



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 20, 1999

0136
Ms. Patricia Simpson
Cedars Medical Center
Department of Pathology
1400 Northwest 12th Ave.
Miami, FL 33136

Dear Ms. Simpson:

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 is highly acceptable. However, the following issues were raised:

E. The Standard Operating Procedures (SOP) section



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

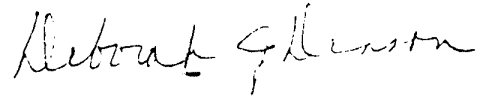


RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the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

Ms. Simpson
January 20, 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/M1



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0136
Document No. Final

Laboratory: Cedars Medical Center

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M16 Date: 3 December 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 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



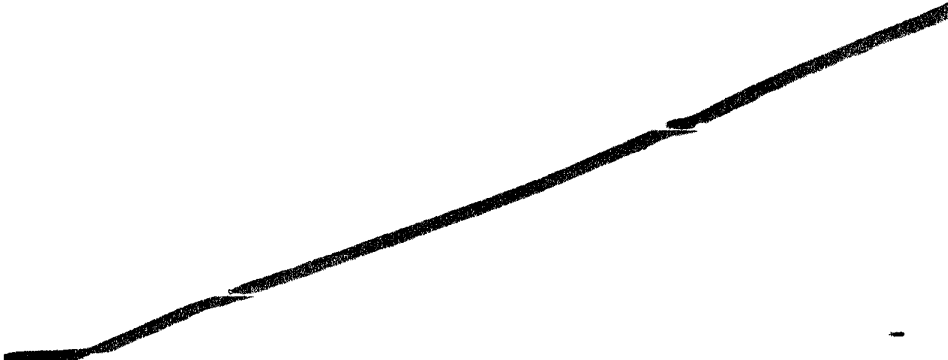
Section G. Quality Control



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

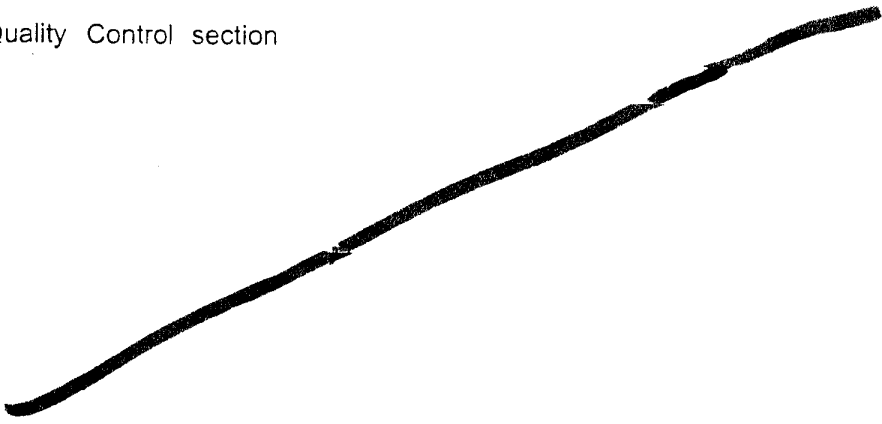
August 17, 1999

0136
Dr. Jack Lin
Integrated Regional Laboratories
Department of Pathology
1400 Northwest 12th Ave.
Miami, FL 33136

Dear Dr. Lin:

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. However, the laboratory must correct the following:

G. The Quality Control section

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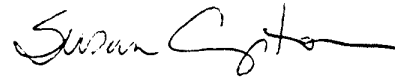
RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issue cited above. The laboratory must also review the 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. Lin
Page 2 of 2
08/17/99

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


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0136
Document No. Final

Laboratory: Integrated Regional Laboratories

Location: Miami, FL

Document Reviewed: Application Form
 Inspection Report #M17 Date: 8 July 1999
 Other _____

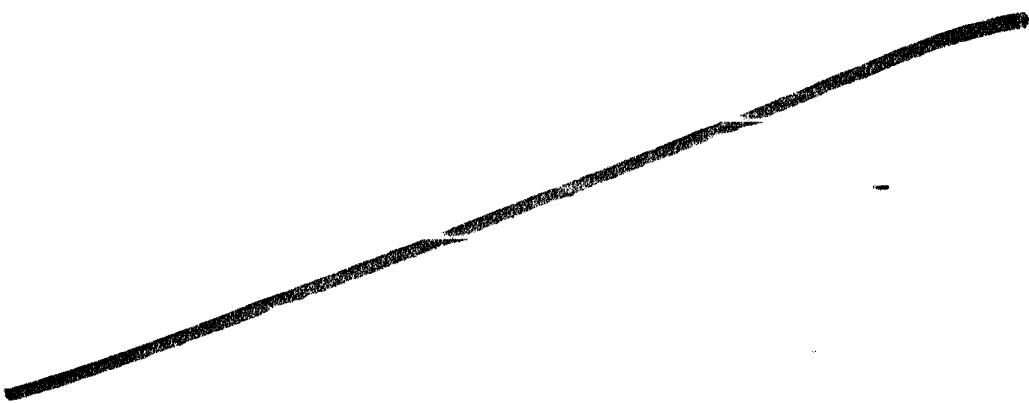
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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:

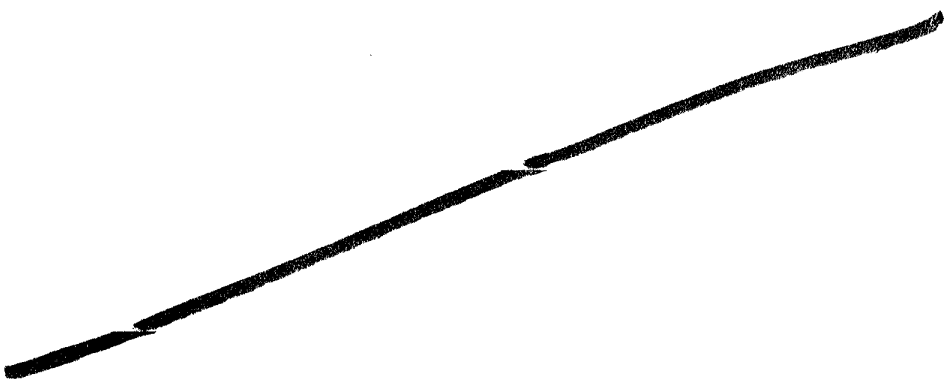
Section E. Standard Operating Procedures - Procedures Manual




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



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit

[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

0136
Dr. Jack Lin
Integrated Regional Laboratories
5631 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Dr. Lin:

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. The inspection team had some areas of concern, which are detailed in the attached critique.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Susan Crumpton".

Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M18




NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0136
Document No. Final

Laboratory: Integrated Regional Laboratories

Location: Fort Lauderdale, FL

Document Reviewed: Application Form
 Inspection Report #M18 Date: 17 February 2000
 Other _____

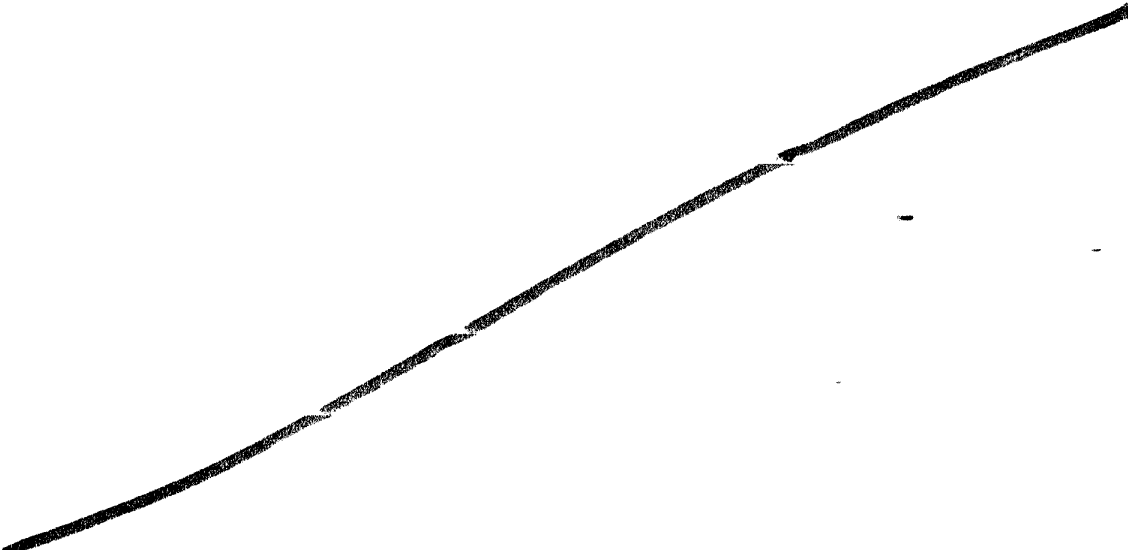
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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




Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit

[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

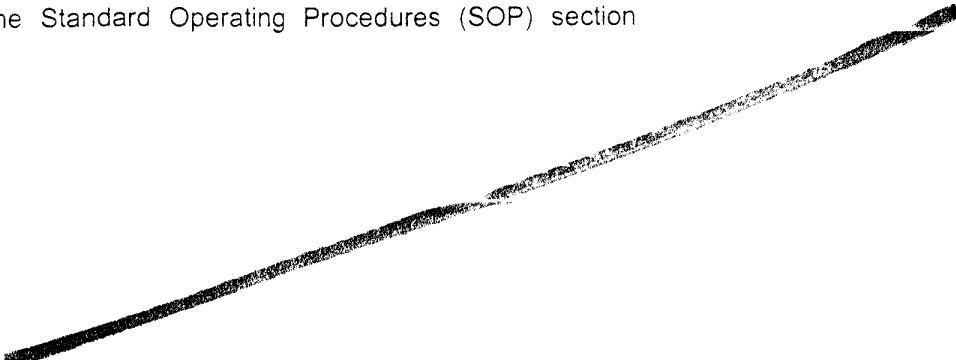
September 12, 2000

0136
Dr. Jack Lin
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309


Dear Dr. Lin:

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 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

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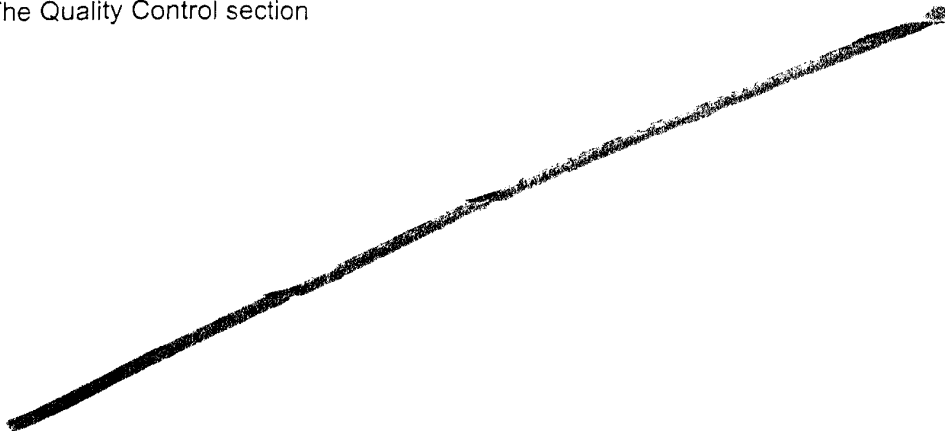
F. The Chain of Custody, Accessioning, and Security section

A large, thick, black diagonal line redacting the text of item F.

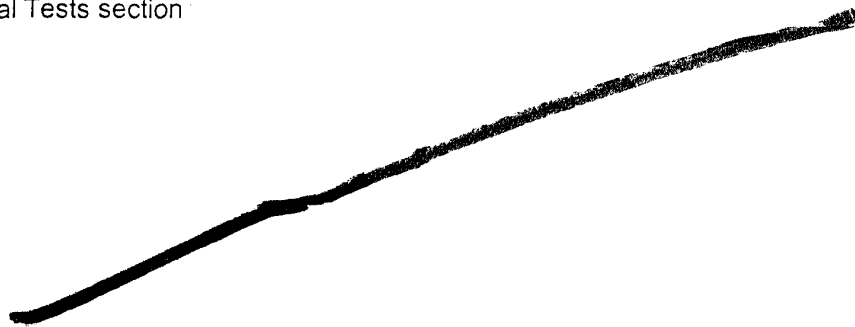





G. The Quality Control section



H. The Initial Tests section





I. The Confirmatory Tests section



J. The Records section



M. The Equipment and Maintenance section

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

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0136
Document No. Final

Laboratory: Integrated Regional Laboratories

Location: Fort Lauderdale, FL

Document Reviewed: Application Form
 Inspection Report #M19 Date: 20 July 2000
 Other _____

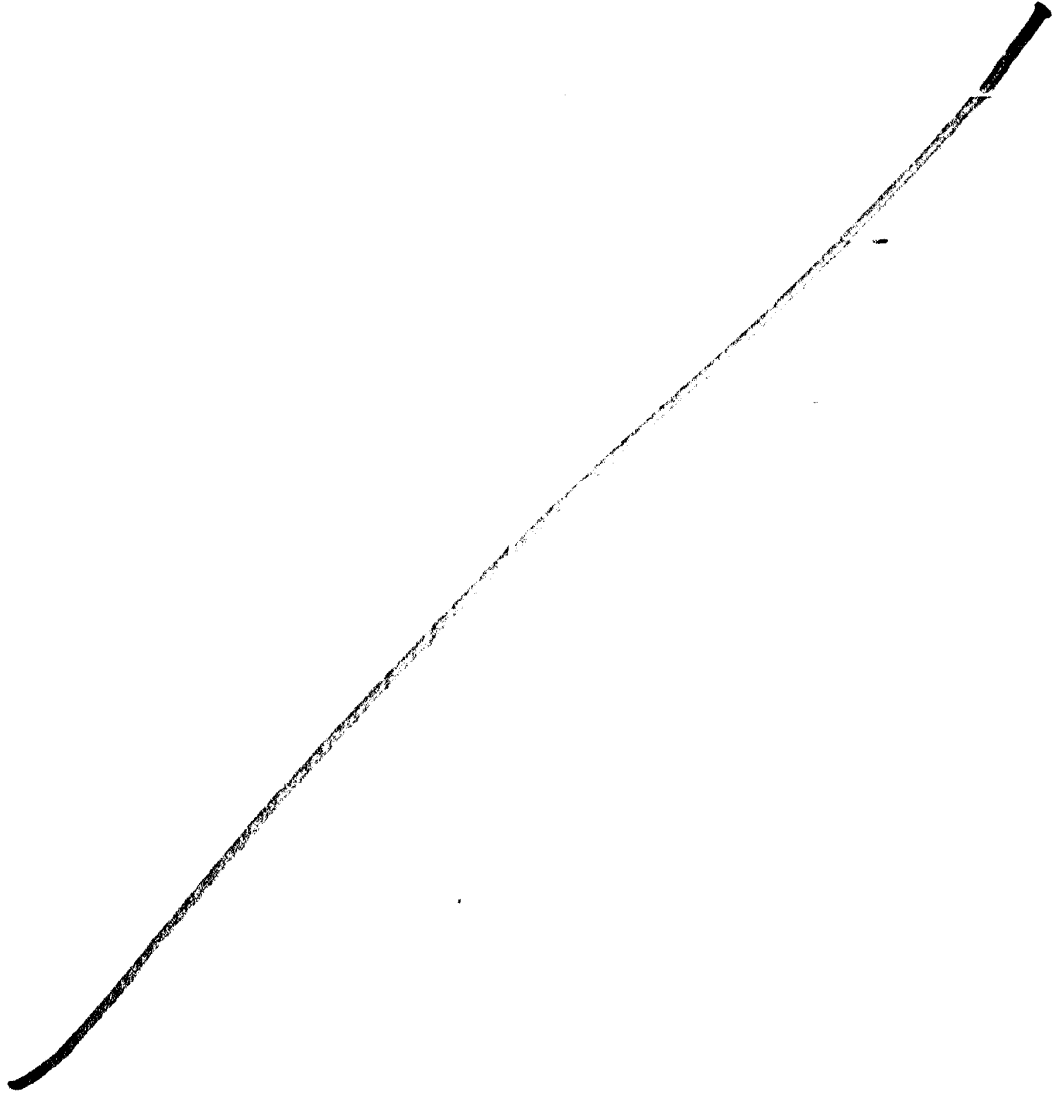
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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 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.

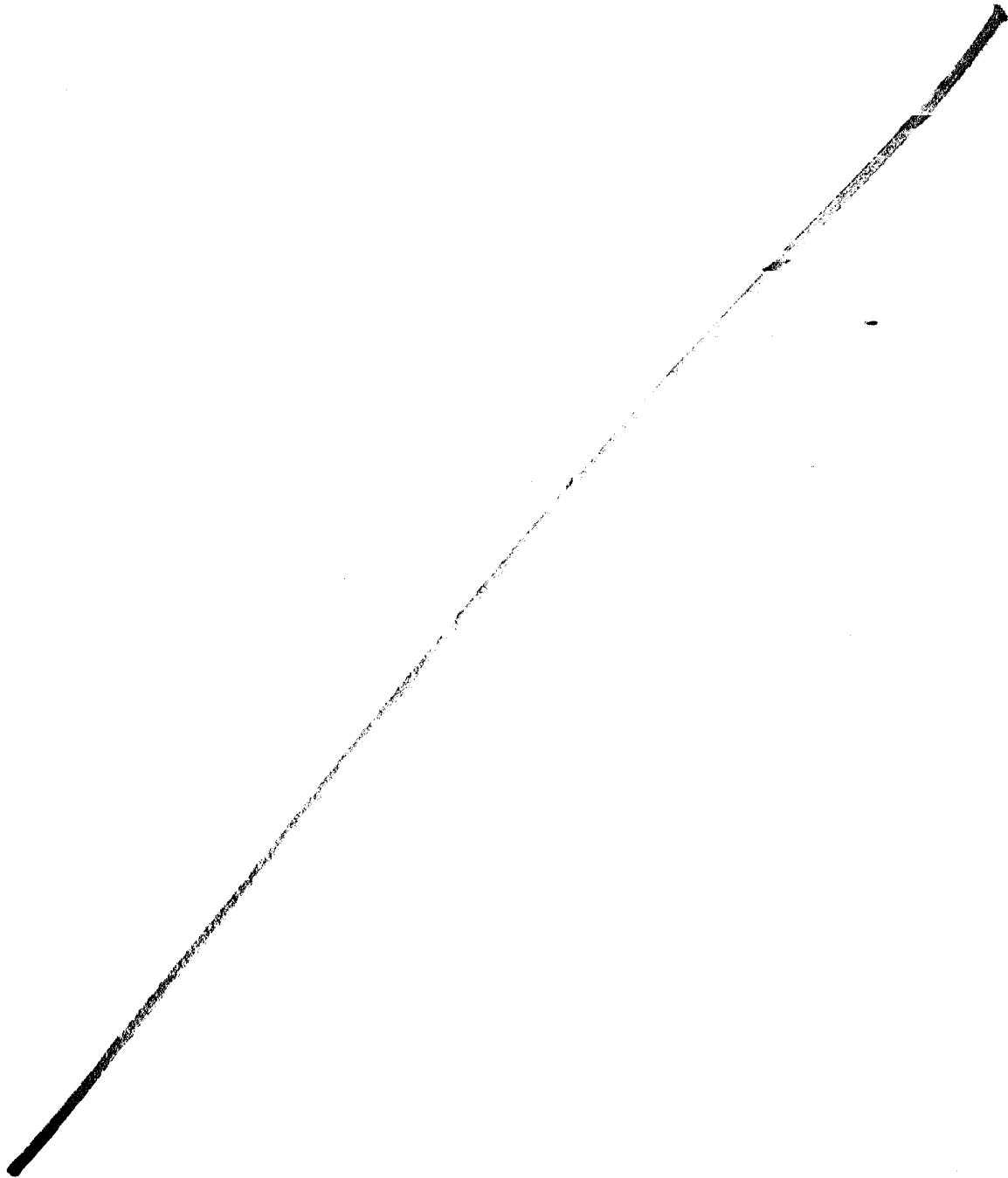
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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. Quality Control



Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

received
SDC 9118100

5361 N.W. 33rd Avenue
Fort Lauderdale, Florida 33309



954 777-0018
1-800 522-0232
fax: 954 777-0211

September 18, 2000

Ms. Susan Crumpton
NLCP Technical Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
P. O. Box 12194
Research Triangle Park, N.C. 27709

Re: Laboratory # 0136

Dear Ms. Crumpton:

The enclosed is the plan of action for the report, which we received on September 13, 2000, of the nineteenth maintenance inspection. We will submit the revised SOP, implementation records, and training records, etc. within 30 days when this plan of action is approved by RTI.

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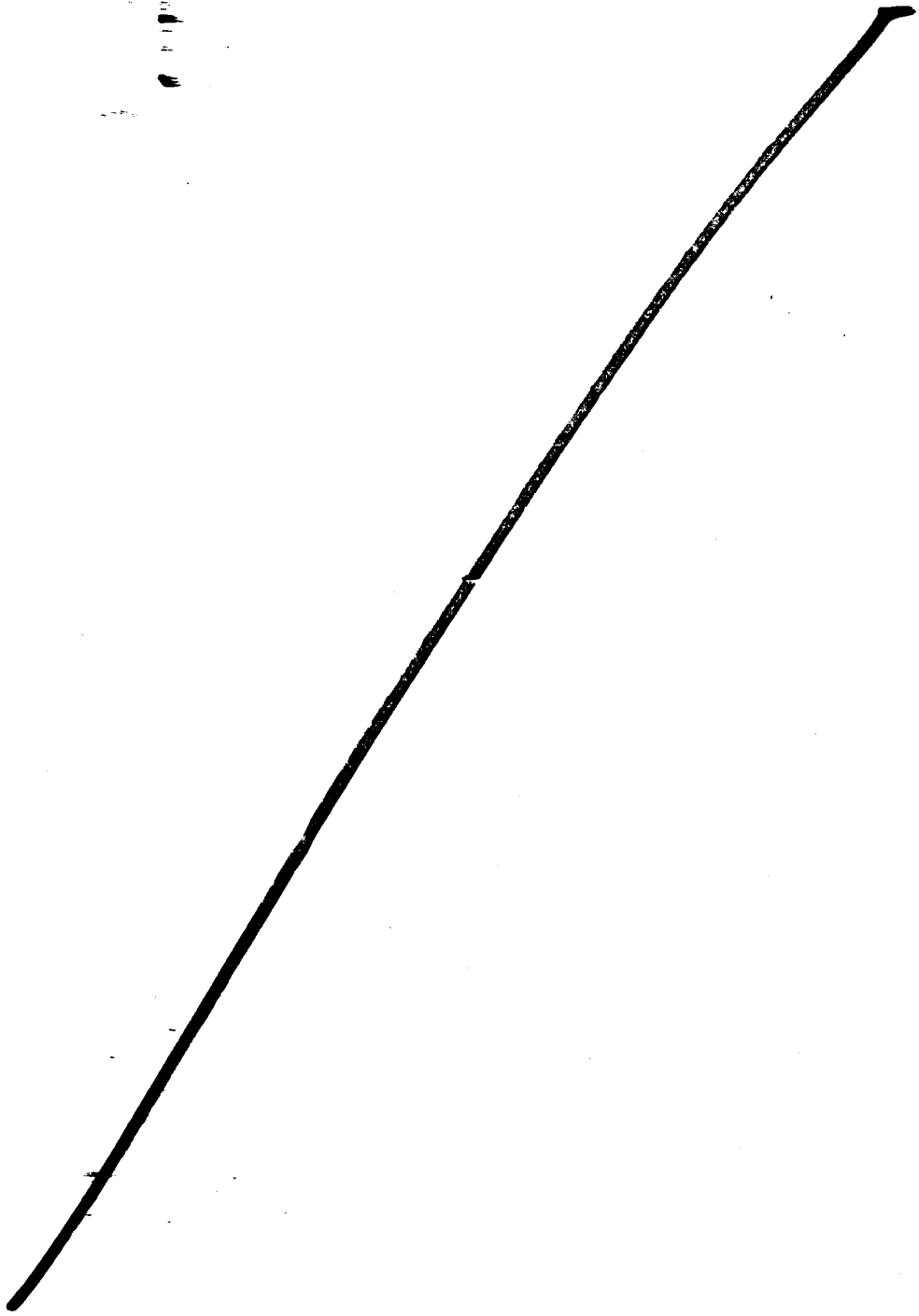
Please let me know if there is any additional information we should submit for review at this time. I can be reached at 954-275-0018 ext. 275.

Thank you very much for your assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jack Lin". The signature is fluid and cursive, with a large initial "J" and "L".

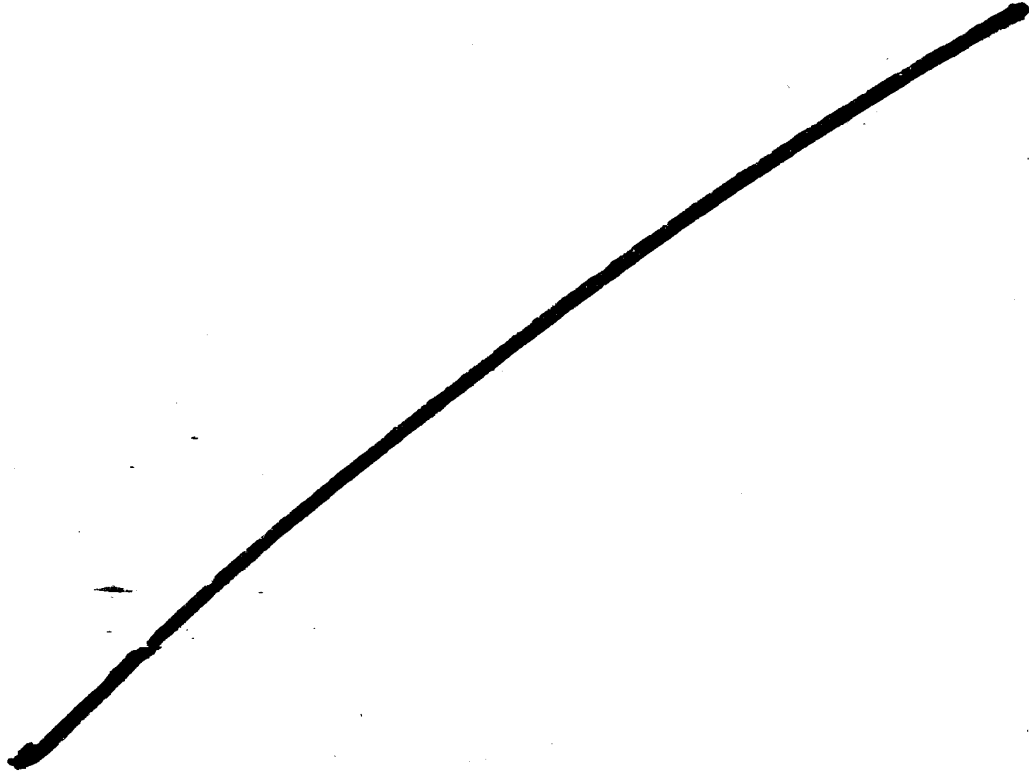
Jack Lin, Ph.D.
Responsible Person / Director
Toxicology



136
Dr. Jack Lin
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Dr. Lin:

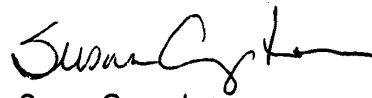
We have reviewed the laboratory's proposed action plan submitted in your correspondence of September 18, 2000, provided in response to the deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of September 12, 2000. The plan to correct the deficiencies noted was found acceptable with the following exceptions:



The laboratory must submit the final report within 30 calendar days of receipt of this letter. This report must include supporting documentation to demonstrate completion of the planned remedial actions and to address the issues raised in this correspondence (i.e., revised SOPs, documentation of training, completed examples of forms to illustrate revised documentation procedures).

If you have any questions or want to further clarify any of these issues, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/M19

received
10/26/00 SDG

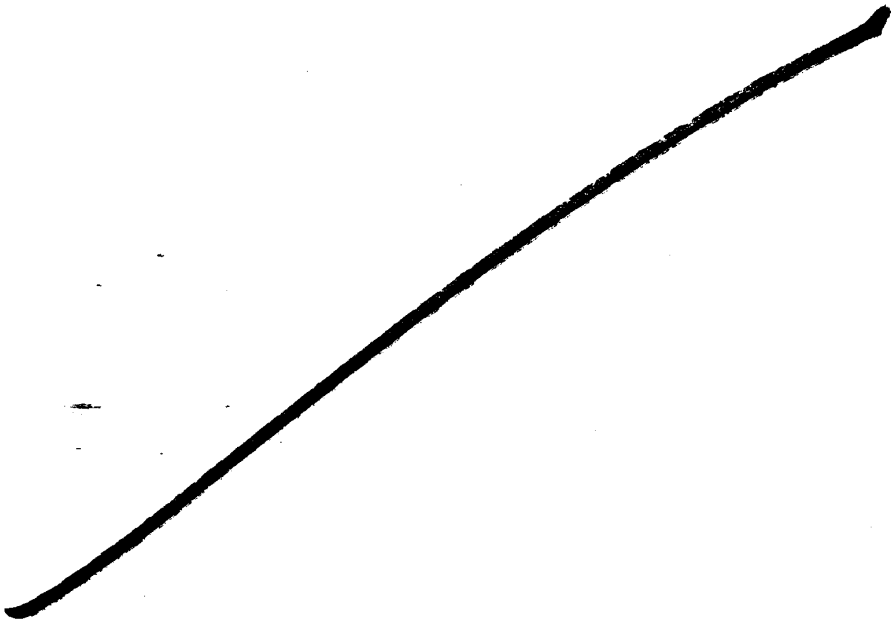
October 26, 2000

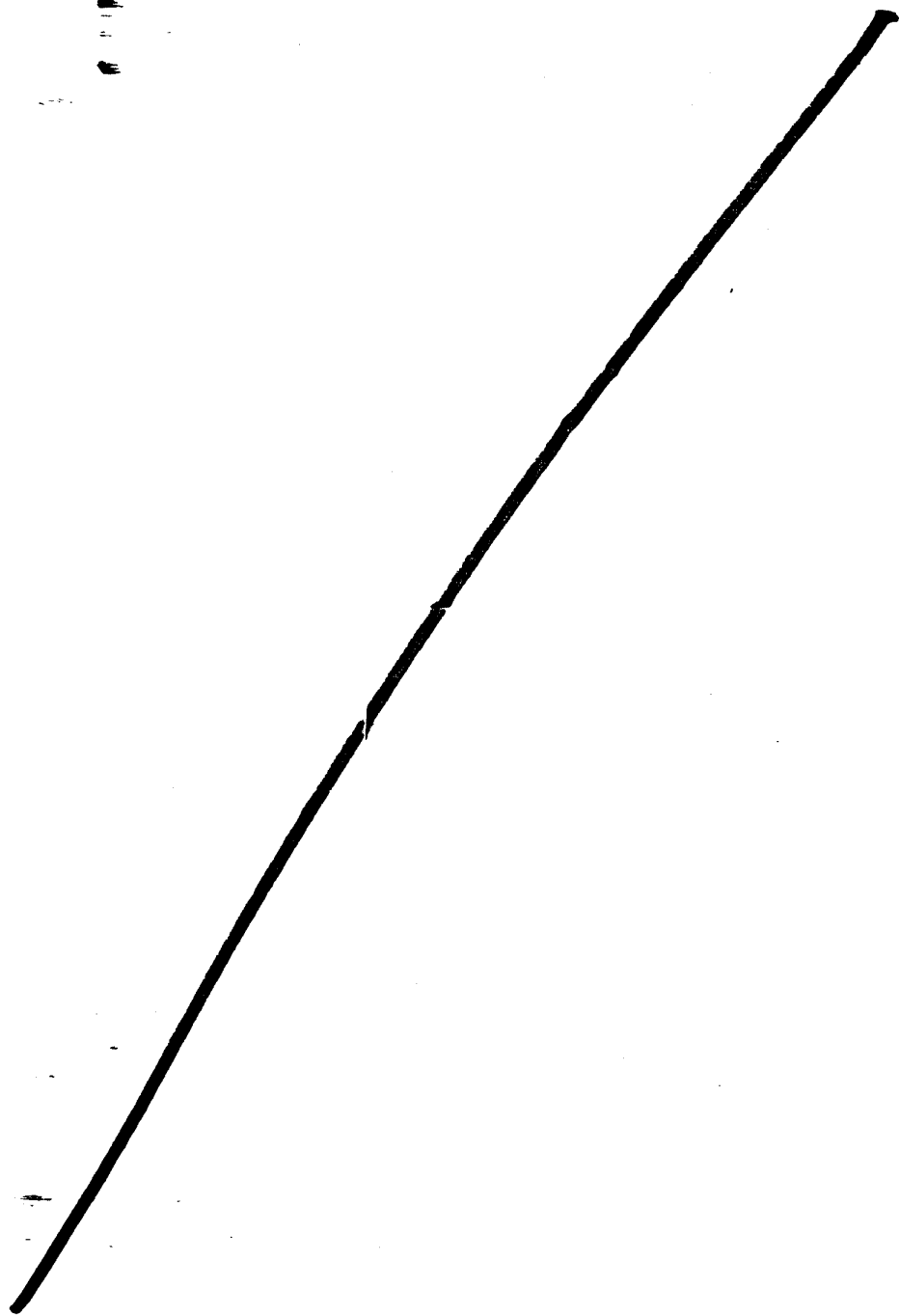
Ms. Susan Crumpton
NLCP Technical Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
P. O. Box 12194
Research Triangle Park, N. C. 27709

Re: Laboratory # 0136

Dear Ms. Crumpton:

This is the corrective action with the reviewed SOPs, implementation, and training records in responding to the RTI reports dated September 13, 2000 and September 27, 2000.





Please let me know if there is any additional information we should submit for review at this time.

Thank you very much for your assistance.

Sincerely yours,

Pat Lin
Patricia C Simpson A.H.R.P.
TOXICOLOGY

Jack Lin, Ph.D.
Responsible Person / Director

received
11/15/00 Ed

5361 NW 33rd Ave
Ft. Lauderdale, FL 33309

INTEGRATED
REGIONAL
LABORATORIES **IRL**

954-777-0018

fax: 954-777-0211

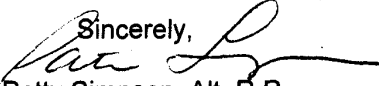
Ms. Susan Crumpton
NLCP Technical Analyst
3040 Cornwallis Road
Research Triangle Park
North Carolina, 27709-2194

Dear Ms. Crumpton,

The following is the response to the letter sent by you on 11/6/00:

[Redacted content]

If you have any questions please don't hesitate to call me at 1-800-522-0232 ext.410

Sincerely,

Patty Simpson, Alt. R.P.

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 3, 2000

136
Ms. Patricia Simpson
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Ms. Simpson:

We have reviewed the material provided in your correspondence of October 26, 2000, submitted in response to deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of September 12 and 27, 2000. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address most deficiencies cited. However, the laboratory must submit additional information to address the following:

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100

Ms. Simpson
Page 2 of 2
11/03/00

The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues described above. RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP) upon receipt of documentation to demonstrate that the unresolved issues have been addressed. If, however, the laboratory fails to address these unresolved issues within this time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of all remedial actions are subject to review by the next inspection team.

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. at (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/M19

December 1, 2000

0136
Ms. Patricia Simpson
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Ms. Simpson:

We have reviewed the material provided in your correspondence received November 15, 2000, submitted in response to issues remaining from the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of November 3, 2000. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the remaining issues. The implementation of the remedial 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. 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 Technical Analyst

cc: Dr. Michael Baylor
Project Files/M19

