



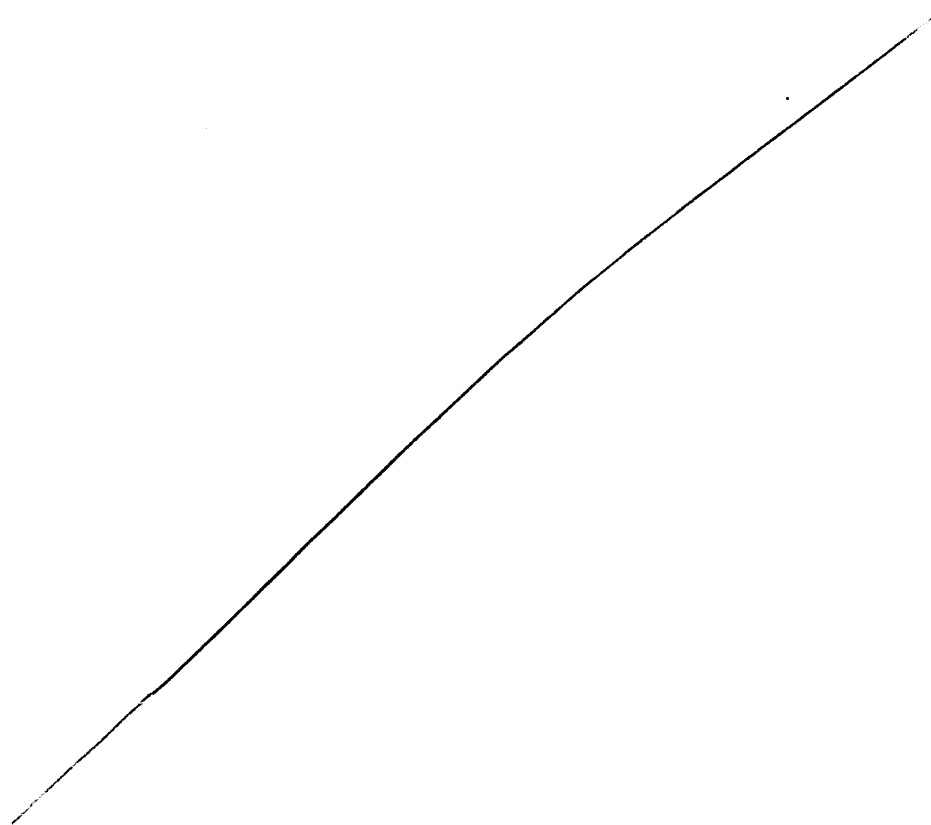
February 15, 1999

0797

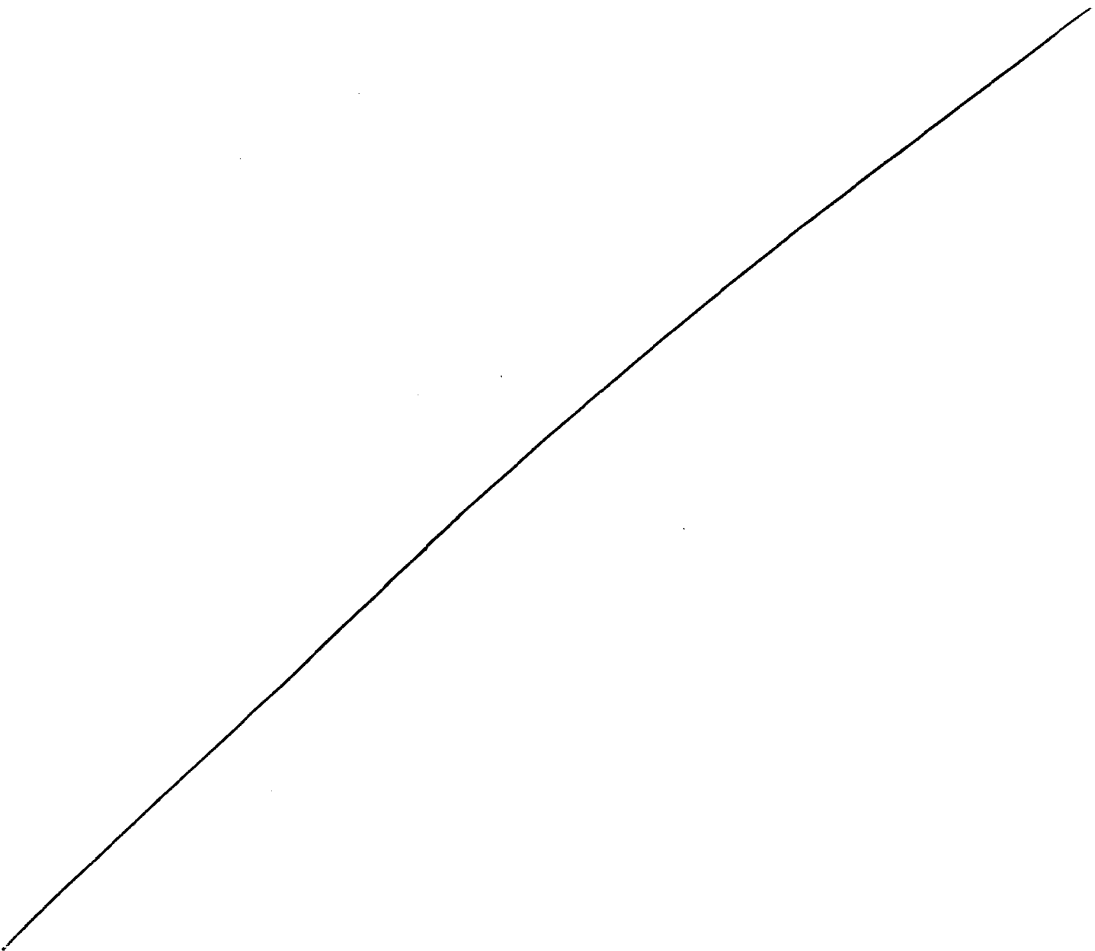
Dr. Pierre Beaumier
Dr. John Wells
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CN CAN L4Z 1P1

Dear Dr. Beaumier and Dr. Wells:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the third 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 acceptable. However, the following issues were raised:



Dr. Beaumier and Dr. Wells
February 15, 1999
Page 2 of 3

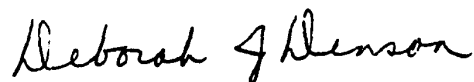


The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item 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.

Dr. Beaumier and Dr. Wells
February 15, 1999
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:



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0797
Document No. Final

Laboratory: MAXXAM Analytica, Inc.

Location: Mississauga, ON

Document Reviewed: Application Form
 Inspection Report #M3
 Other _____

Date: 7 January 1999

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

received
3/12/99 ND

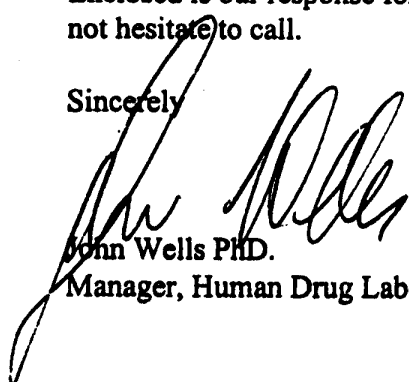
March 11, 1999

Deborah J. Denson
Laboratory Accreditation Program
Substance Abuse,
Research Triangle Institute,
Research Triangle Park
North Carolina, 27709

Dear Ms. Denson

Enclosed is our response for the RTI critique of our inspection. If there any questions, do not hesitate to call.

Sincerely


John Wells PhD.
Manager, Human Drug Laboratory

RTI Deficiencies for the January 7-8 1999 Inspection

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. Records Audit

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 16, 1999

0797
Dr. Pierre Beaumier
Dr. John Wells
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Beaumier and Dr. Wells:

We have reviewed the material provided in your correspondence of March 11, 1999, submitted in response to issues raised during the third maintenance inspection of your laboratory as outlined in our correspondence of February 12, 1999. 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 Baylor, Ph.D. (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M3



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

August 30, 1999

0797
Dr. John Wells
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Wells:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourth 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 issues raised:



Dr. Wells
Page 2 of 2
08/30/99

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/M4

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0797
Document No. Final

Laboratory: MAXXAM Analytics Inc.

Location: Mississauga, ON

Document Reviewed: Application Form
 Inspection Report #M4 Date: 15 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

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

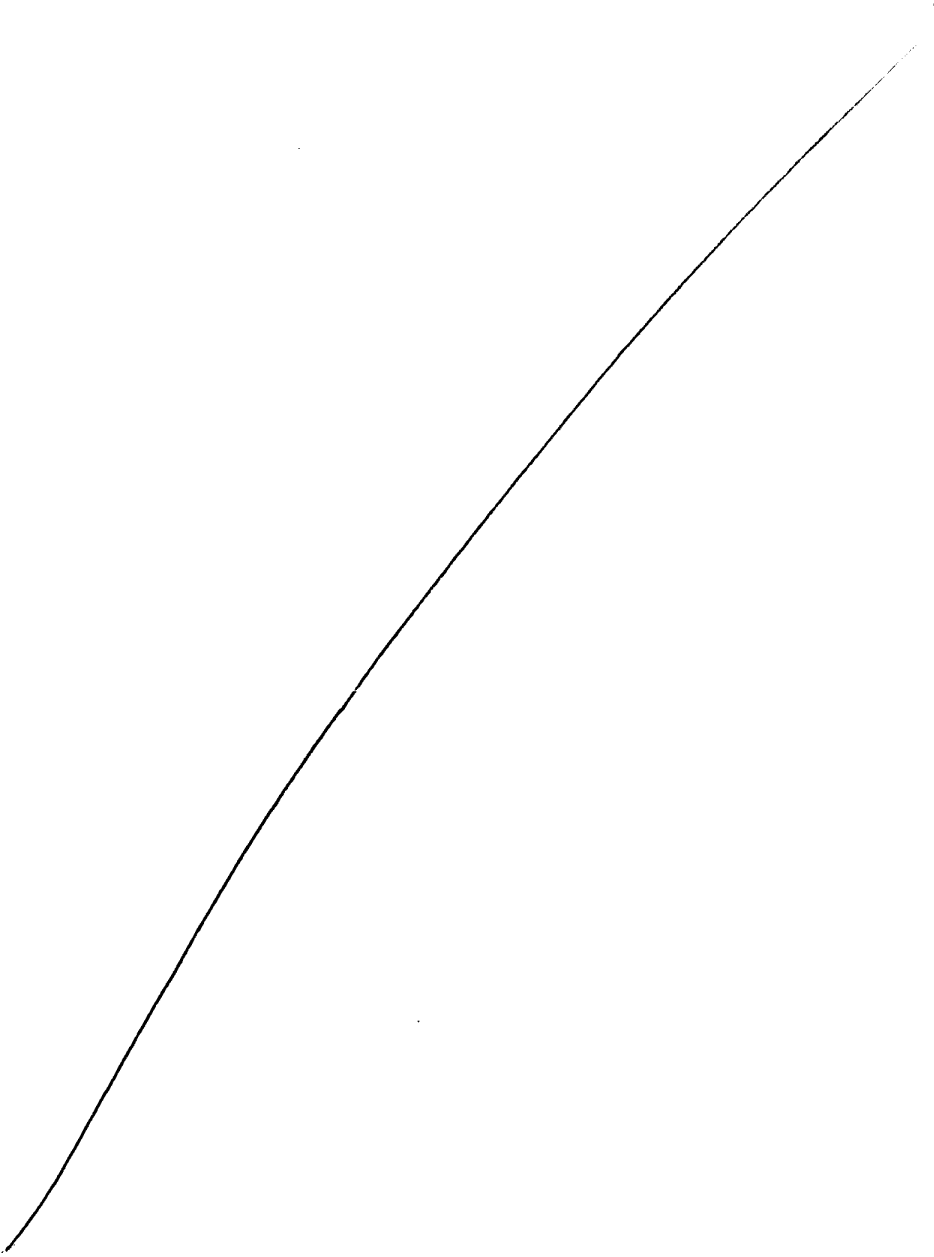
February 22, 2000

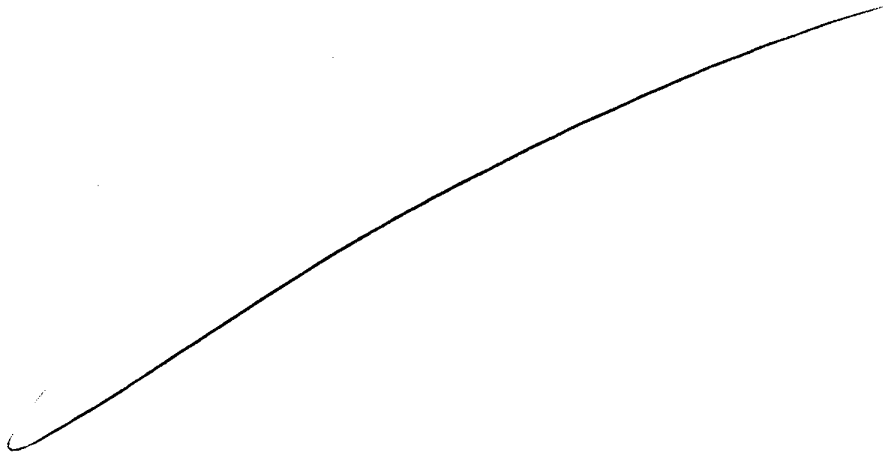
0797
Dr. John Wells
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Wells:

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

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/M5



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0797
Document No. Final

Laboratory: MAXXAM Analytics Inc.

Location: Mississauga, ON

Document Reviewed: Application Form
 Inspection Report #M5 Date: 20 January 2000
 Other _____

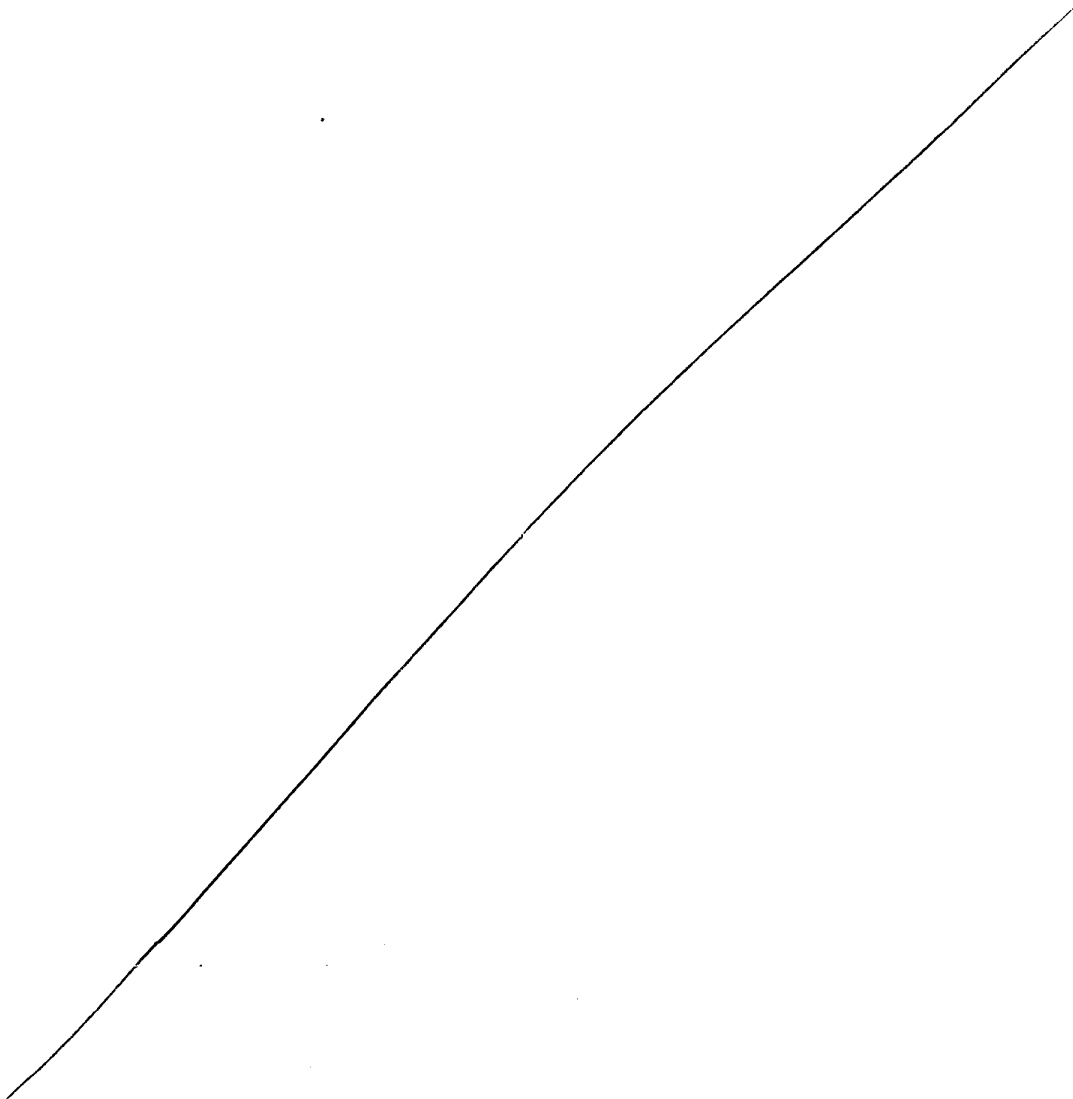
Status: Highly Acceptable Acceptable
 Unacceptable Failure

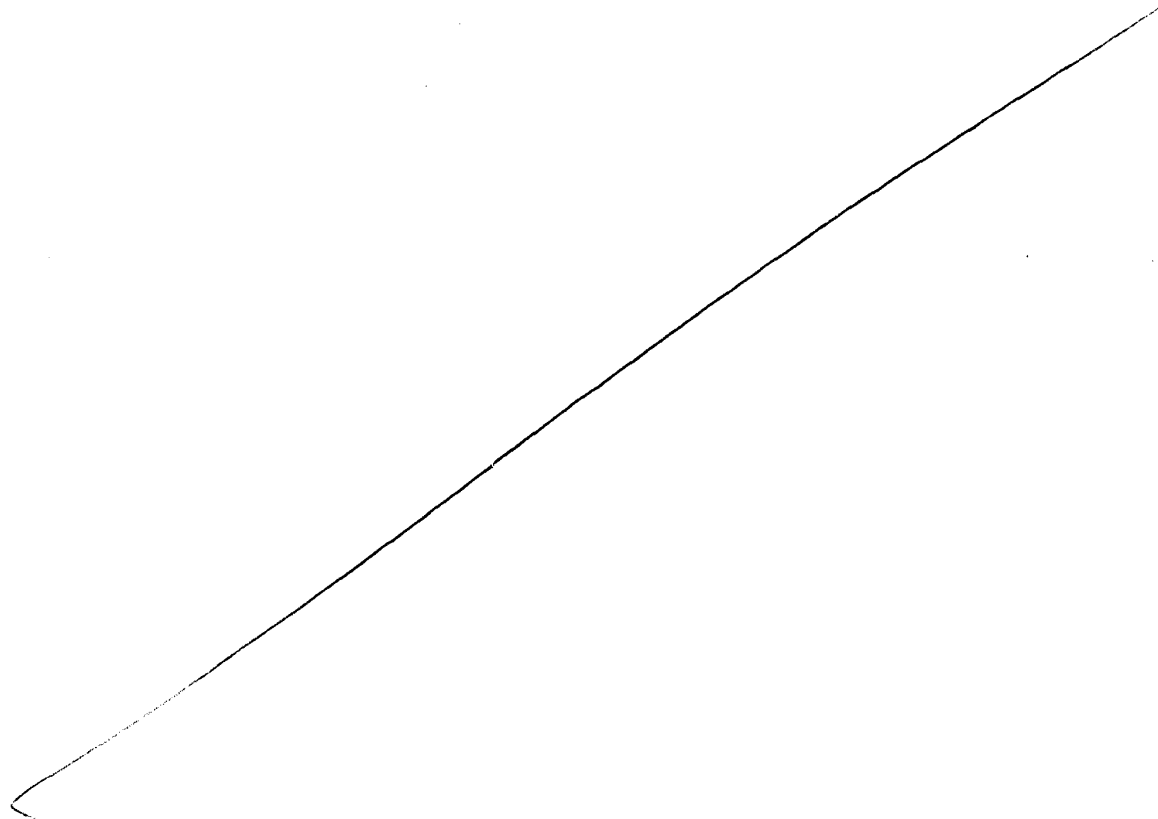
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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:

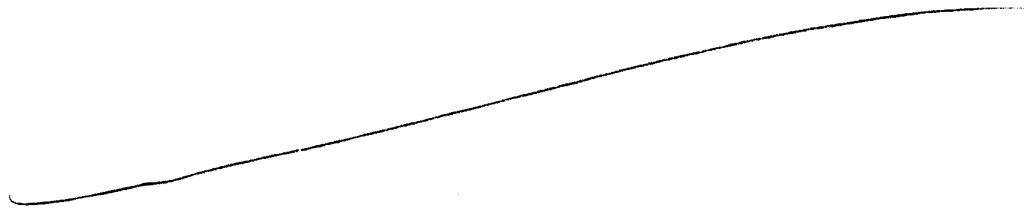
Section E. Standard Operating Procedures - Procedures Manual



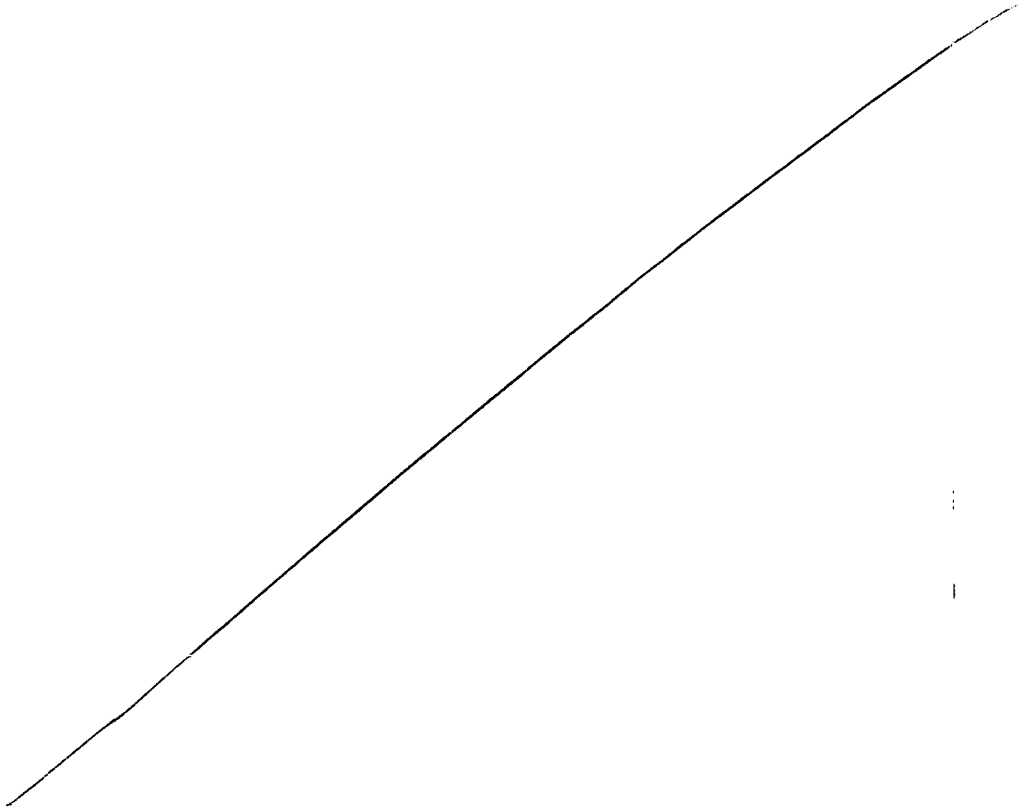


Section F. Chain-of-Custody, Accessioning, and Security

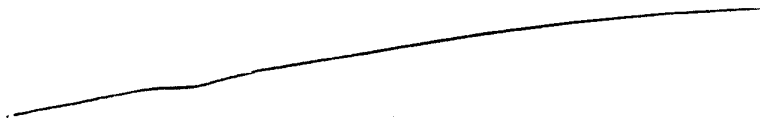


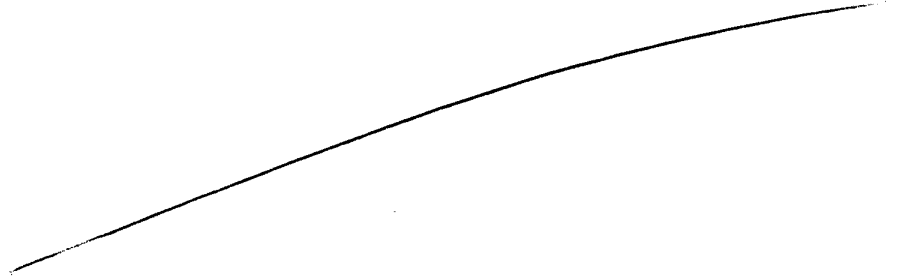


Section G. Quality Control



Section H. Initial Tests





Section I. Confirmatory Tests




Section J. Records Audit

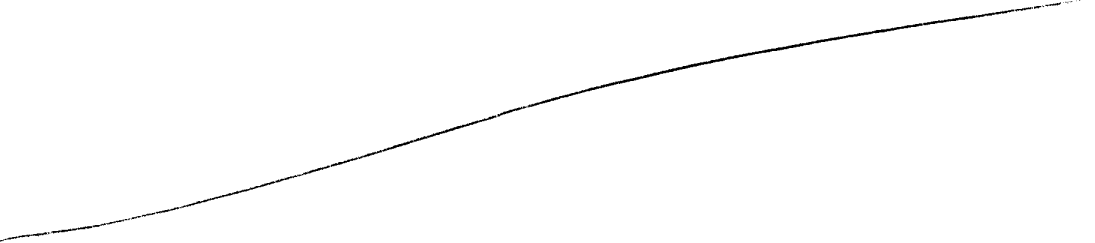
Section K. Reporting



Section L. Computers, Software, and LIMS

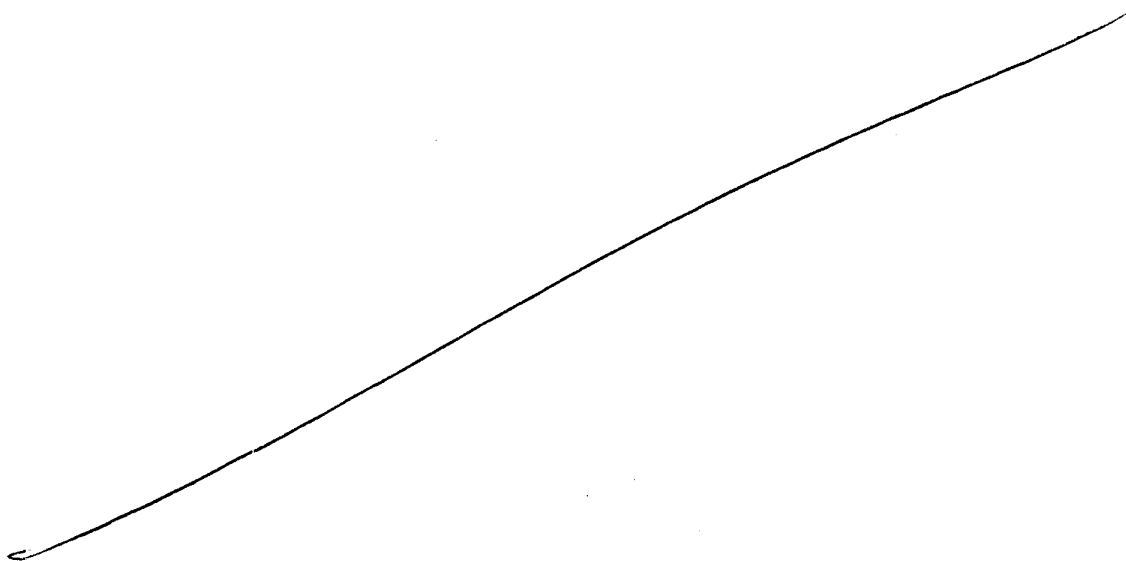


Section M. Equipment and Maintenance



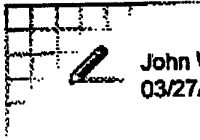
Section N. Personnel







A, Cremex Labs Alberta/Novamann International Partnership



John Wells
03/27/2000 10:47 AM

To: Deborah J.Denson, NLCP Inspection Analyst
cc:

Subject: RTI Inspection Reply

Please find enclosed the Reply to the questions raised in our last inspection dated February 22/2000.

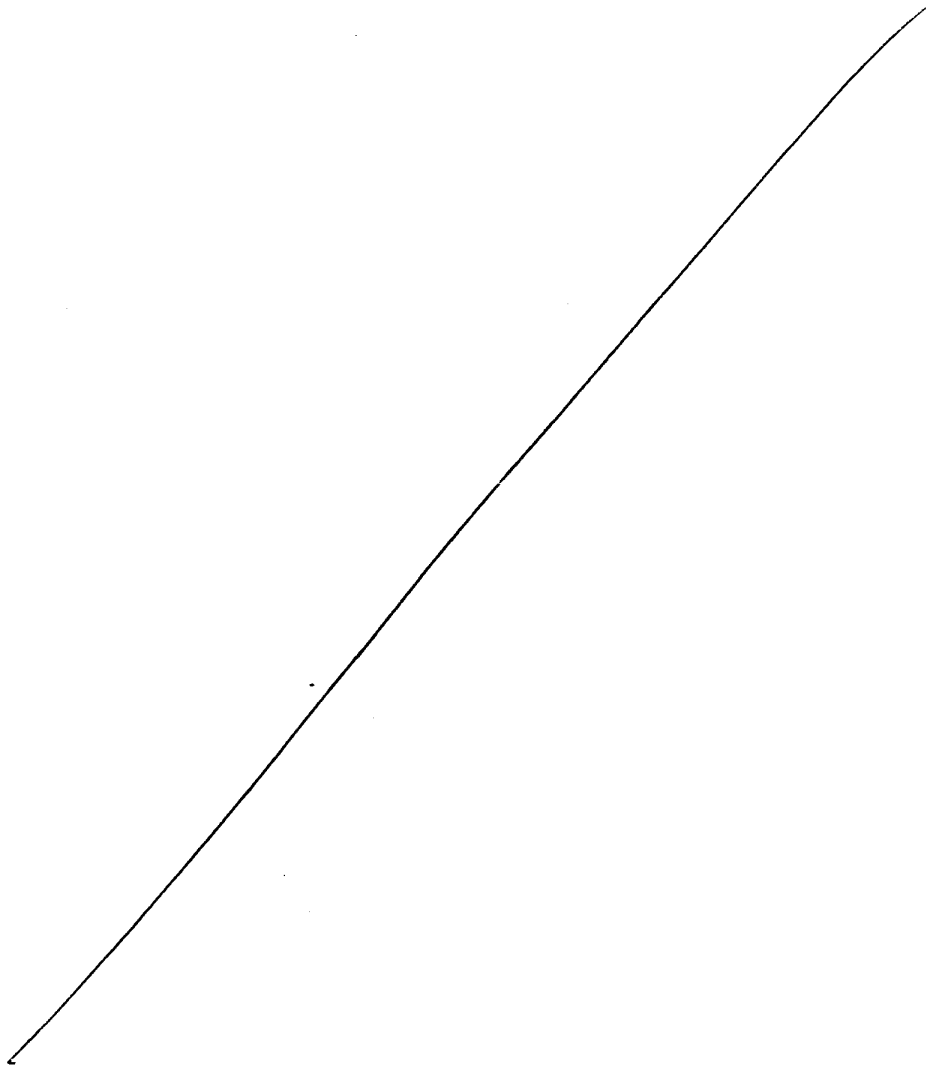
Yours Sincerely,

A handwritten signature in black ink, appearing to read "John Wells". The signature is written in a cursive, flowing style.

John Wells, Ph.D, Head Human Drug Testing Laboratory
1-800-653-6266 ext.230

Response to Inspection Report January 2000

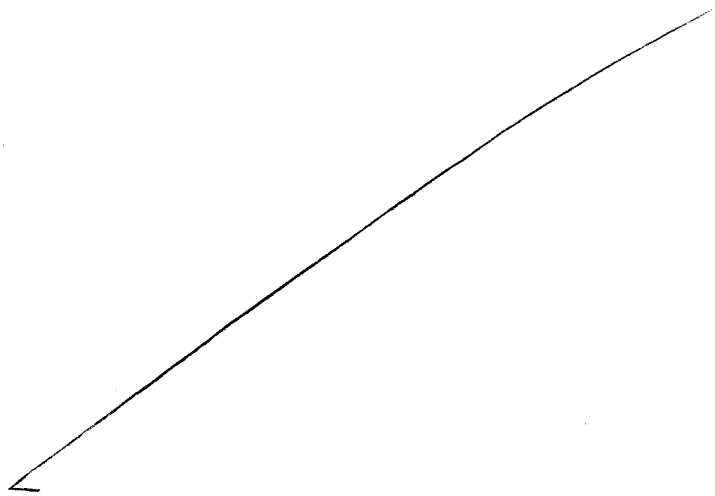
Section E



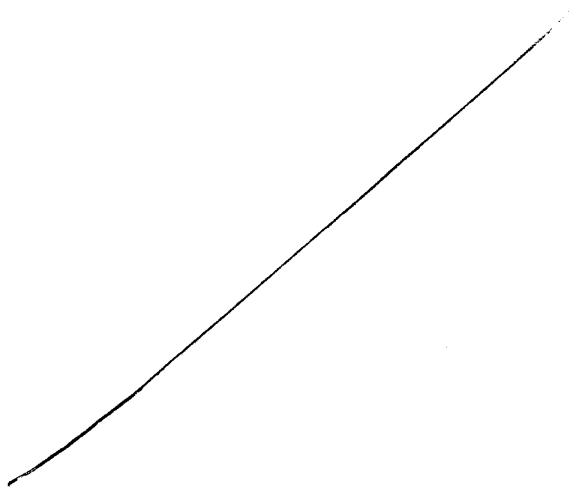
Section F



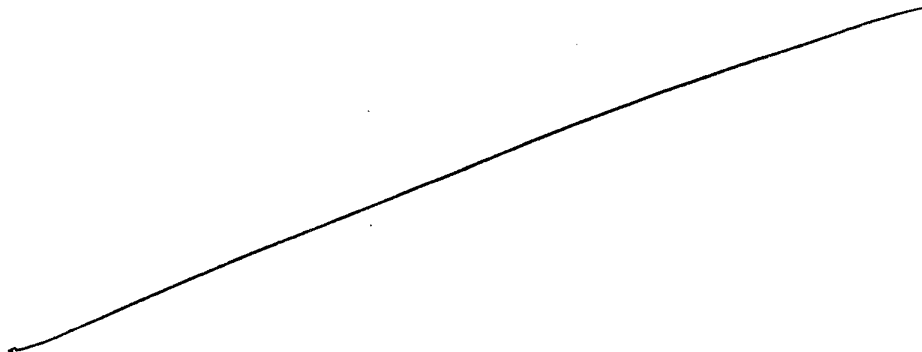
Section G.



Section H



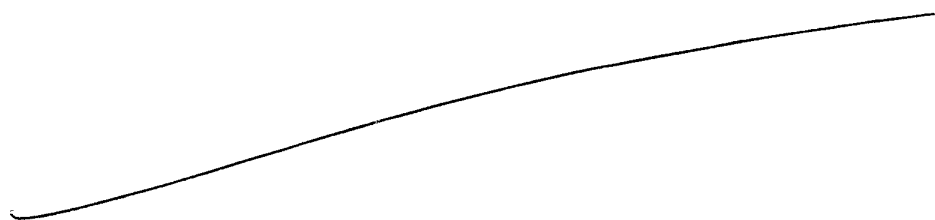
Section I



Section J



Section K



Section M



Section N

1/0



RESEARCH TRIANGLE INSTITUTE

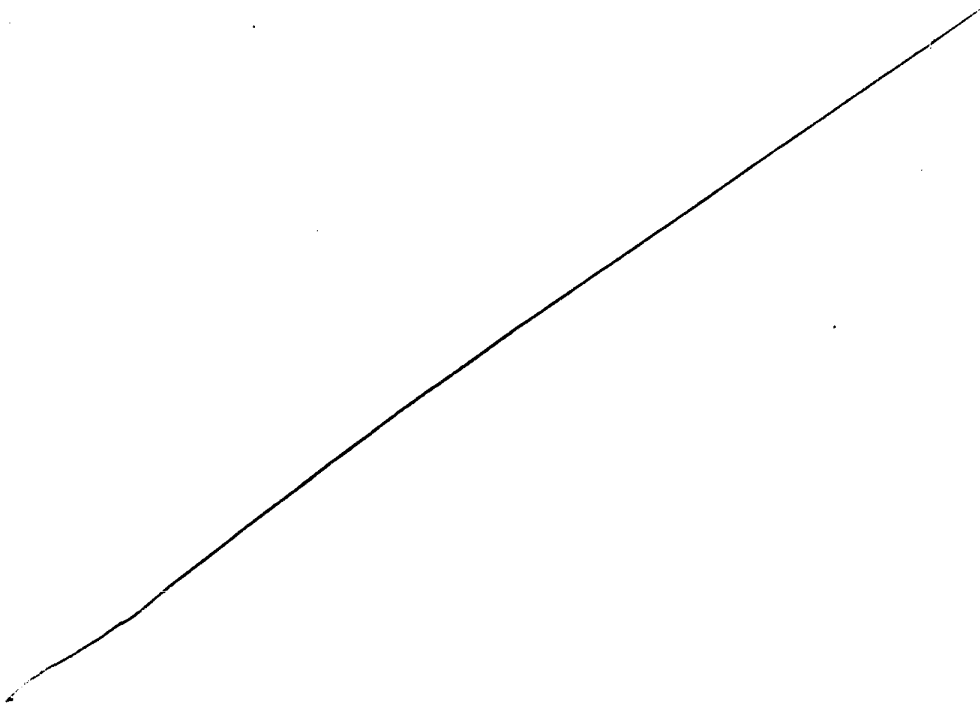
National Laboratory Certification Program

April 03, 2000

0797
Dr. John Wells
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Wells:

We have reviewed the material provided in your correspondence received March 27, 2000 submitted in response to issues raised during the fifth 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 actions have been completed to address the issues raised. The following is a review of the material submitted:

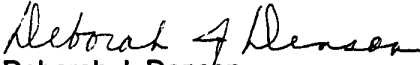


Dr. Wells
April 3, 2000
Page 2 of 2

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 Technical Analyst

cc: Project Files/M5

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

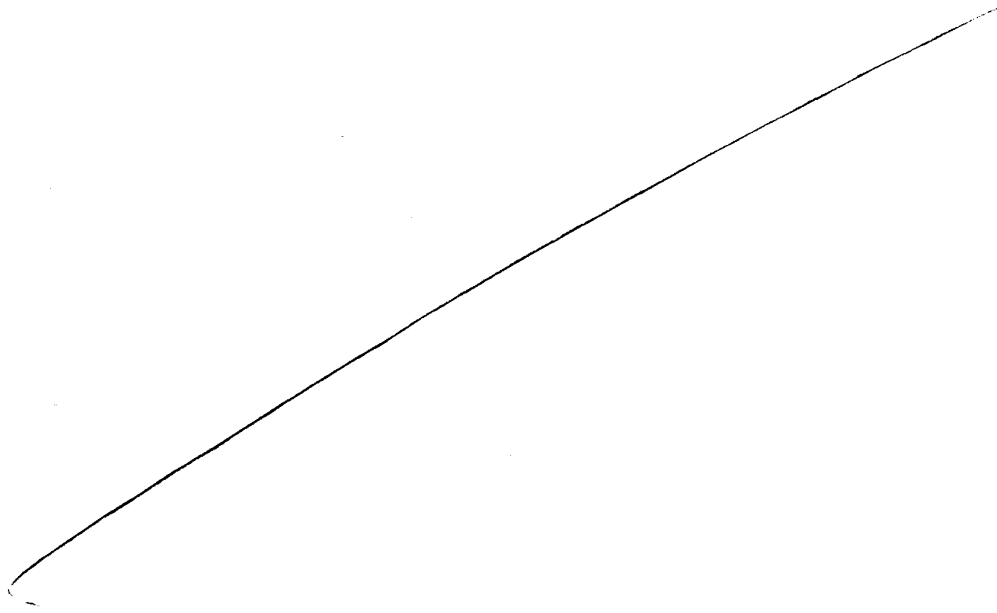
September 15, 2000

0797
Dr. John Wells
Ms. Lynn McGrath
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

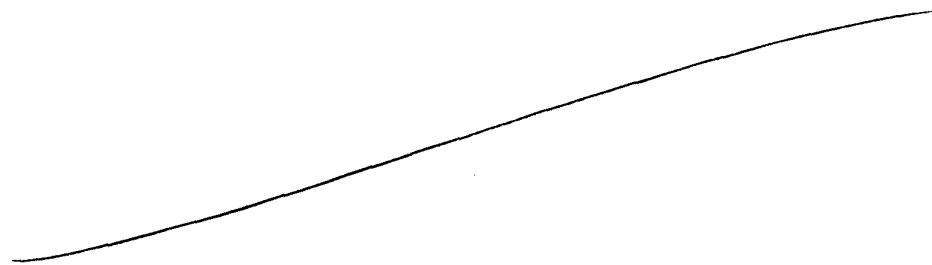
Dear Dr. Wells and Ms. McGrath:

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

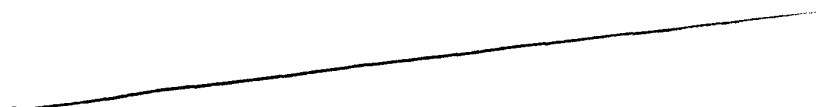




H. The Initial Tests section was found overall acceptable. However, the following issue was raised:



K. The Reporting Section was found overall acceptable. However, the following issue was raised:



Dr. Wells
Ms. McGrath
Page 3 of 3
09/15/00

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,



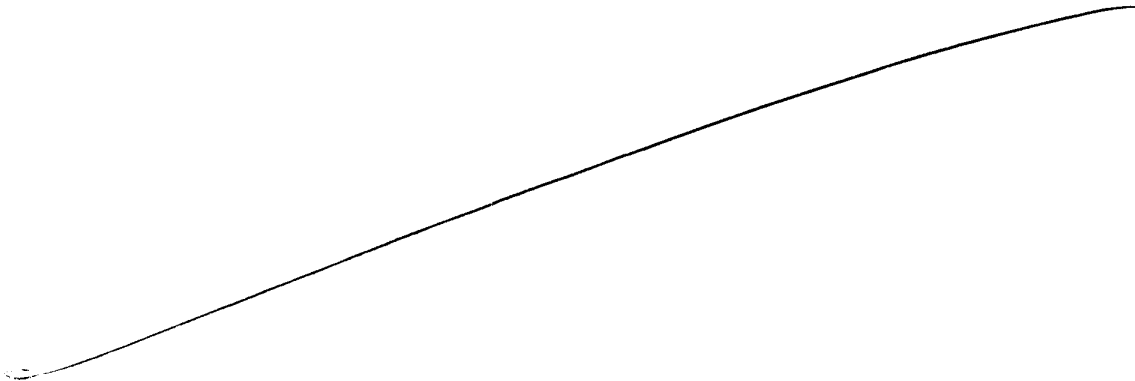
Susan Crumpton
NLCP Technical Analyst

Enclosure

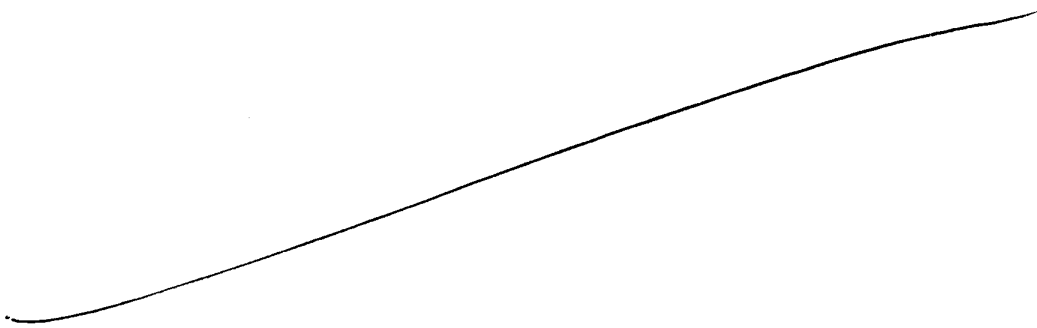
cc: Project Files/M6

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

received
SDC 10/11/00

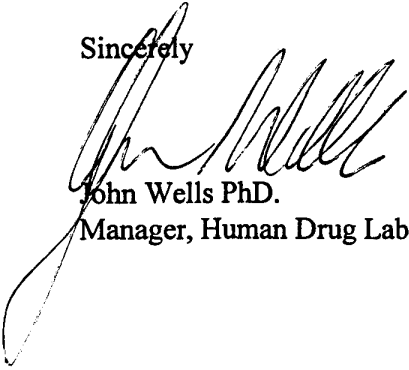
October 13, 2000

Susan Crumpton
Laboratory Accreditation Program
Substance Abuse,
Research Triangle Institute,
Research Triangle Park
North Carolina, 27709

Dear Ms. S. Crumpton

Enclosed is our response for the RTI critique of our inspection. If there any questions, do not hesitate to call.

Sincerely



John Wells PhD.
Manager, Human Drug Laboratory

Response to Inspection Report July 2000

Section H.

[Redacted content]

Section K.

[Redacted content]

Section M.

[Redacted content]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 23, 2000

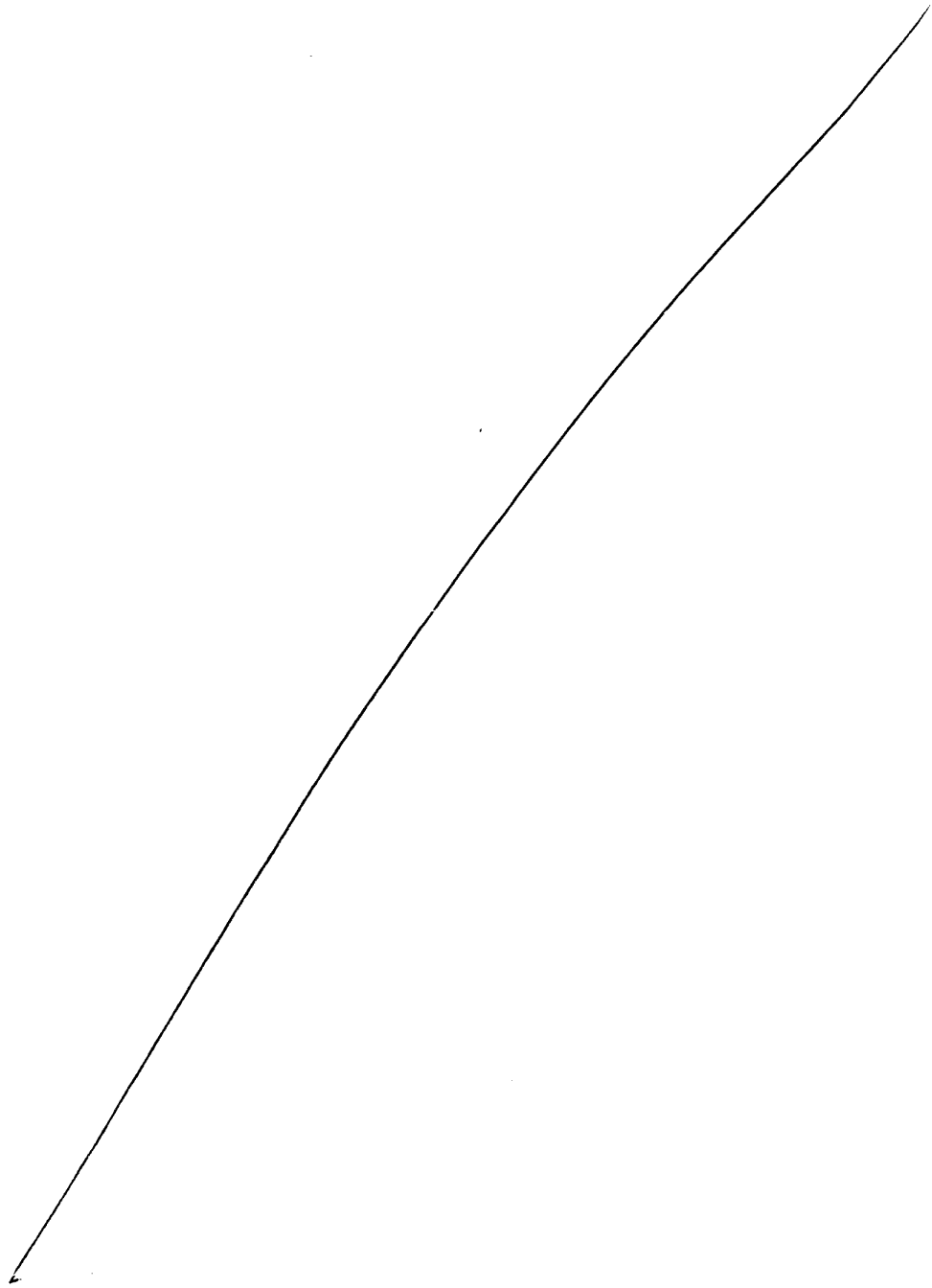
0797
Dr. John Wells
Ms. Lynn McGrath
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Wells and Ms. McGrath:

We have reviewed the material provided in your correspondence of October 13, 2000, submitted in response to issues raised during the sixth maintenance inspection of your laboratory as outlined in our correspondence of September 15, 2000. The following is a review of the material submitted:



Dr. Wells
Ms. McGrath
Page 2 of 3
10/23/00



Dr. Wells
Ms. McGrath
Page 3 of 3
10/23/00

Based upon our review of the material submitted, RTI is recommending to 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) 541-6176 or Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/M6

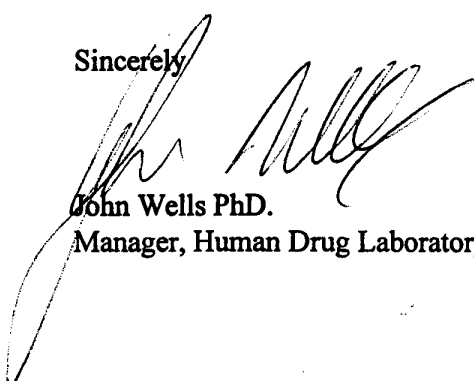
November 22, 2000

Susan Crumpton
Laboratory Accreditation Program
Substance Abuse,
Research Triangle Institute,
Research Triangle Park
North Carolina, 27709

Dear Ms. S. Crumpton

Enclosed is our response to our Inspection of July 2000. If there any questions, do not hesitate to call.

Sincerely



John Wells PhD.
Manager, Human Drug Laboratory

Response to Inspection Letter Dated October 23, 2000

Section H.

[Redacted]

Section K.

[Redacted]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 4, 2000

0797
Dr. John Wells
Ms. Lynn McGrath
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Wells and Ms. McGrath:

We have reviewed the material provided in your correspondence of November 22, 2000, submitted in final response to issues raised during the sixth maintenance inspection of your laboratory as outlined in our correspondence of October 23, 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.

As noted in our previous correspondence, RTI has recommended 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,

A handwritten signature in cursive script that reads "Susan Crumpton".

Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/797

