

March 3, 1999

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

Dear Mr. West:

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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following corrective actions:

E. The Standard Operating Procedures (SOP) section



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




G. The Quality Control and Standards section



J. The Records section

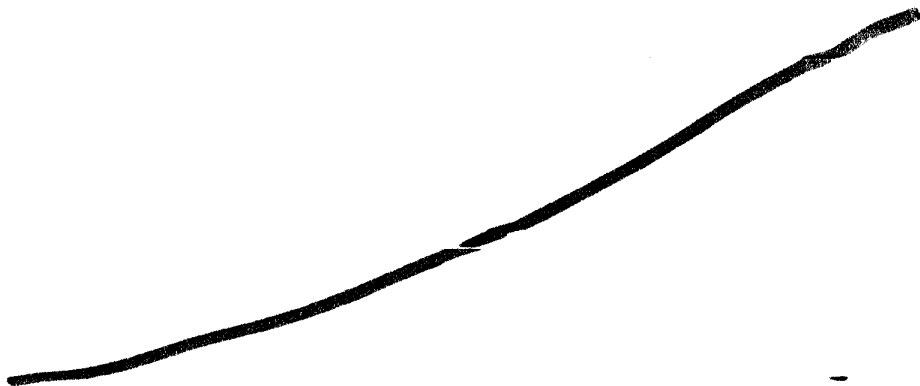


L. The Computers, Software, and Laboratory Information Management System (LIMS) section



N. The Personnel 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/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0124
Document No. Final

Laboratory: Poisonlab, Inc.

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M18 Date: 28 January 1999
 Other _____

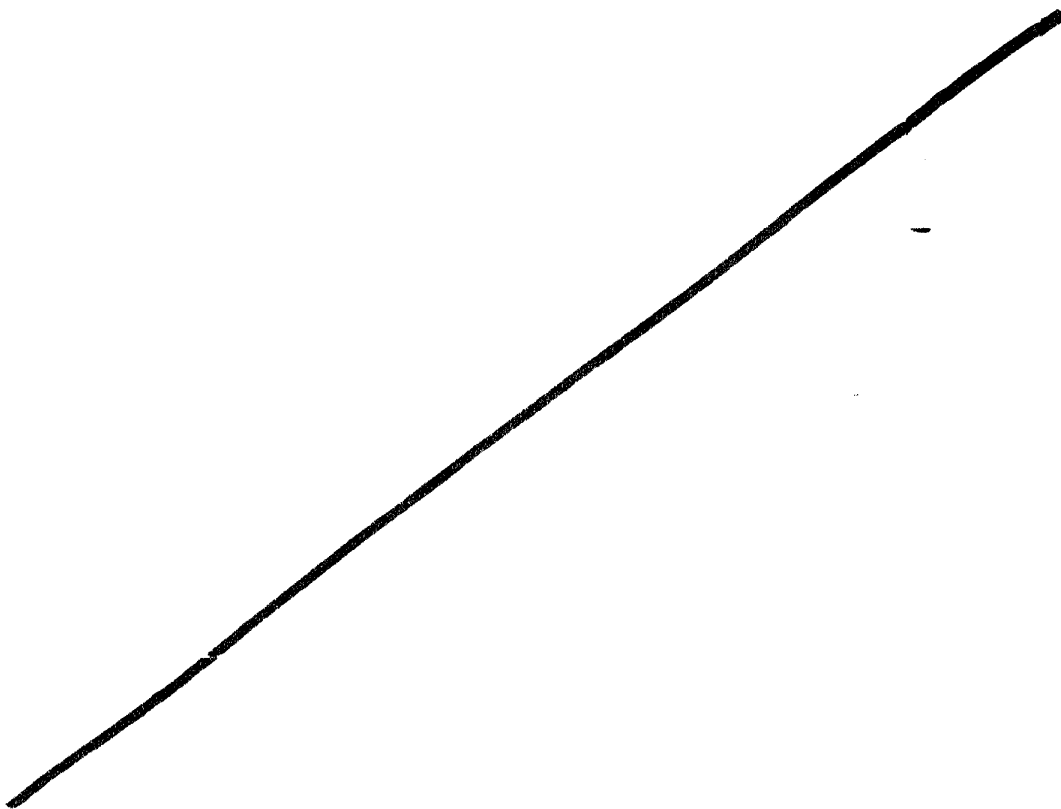
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests




Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS





Ver. Final

Lab ID# 0124

Section M. Equipment and Maintenance

[Redacted content]

Section N. Personnel

[Redacted content]

[Redacted content]

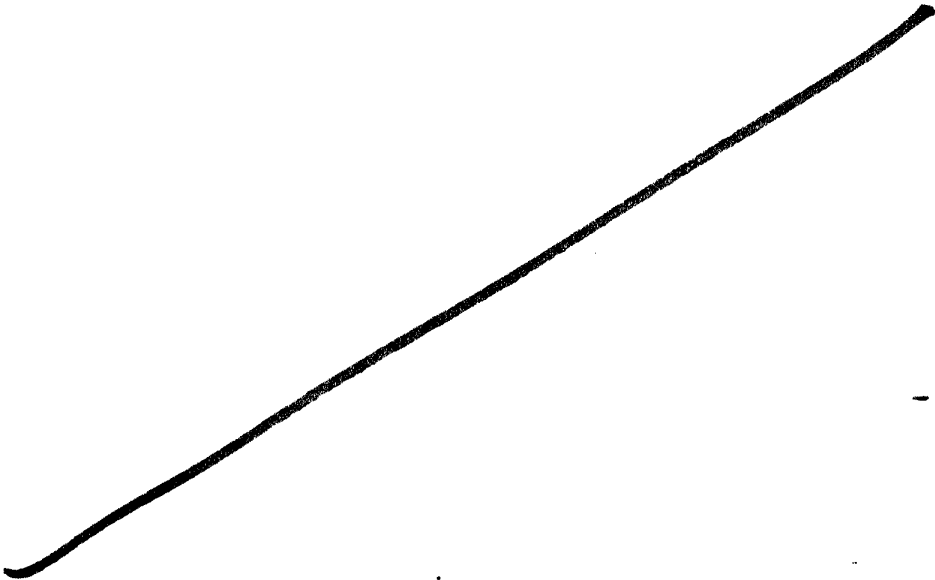
3/25/99

Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

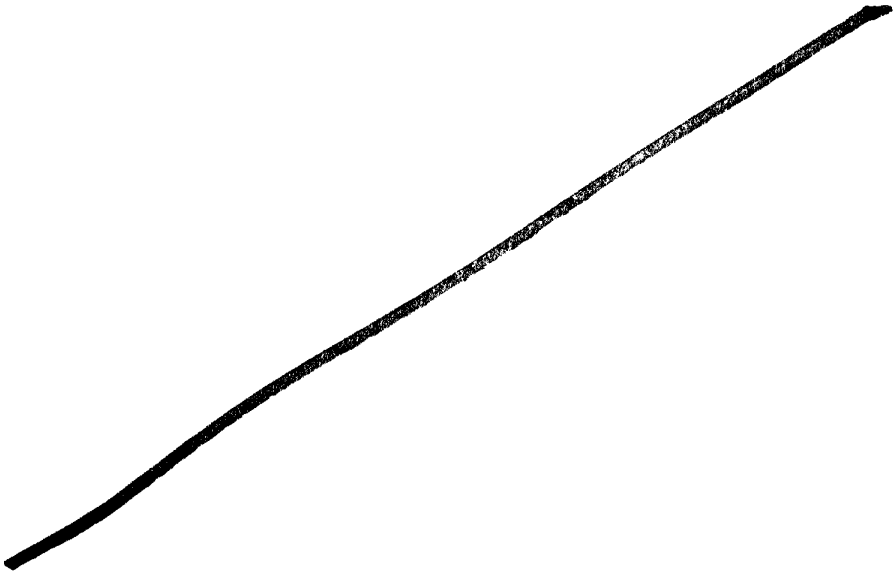
Dear Ms. Crumpton;

I am responding to your inspection critique of 3/3/99.

Section E. Standard Operating Procedures

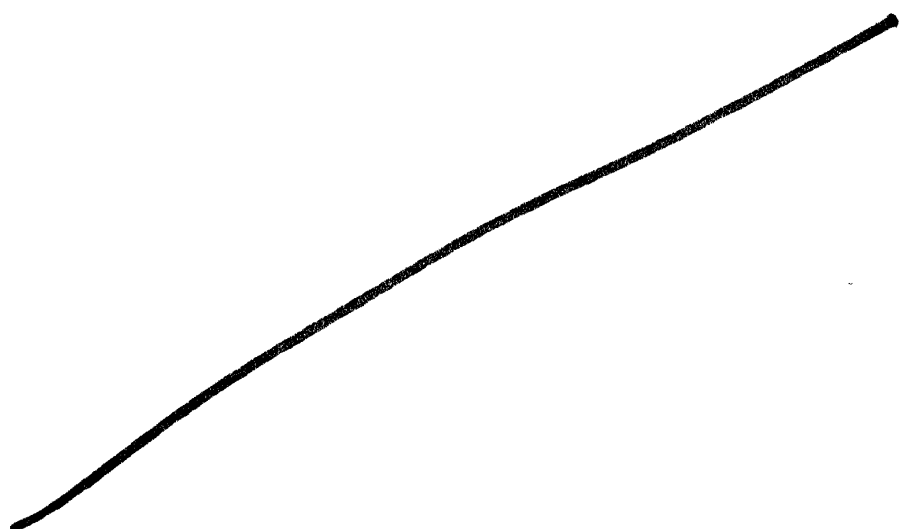


Section G. Quality Control





Section J. Records Audit



Section L. Computers, Software, and LIMS



Section N. Personnel;

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 30, 1999

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

Dear Mr. West:

We have reviewed the material provided in your correspondence of March 25, 1999, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of March 3, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and 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 Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M18



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

September 8, 1999

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

Dear Mr. West:

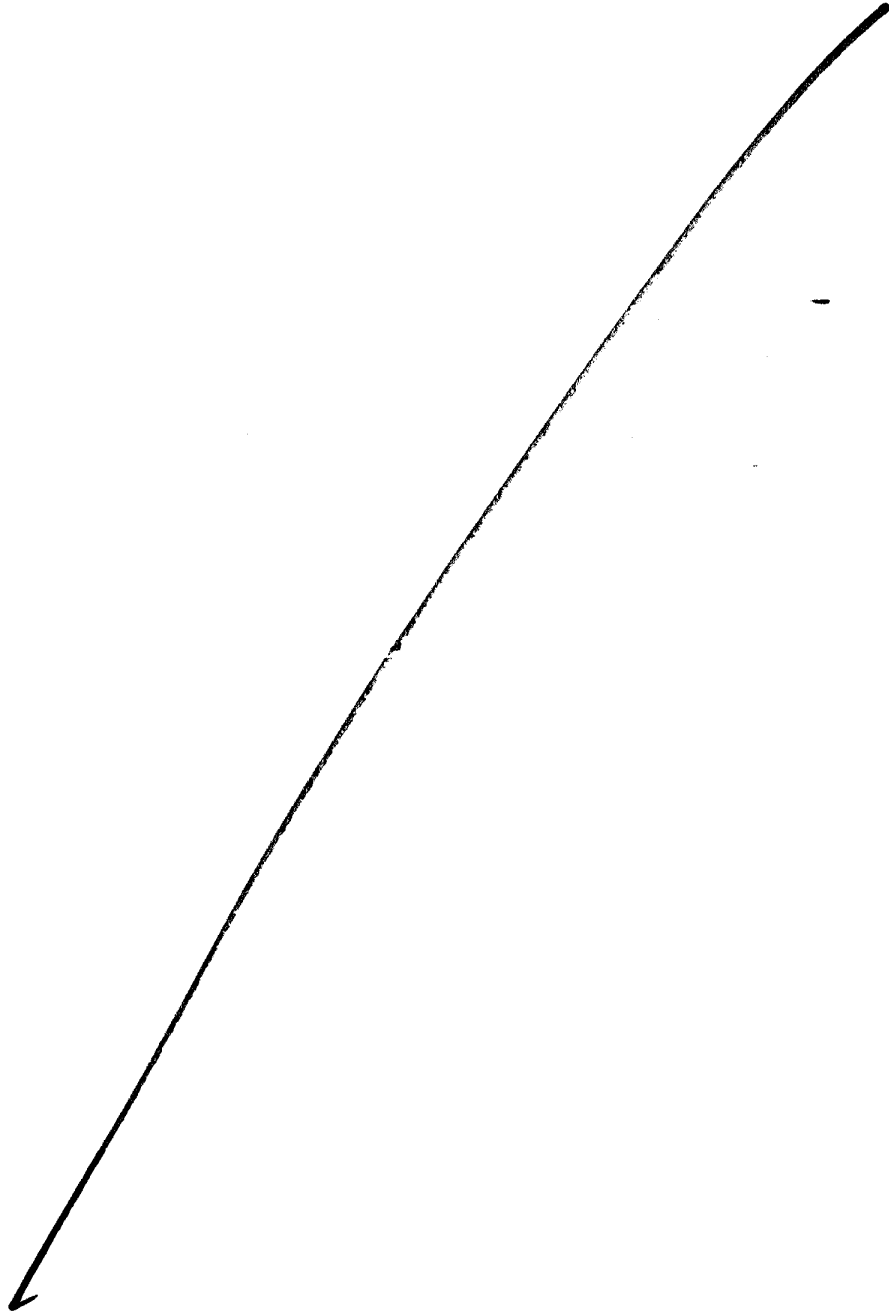
The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection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

E. The Standard Operating Procedures (SOP) section

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

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Mr. West
Page 3 of 3
09/08/99

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/M19


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0124
Document No. Final

Laboratory: Poisonlab, Inc.

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M19 Date: 29 July 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.

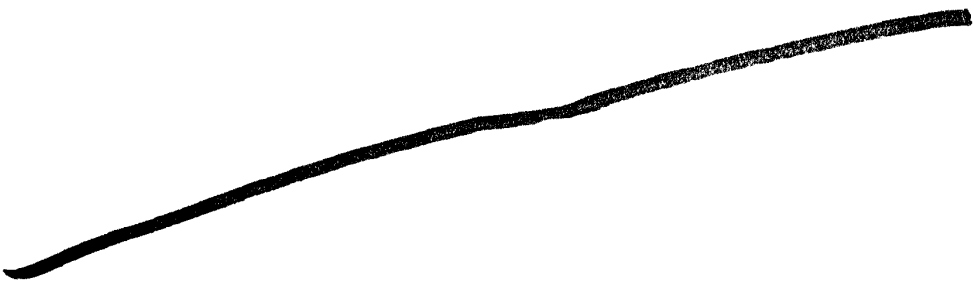
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

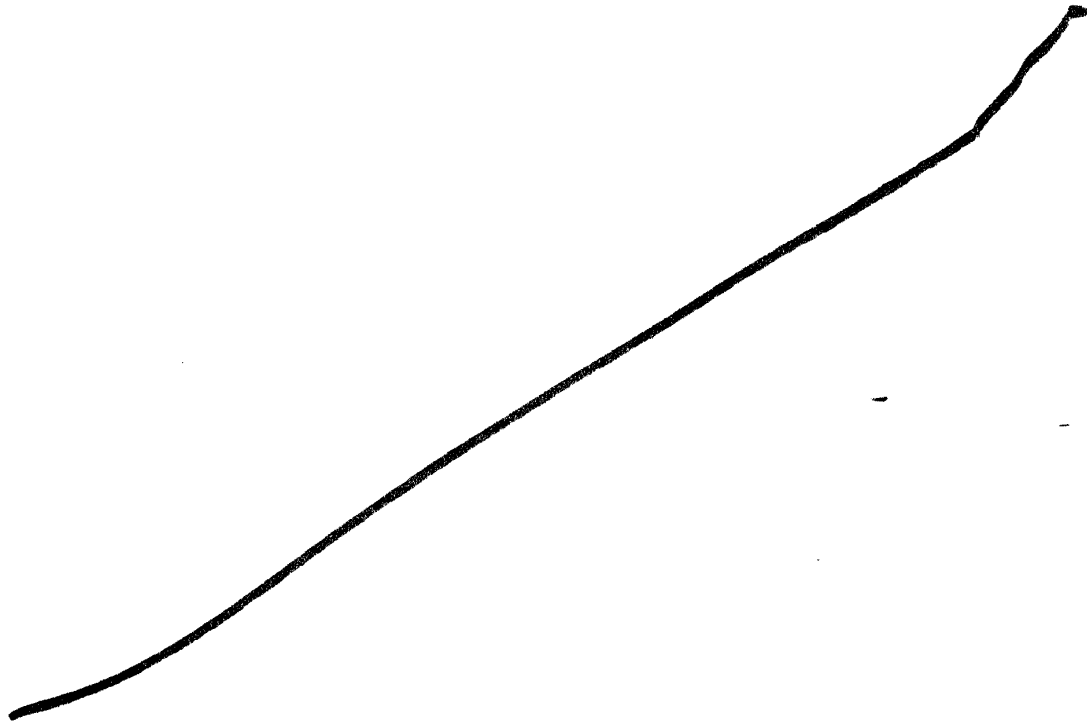
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

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]

[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

March 8, 2000

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

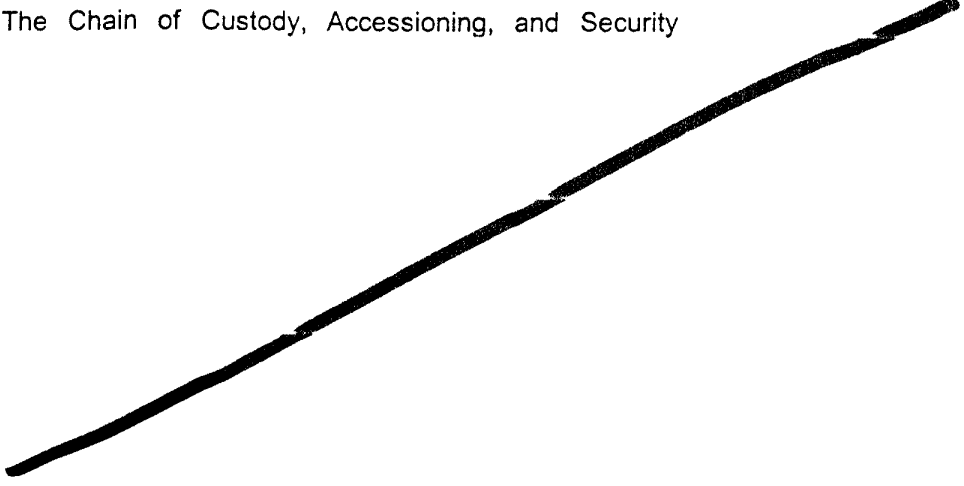
Dear Mr. West:

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



F. The Chain of Custody, Accessioning, and Security



K. The Reporting section

RTI is recommending to 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/M20

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0124
Document No. Final

Laboratory: Poisonlab, Inc.

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M20 Date: 20 January 2000
 Other _____

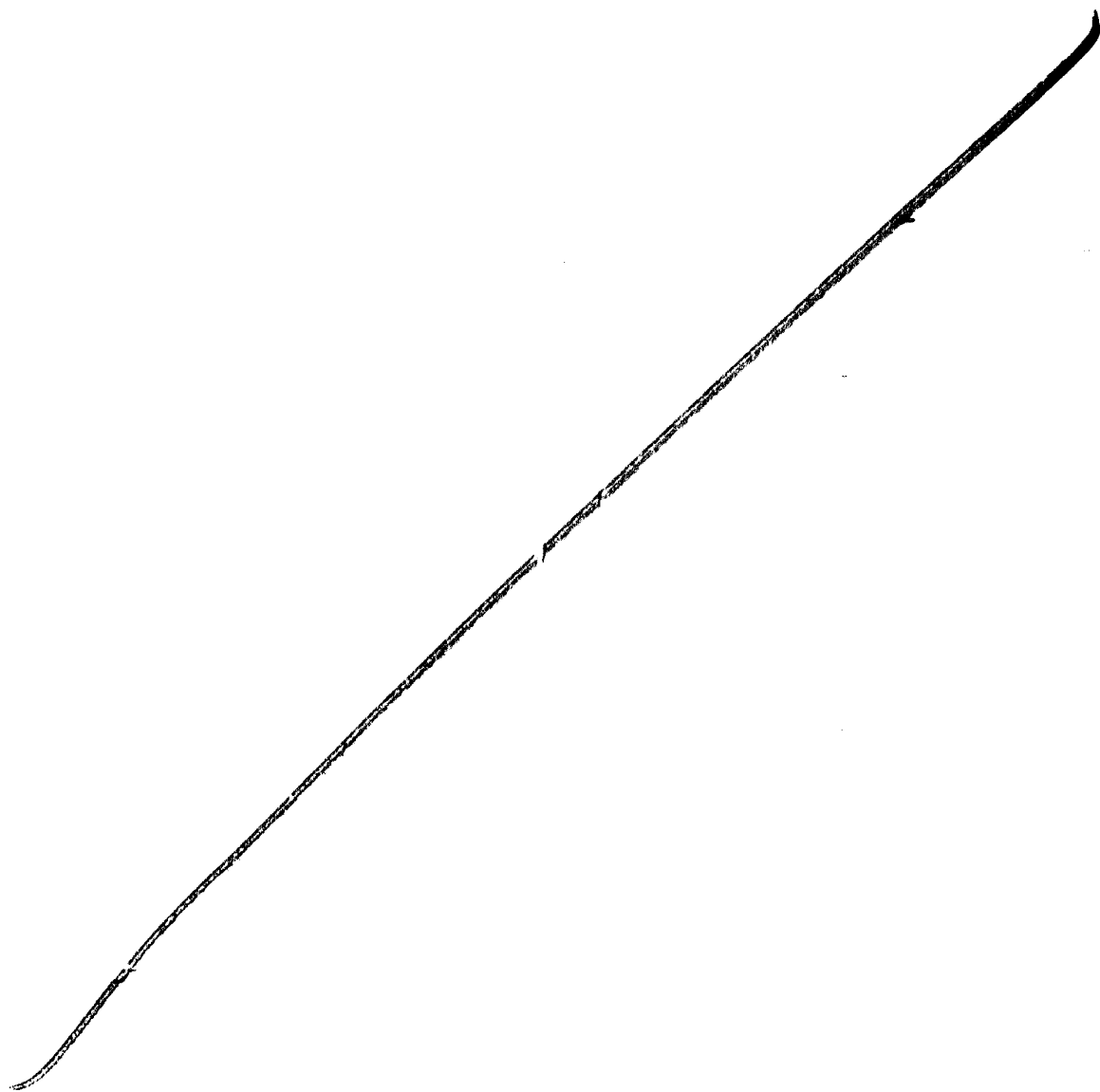
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

[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 content]

Section K. Reporting

[Redacted content]

[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

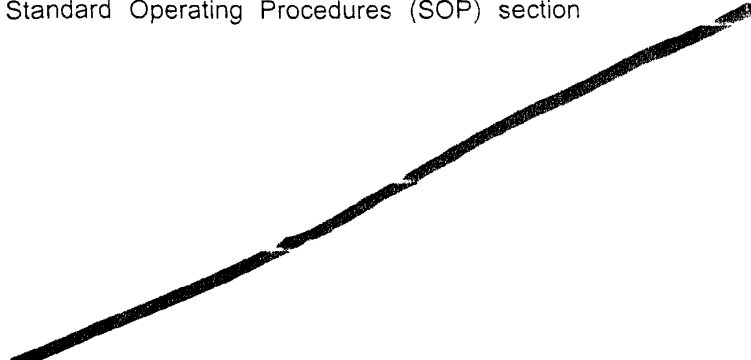
September 8, 2000

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

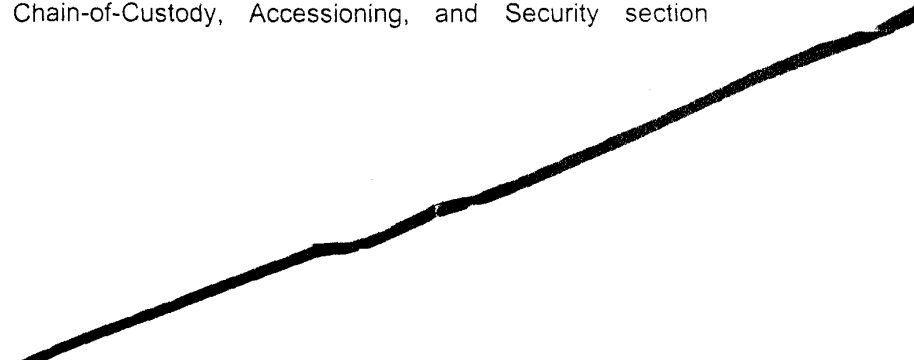
Dear Mr. West:

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 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

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

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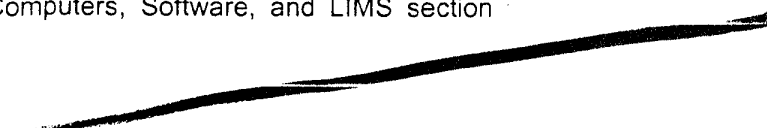
H. The Initial Tests section



J. The Records Audit section



L. The Computers, Software, and LIMS section

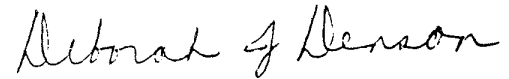


RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the 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.

Mr. West
September 8, 2000
Page 3 of 3

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/M21



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0124
Document No. Final

Laboratory: Poisonlab, Inc.

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M21 Date: 20 July 2000
 Other _____

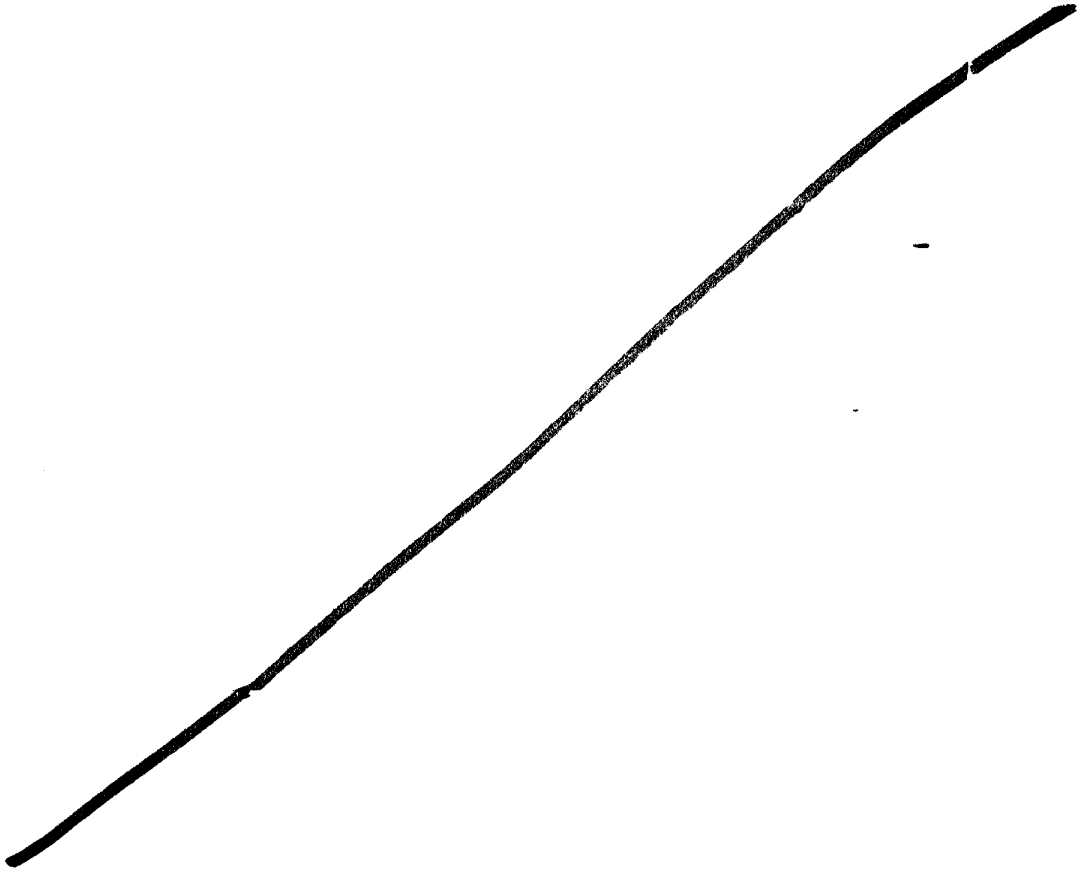
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

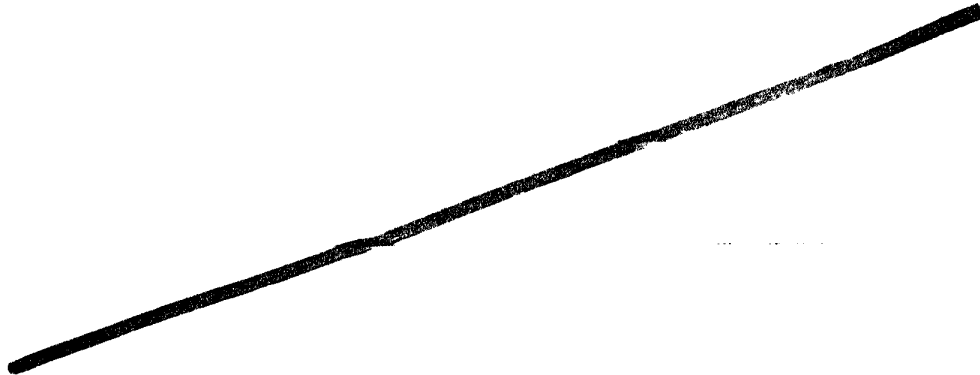
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Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

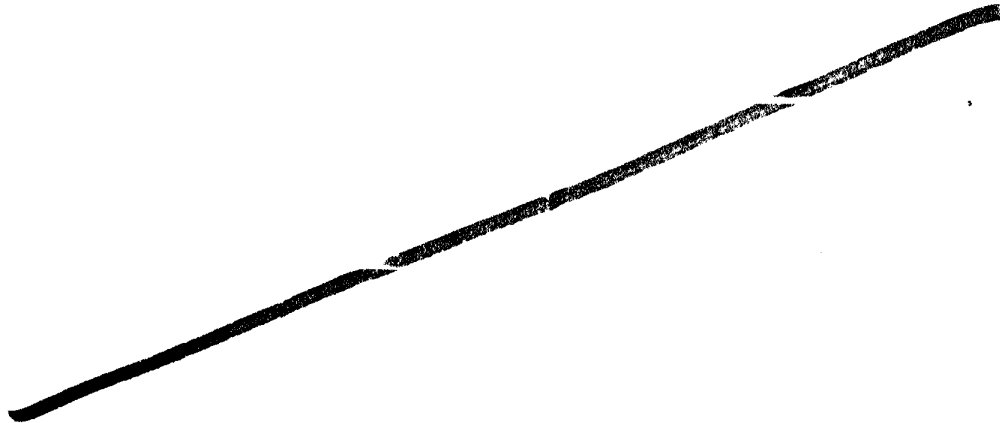
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Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance

Section N. Personnel