Validity Testing Information Part I

Laboratory Name: Maxxam Analytics Inc
Address: 5540 McAdam Rd Miss Canada

Responsible Person: John Wells (Printed Name)

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001, 31 U.S.C. 3801-812).

Signature, Responsible Person

OCT 4 | 00
Date

JOHN WELLS
Printed Name, Responsible Person

Frank Wallace

From: <pwilson@mail.maxxam.ca>
To: <FNW@rti.org>
Cc: <jwells@mail.maxxam.ca>
Sent: Tuesday, October 17, 2000 12:41 PM
Attach: DOTadulter2.xls
Subject: Adulterated samples

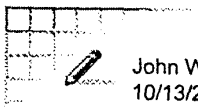
Hi Frank.

(See attached file: DOTadulter2.xls)

Penny Wilson
Maxxam Analytics Inc.

Specimen ID	LAN	Date Received	Date Reported	Result	Creatinine	S.G.

Maxxam
Analytics Inc



John Wells
10/13/2000 08:32 AM

To: Dr John M Mitchell
cc:

Yours Sincerely

John Wells

5540 McAdam Road, Mississauga, Ontario, Canada L4Z 1P1 Tel.: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.ca

Validity Testing Information Part II

Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for *each* DOT regulated specimen that was reported either adulterated or substituted:

- **Specimen ID number**
- **Laboratory Accession Number**
- **Date of receipt**
- **Date reported**
- **Reported result (i.e., adulterated or substituted)**
- **Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)**

Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.

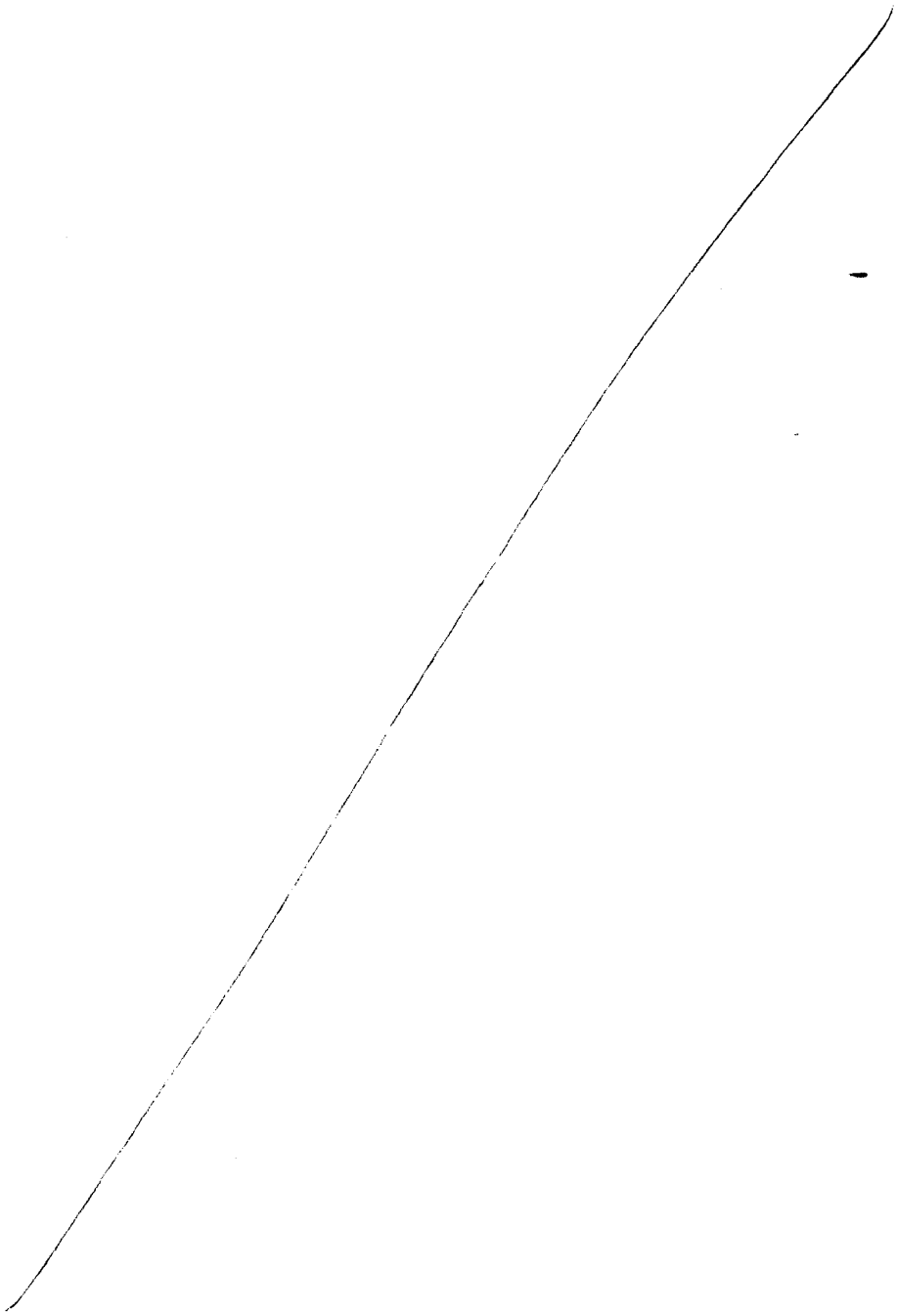
I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

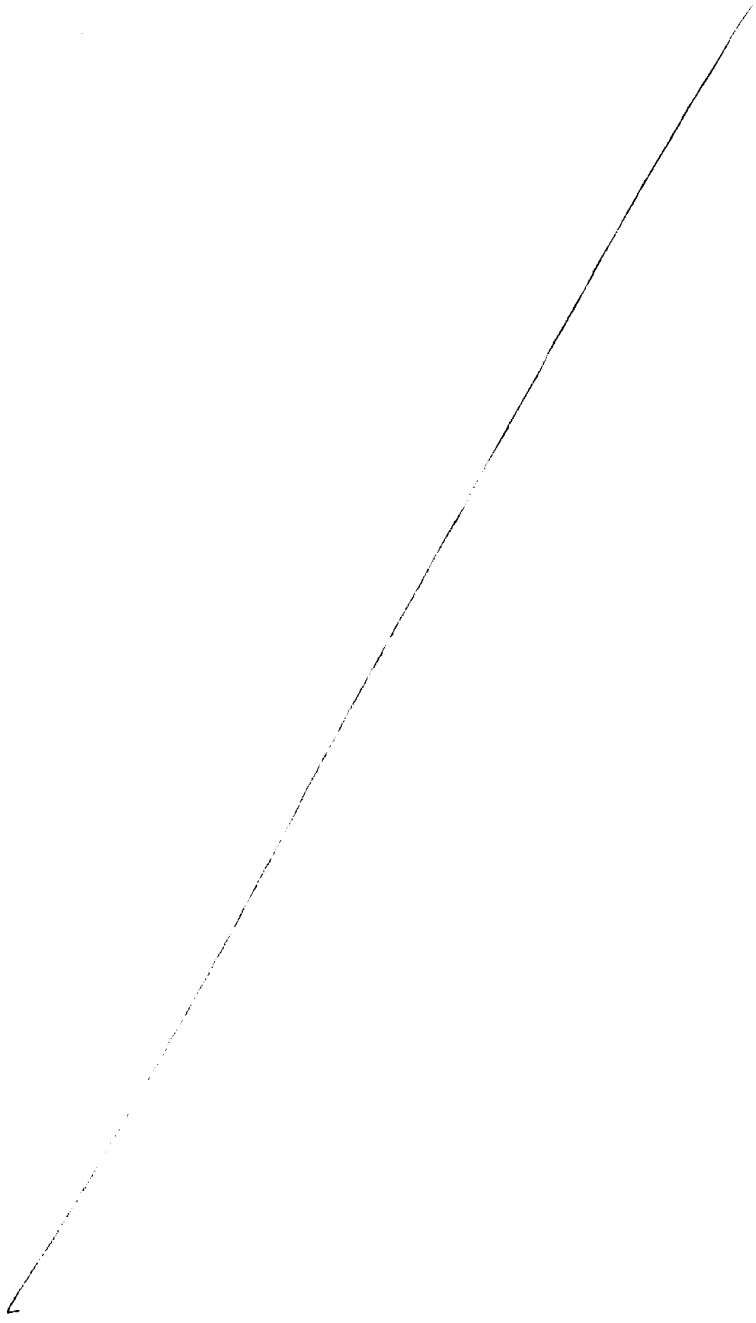
Signature, Responsible Person

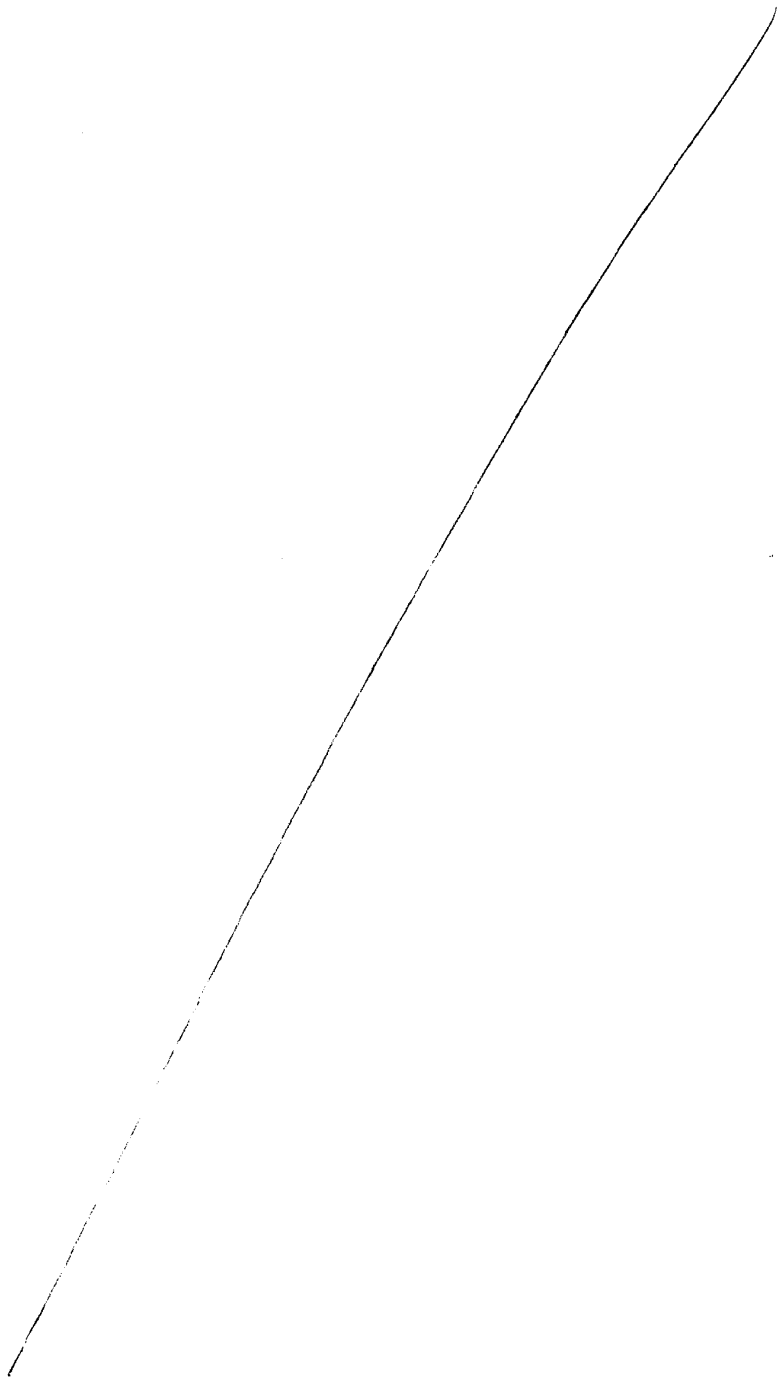
OCT 16/00.
Date

John W Bliss
Printed Name, Responsible Person

Specimen ID	LAN	Date Received	Date Reported	Result	Creatinine	S.G.







RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

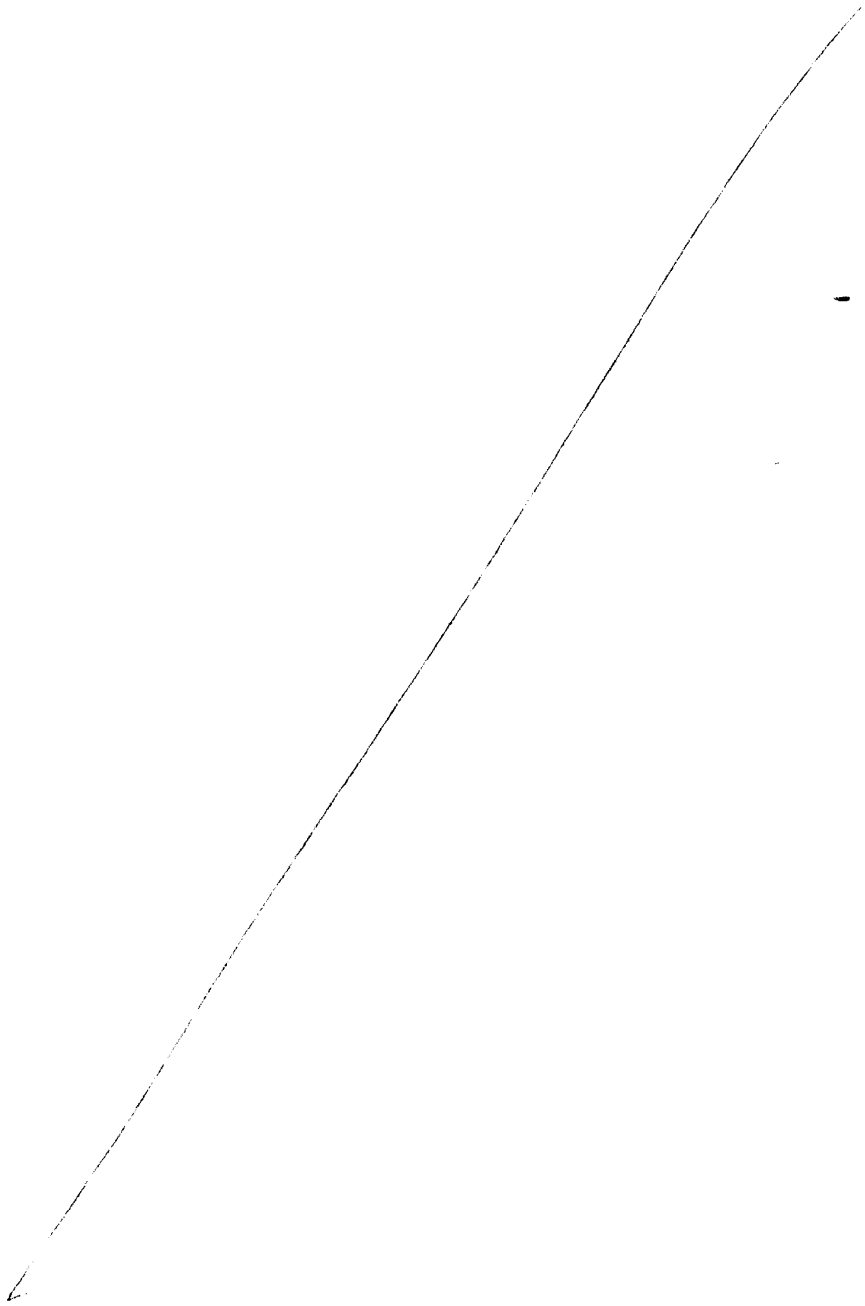
December 11, 2000

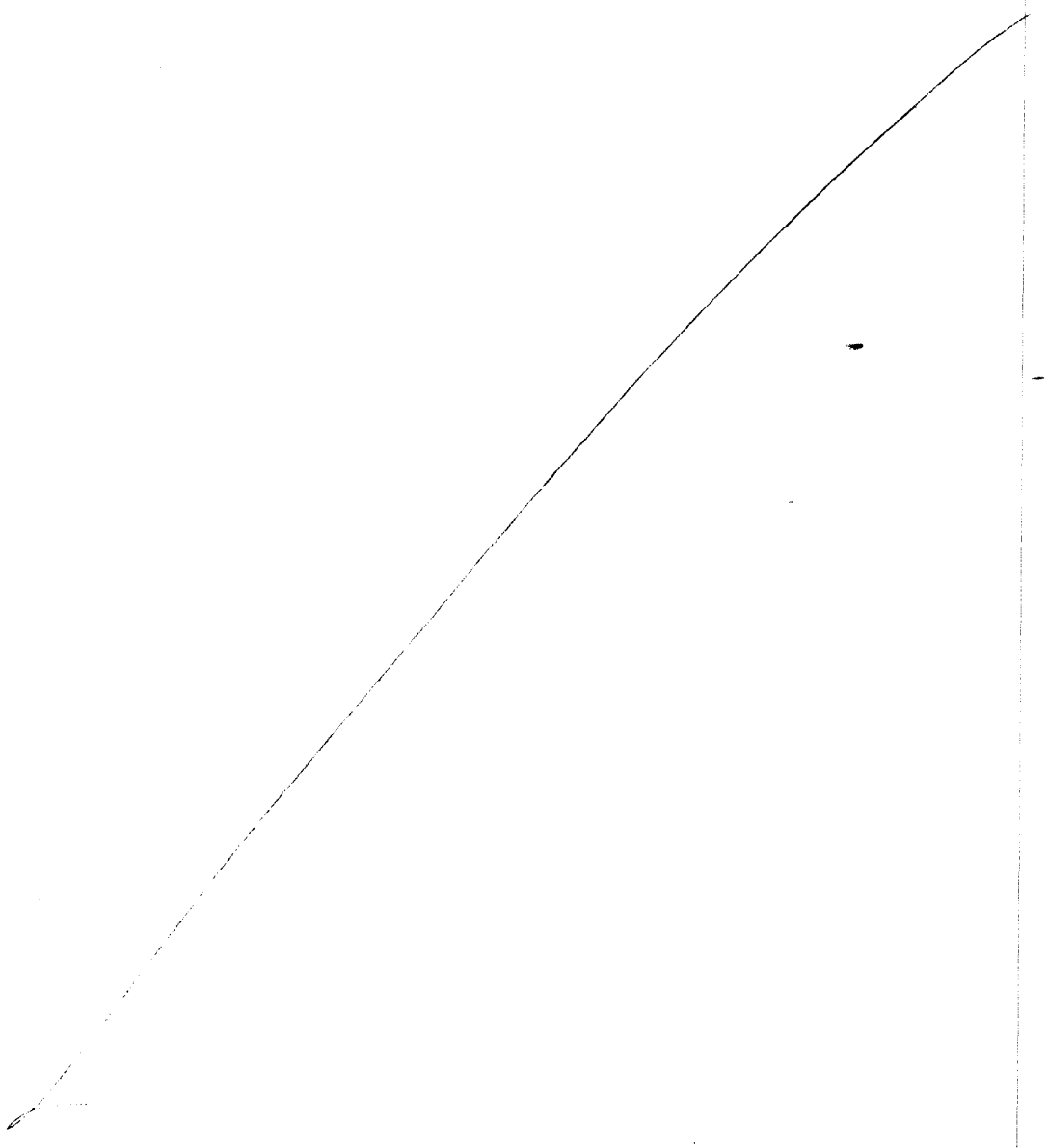
0797
Dr. John Wells
Ms. Lynn McGrath
Maxxam Analytics, Inc.
5540 McAdam Road
Mississauga, Ontario, CAN L4Z 1P1

Dear Dr. Wells and Ms. McGrath:

The enclosed critique was developed from the inspection report associated with the November 29-30, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to address the following issues raised:

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





The laboratory must submit, within 30 calendar days of receipt of [redacted], documentation to demonstrate that corrective actions have been implemented to address the issues raised. The information from the MRO inquiry must be submitted within 5 working days as noted in I7 above. 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. 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. ***Failure to comply may result in the laboratory's suspension to perform specimen validity***

testing on federally regulated specimens. All corrective actions 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/svt797

INQUIRY TO MRO

Lab Number _____

Name of person contacted at MRO office: _____

Phone Number: (____)_____

Specimen ID Number: _____

MRO Disposition:

- ❑ Substituted, **substitution admitted by donor during interview**
- ❑ Substituted, **substitution denied by donor during interview**
- ❑ Substituted, **substitution not admitted or denied during interview**
- ❑ Substituted, **donor not contacted**
- ❑ Substituted, **no comments regarding donor contact**
- ❑ **Refusal to test**
- ❑ **Interpreted as negative by MRO**
- ❑ **Records not available from MRO**
- ❑ Cancelled, **medical explanation**
- ❑ Cancelled, **other (briefly explain)**_____
- ❑ **Other (briefly explain)**_____

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: [XX] Specimen Validity Testing Inspection Report

Date: 29 November 2000

A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

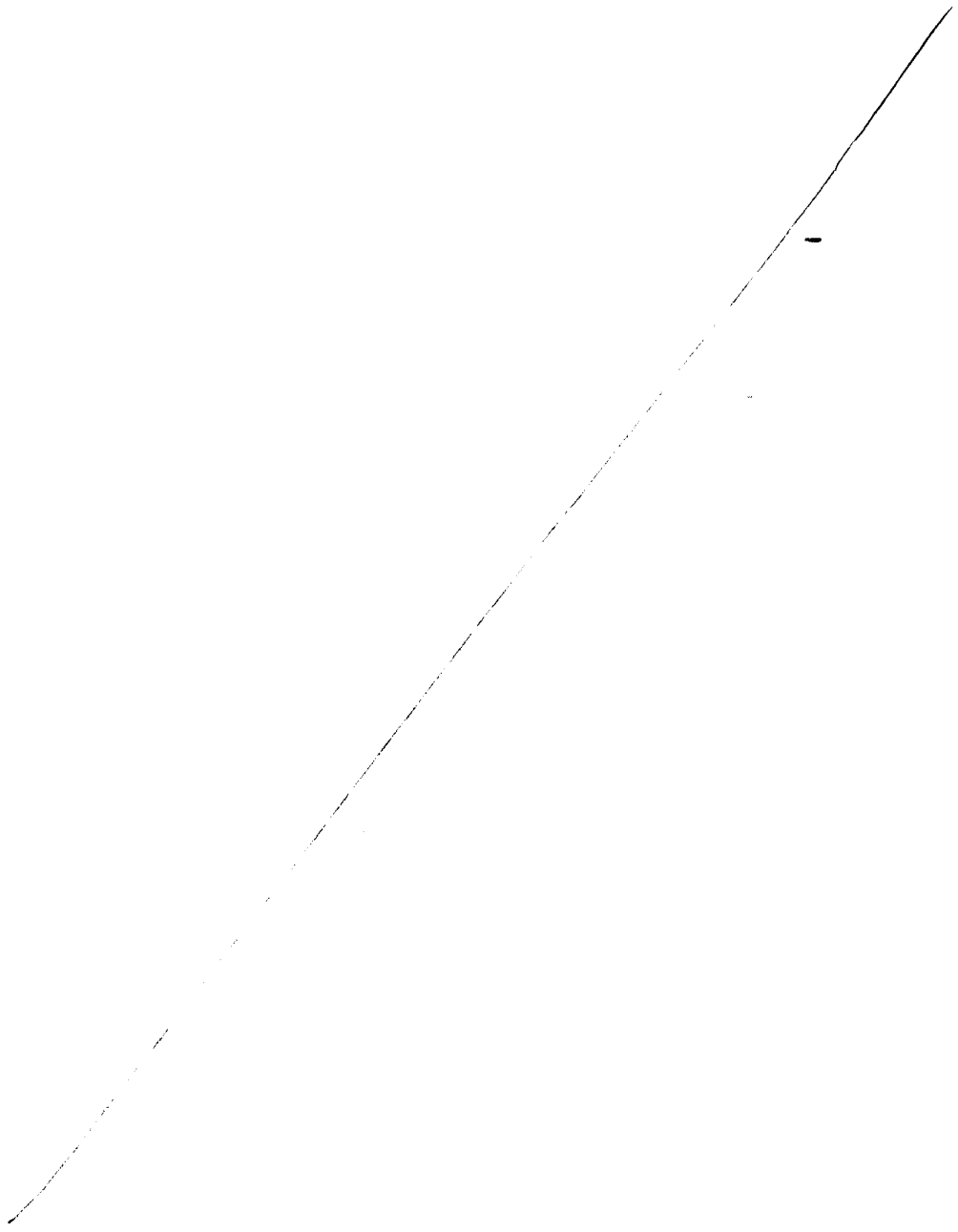
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests



Section K. Records Audit

Section L. Certification and Reporting

Section O. Overall

Maxxam Analytics Inc

A Chemex Labs Alberta/Novamann International Partnership

received
12/19/00

December 18, 2000

National Laboratory Certification Program
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Dr. Baylor

Please do not hesitate to call if there are any questions regarding this explanation.

Sincerely

John Wells, PhD.
Manager of Human Drug Laboratory

5540 McAdam Road, Mississauga, Ontario Canada L4Z 1P1 Tel: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.c

Maxxam
Analytics Inc

January 10, 2001

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

Dear Ms. S. Crumpton

Enclosed is the response to the audit associated with the specimen validity testing. Unfortunately, not all of the responses are present. The laboratory will submit the remainder of the response to your office by January 19, 2001. If there are any questions please do not hesitate to call.

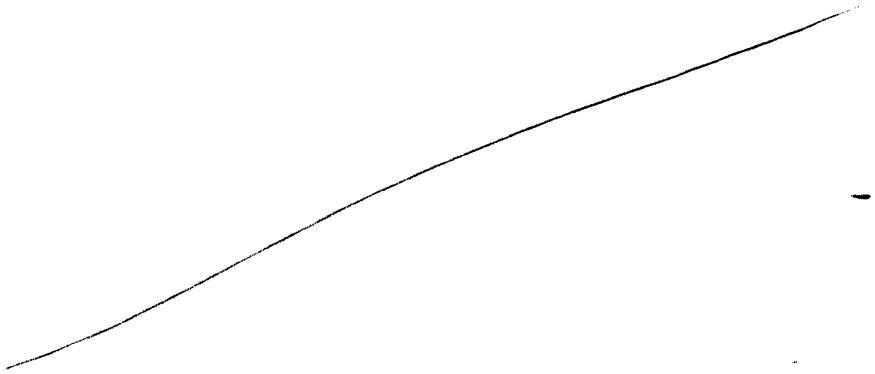
Sincerely

Lynn McGrath B.Sc. C.Chem
Assistant Manager, Human Drug / For John Wells Ph.D.

encl.

5540 McAdam Road, Mississauga, Ontario, Canada L4Z 1P1 Tel.: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.ca

Section E:



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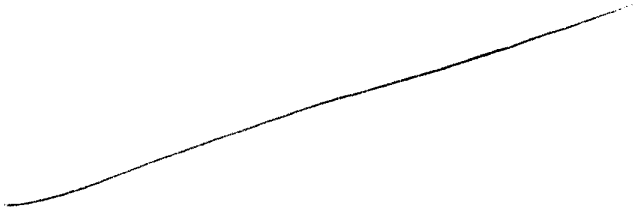
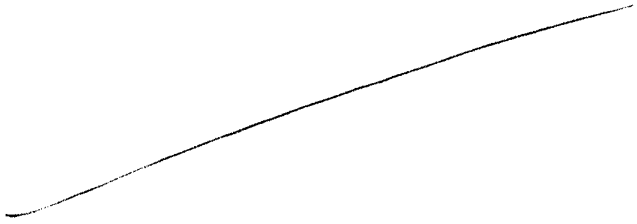
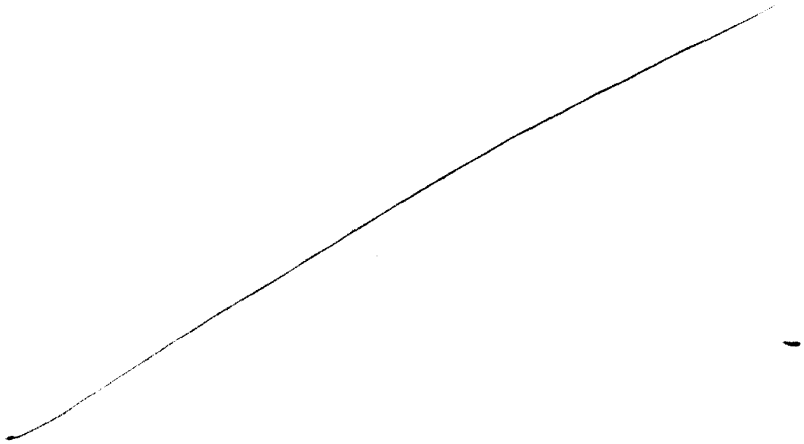
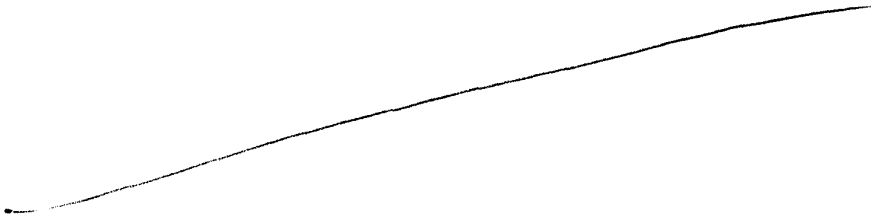


Section I:





Section L:



Maxxam
Analytics Inc

received
1/19/01 SAC

January 18, 2001

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

Dear Ms. S. Crumpton

Enclosed is the remainder to our response to the audit associated with the specimen validity testing. If there are any questions please do not hesitate to call.

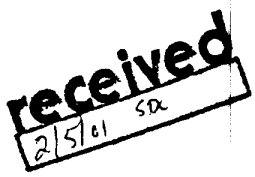
Sincerely

John Wells, PhD. C.Chem
Manager, Human Drug

encl.

5540 McAdam Road, Mississauga, Ontario, Canada L4Z 1P1 Tel.: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.ca

Maxxam
Analytics Inc



February 1, 2001

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

Dear Ms. S. Crumpton

Enclosed is the response to the audit associated with the specimen validity testing. If there are any questions please do not hesitate to call.

Sincerely

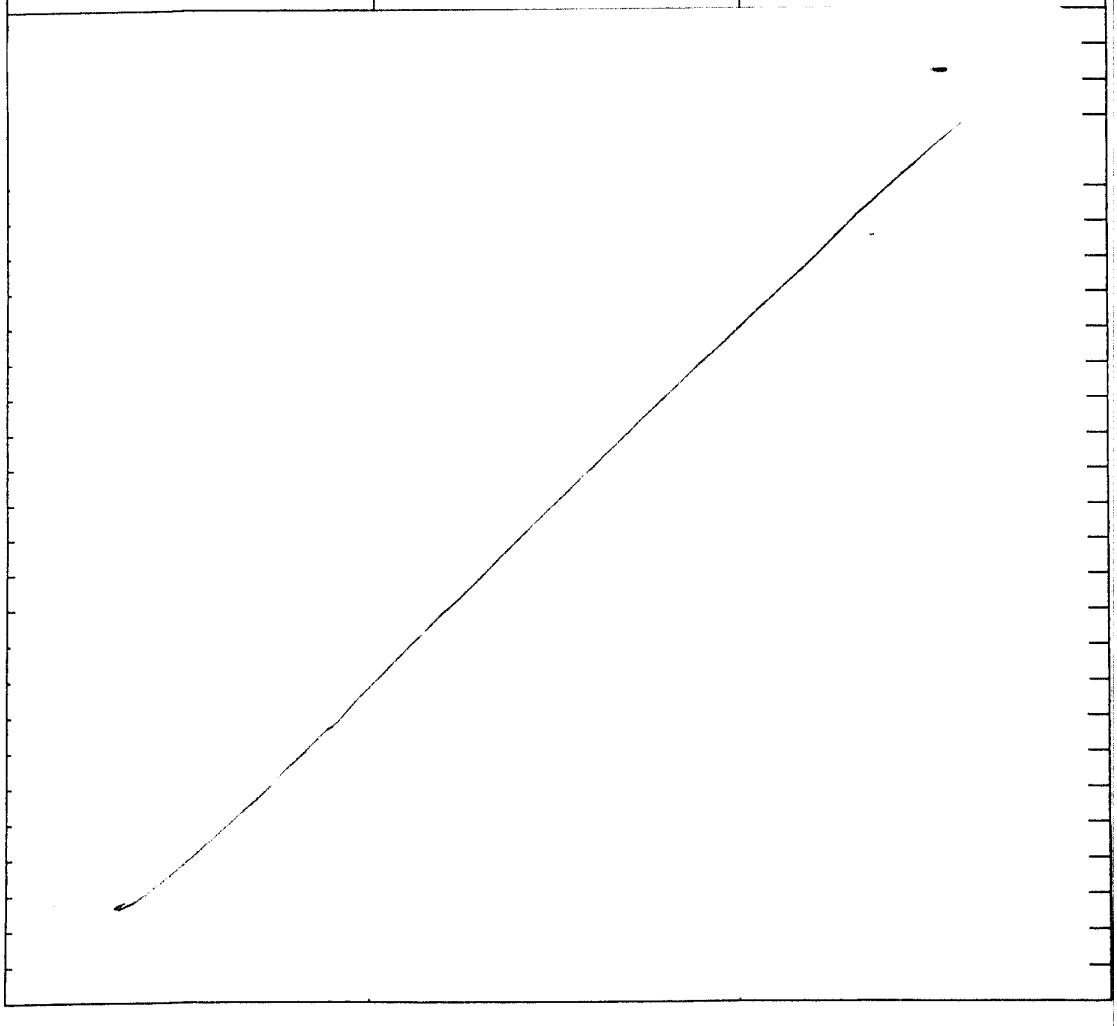
Lynn McGrath

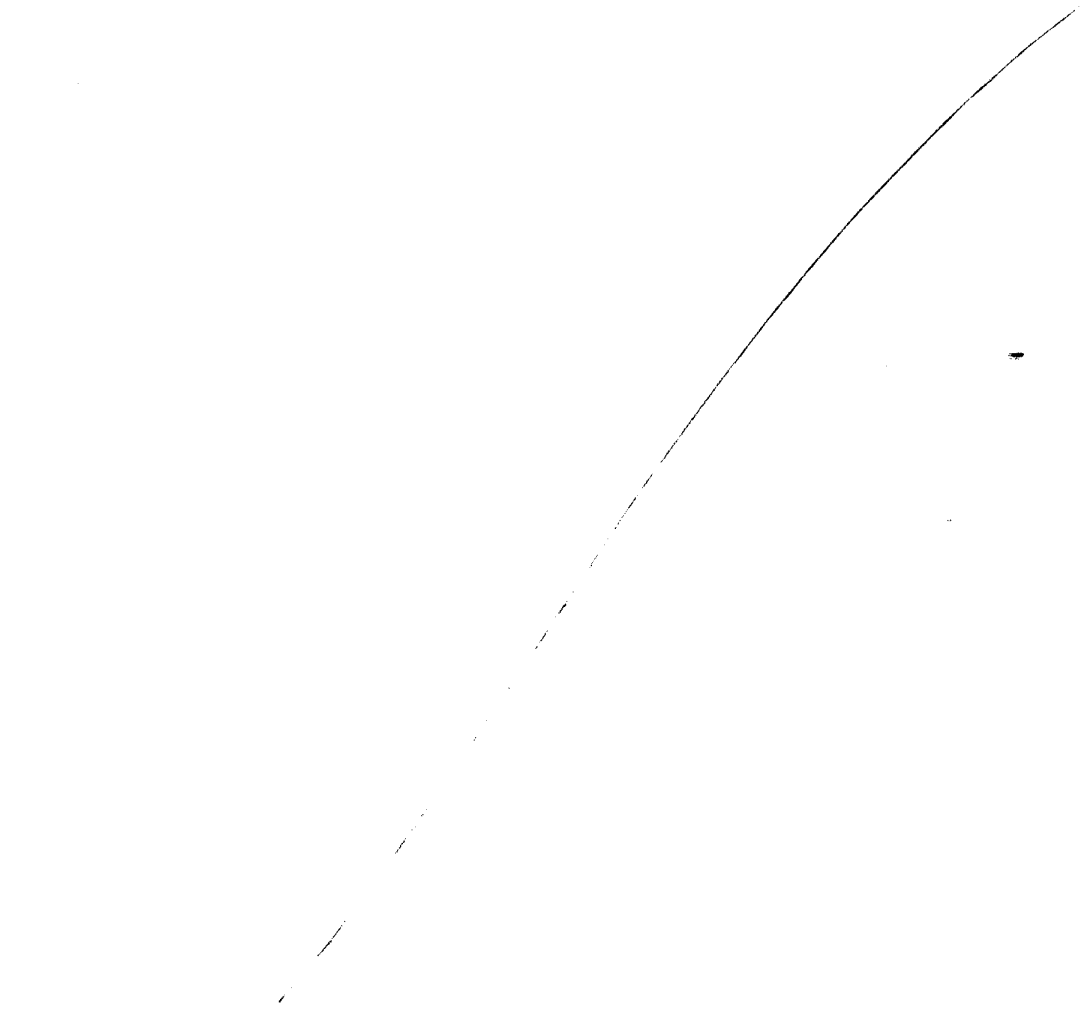
Lynn McGrath, B.Sc. C.Chem
Assistant Manager, Human Drug

encl.

5540 McAdam Road, Mississauga, Ontario, Canada L4Z 1P1 Tel.: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.ca

Calibrator or Control	Concentration	Source





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

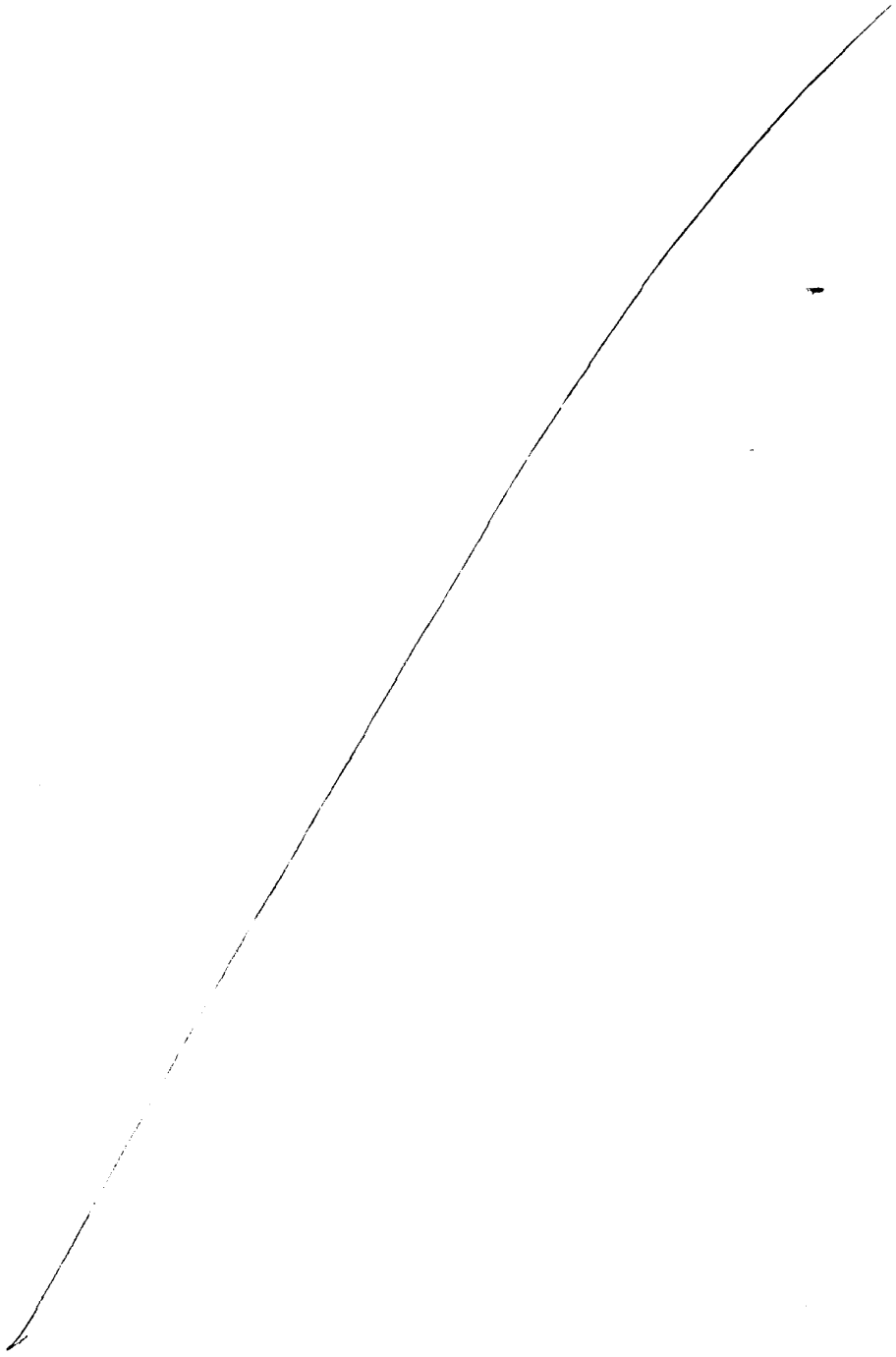
January 23, 2001

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 December 18, 2000, January 10, 2001, and January 18, 2001, submitted in response to issues raised during the November 29-30, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 11, 2000. The information submitted by the laboratory appears to demonstrate that the laboratory has taken corrective actions to address the issues raised. However, the following issues require additional clarification and corrective action:

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



The laboratory must submit, within 10 calendar days of receipt of this letter, documentation of corrective actions addressing the issues listed in this correspondence. All corrective actions must be implemented within 30 days of the receipt of this correspondence. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.***

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0797

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 19, 2001

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 February 1, 2001. The laboratory submitted information in response to issues raised during the November 29, 2000, specimen validity testing inspection and issues raised during RTI staff's review of remedial correspondence, as outlined in our correspondence of January 23, 2001. The following issues require additional clarification or corrective action:

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

The laboratory must submit, within 10 calendar days of receipt of this letter, information to clarify the issues listed in this correspondence. All corrective actions must be implemented within 30 days of the receipt of this correspondence. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.***

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT797

Maxxam Analytics Inc

received
2/27/01 SDC

February 23, 2001

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

Dear Ms. S. Crumpton

Enclosed is the response to the audit associated with the specimen validity testing. If there are any questions please do not hesitate to call.

Sincerely

Lynn McGrath, B.Sc. C.Chem
Assistant Manager, Human Drug

encl.

5540 McAdam Road, Mississauga, Ontario, Canada L4Z 1P1 Tel.: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.ca

Responses to RTI Deficiency Letter of February 19, 2001

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 1, 2001

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 February 23, 2001, submitted in response to remaining issues from the November 29, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of February 19, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0797

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

Maxxam Analytics Inc

received 3/7/01 SPC

March 6, 2001

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

Dear Ms. S. Crumpton

Enclosed are SOP changes corresponding to the letter dated March 1, 2001 regarding the specimen validity testing. If there are any questions please do not hesitate to call.

Sincerely

Lynn McGrath

Lynn McGrath, B.Sc. C.Chem
Assistant Manager, Human Drug

encl.

5540 McAdam Road, Mississauga, Ontario, Canada L4Z 1P1 Tel.: (905) 890-2555 Toll-free: 800-563-6266 Fax: (905) 890-0370 Website: www.maxxam.ca

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 12, 2001

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 March 6, 2001, submitted in response to one specimen validity testing issue as outlined in our correspondence of March 1, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issue. The implementation of the revised procedures 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/0797

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