



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 15, 1999

0412  
Dr. David K. Roberts  
Physicians Reference Laboratory  
7800 West 110th Street  
Overland Park, KS 66210

Dear Dr. Roberts:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twelfth 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:

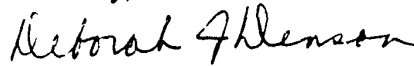


Dr. Roberts  
February 15, 1999  
Page 2 of 2

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/M12



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0412  
Document No. Final

Laboratory: Physicians Reference Laboratory

Location: Overland Park, KS

Document Reviewed:     Application Form  
                               Inspection Report #M12                      Date: 28 January 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

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Section H. Initial Tests

Section I. Confirmatory Tests

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Section J. Records Audit

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Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

September 8, 1999

0412  
Dr. David K. Roberts  
Physicians Reference Laboratory  
7800 West 110th Street  
Overland Park, KS 66210


Dear Dr. Roberts:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth 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 was 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 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



Dr. Roberts  
September 8, 1999  
Page 2 of 2

cc: Project Files/M13



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0412  
Document No. Final

Laboratory: Physicians Reference Laboratory

Location: Overland Park, KS

Document Reviewed:     Application Form  
                               Inspection Report #M13                    Date: 29 July 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

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# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

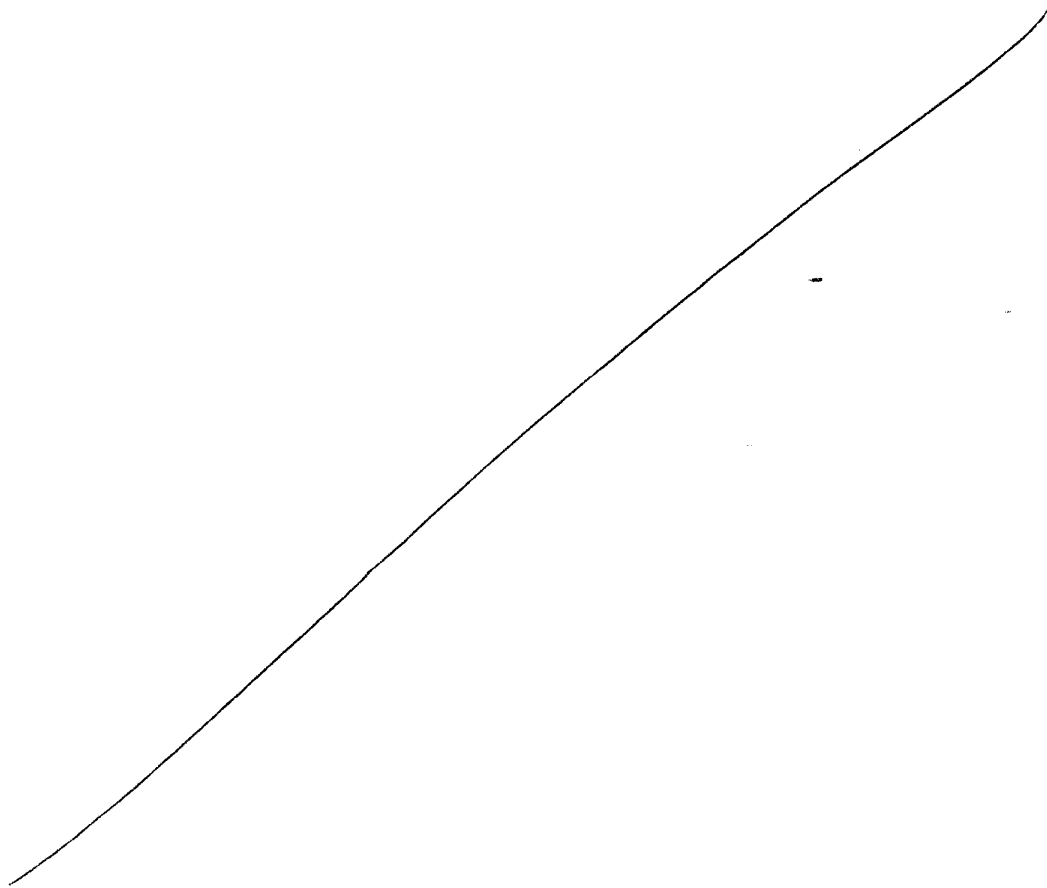
February 22, 2000

0412  
Dr. David K. Roberts  
Physicians Reference Laboratory  
7800 West 110th Street  
Overland Park, KS 66210

Dear Dr. Roberts:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourteenth 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.





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. Roberts  
February 22, 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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M14

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**NATIONAL LABORATORY CERTIFICATION PROGRAM**

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**Document Review and Critique**

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Laboratory I.D. Number: 0412  
Document No. Final

Laboratory: Physicians Reference Laboratory

Location: Overland Park, KS

Document Reviewed:      Application Form  
                               Inspection Report #M14             Date: 27 January 2000  
                               Other \_\_\_\_\_

Status:            Highly Acceptable      Acceptable  
                      Unacceptable            Failure

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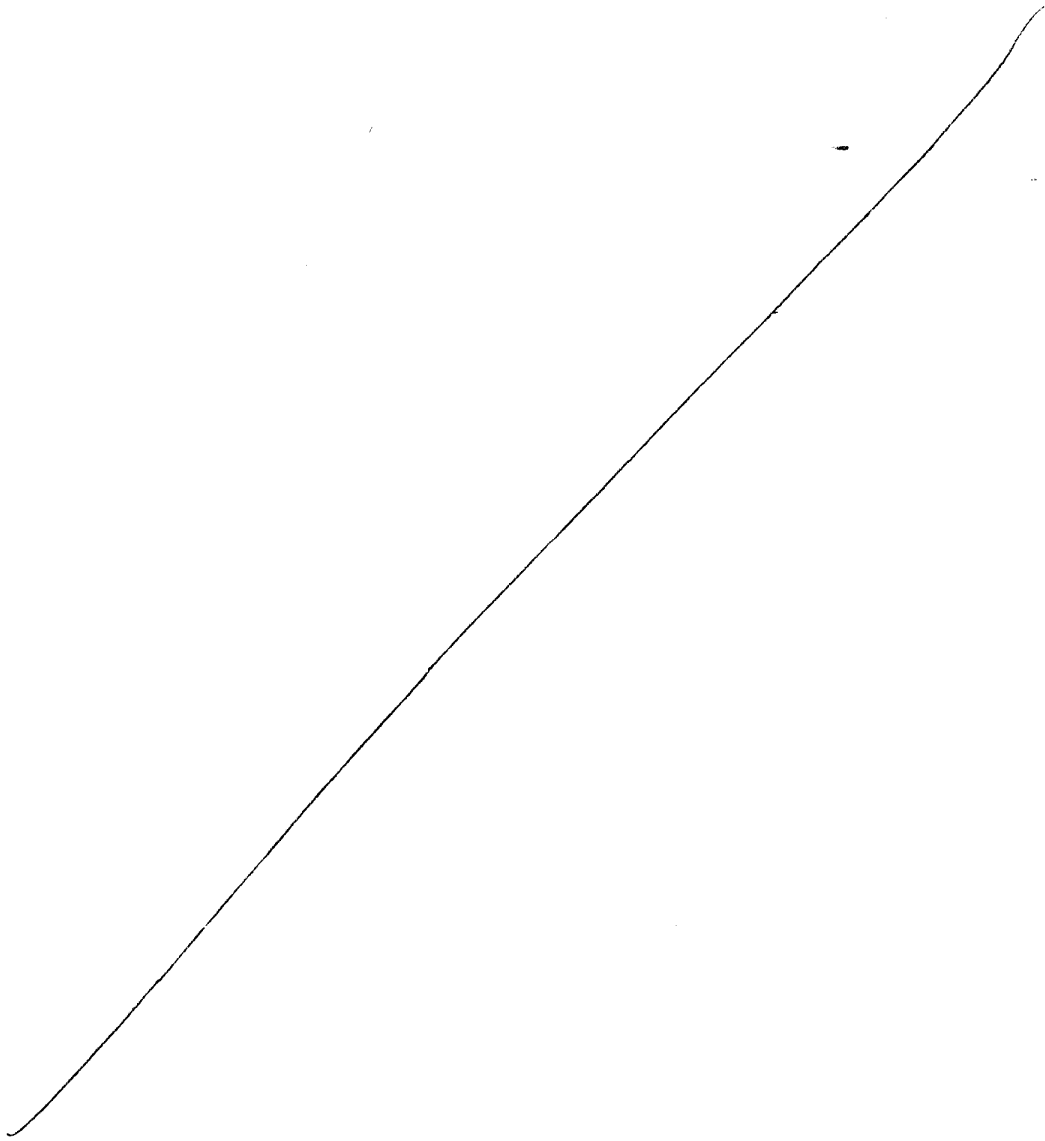
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

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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





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

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Section G. Quality Control

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Section H. Initial Tests

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Section I. Confirmatory Tests

result to be no less than the lowest calibrator or control in the batch as described on page I-9 of the NLCP Guidance Document for Laboratories and Inspectors, October 1998.

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



received  
3/10/2000 NS

PHYSICIANS REFERENCE LABORATORY  
Toxicology Section  
7800 W. 110<sup>th</sup> Street  
Overland Park, KS 66210

March 9, 2000

John Mitchell, Ph.D.  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC

Re: 02/22/00 Inspection Report Response

Dear Dr. Mitchell:



Conclusion

Thank you, in advance, for your review of our response. Please do not hesitate to contact us if you have any questions or require additional information. We look forward to hearing from you in this regard.

Respectfully,



David K. Roberts, Ph.D.  
Toxicology Director

Enclosures



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 20, 2000

0412  
Dr. David K. Roberts  
Physicians Reference Laboratory  
7800 West 110th Street  
Overland Park, KS 66210

Dear Dr. Robert:

We have reviewed the material provided in your correspondence of March 9, 2000, submitted in response to issues raised during the fourteenth maintenance inspection of your laboratory as outlined in our correspondence of February 22, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

*[A large, diagonal line is drawn across the page, likely indicating redacted content.]*

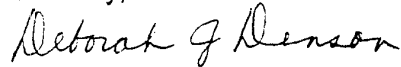


Dr. Roberts  
March 20, 2000  
Page 2 of 2

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) 541-7265 or Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Inspection Analyst

cc: Project Files/M14



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

September 26, 2000

0412  
Dr. David K. Roberts  
Physicians Reference Laboratory  
7800 West 110th Street  
Overland Park, KS 66210

Dear Dr. Roberts:

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. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

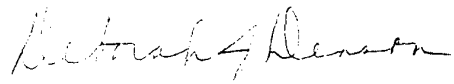


Dr. Roberts  
September 26, 2000  
Page 2 of 2

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 R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

Enclosure

cc: Project Files/M15  
Dr. Michael L. Smith  
Mr. Robert E. West

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0412  
Document No. Final

Laboratory: Physicians Reference Laboratory

Location: Overland Park, KS

Document Reviewed:     Application Form  
                               Inspection Report #M15                      Date: 27 July 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

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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



PHYSICIANS REFERENCE LABORATORY  
Toxicology Section  
7800 W. 110<sup>th</sup> Street  
Overland Park, KS 66210

**received**  
11/3/00 SDC

November 2, 2000

John Mitchell, Ph.D.  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC

Re: 07/27/00 Inspection Report Response

Dear Dr. Mitchell:

H. Quality Control

Thank you, in advance, for your review of our response. Please do not hesitate to contact us if you have any questions or require additional information. We look forward to hearing from you in this regard.

Respectfully,



David K. Roberts, Ph.D.  
Toxicology Director

Enclosures: Exhibits



# RESEARCH TRIANGLE INSTITUTE

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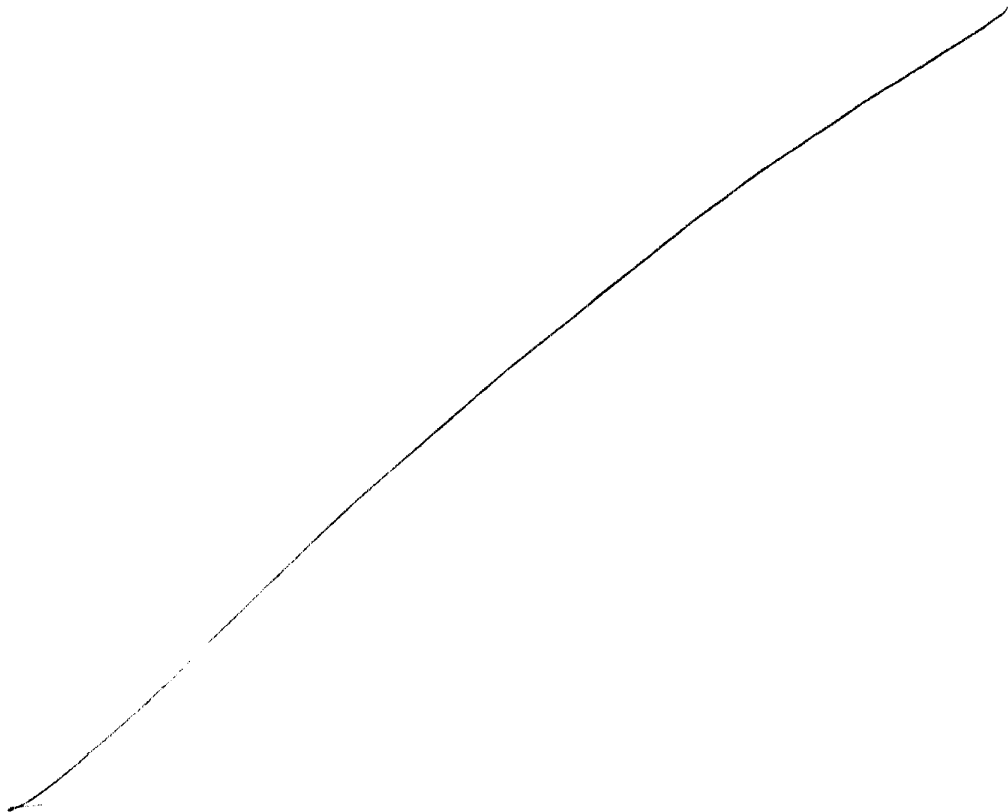
National Laboratory Certification Program

November 17, 2000

0412  
Dr. David K. Roberts  
Physicians Reference Laboratory  
7800 West 110th Street  
Overland Park, KS 66210

Dear Dr. Roberts:

We have reviewed the material provided in your correspondence of November 02, 2000 submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of September 26, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:





Dr. Roberts  
November 17, 2000  
Page 2 of 2

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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) 541-7265 or Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/M15