

July 21, 2000

0140
Dr. Manok Kim
Quest Diagnostics Incorporated
4444 Giddings Road
Auburn Hills, MI 48326

Dear Dr. Kim:

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. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

G. The Quality Control section



I. The Confirmatory Tests section



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 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

[Redacted content]

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

[Redacted content]

Section G. Quality Control

[Redacted content]

Section H. Initial Tests

[Redacted content]

Section I. Confirmatory Tests

[Redacted content]

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

February 8, 2000

0140
Dr. Manok Kim
Quest Diagnostics Incorporated
4444 Giddings Road
Auburn Hills, MI 48326

Dear Dr. Kim:

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 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



G. The Quality Control section



I. The Confirmatory Tests section

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) 541-6176 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: 0140
Document No. Final

Laboratory: Quest Diagnostics, Inc.

Location: Auburn Hills, MI

Document Reviewed: Application Form
 Inspection Report #M17 Date: 16 December 1999
 Other _____

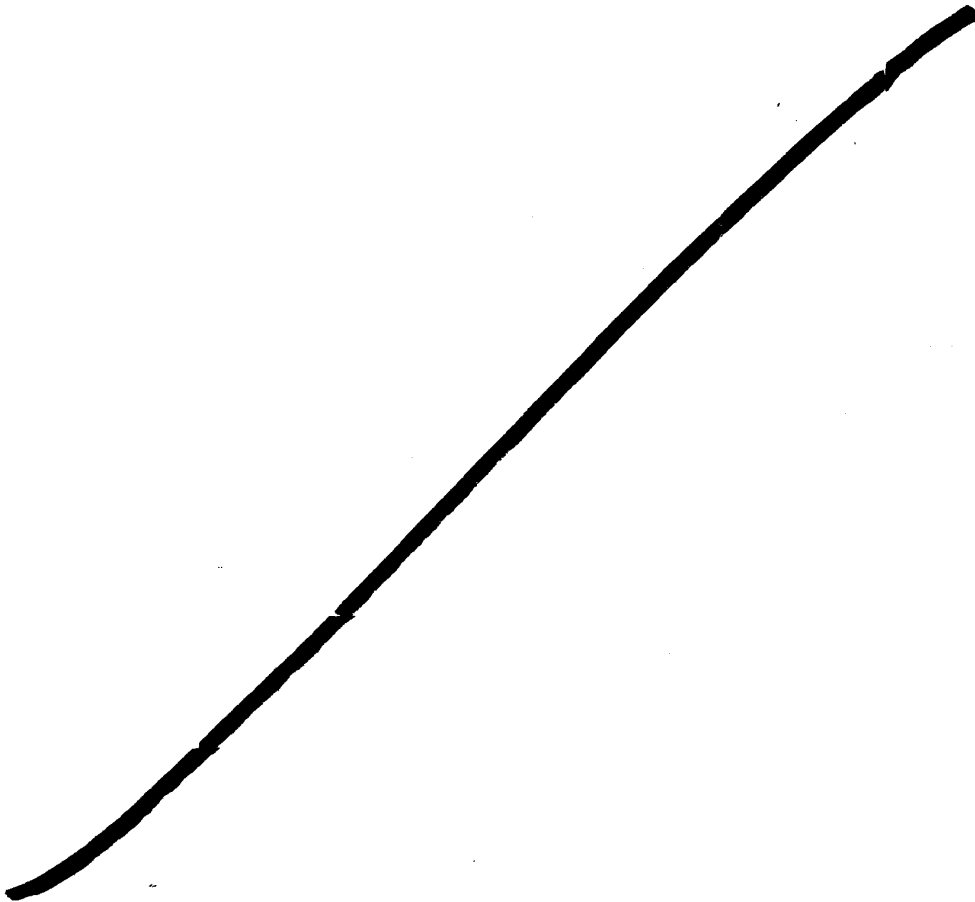
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



Section G. Quality Control



[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0140
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Auburn Hills, MI

Document Reviewed: Application Form
 Inspection Report #M16 Date: 24 June 1999
 Other _____

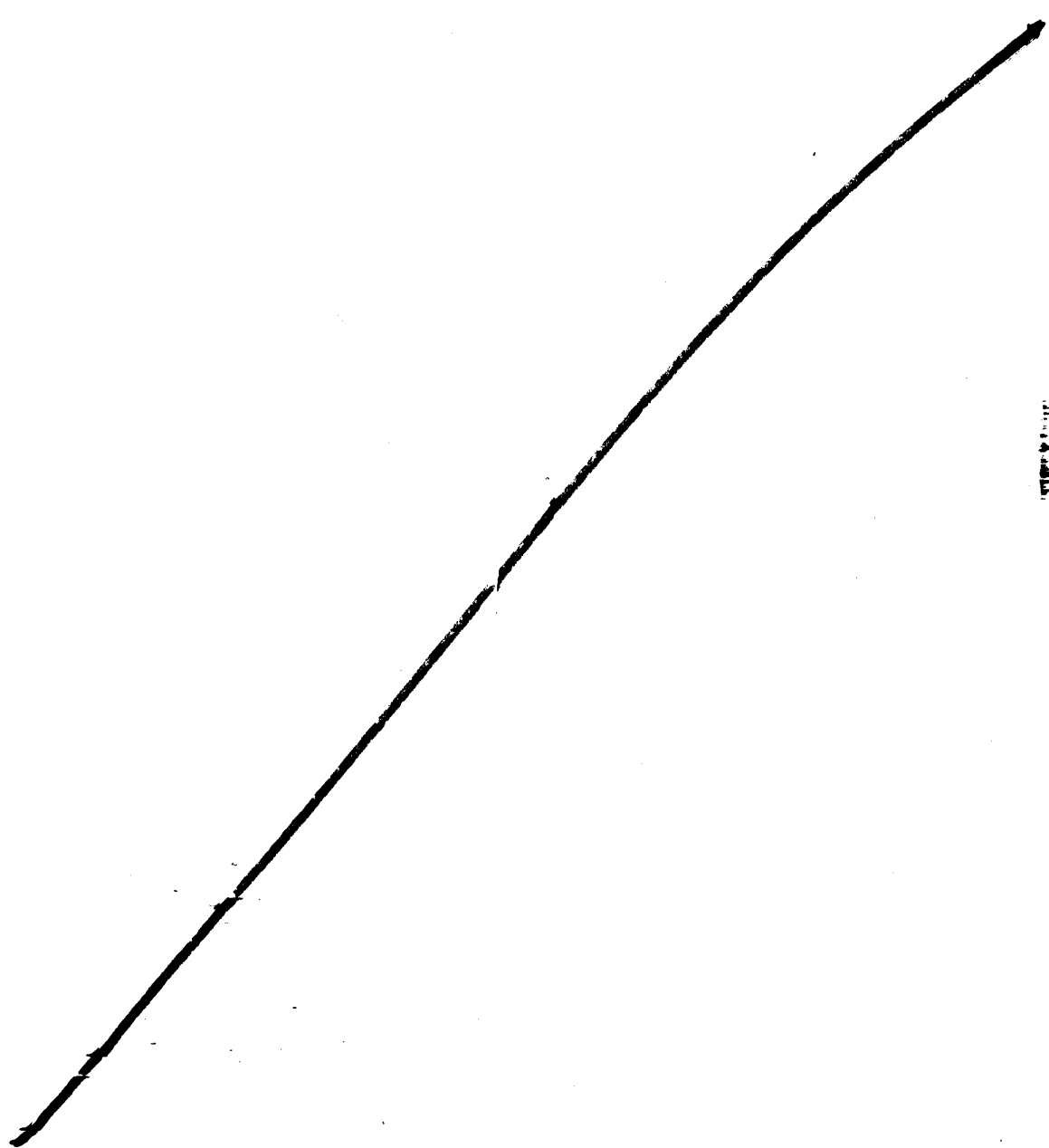
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



[Redacted]

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

[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

11/11/11

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 5, 1999

0140
Dr. Manok Kim
Quest Diagnostics Incorporated
4444 Giddings Road
Auburn Hills, MI 48326

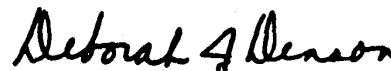
Dear Dr. Kim:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth 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.

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. Derison
NLCP Inspection Analyst

Enclosure

cc: Project Files/M15



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0140
Document No. Final

Laboratory: Quest Diagnostics, Inc.

Location: Auburn Hills, MI

Document Reviewed: Application Form
 Inspection Report #M15
 Other _____

Date: 10 December 1998

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

[Redacted]

Section N. Personnel

[Redacted]

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