Validity Testing Information Part I

Laboratory Name: General Medical Laboratories
Address: 36 South Brooks ST
Madison WI 53715
Responsible Person: Terry Dickinson (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).

Terry Dickinson
Signature, Responsible Person

10/5/00
Date

Terry Dickinson
Printed Name, Responsible Person

MERIETER

October 18, 2000

Kenneth H. Davis, Jr.
National Laboratory Certification Program
Research Triangle Park
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Re: Adulterated/substituted Samples

Dear Ken:

After reviewing the available data for the last two years,

General Medical Laboratories
36 S. Brooks Street
Madison, WI 53715-1304
608 267-6267

Sales and Marketing
309 W. Washington Avenue
Madison, WI 53703-2795
[illegible]4-3311

If you have any questions you can reach us at the laboratory at (608) 267-6225.

Sincerely,

Terry Dickinson
Temporary Alternate Responsible Person

Javier Velasco
Responsible Person

MERITER

November 1, 2000

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

Re: Adulterated/substituted Samples

General Medical Laboratories
36 S. Brooks Street
Madison, WI 53715-1304
608 267-6267

Sales and Marketing
202 S. Park Street
Madison, WI 53715-1599
608 267-5500

Dear Frank:

After reviewing the available data for the last two years,

If you have any questions you can reach us at the laboratory at (608) 267-6225.

Sincerely,

Terry Dickinson
Temporary Alternate Responsible Person

Javier Velasco
Responsible Person

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 27, 2000

0119
Mr. Terry Dickinson
General Medical Laboratories
36 South Brooks Street
Madison, WI 53715

Dear Mr. Dickinson:

The enclosed critique was developed from the inspection report associated with the November 01, 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:

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.***

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

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

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt119

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0119
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 1 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

MERETER

received
12/27/00 DD

December 21, 2000

Michael R. Baylor, Ph.D.
National Laboratory Certification Program
Research Triangle Park
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Re: Response to the November 01, 2000 specimen validity inspection critique.

General Medical Laboratories
36 S. Brooks Street
Madison, WI 53715-1304
608 267-6267

Sales and Marketing
202 S. Park Street
Madison, WI 53715-1599
608 267-5500

Dear Michael:

As stated in the letter dated November 27, 2000, General Medical Laboratories must submit, within 30 calendars days of the receipt of the letter a written response to demonstrate the corrective actions taken to remedy the issues brought up by the inspection team on the specimen validity inspection.

If you have any questions you can reach me at the laboratory at (608) 267-6274.

Sincerely,

Javier Velasco
Responsible Person/Toxicology Director

Enclosures.

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 8, 2001

0119
Mr. Javier Velasco
General Medical Laboratories
36 South Brooks Street
Madison, WI 53715

Dear Mr. Velasco:

We have reviewed the material provided in your correspondence of December 21, 2000 submitted in response to issues raised during the November 1, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of November 27, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:

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

Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its 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.

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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT119