

February 5, 1999

0035  
Dr. Romeo Solano  
SmithKline Beecham Clinical Laboratories  
8000 Sovereign Row  
Dallas, TX 75247

Dear Dr. Solano:

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 laboratory must correct/clarify the following issues raised:

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



G. 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.



Dr. Solano  
- Page 2 of 2  
02/05/99

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: 00  
Document No. Fir

Laboratory: SmithKline Beecham Clinical Laboratories

Location: Dallas, TX

Document Reviewed:     Application Form  
                              Inspection Report #M17                      Date: 17 December 1998  
                              Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                                Unacceptable                         Failure

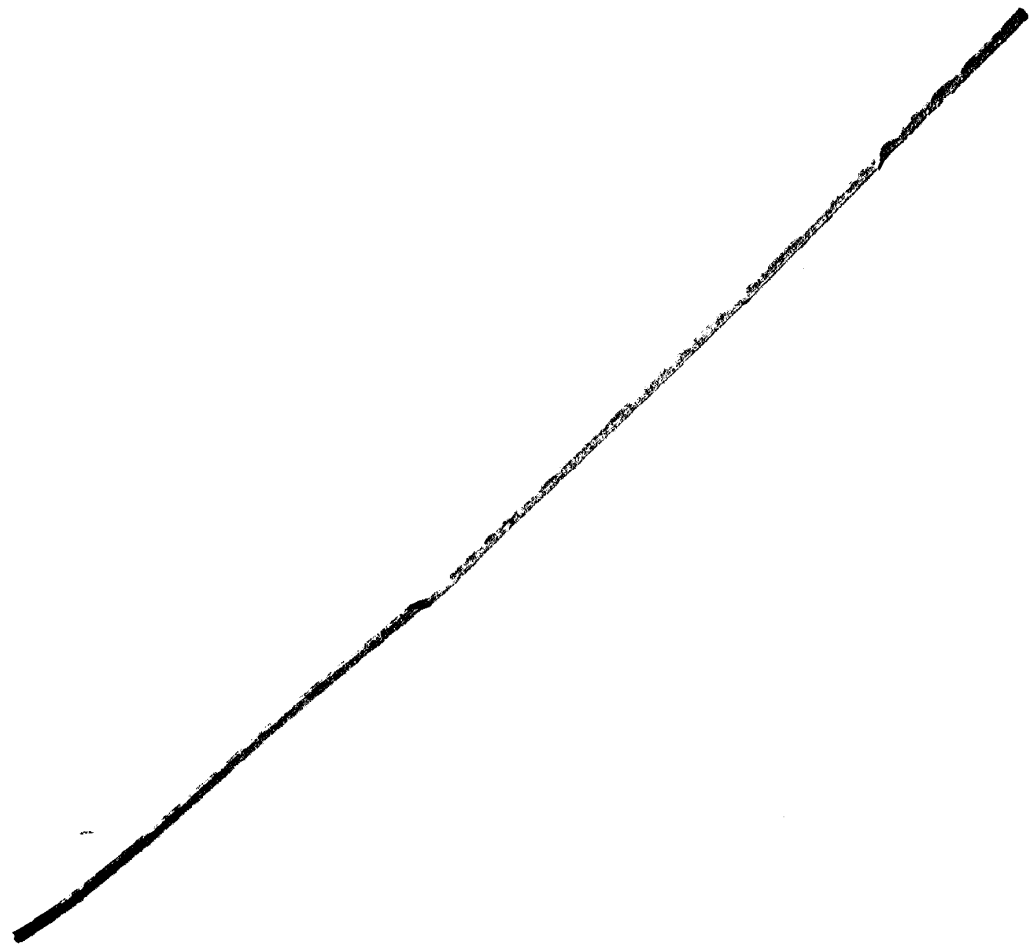
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

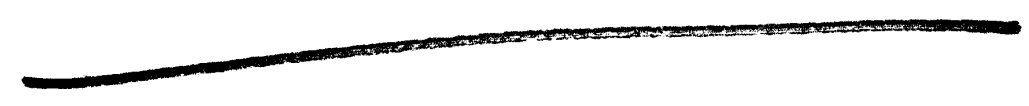
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



Ver. Final

Lab ID# 0035

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



August 13, 1999

0035  
Dr. Romeo Solano  
SmithKline Beecham Clinical Laboratories  
8000 Sovereign Row  
Dallas, TX 75247

Dear Dr. Solano:

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. However, the laboratory must clarify/correct the following issues raised:

H. The Initial Tests section



J. The Records Audit 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/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: 0035  
Document No. Final

Laboratory: SmithKline Beecham Clinical Laboratories

Location: Dallas, TX

Document Reviewed:     Application Form  
                               Inspection Report #M18                    Date: 24 June 1999  
                               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 J. Confirmatory Tests



Section I. 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 16, 2000

0035  
Dr. Romeo Solano  
Quest Diagnostics Incorporated  
8000 Sovereign Row  
Dallas, TX 75247

Dear Dr. Solano:

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.

E. The Standard Operating Procedures (SOP) section

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G. The Quality Control section

A large, dark, diagonal redaction mark covers the text in this section.

H. The Initial Tests section:



J. The Records Audit 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
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: 0035  
Document No. Final

Laboratory: Quest Diagnostics Inc.

Location: Dallas, TX

Document Reviewed:     Application Form  
                               Inspection Report #M20                      Date: 16 December 1999  
                               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.

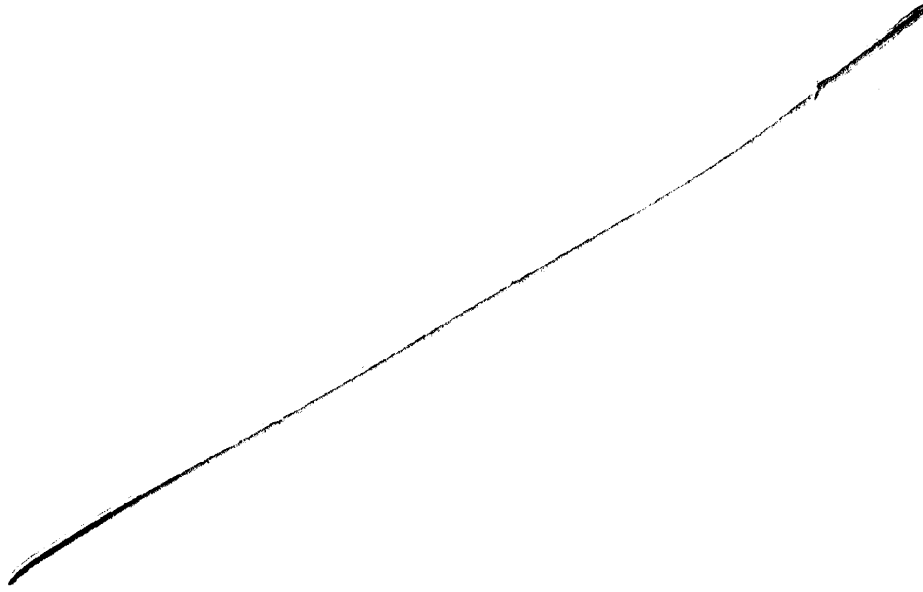
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

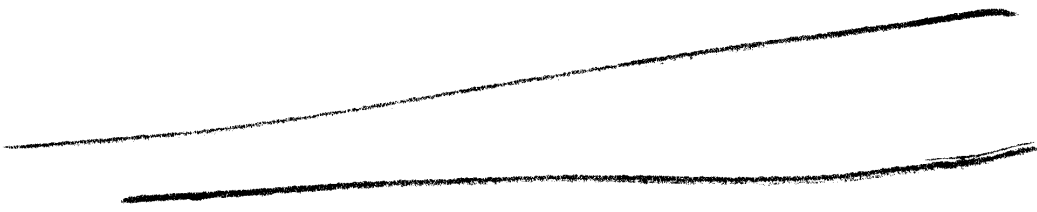
Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Quality Control



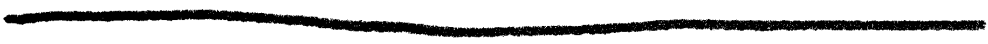
Section H. Initial Tests



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



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 10, 2000

0035  
Dr. Romeo Solano  
Quest Diagnostics Incorporated  
8000 Sovereign Row  
Dallas, TX 75247

Dear Dr. Solano:

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.

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.

Dr. Solano  
Page 2 of 2  
03/10/00

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

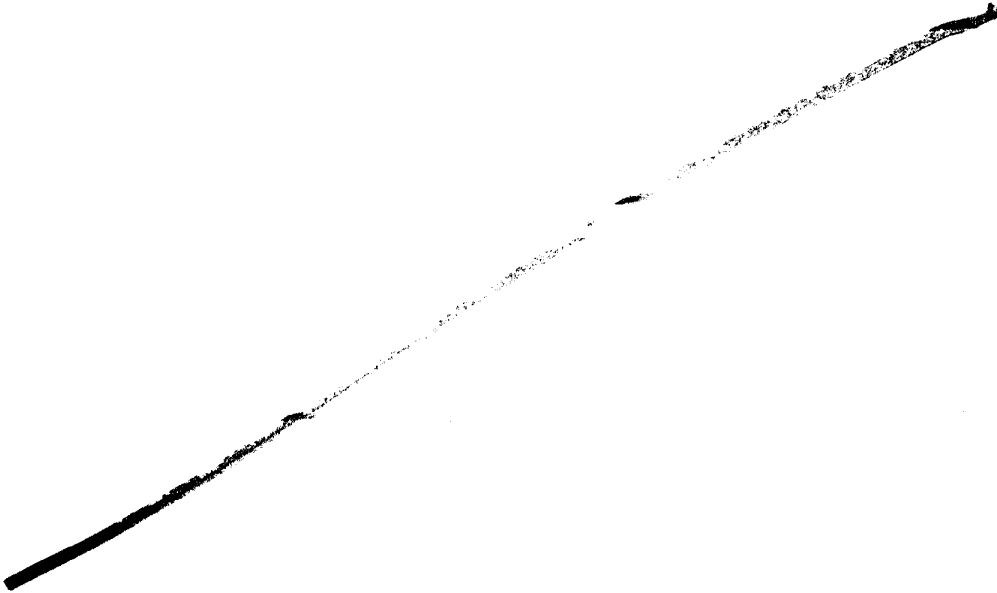
cc: Project Files/M20






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





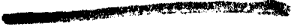
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 05, 2001

0035  
Dr. Romeo Solano  
Quest Diagnostics Incorporated  
8000 Sovereign Row  
Dallas, TX 75247

Dear Dr. Solano:

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 appeared to meet a number of the minimum technical criteria. 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

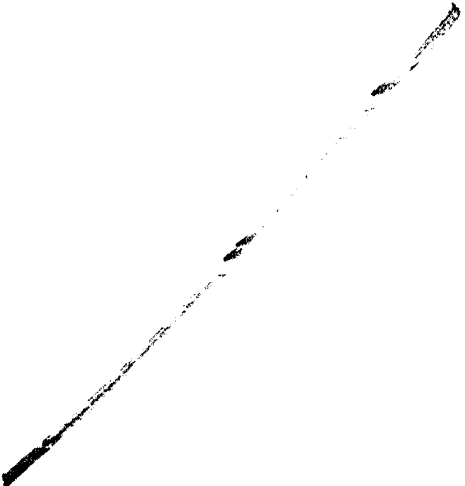
F. The Chain-of-Custody, Accessioning, and Security section

G. The Quality Control and Quality Assurance section

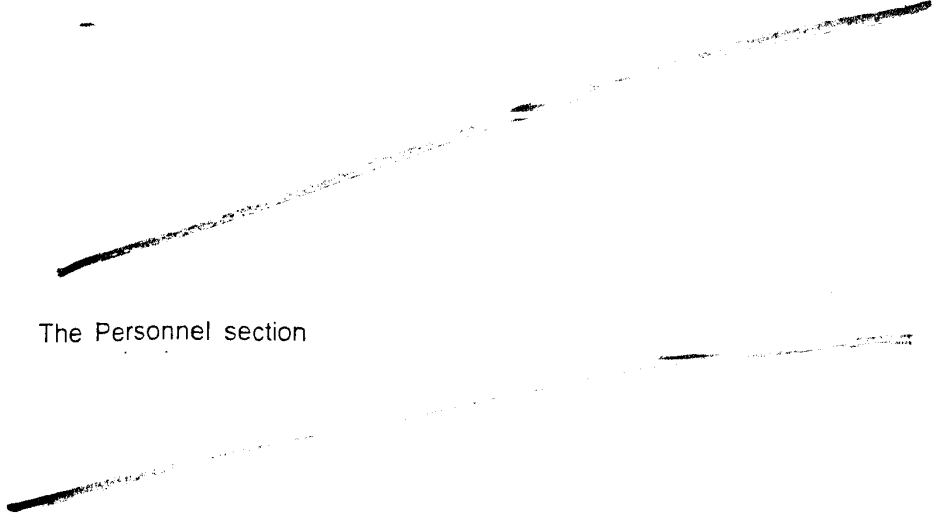
J. The Confirmatory Tests section



K. The Records Audit section



N. The Personnel section





Dr. Solano  
March 05, 2001  
Page 3 of 4

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.

Dr. Solano  
March 05, 2001  
Page 4 of 4

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



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0035  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Dallas, TX

Document Reviewed:     Application Form  
                               Inspection Report #M21                      Date: 14 December 2  
                               Other \_\_\_\_\_

Status:                     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

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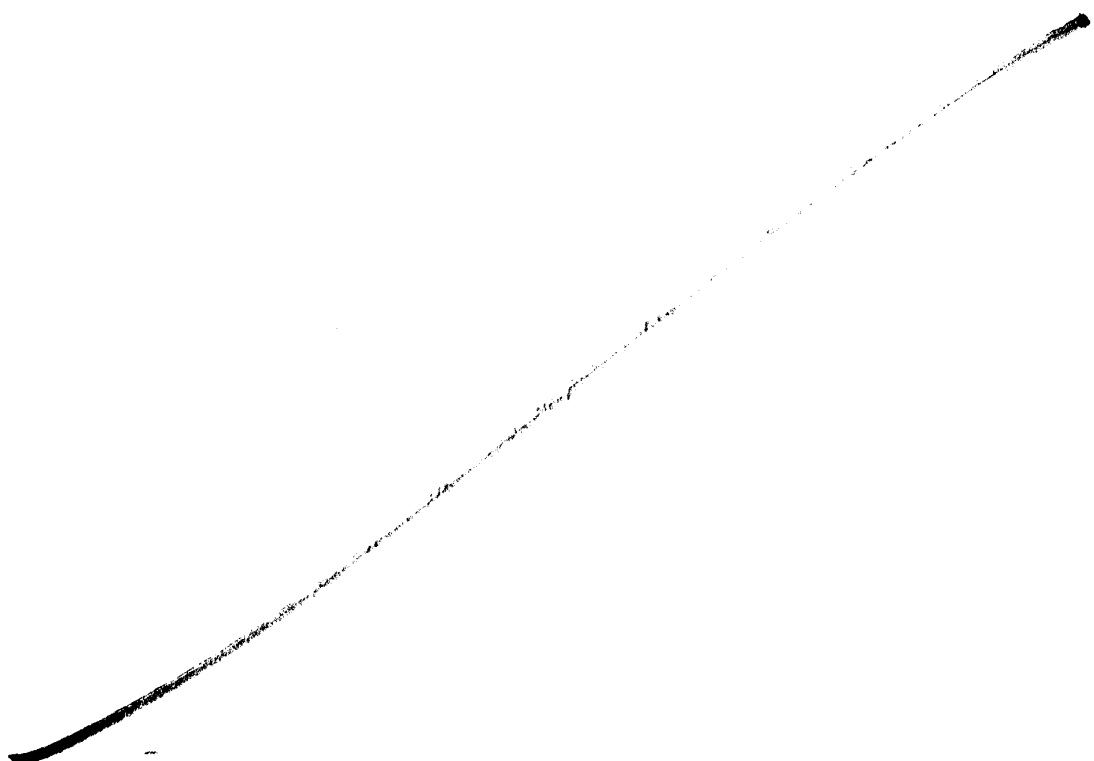
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet a number of the minimum technical criteria required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

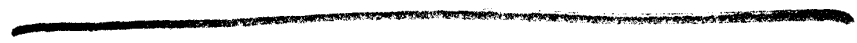
Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before the next inspection.

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