



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 12, 1999

0044

Dr. Gordon F. James
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Dr. James:

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 outcome of the laboratory's performance in this inspection is unacceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following remedial actions:

E. The Standard Operating Procedures (SOP) section

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



G. The Records Audit section

H. The Personnel Section

Dr. James
January 12, 1999
Page 3 of 3

The laboratory must submit, within 5 calendar days of receipt of this letter, a plan to complete all remedial actions. Once this plan is approved, the laboratory will have a maximum of 30 calendar days to implement the plan and to complete all necessary remedial actions. If the laboratory fails to provide and execute an approved plan, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be suspended and/or revoked. The laboratory should also review the enclosed critique and take all necessary corrective actions.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to sustain acceptable performance in the inspection phase of this program may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the Mandatory Guidelines.

In responding to the issues raised, please organize the material in accordance with the item numbers listed in the text of this letter. If we can be of assistance or answer any questions, 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



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0044
Document No. Final

Laboratory: Alliance Laboratory Services

Location: Cincinnati, OH

Document Reviewed: Application Form
 Inspection Report #M12 Date: 12 November 1998
 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 not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required for continued certification.

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

Section H. Personnel

Section I. Reagents

Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry

received
1/20/99 DN

Alliance Laboratory Services

Health Alliance 

3200 Burnet Avenue
Cincinnati, OH 45229

January 19, 1999

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

This letter is in response to your January 12 letter regarding our M-12 inspection. I will respond to the issues in the order they appear in your letter.



Ms. Deborah J. Denson

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January 19, 1999

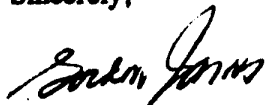


cc.

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I think I have addressed the issues raised by the inspectors. If you need further information please inform me.

Sincerely,

A handwritten signature in cursive script, appearing to read "Gordon James".

Gordon James, Ph.D.



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 22, 1999

0044
Dr. Gordon P. James
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Dr. James:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of January 19, 1999, provided in response to the deficiencies cited during the twelfth maintenance inspection of your laboratory as outlined in our correspondence of January 12, 1999. The plan to correct the deficiencies noted was found acceptable. The following is a summary of our review:

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



Dr. James
January 22, 1999
Page

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. (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M12



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

July 1, 1999

0044
Dr. Gordon P. James
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Dr. James:

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 laboratory must correct/clarify the following issue 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/M13

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0044
Document No. Final

Laboratory: Alliance Laboratory Services

Location: Cincinnati, OH

Document Reviewed: Application Form
 Inspection Report #M13 Date: 13 May 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

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

December 21, 1999

0044
Dr. Gordon P. James
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Dr. James:

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.

I. The Confirmatory Tests section:

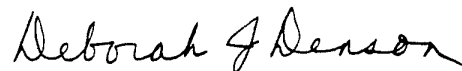
RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the 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. James
December 21, 1999
Page 2 of 2

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


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0044
Document No. Final

Laboratory: Alliance Laboratory Services

Location: Cincinnati, OH

Document Reviewed: Application Form
 Inspection Report #M14 Date: 11 November 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

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

[REDACTED]

Section M. Equipment and Maintenance

[REDACTED]

[REDACTED]

Section N. Personnel

[REDACTED]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 30, 2000

0044
Mr. Mark Wuest
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Mr. Wuest:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth 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 all corrective actions described in the critique and/or cover letter:

E. The Standard Operating Procedures (SOP) section

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



Mr. Wuest
June 30, 2000
Page 2 of 3

G. The Quality Control section

H. The Initial Tests section

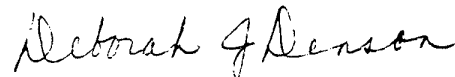
I. The Confirmatory Tests section

Mr. Wuest
June 30, 2000
Page 3 of 3

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



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0044
Document No. Final

Laboratory: Alliance Laboratory Services

Location: Cincinnati, OH

Document Reviewed: Application Form
 Inspection Report #M15 Date: 11 May 2000
 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

Section M. Equipment and Maintenance

Section N. Personnel

Alliance Laboratory Services

Health Alliance

3200 Burnet Avenue
Cincinnati, OH 45229

received
08/07/2000 DD

August 4, 2000

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

This letter is in response to your June 30 letter regarding our M-15 inspection. I am responding to issues in the order they appear in your letter.

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I believe I have addressed the issues raised by inspection M-15. If you need further information, please inform me.

Sincerely,



Mark Wuest
Alternate RP



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 10, 2000

0044
Mr. Mark Wuest
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Mr. Wuest:

We have reviewed the material provided in your correspondence of August 04, 2000, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of June 30, 2000. 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) 541-7265 or Michael R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,

A handwritten signature in cursive script that reads 'Deborah J. Denson'.

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M15





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 24, 2001

0044
Mr. Mark Wuest
Alliance Laboratory Services
3200 Burnet Avenue
Cincinnati, OH 45229

Dear Mr. Wuest:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth 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 Minimum Technical Criteria. However, the laboratory must take steps to correct the following issues raised:

E. The Standard Operating Procedures (SOP) section

G. The Quality Control and Quality Assurance section

I. The Specimen Validity Tests section

J. The Confirmatory Tests section

L The Certification and Reporting section

Mr. Wuest
Page 3 of 3
01/24/01

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

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0044
Document No. Final

Laboratory: Alliance Laboratory Services

Location: Cincinnati, OH

Document Reviewed: Application Form
 Inspection Report #M16 Date: 9 November 2000
 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

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