RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 1, 1999

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

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.

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 D. Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M17

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

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 02
Document No. Fir

Laboratory: DrugScan, Inc.

Location: Warminster, PA

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M17 Date: December 10, 1998
[ ] Other _____

Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

There were a number of comments and observations generated as a result of the inspectio 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

July 27, 1999

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

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.

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/M18

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

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0224
Document No. Final

Laboratory: DrugScan, Inc.

Location: Warminster, PA

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M16 Date: 17 June 1999
[ ] Other _____

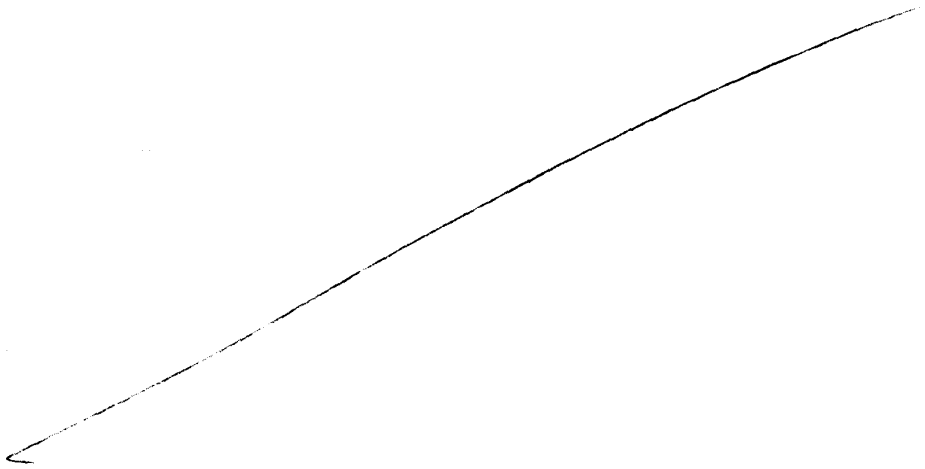
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

January 24, 2000

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

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.

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

Deborah J. Denson
NLCP Inspection Analyst

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

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0224
Document No. Final

Laboratory: DrugScan, Inc.

Location: Warminster, PA

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M19 Date: 9 December 1999
[ ] Other _____

Status: [XX] 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

July 12, 2000

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

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

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M20

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

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0224
Document No. Final

Laboratory: DrugScan, Inc.

Location: Warminster, PA

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M20 Date: 8 June 2000
[ ] Other _____

Status: [XX] 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 15, 2001

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

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 appeared to meet most of the minimum technical criteria. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

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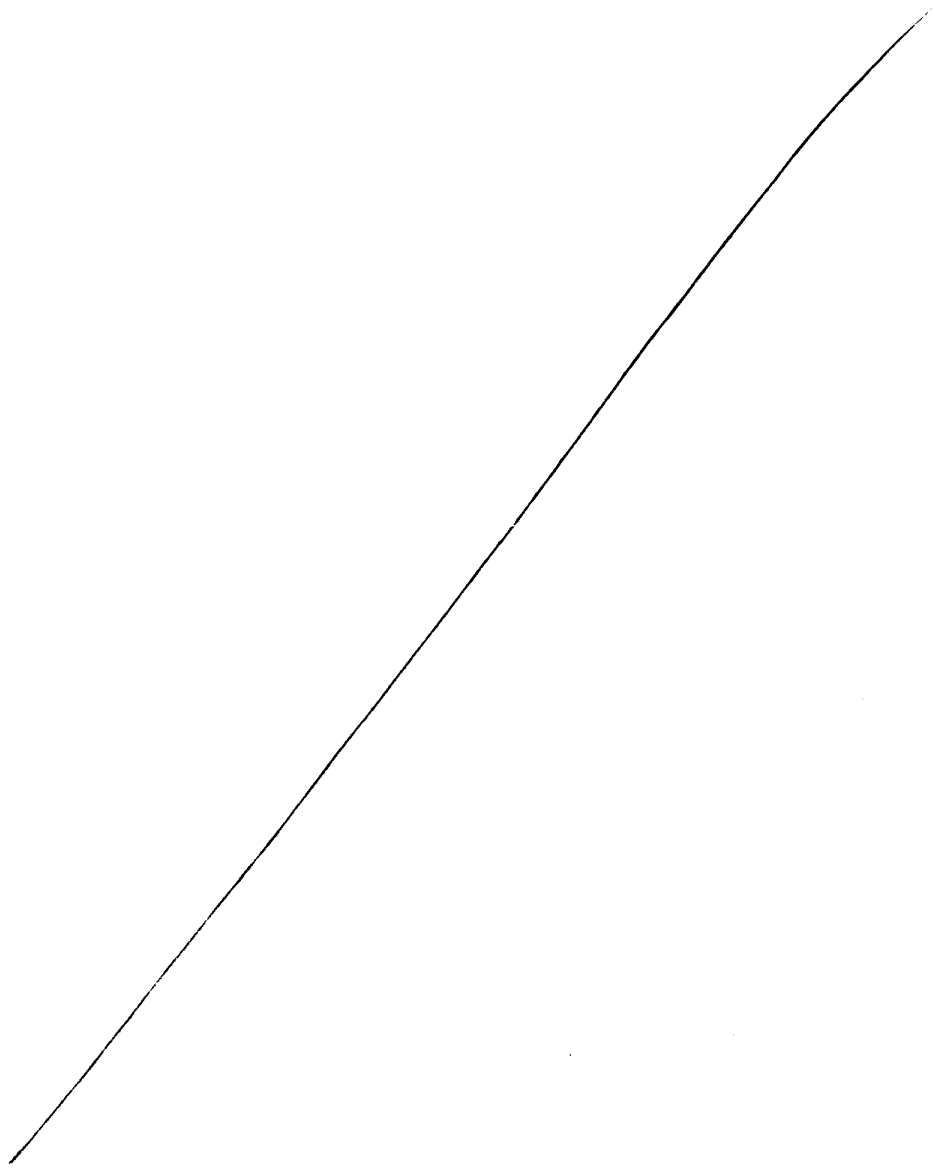
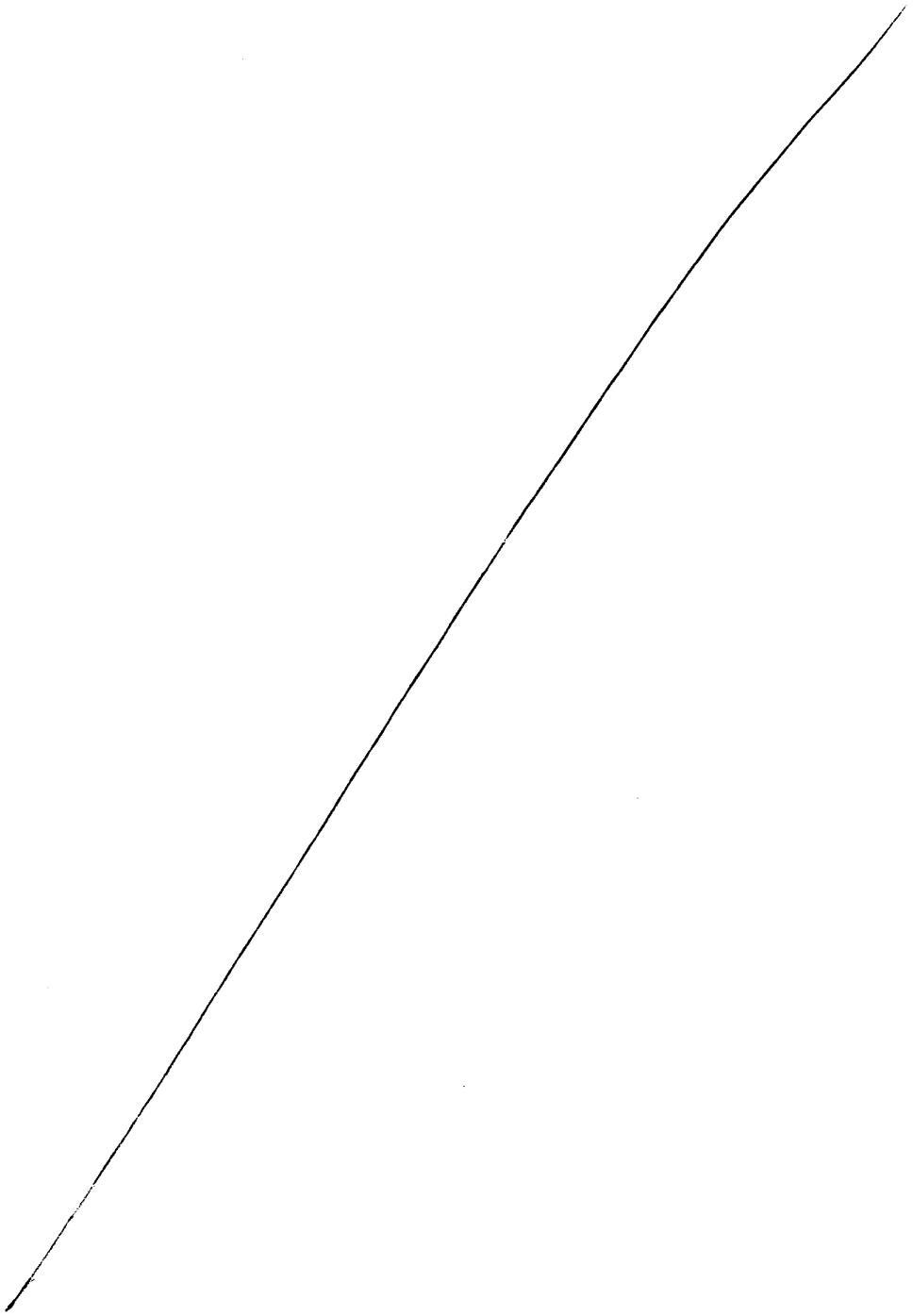
Telephone 919 541-6709 • Fax 919 541-7042





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. 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M21

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0224
Document No. Final

Laboratory: DrugScan, Inc.

Location: Warminster, PA

Document Reviewed:
[ ] Application Form
[XX] Inspection Report #M21 Date: 7 December 2000
[ ] Other _____

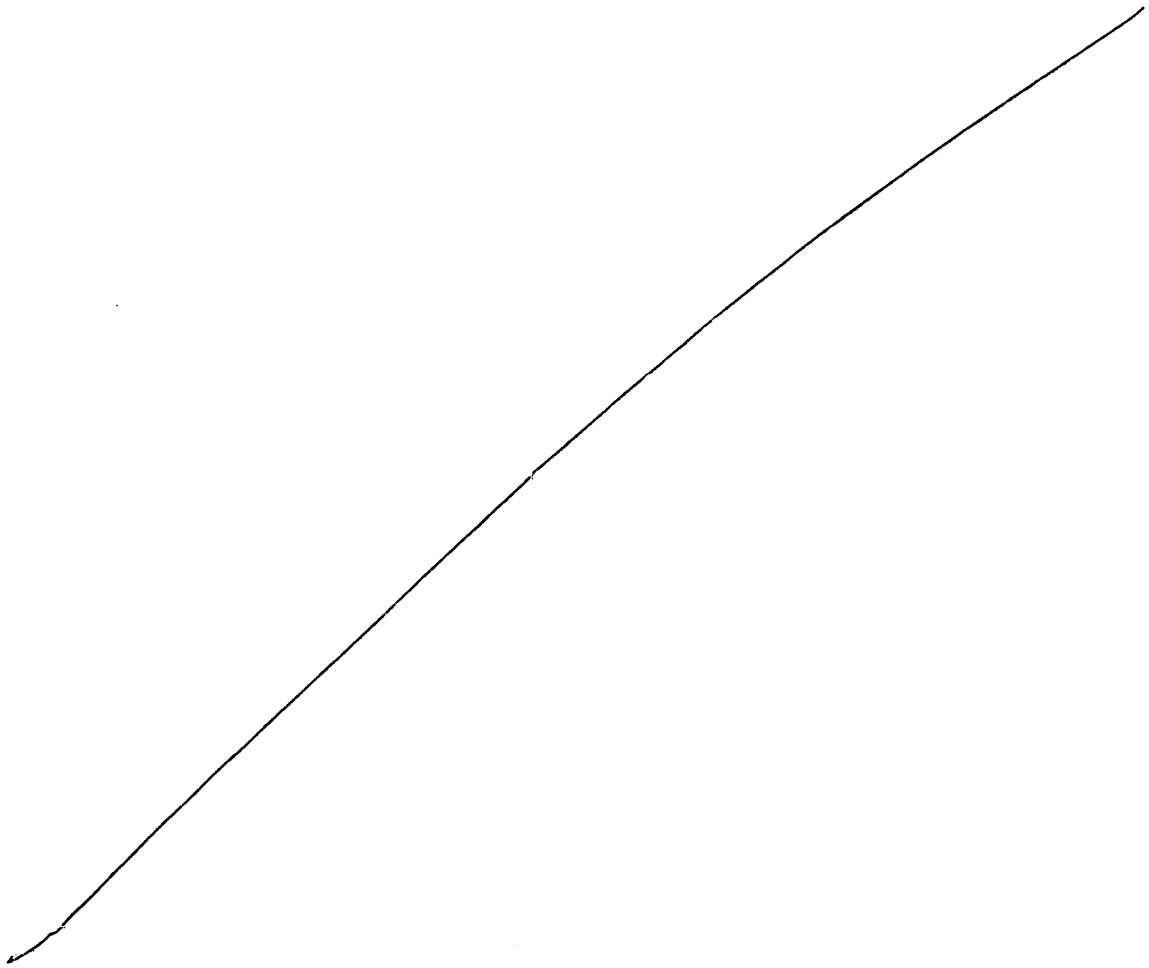
Status:
[XX] Appeared to meet most of the minimum technical criteria
[ ] Appeared to meet a number of the minimum technical criteria
[ ] Failed to meet a number of the minimum technical criteria
[ ] Failed to meet a significant number of the minimum technical criteria

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

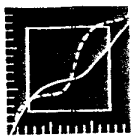
Section J. Confirmatory Tests

Section K. Records Audit

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel



DRUGSCAN®

Medical and Forensic Toxicology Services

March 9, 2001

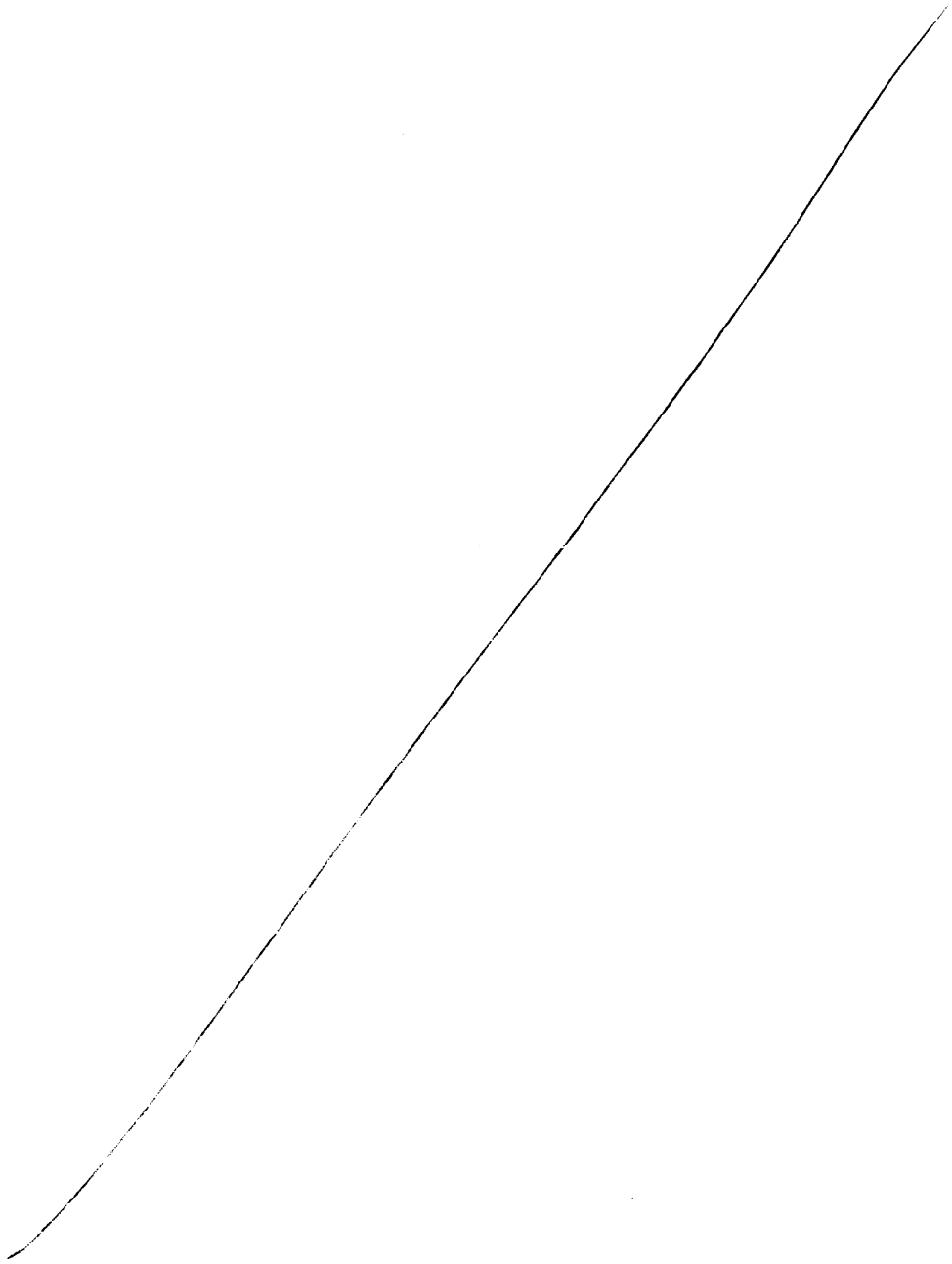
John Mitchell, PhD
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

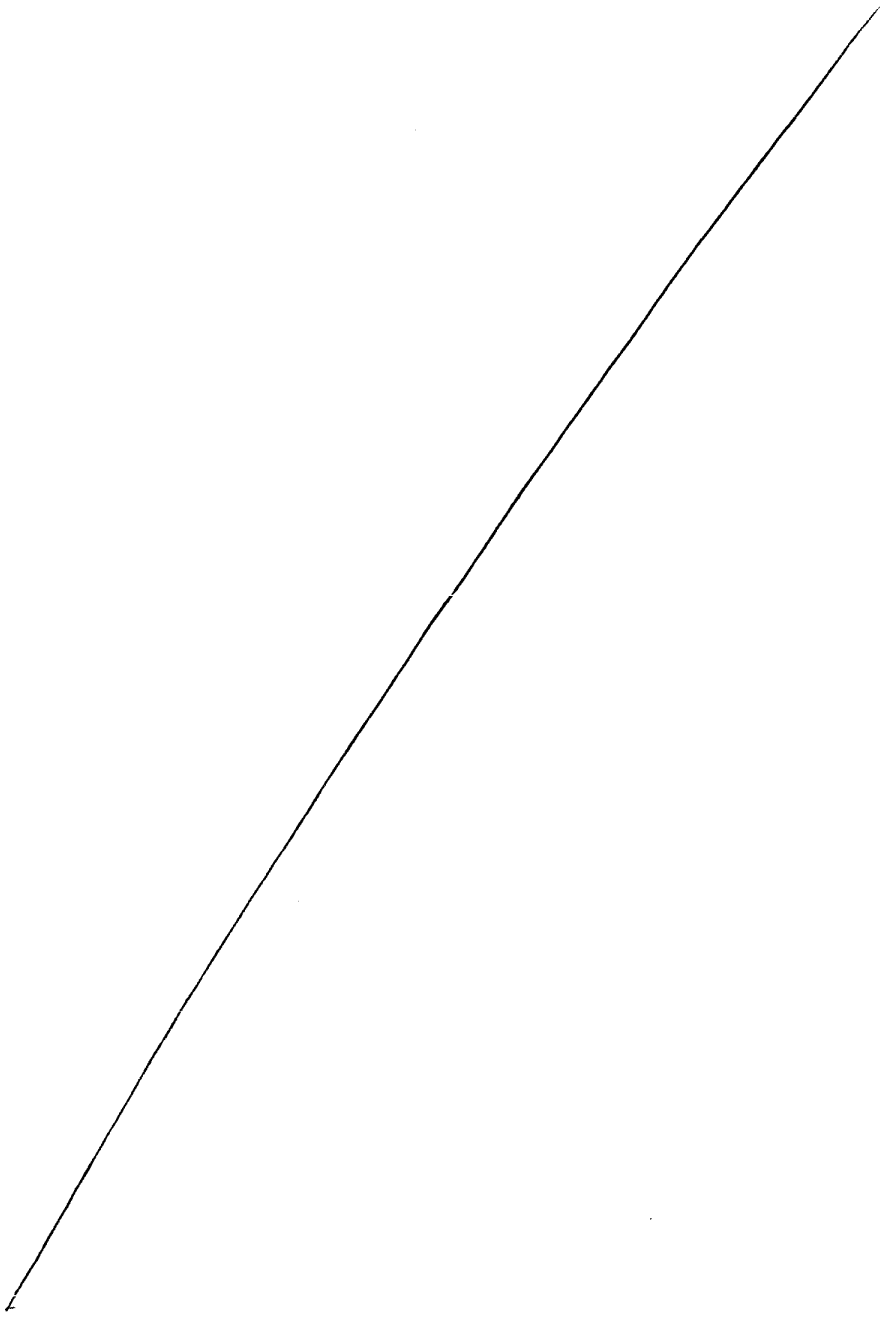
RE: M-21 inspection critique

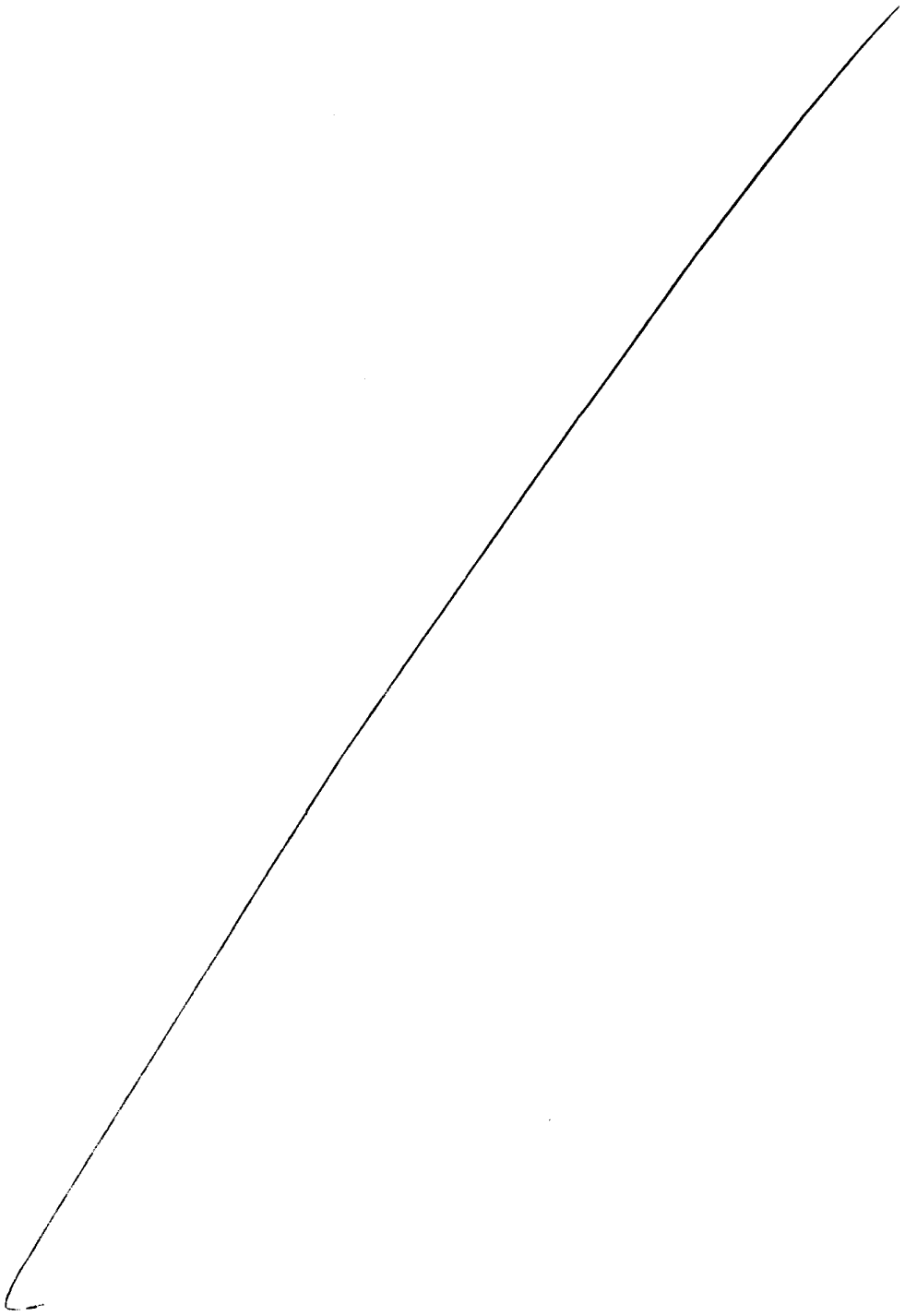
Dear Dr. Mitchell

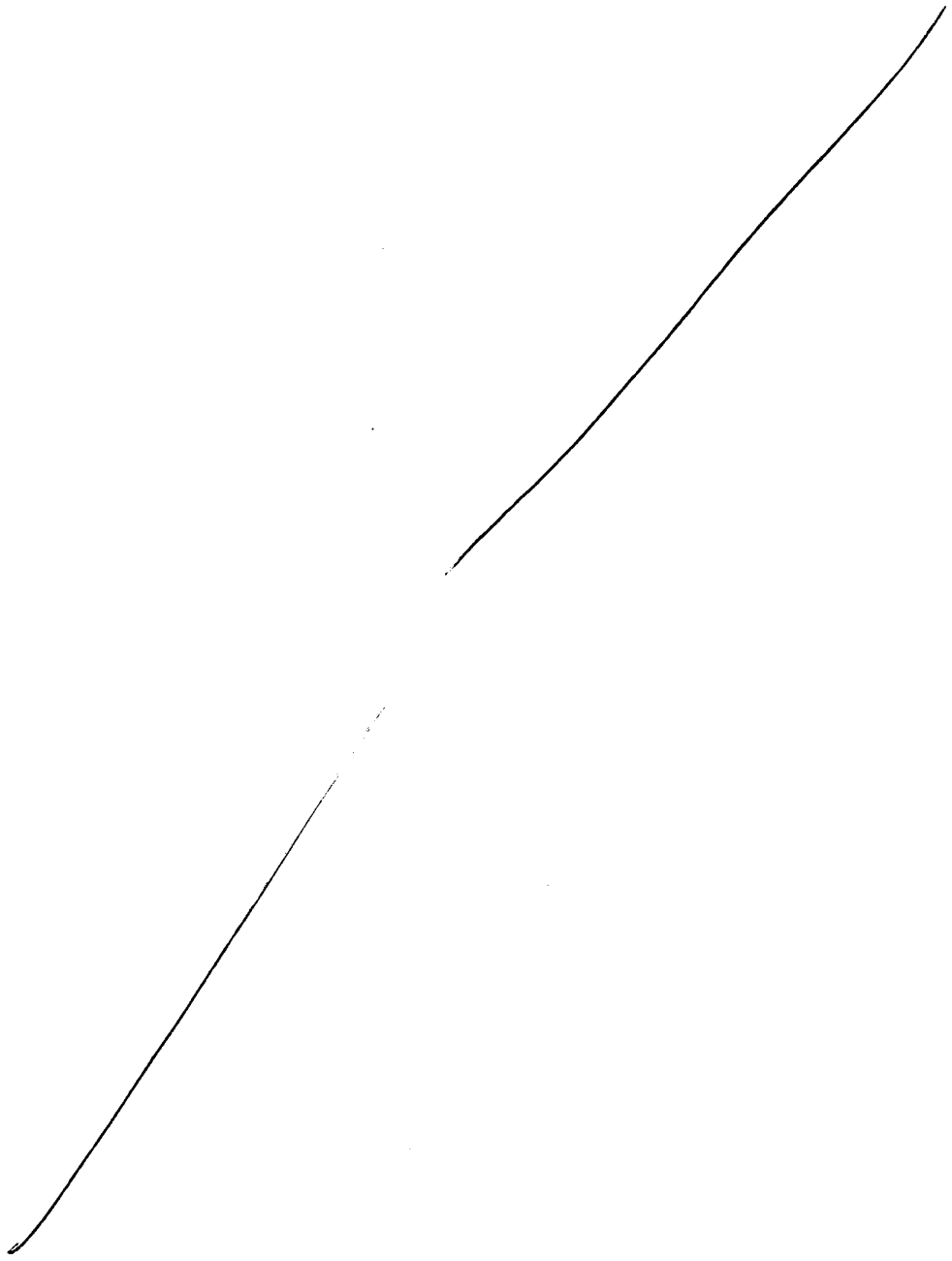
We have received your letter of February 15, 2001, in which several areas of concern were noted, and requesting a letter of proposed corrective actions. The issues are addressed as follows:

1119 Mearns Road, P.O. Box 2969, Warminster, PA 18974-0097, Telephone (215) 674-9310









Mark Lichtenwalner, PhD

Mark Lichtenwalner
Responsible Person
DrugScan #0224