 11 November 1999
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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 G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

July 12, 2000

0073
Ms. Susan Mills
Quest Diagnostics Incorporated
400 Egypt Road
Norristown, PA 19403

Dear Ms. Mills:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

E. The Standard Operating Procedures (SOP) section v

F. The Chain of Custody, Accessioning, and Security section



Ms. Mills
July 12, 2000
Page 2 of 2

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M20

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0073
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Norristown, PA

Document Reviewed: Application Form
 Inspection Report #M20 Date: 18 May 2000
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 12, 2001

0073
Ms. Susan Mills
Quest Diagnostics Incorporated
400 Egypt Road
Norristown, PA 19403

Dear Ms. Mills:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-first maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection appeared to meet most of the minimum technical criteria. However, the laboratory must take steps to correct the following issues raised:

F. The Chain of Custody, Accessioning, and Security section

I. The Specimen Validity Tests section

Ms. Mills
Page 2 of 2
02/12/01

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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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/M21

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0073
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Norristown, PA

Document Reviewed: Application Form
 Inspection Report #M21 Date: 16 November 2000
 Other _____

Status: Appeared to meet most of the minimum technical criteria
 Appeared to meet a number of the minimum technical criteria
 Failed to meet a number of the minimum technical criteria
 Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

The following deficiencies were identified, 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 H. Initial Tests

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section K. Records Audit

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

February 12, 2001

0073
Ms. Susan Mills
Quest Diagnostics Incorporated
400 Egypt Road
Norristown, PA 19403

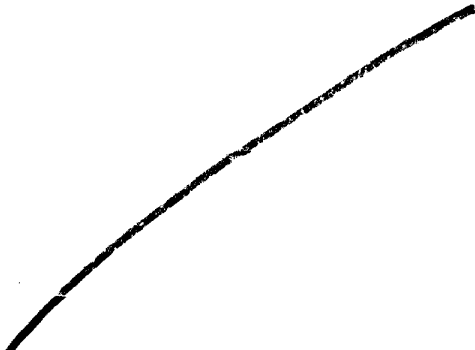
Dear Ms. Mills:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-first maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection appeared to meet most of the minimum technical criteria. However, the laboratory must take steps to correct the following issues raised:

F. The Chain of Custody, Accessioning, and Security section

I. The Specimen Validity Tests section :

Ms. Mills
Page 2 of 2
02/12/01



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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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/M21



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0073
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Norristown, PA

Document Reviewed: Application Form
 Inspection Report #M21 Date: 16 November 2000
 Other _____

Status: Appeared to meet most of the minimum technical criteria
 Appeared to meet a number of the minimum technical criteria
 Failed to meet a number of the minimum technical criteria
 Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

The following deficiencies were identified, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section G. Quality Control and Quality Assurance

Section H. Initial Tests

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section K. Records Audit

12

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

Quest Diagnostics Incorporated

400 Egypt Road
Norristown, Pennsylvania 19403
610.631.4200

received

3/10/01 SDC



March 7, 2001

Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
P. O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

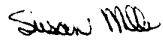
Dear Ms. Crumpton:

I am writing in response to the critique for the twenty-first maintenance inspection report of our laboratory (#0073) under the National Laboratory Certification Program. The following items are being clarified or submitted for your review:

[A large, dark, diagonal scribble or mark covers the majority of the lower half of the page, obscuring any text that might have been present.]

If you require any additional information or clarification, please call me at (800) 523-0289 extension 4502.

Sincerely,



Susan Mills
Operations Director, Forensic Toxicology