



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 24, 1998

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

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 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/M15



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0001
Document No. Final

Laboratory: Toxicology Testing Service, Inc.

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M15 Date: 5 November 1998
 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. Records Audit

[Redacted]

Section H. Personnel

[Redacted]

Section I. Reagents

[Redacted]

Section J. Quality Control and Standards

[Redacted]

Section K. Reporting

[Redacted]

Section L. Equipment and Maintenance

[Redacted]

Section M. Immunoassay

[Redacted]

Section N. Gas Chromatography/Mass Spectrometry

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 10, 1999

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth 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 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: 0001
Document No. Final

Laboratory: Toxicology Testing Service, Inc.

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M16 Date: 6 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

[Redacted]

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

[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

1.

[Redacted]

Section J. Records Audit

[Redacted]


Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

A thick black horizontal line redacting the content of Section M.

Section N. Personnel

A thick black horizontal line redacting the content of Section N.



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

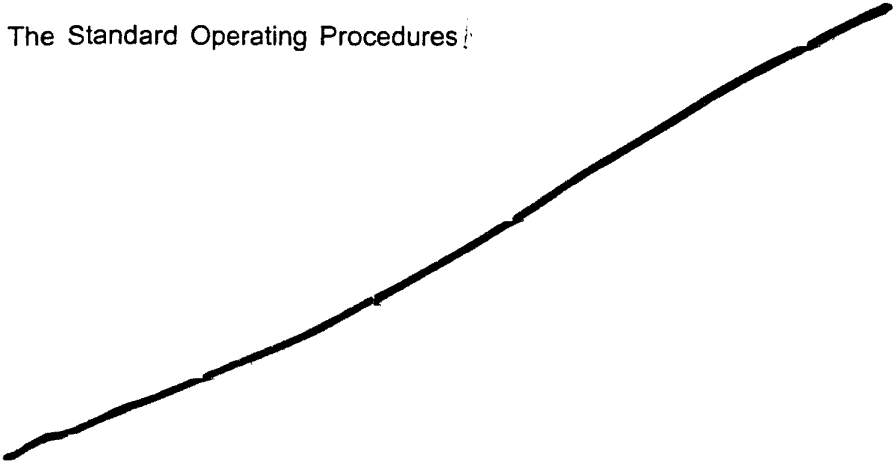
December 21, 1999

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166


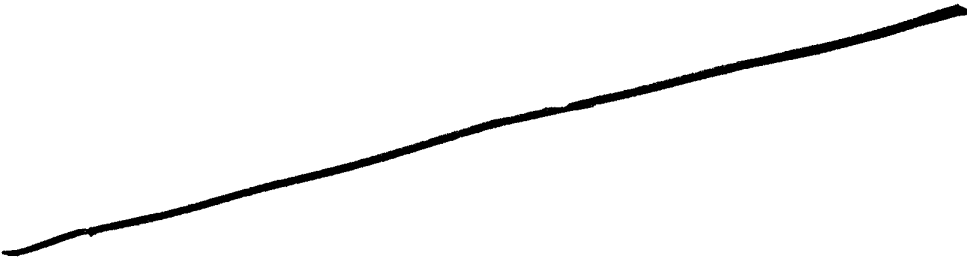
Dear Dr. Hall:

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

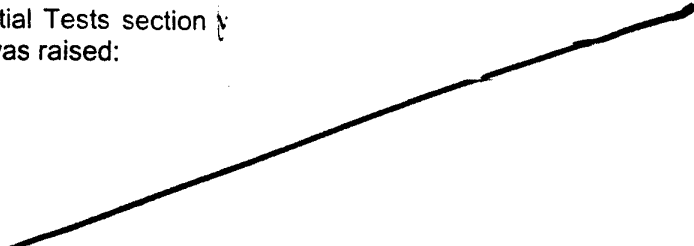


F. The Chain of Custody, Accessioning, and Security section acceptable. However, the following issues were raised:

Dr. Hall
December 21, 1999
Page 2 of 2

H. The Initial Tests section
issue was raised:




I. The Confirmatory Tests section
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

Enclosure
cc: Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0001
Document No. Final

Laboratory: Toxicology Testing Service, Inc.

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M17 Date: 18 November 1999
 Other _____

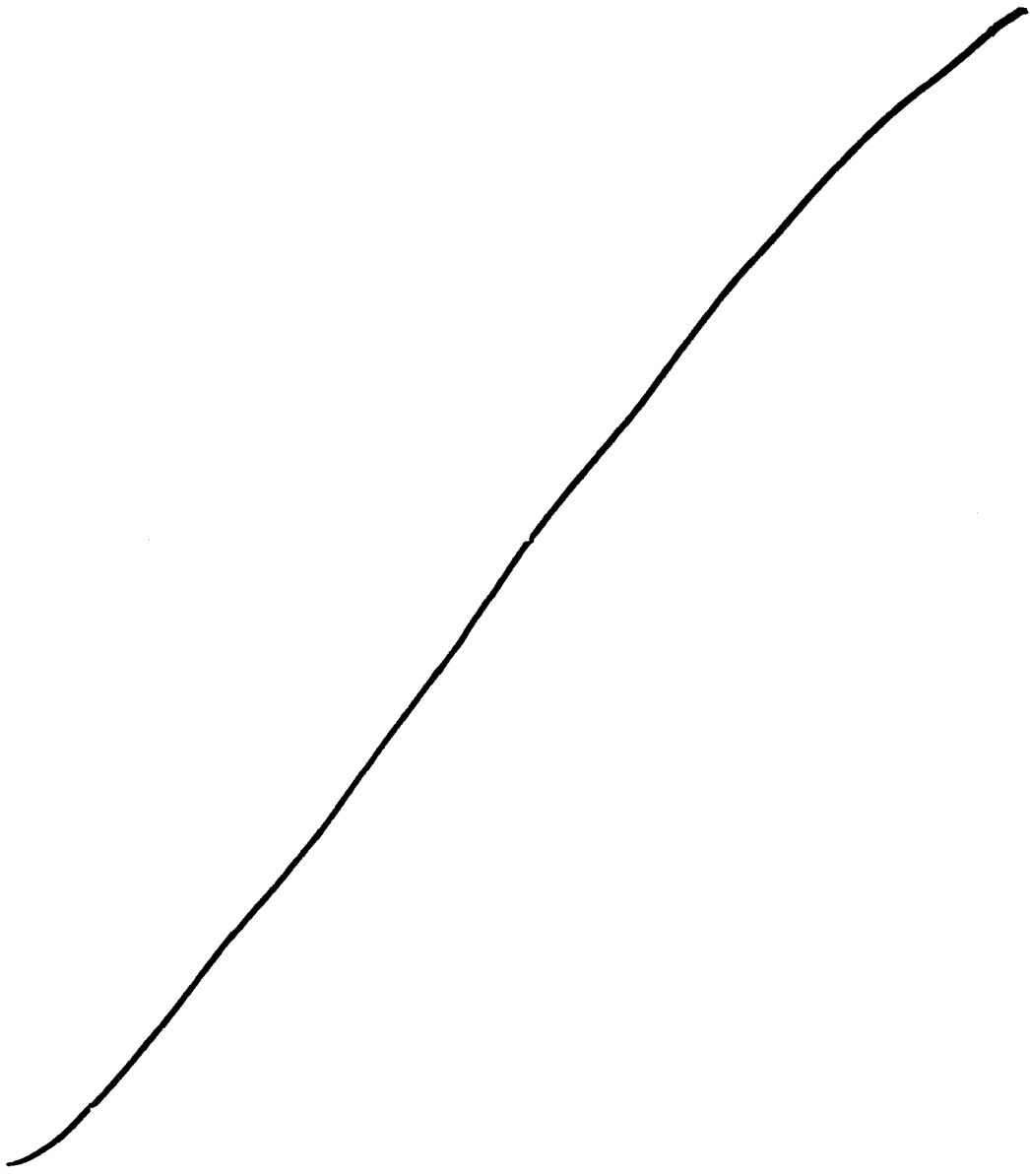
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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 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]

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]

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 13, 2000

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

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 the attached critique.

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 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,

A handwritten signature in cursive script that reads "Deborah J. Denson".

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M18

A thick, black, curved line drawn over the text, likely to redact sensitive information.

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0001
Document No. Final

Laboratory: Toxicology Testing Service, Inc.

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M18 Date: 11 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

[REDACTED]

Section K. Reporting

[REDACTED]

Section L. Computers, Software, and LIMS

[REDACTED]

Section M. Equipment and Maintenance

[REDACTED]

Section N. Personnel

[REDACTED]



RESEARCH TRIANGLE INSTITUTE

January 12, 2001

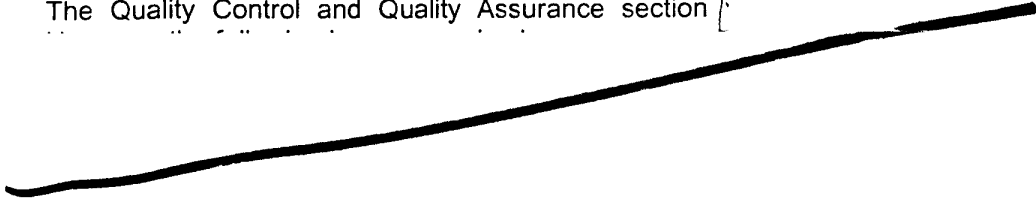
National Laboratory Certification Program

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

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.

G. The Quality Control and Quality Assurance 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 issue 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 Technical Analyst

Enclosure

cc: Project Files/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0001
Document No. Final

Laboratory: Toxicology Testing Service, Inc.

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M19 Date: 16 November 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 and Quality Assurance

Section H. Initial Tests

[REDACTED]

Section I. Specimen Validity Tests

[REDACTED]

Section J. Confirmatory Tests

[REDACTED]

Section K. Records Audit

[REDACTED]

Section L. Certification and Reporting

[REDACTED]

Section M. Laboratory Information Management System (LIMS)

[REDACTED]

Section N. Personnel

[REDACTED]