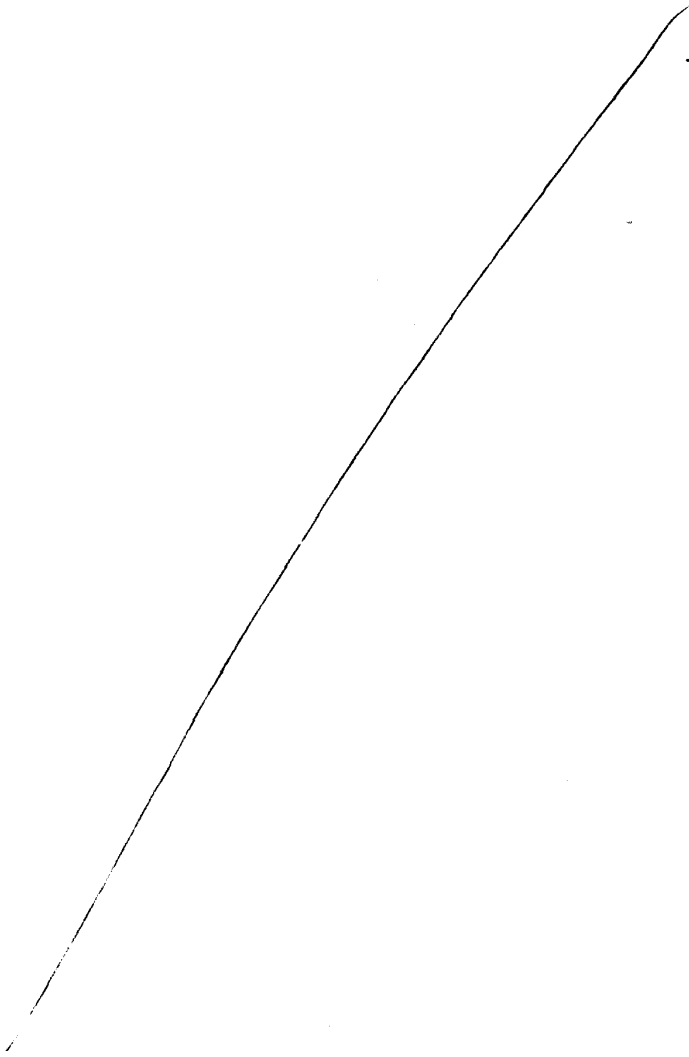


Validity Testing Information Part I

Laboratory Name: Navy Drug Screening Laboratory
Address: Great Lakes, IL 60088-6819
Responsible Person: Robert W. Romberg (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).

Robert W. Romberg

Signature, Responsible Person

OCT 03 2000

Date

Robert W. Romberg

Printed Name, Responsible Person

Robert W Romberg
NDSL GREAT LAKES
PO Box 88 6819
Great Lakes, IL 60088-6819
Phone: (847) 688-2045, ext. 24 or ext 16
Fax: (847) 688-3701



Fax

To: John M. Mitchell, Ph. D.

From: Bob Romberg, Ph.D.

Fax: (919) 541-7042

Date: October 3, 2000

Phone: (919) 541-7223

Pages: 3

Re: Validity Testing

CC:

Urgent For Review Please Comment **Please Reply** Please Recycle

Enclosed is the completed Validity Testing Information, Part I. Note that we test only HHS Federal Civil Service specimens. We do not test DOT specimens. We have included the information on HHS specimens because they are regulated by the same guidelines.

Robert W. Romberg

Responsible Person, Laboratory 0739

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
R. W. ROMBERG, Ph.D.

OCT 12 2000

Date

Printed Name, Responsible Person



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 22, 2000

0739
Dr. Robert W. Romberg
Navy Drug Screening Laboratory
Building 38-H - Great Lakes
P. O. Box 88-6819
Great Lakes, IL 60088

Dear Dr. Romberg:

The enclosed critique was developed from the inspection report associated with the December 14, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures appeared to be in compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999).



Dr. Romberg
December 22, 2000
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 Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt739

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0739
Document No. Final

Laboratory: Navy Drug Screening Laboratory

Location: Great Lakes, IL

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 14 December 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