



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 9, 1999

0798

Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, Canada T5V1B4

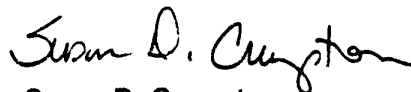
Dear Dr. Kinniburgh:

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

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 D. Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M2

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0798
Document No. Final

Laboratory: Dynacare Kasper Medical Laboratories

Location: Edmonton, Alberta

Document Reviewed: Application Form
 Inspection Report #M2 Date: 7 January 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



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

March 11, 1999

RECEIVED
SPC 3/16/99



DKML
MEDICAL LABORATORIES

Ms. Susan D. Crumpton
NLCP Inspection Analyst
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, North Carolina
27709-2194 USA

14940 - 123 Avenue
Edmonton, Alberta Canada T5V 1B4

Dear Ms. Crumpton:

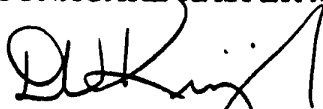
This is in response to the issues raised in your letter to me dated February 9, 1999. Specifically, you asked for a written response to the deficiencies indicated under G.12 and G.28.

Appropriate sections of the SOP are enclosed in support of these changes.

I trust that this information is satisfactory. If you have any questions or require any further information, please contact me.

Sincerely,

DYNACARE KASPER MEDICAL LABORATORIES



David W. Kinniburgh, PhD, FCACB
National Director, Substance Abuse Testing

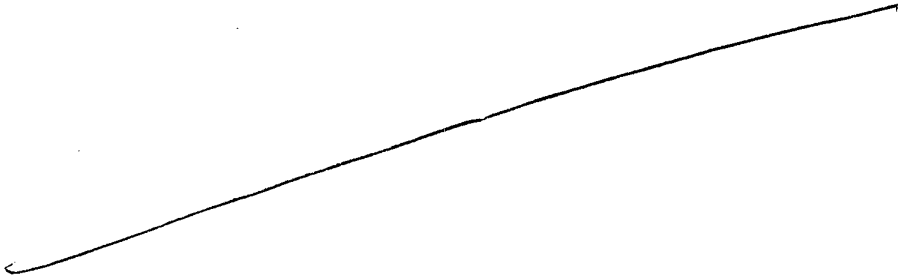
March 25, 1999

0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, CAN T5V1B4

Dear Dr. Kinniburgh:

We have reviewed the material provided in your correspondence of March 11, 1999, and your faxed correspondence of March 23, 1999, submitted in response to issues raised during the second maintenance inspection of your laboratory as outlined in our correspondence of February 9, 1999. The following is a summary of our review:

Dr. Kinniburgh
Page 2 of 2
03/25/99



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 (NLCP). The laboratory must take steps to correct the issue cited above. All corrective actions must be implemented within 30 days of 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 Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

cc: Project Files/M2



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

September 8, 1999

0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, CAN T5V1B4

Dear Dr. Kinniburgh:

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 highly acceptable.

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,


Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M3



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0798
Document No. Final

Laboratory: Dynacare Kasper Medical Laboratories

Location: Edmonton, Alberta

Document Reviewed: Application Form
 Inspection Report #M3 Date: 12 August 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

April 18, 2000

0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, CAN T5V1B4

Dear Dr. Kinniburgh:

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.

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 that reads 'Susan Crumpton'.

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M4



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0798
Document No. Final

Laboratory: Dynacare Kasper Medical Laboratories

Location: Edmonton, Alberta

Document Reviewed: Application Form
 Inspection Report #M4
 Other _____

Date: 16 March 2000

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

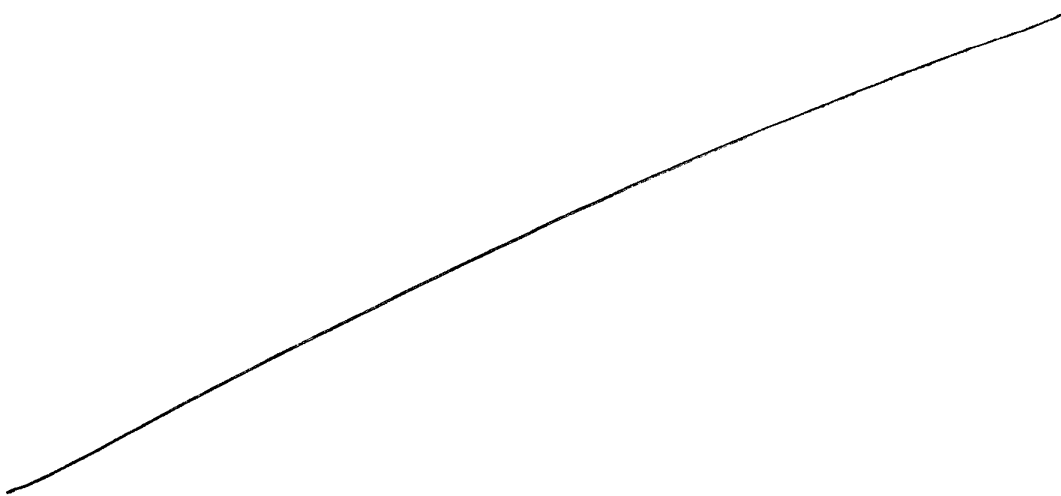
October 27, 2000

0798
Dr. David W. Kinniburgh
Dynacare Kasper Medical Laboratories
14940 123rd Avenue
Edmonton, Alberta, CAN T5V1B4

Dear Dr. Kinniburgh:

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.

While not noted by the inspectors, the following concerns were raised during RTI staff's



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.



Dr. Kinniburgh
Page 2 of 2
10/27/00

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/M5

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0798
Document No. Final

Laboratory: Dynacare Kasper Medical Laboratories

Location: Edmonton, Alberta

Document Reviewed: Application Form
 Inspection Report #M5 Date: 21 September 2000
 Other _____

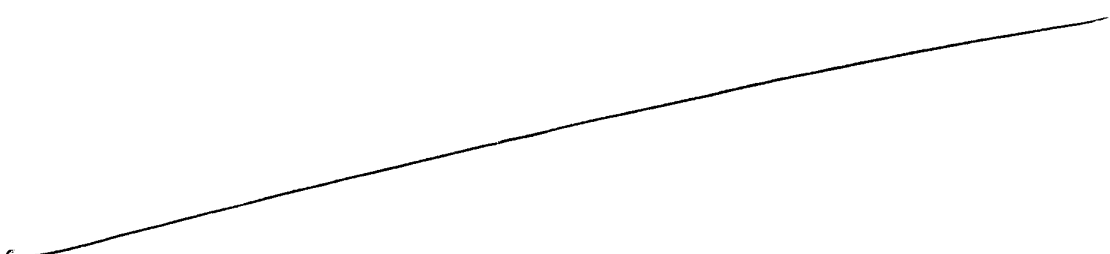
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

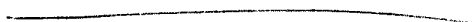
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

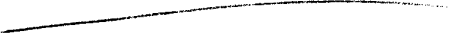
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



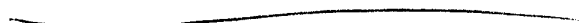
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance

Section N. Personnel
