

0032  
Dr. Arthur M. Zebelman  
Drug Proof, Div. of Dynacare/Lab of Pathology, LLC  
1229 Madison St. Suite 500  
Nordstrom Medical Tower  
Seattle, WA 98104

Dear Dr. Zebelman:

The enclosed critique was developed from the inspection reports of the three 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. However, the laboratory must correct/clarify the following:

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



J. The Quality Control and Standards section

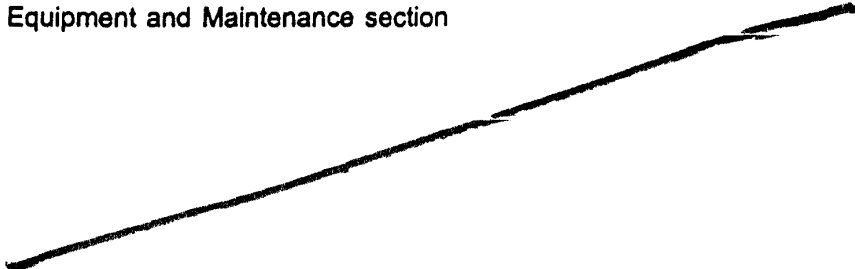


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Dr. Zebelman  
Page 2 of 2  
09/29/98

K. The Equipment and Maintenance section



N. The Gas Chromatography/Mass Spectrometry (GC/MS) 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



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0032  
Document No. Final

Laboratory: DrugProof

Location: Seattle, WA

Document Reviewed:     Application Form  
                               Inspection Report #M17                      Date: 10 September 1998  
                               Other \_\_\_\_\_

Status:            Highly Acceptable            Acceptable  
                          Unacceptable                Failure

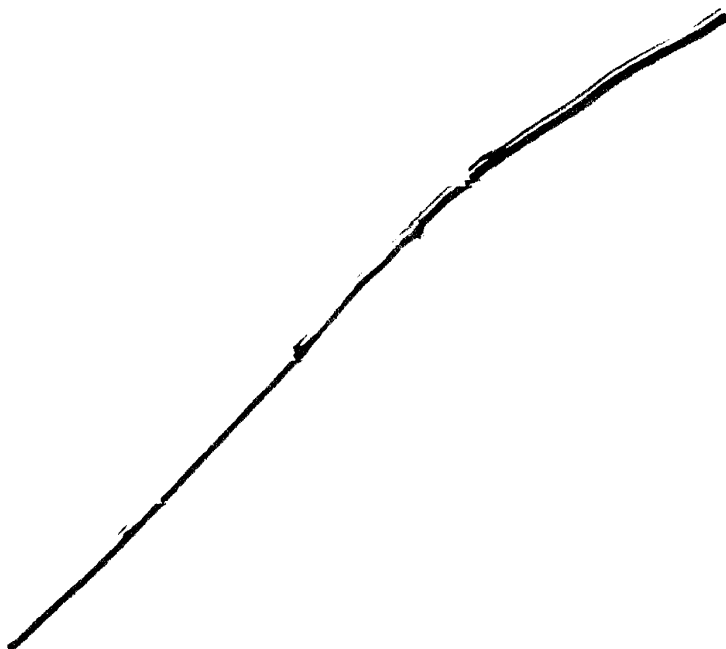
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A review of the three independent National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

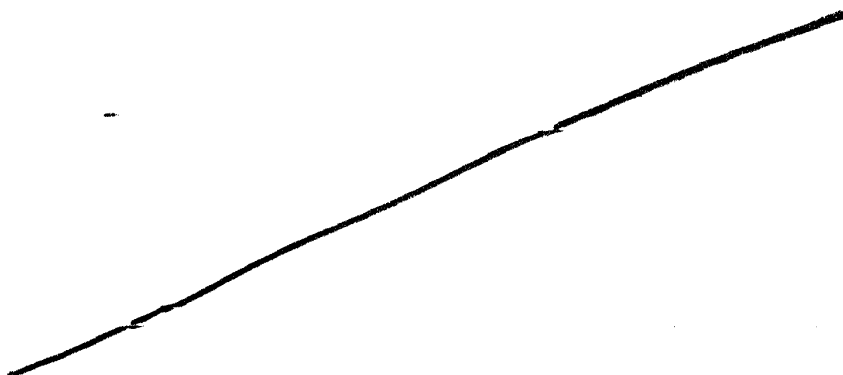
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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. 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

[Redacted]



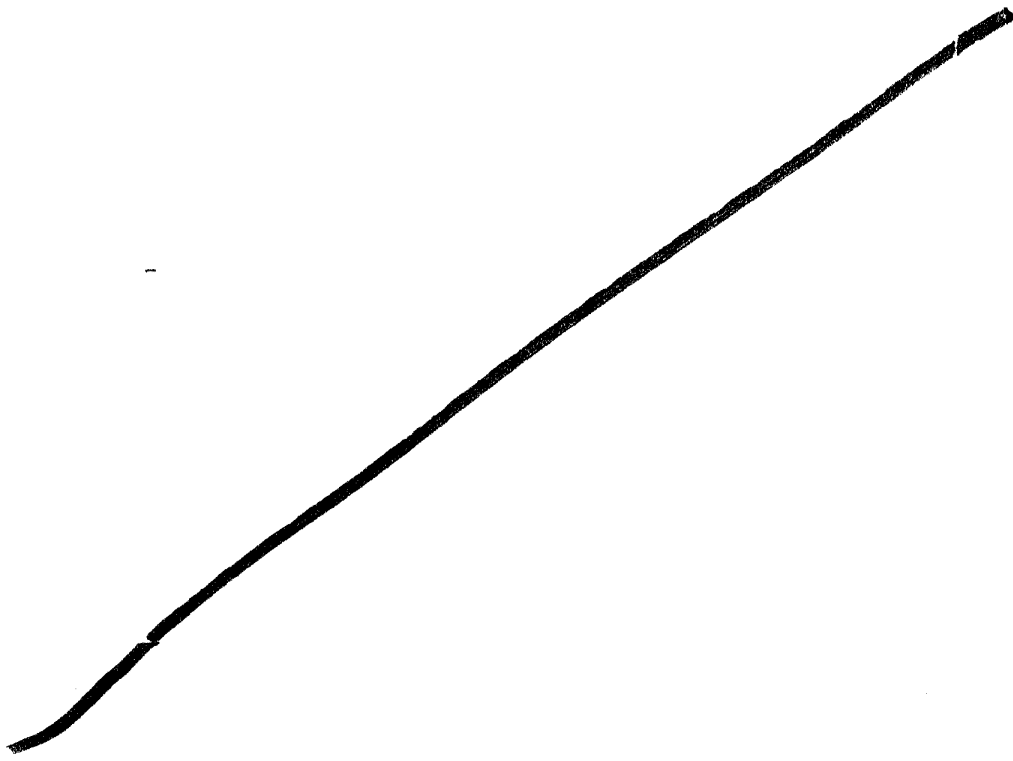
10/29/98

Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

This report is written in response to your letter of September 29, 1998 regarding the 17<sup>th</sup> maintenance inspection of this laboratory. The following responses will be in the same order and headings as your letter.

F. Chain of Custody, Accessioning, Security



[Redacted]

J. Quality Control and Standards

[Redacted]

K. Equipment and Maintenance

[Redacted]

N. GC/MS

[Redacted]



Please let me know if you require further information regarding this inspection. Feel free to call me at (206) 386 2438 or Greg Randall at (800) 898 0180.

Sincerely,

Arthur M. Zebelman, Ph.D.  
Responsible Person

RESEARCH TRIANGLE INSTITUTE



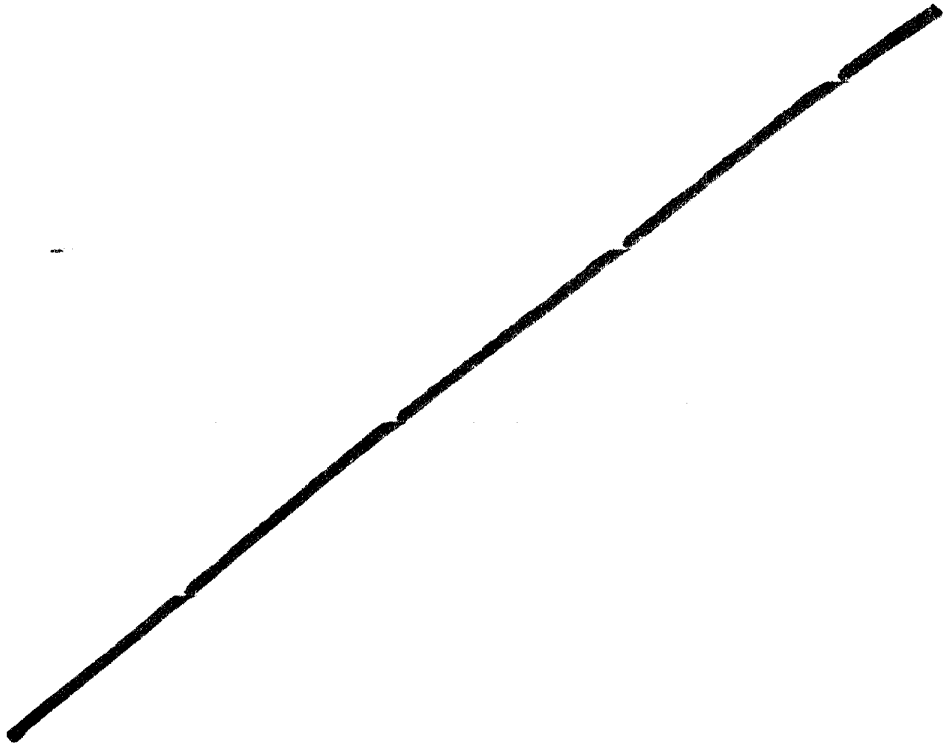
National Laboratory Certification Program

November 4, 1998

0032  
Dr. Arthur M. Zebelman  
Drug Proof, Div. of Dynacare/Lab of Pathology, LLC  
1229 Madison St. Suite 500  
Nordstrom Medical Tower  
Seattle, WA 98104

Dear Dr. Zebelman:

We have reviewed the material submitted in your correspondence of October 29, 1998, provided in final response to issues raised during the seventeenth maintenance inspection of your laboratory as originally outlined in our correspondence of September 29, 1998. The following is a review of the material submitted:




Dr. Zebelman  
Page 2 of 2  
11/04/98

Based upon our review of the material submitted, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the 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

April 7, 1999

0032  
Dr. Arthur M. Zebelman  
Drug Proof, Div. of Dynacare/Lab of Pathology, LLC  
1229 Madison St. Suite 500  
Nordstrom Medical Tower  
Seattle, WA 98104

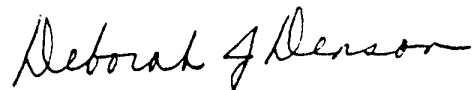
Dear Dr. Zebelman:

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

Sincerely,



Deborah J. Denson  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M18



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0032  
Document No. Final

Laboratory: DrugProof, a Division of Dynacare

Location: Seattle, WA

Document Reviewed:     Application Form  
                               Inspection Report # M18  
                               Other \_\_\_\_\_

Date: 4 March 1999

Status:            Highly Acceptable        Acceptable  
                       Unacceptable            Failure

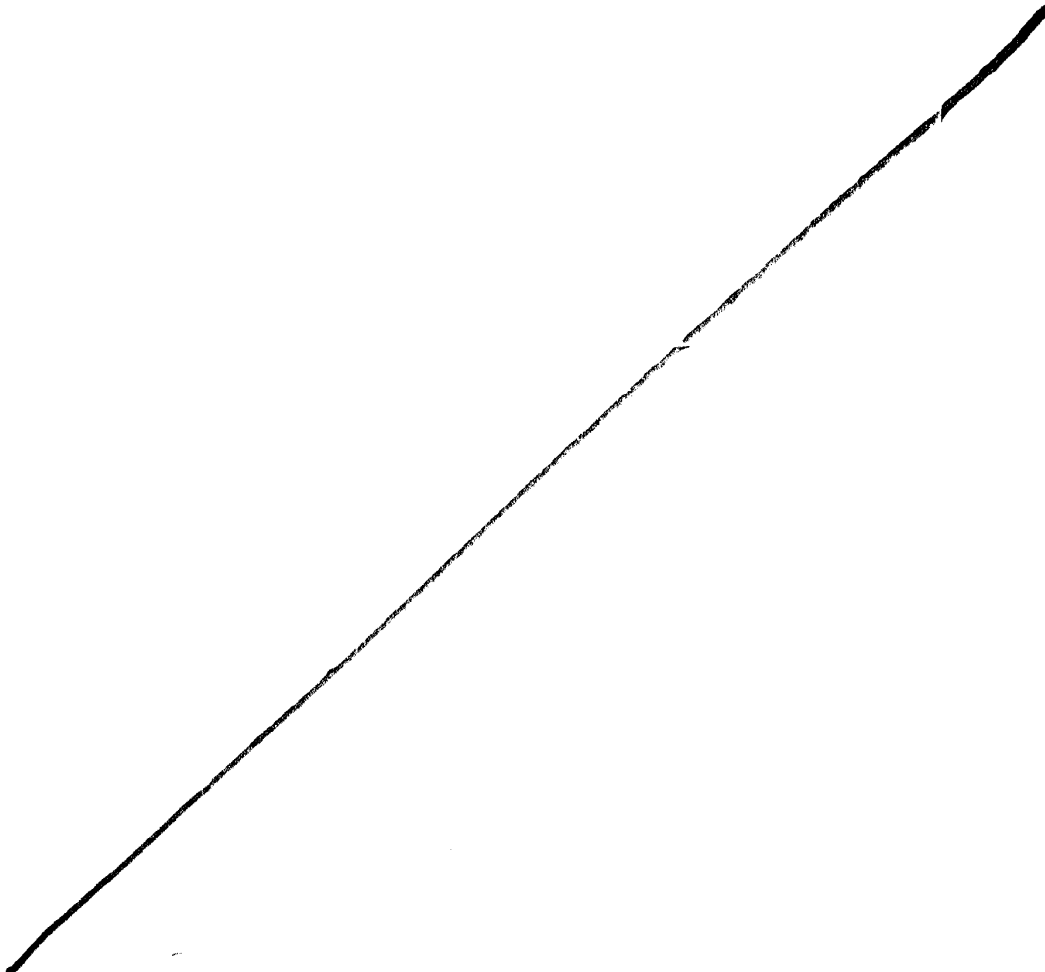
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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



October 20, 1999

0032  
Dr. Arthur M. Zebelman  
Drug Proof, Div. of Dynacare/Lab of Pathology, LLC  
1229 Madison St. Suite 500  
Nordstrom Medical Tower  
Seattle, WA 98104



Dear Dr. Zebelman:

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 following issues were raised:

E. The Standard Operating Procedures (SOP) section



G. The Quality Control section  
following issue was raised:



H. The Initial 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/M19

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0032  
Document No. Final

Laboratory: DrugProof

Location: Seattle, WA

Document Reviewed:     Application Form  
                              Inspection Report #M19                      Date: 9 September 1999  
                              Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                              Unacceptable                         Failure

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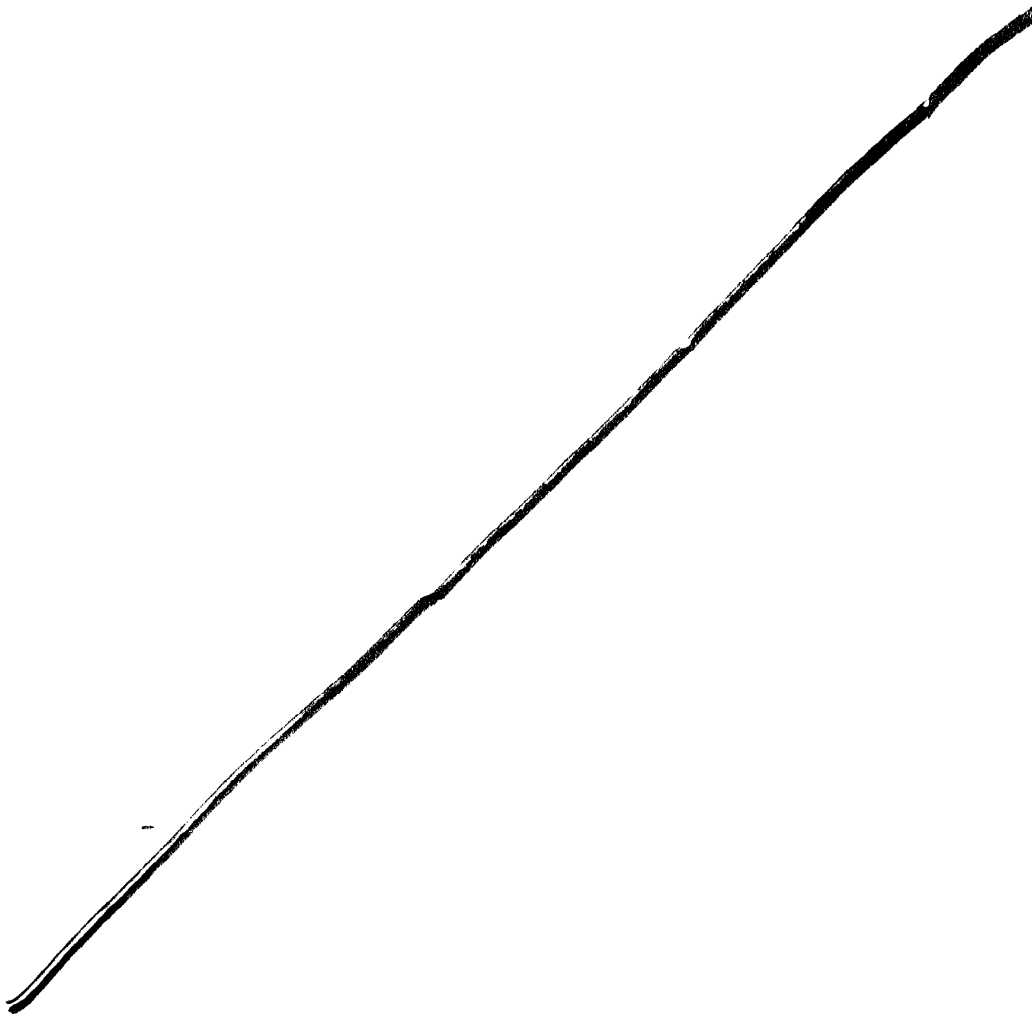
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

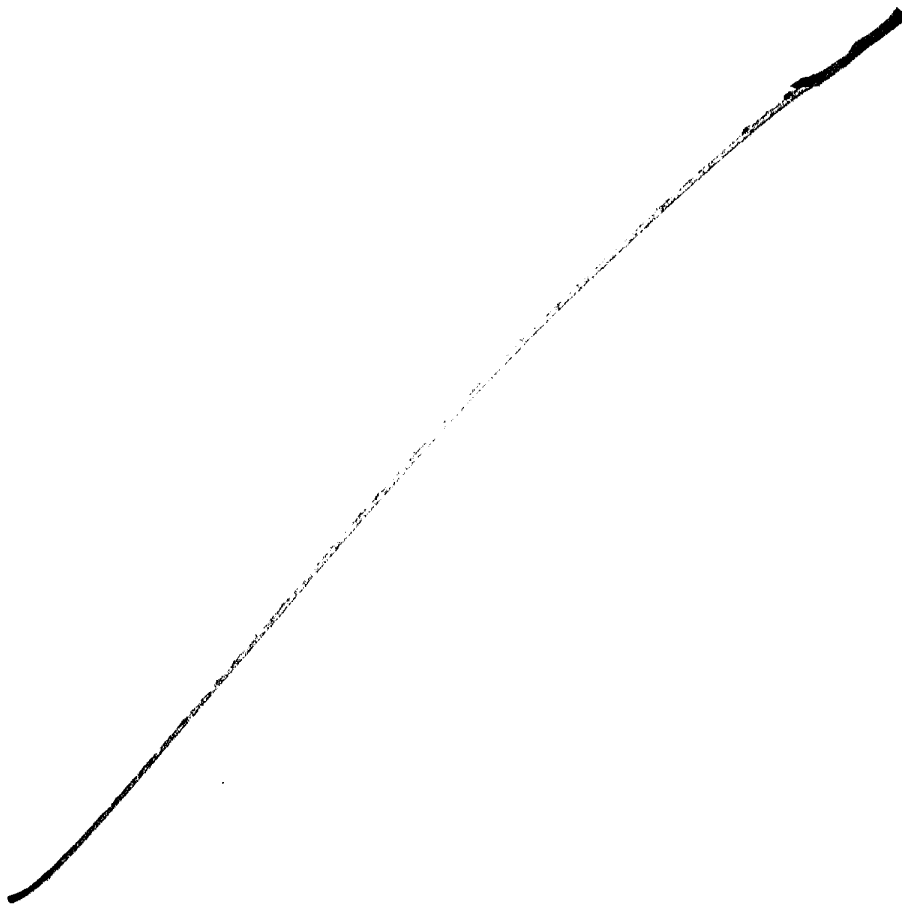


Section M. Equipment and Maintenance



Section N. Personnel







# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

April 18, 2000

0032  
Dr. Arthur M. Zebelman  
Drug Proof, Div. of Dynacare/Lab of Pathology, LLC  
1229 Madison St. Suite 500  
Nordstrom Medical Tower  
Seattle, WA 98104

Dear Dr. Zebelman:

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

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J. The Records Audit section

A large, dark, diagonal redaction mark covers the text of this 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



Dr. Zebelman  
April 18, 2000  
Page 2 of 2

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 Technical Analyst

Enclosure

cc: Project Files/M20



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0032  
Document No. Final

Laboratory: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC

Location: Seattle, WA

Document Reviewed:     Application Form  
                           Inspection Report #M20           Date: 2 March 2000  
                           Other \_\_\_\_\_

Status:            Highly Acceptable        Acceptable  
                      Unacceptable            Failure

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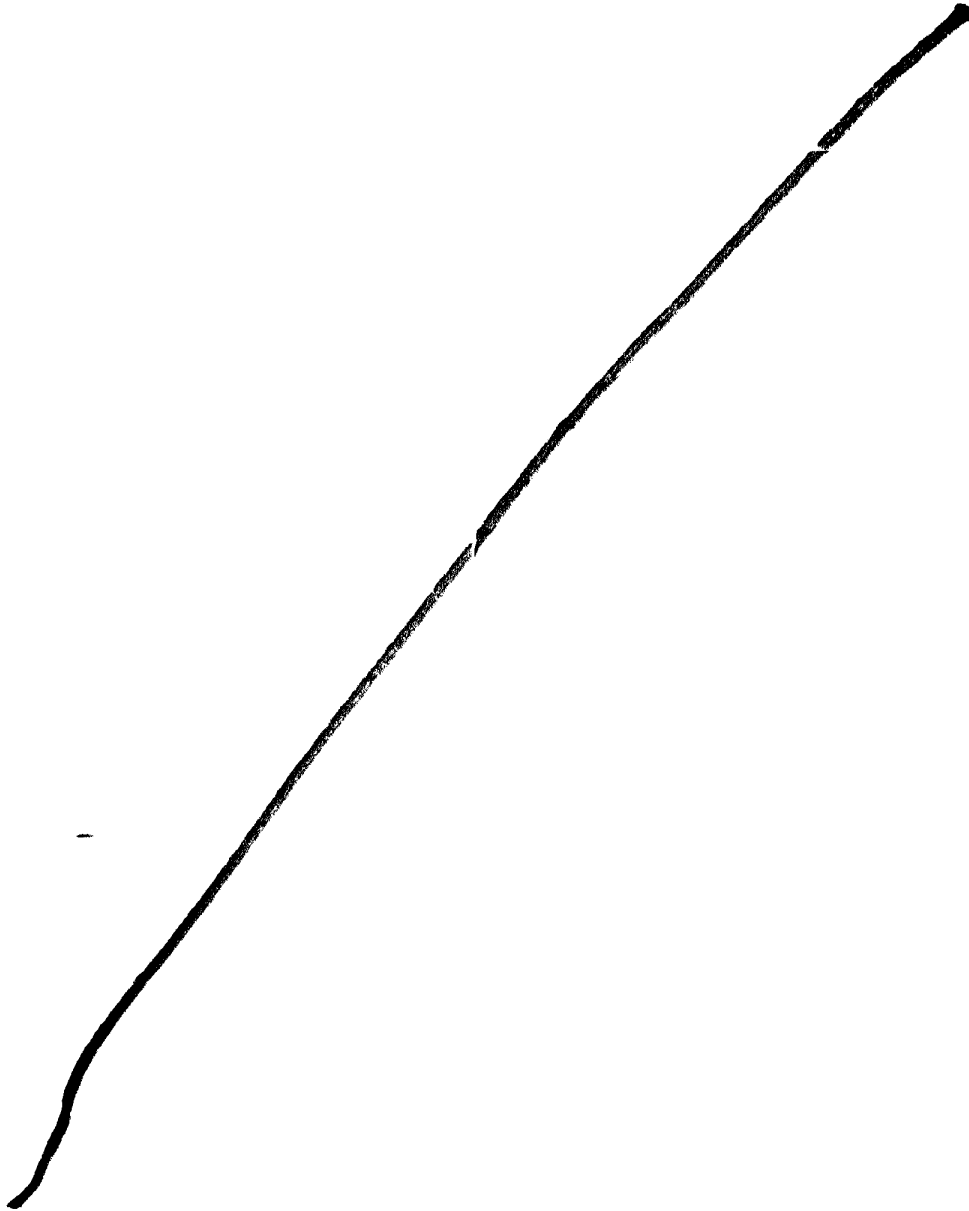
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.



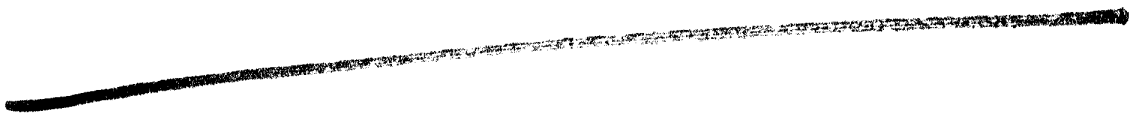
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual





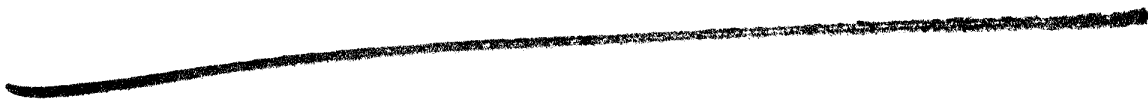
Section F. Chain-of-Custody, Accessioning, and Security




Section G. Quality Control




Section H. Initial Tests



Section I. Confirmatory Tests



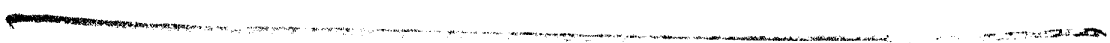
Section J. Records Audit




Section K. Reporting




Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel





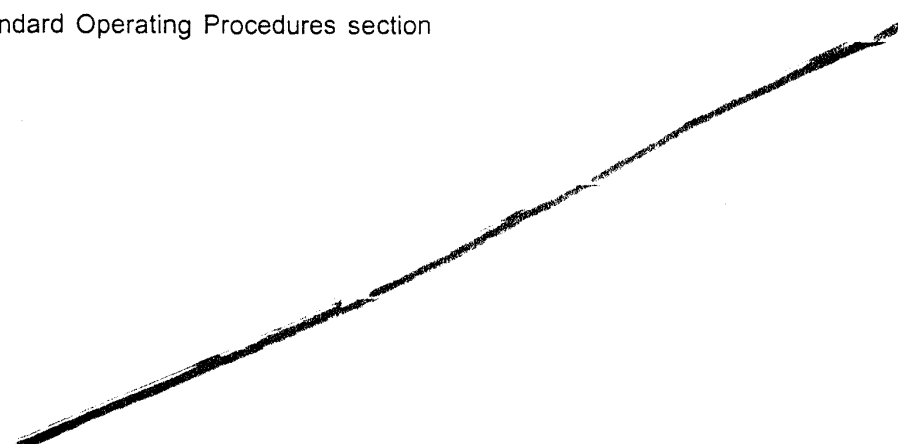
October 23, 2000

0032  
Dr. Arthur M. Zebelman  
Drug Proof, Div. of Dynacare/Lab of Pathology, LLC  
1229 Madison St. Suite 500  
Nordstrom Medical Tower  
Seattle, WA 98104

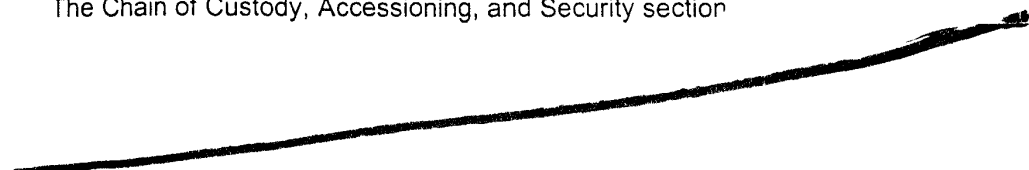
Dear Dr. Zebelman:

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 section

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

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Dr. Zebelman  
Page 2 of 2  
10/23/00

N. The Personnel 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 Technical Analyst

Enclosure

cc: Project Files/M21



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0032  
Document No. Final

Laboratory: DrugProof

Location: Seattle, WA

Document Reviewed:      Application Form  
                           Inspection Report #M21             Date: 14 September 2000  
                           Other \_\_\_\_\_

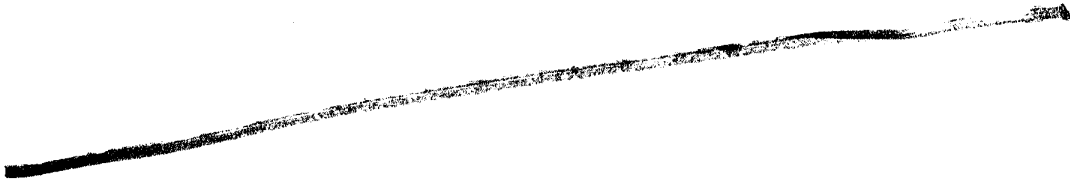
Status:            Highly Acceptable      Acceptable  
                     Unacceptable            Failure

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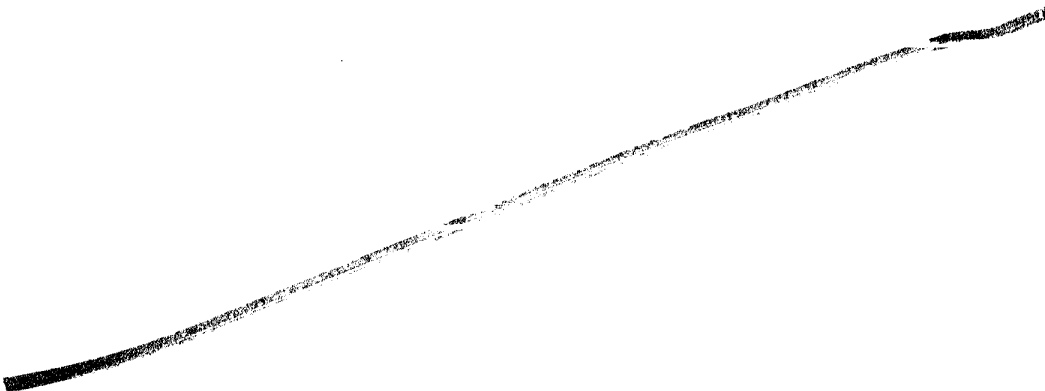
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

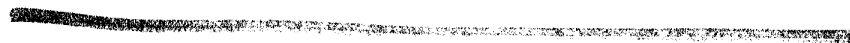
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.



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

