Validity Testing Information Part I

Laboratory Name: Integrated Regional Lab
Address: 5369 NW 33rd Ave.
Fort Lauderdale, FL 33309
Responsible Person: Jack Lin, Ph.D. (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. 5, 2000
Date

Jack Lin, Ph.D.
Printed Name, Responsible Person

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. 13, 2000
Date

Jack Lin, Ph.D.
Printed Name, Responsible Person

Lab 0136

Validity Testing Information Part II

Laboratory: Integrated Regional Laboratories

Audit Period: Jan. 1999 to Oct. 6, 2000

Type of Specimen: DOT regulated specimens

Specimen COC #	Lab Accession #	Date of Receipt	Date of Report	Report Result	Quant Test Reading

October 5, 2000

To: **All Screen Tech**

From: **Jack Lin, Ph.D**

Re: **Adulteration Check Results Reporting**

Effective immediately, please report the **adulteration check results** to *Meditech* as following:

Specimen I.D.	Date Received	Date Reported	Result Reported	Quantitation

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 1, 2000

0136
Ms. Patricia Simpson
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Ms. Simpson:

The enclosed critique was developed from the inspection report associated with the October 18, 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 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. 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 R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt136

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0136
Document No. Final

Laboratory: Integrated Regional Laboratories

Location: Fort Lauderdale, FL

Document Reviewed: [XX] Specimen Validity Testing Special Inspection Report

Date: 18 October 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

INTEGRATED REGIONAL LABORATORIES IRL

5361 NW 33rd Ave
Ft. Lauderdale, FL 33309

954-777-0018
fax: 954-777-0211

Ms. Deborah Denson
NLCP Technical Analyst
Research Triangle Park
3040 Cornwallis Road
North Carolina, 27709-2194

Dear Ms. Denson, 11-17-00

This letter is in response to the last validity check inspection report.

If there are any questions please don't hesistate to call me at 1-800-522-0232 ext.410

Sincerely,

Patty Simpson, Alt.R.P

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 29, 2000

0136
Ms. Patricia Simpson
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Ms. Simpson:

We have reviewed the material provided in your correspondence of November 17, 2000 submitted in response to issues raised during the October 18, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of November 01, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. However, the following issues require additional clarification and corrective action. 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

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.***

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/SVT0136

INTEGRATED REGIONAL LABORATORIES IRL

5361 NW 33rd Ave
Ft. Lauderdale, FL 33309

954-777-0018
fax: 954-777-5047

Ms.Deborah Denson
3040 Cornwallis Road
Research Triangle Park
North Carolina, 27709-2194

12-8-00

Dear Ms. Denson,

This is in response to the letter sent on 11-29-00.i reviewed the response and have sent the following attachments:

If more information is needed please do not hesitate to cal me at 1-800-5220232 ext.410 or e-mail me at Patricia.Simpson@HCAHealthcare.com

Thankyou
Sincerely,

Patricia C. Simpson, Alt.R.P.

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 22, 2000

0136
Ms. Patricia Simpson
Integrated Regional Laboratories
5361 NW 33rd Avenue
Fort Lauderdale, FL 33309

Dear Ms. Simpson:

We have reviewed the material provided in your correspondence of December 8, 2000 submitted in response to issues raised during the October 18, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of November 29, 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 it'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.

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/SVT0136