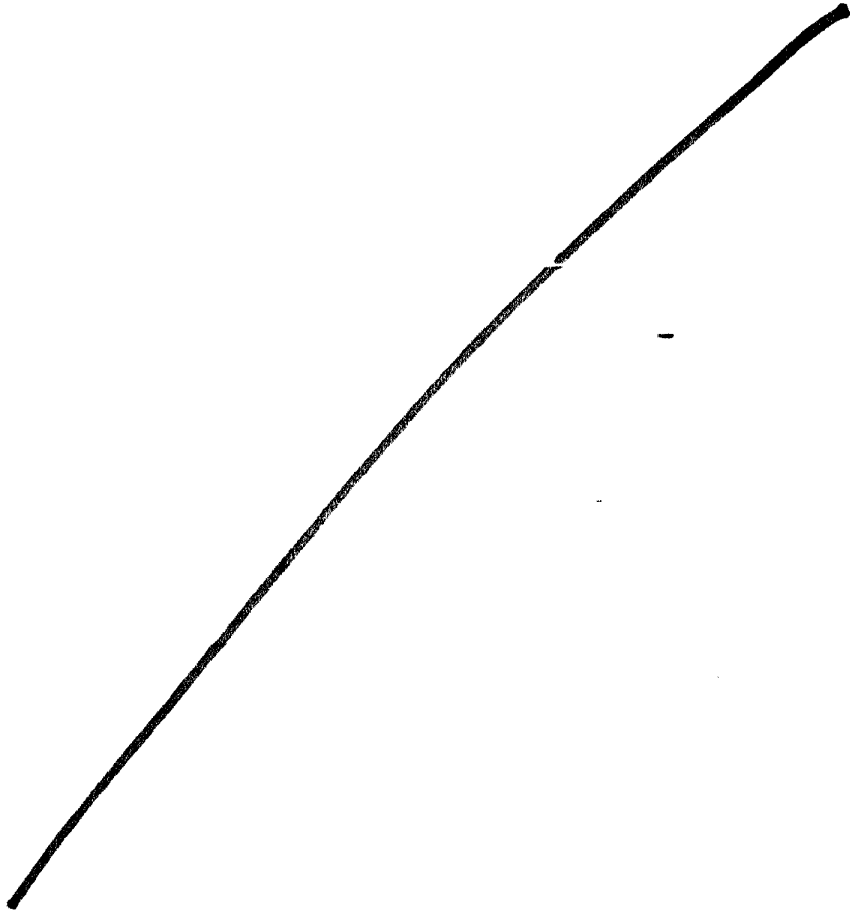


## Validity Testing Information Part I

Laboratory Name: Gamma-Dynacare Medical Laboratories  
Address: 245 Pall Mall Street, London, Ontario N6A 1P4  
Responsible Person: Dr Younn-Ing Yeh (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).

R. Ashcroft  
Signature, Responsible Person

Oct. 4/2000.  
Date

Ron Ashcroft  
Printed Name, Responsible Person

→ In Dr. Yeh's absence

*Gamma-Dynacare*  
Medical Laboratories

Lab No. 0893

2000 October 16

National Laboratory Certification Program  
Research Triangle Institute  
P.O. Box 12194  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194  
USA

Attention: Dr. John M. Mitchell

**BY PUROLATOR**

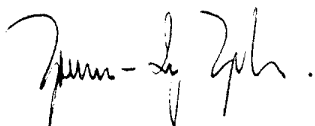
Dear Dr. Mitchell:

Enclosed please find the Validity Testing Information Part II report.

---

Sincerely,

*Gamma-Dynacare*  
Medical Laboratories



Yunn-Ing Yeh, Ph.D.  
SAT Director

Lab No\* 0998

## 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).

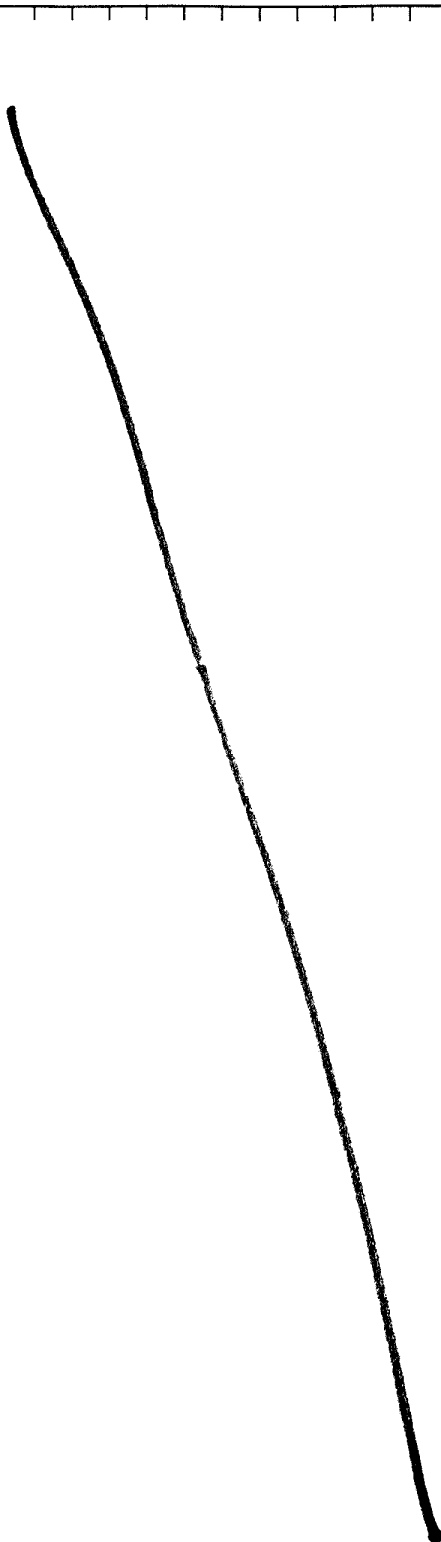
YOUNN - I W G YEH, Ph.D.  
Signature, Responsible Person

October 16, 2000  
Date

YOUNN - I W G YEH  
Printed Name, Responsible Person

# AUDIT OF DOT REGULATED SPECIMENS Validity Testing Information Part II

Lab No. 0898

Specimen ID Number	Laboratory Accession Number	Date of Receipt	Date Reported	Reported Result	Quantitative Test Result
					

*Specimen by John. F. H.D.*  
October 16, 2000

*Gamma-Dynacare*  
Medical Laboratories

2000 October 19

National Laboratory Certification Program  
Research Triangle Institute  
P.O. Box 12194  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194  
USA

Attention: Dr. John M. Mitchell

**BY PUROLATOR**

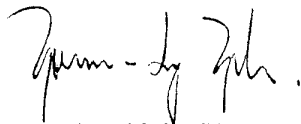
Dear Dr. Mitchell:

Enclosed please find the final Validity Testing Information Part II report.

---

Sincerely,

*Gamma-Dynacare*  
Medical Laboratories



Yunn-Ing Yeh, Ph.D.  
SAT Director

# AUDIT OF DOT REGULATED SPECIMENS Validity Testing Information Part II

Lab No. 0898

Specimen ID Number	Laboratory Accession Number	Date of Receipt	Date Reported	Reported Result	Quantitative Test Result
[Redacted]					

JY:jb  
GD-L  
E-O1/00  
19-Oct-00  
Page 1 of 1

*James G. H. Ph.D.*  
October 19, 2000



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 22, 2000

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

The enclosed critique was developed from the inspection report associated with the December 13, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in 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:

E2. The Standard Operating Procedures (SOP)



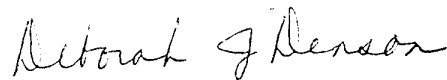


Dr. Yeh  
December 22, 2000  
Page 2 of 2

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 listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. 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. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.***

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/svt898

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0898  
Document No. Final

Laboratory: Gamma-Dynacare Medical Laboratories

Location: London, ON

Document Reviewed:  Specimen Validity Testing Inspection Report

Date: 13 December 2000

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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



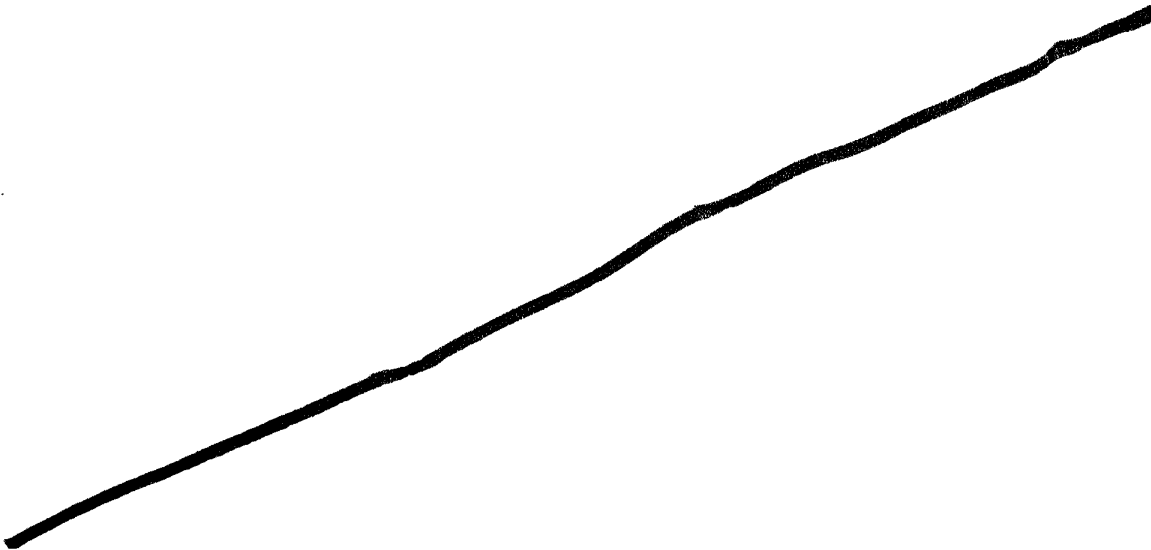
Section F. Chain-of-Custody, Accessioning, and Security




Section G. Quality Control and Quality Assurance




Section I. Specimen Validity Tests



Section K. Records Audit



Section L. Certification and Reporting



2001 January 19

received  
1/22/01 DN

Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Post Office Box 12194  
Research Triangle Park, North Carolina 27709-2194  
U.S.A.

Attention: Deborah J. Denson, NCLP Technical Analyst

**BY COURIER**

Dear Ms. Denson:

*re* **RESPONSE TO INSPECTION REPORT OF DECEMBER 13, 2000**

We acknowledge receipt of your letter of December 22, 2000 and submit for your review a summary of actions taken in response to the issues noted on the inspection report of December 13, 2000.

We have summarized the actions below. Documentation to support these statements (where applicable) is attached and is numbered to correspond with Laboratory Inspection Report Questions.

**DOCUMENTS  
INCLUDED**

**SECTION E: Standard Operating Procedures—Procedure Manual**

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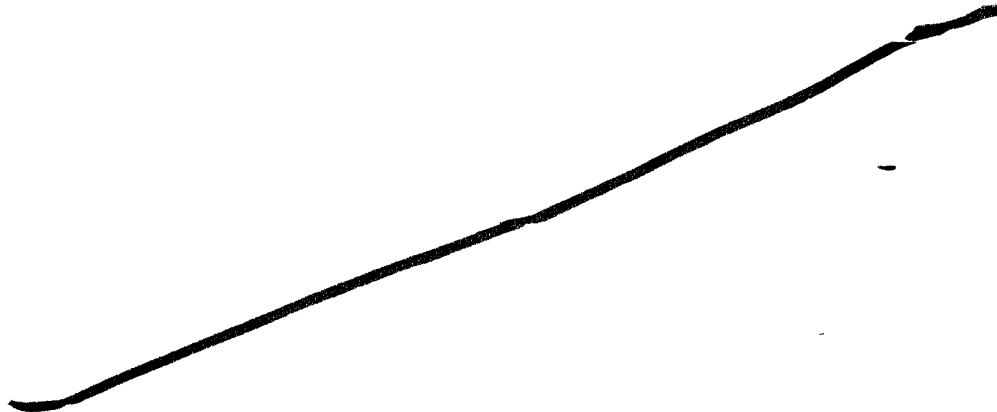
**SECTION G: Quality Control and Quality Assurance**

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Research Triangle Institute  
2001 January 19  
Page 2

DOCUMENTS  
INCLUDED

**SECTION I: Specimen Validity Tests**



If you have any questions please do not hesitate to call.

Sincerely,

***Gamma-Dynacare***  
*Medical Laboratories*

Younn-Ing (John) Yeh, Ph.D.  
Director of Toxicology



# RESEARCH TRIANGLE INSTITUTE

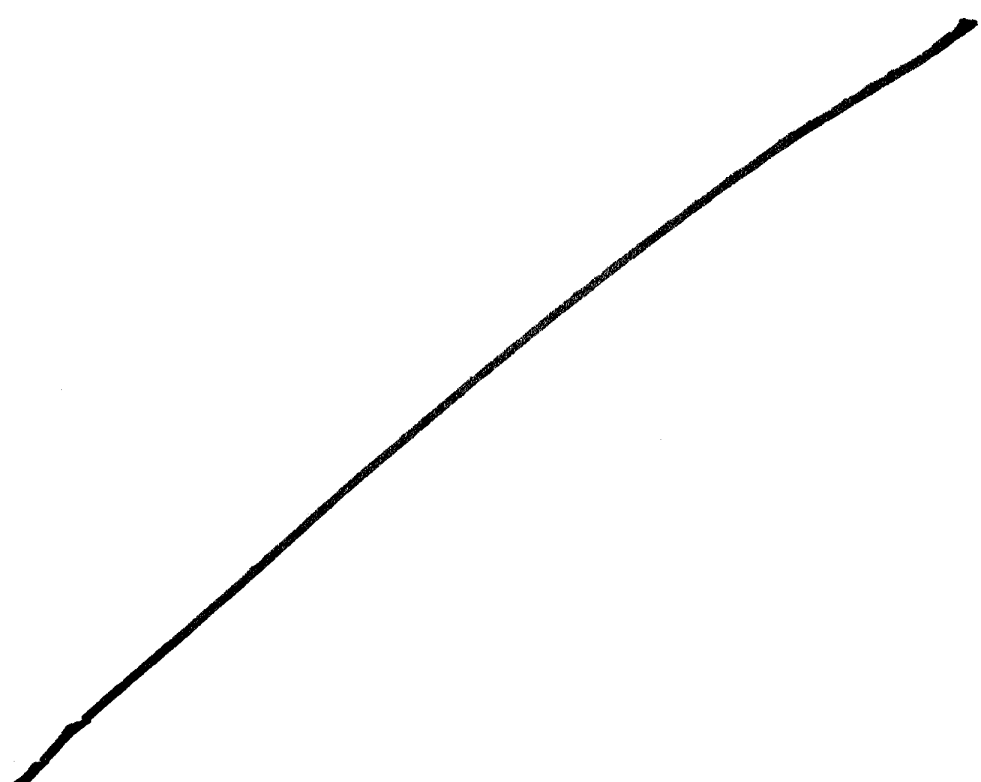
National Laboratory Certification Program

January 30, 2001

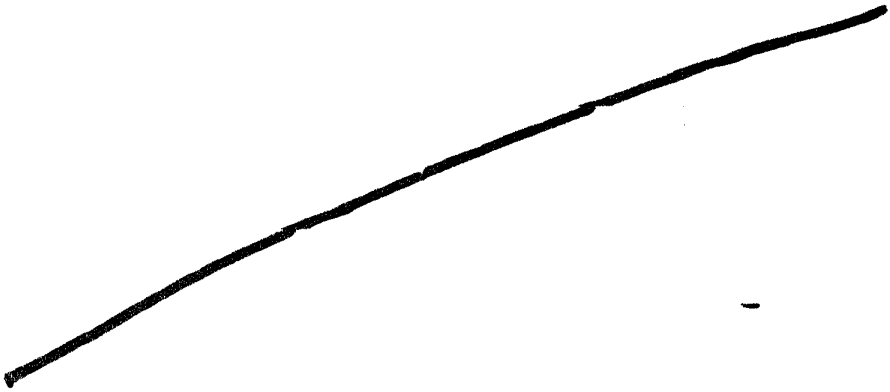
0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

We have reviewed the material provided in your correspondence of January 19, 2001 submitted in response to issues raised during the December 13, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 22, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions are being taken to address the issues raised. The following is a review of the material submitted:



Dr. Yeh  
January 30, 2001  
Page 2 of 2



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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/SVT898



received  
2/09/01 DD

*Gamma-Dynacare*

2001 February 8

*Medical Laboratories*

Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Post Office Box 12194  
Research Triangle Park, North Carolina 27709-2194  
U.S.A.

Attention: Deborah J. Denson, NCLP Technical Analyst

**BY COURIER**

Dear Ms. Denson:

re RESPONSE TO YOUR LETTER OF JANUARY 30, 2001

[Redacted]

DOCUMENTS  
INCLUDED

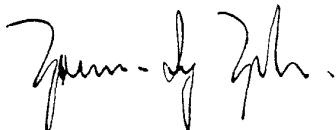
**SECTION I: Specimen Validity Tests**

[Redacted]

If you have any questions please do not hesitate to call.

Sincerely,

*Gamma-Dynacare*  
*Medical Laboratories*



Yunn-Ing (John) Yeh, Ph.D.  
Director of Toxicology

QRTI\Response01  
8-Feb-01  
Encs.

245 Pall Mall Street, London, Ontario N6A 1P4  
Telephone: (519) 679-1630 Fax: (519) 679-0298



# RESEARCH TRIANGLE INSTITUTE

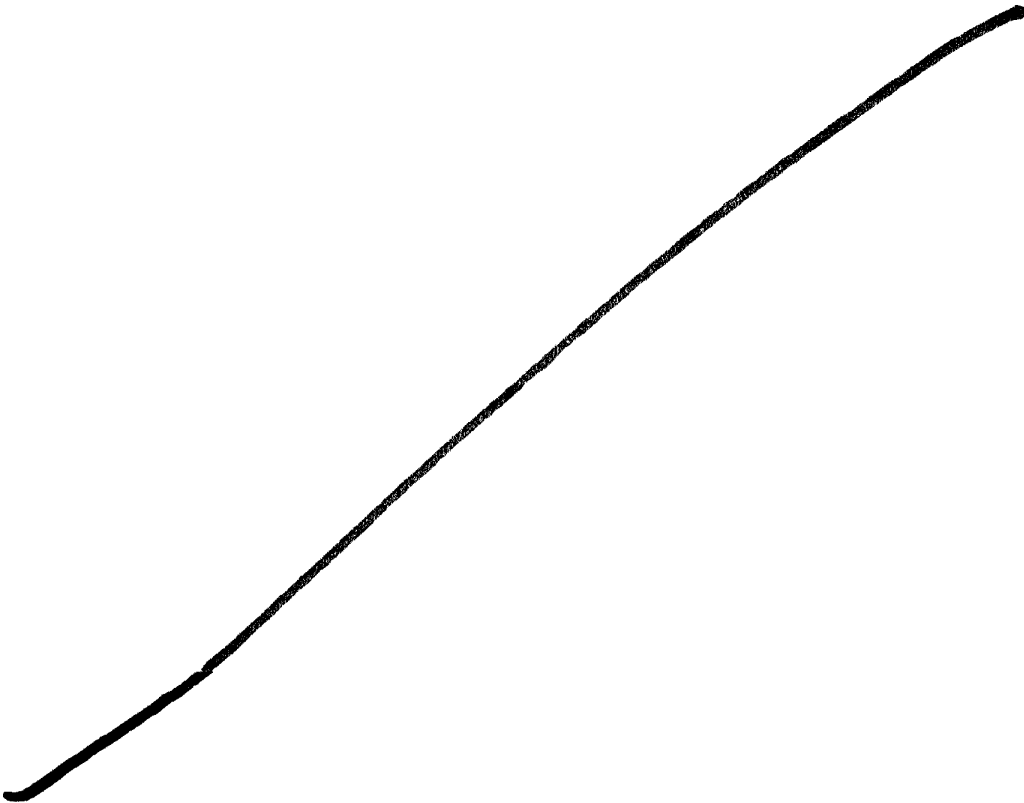
National Laboratory Certification Program

February 12, 2001

0898  
Dr. Younn-Ing Yeh  
Gamma-Dynacare Medical Laboratories  
245 Pall Mall Street  
London, Ontario, CAN N6A 1P4

Dear Dr. Yeh:

We have reviewed the material provided in your correspondence of February 08, 2001 submitted in response to issues raised during the December 13, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 22, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:



Dr. Yeh  
February 12, 2001  
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 R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/SVT898