

Validity Testing Information Part I

Laboratory Name: SAN DIEGO REFERENCE LABORATORY
Address: 6122 NANCY RIDGE DR, SAN DIEGO CA 92121
Responsible Person: KENNETH WAAL (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).

Kenneth Wohl
Signature, Responsible Person

10/2/00
Date

KENNETH WAHL
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).

Kenneth Wahl
Signature, Responsible Person

10/3/00
Date

KENNETH WAHL
Printed Name, Responsible Person

SAN DIEGO REFERENCE LABORATORY

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

San Diego Reference Laboratory
6122 Nancy Ridge Drive, San Diego, CA 92121
ph: (858) 550-7344 fax: (858) 677-7998

October 3, 2000

Mr. Kenneth Davis, Jr.
RESEARCH TRIANGLE INSTITUTE
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

Re: Validity Testing Information – Part II

Dear Mr. Davis;

If you have any questions please do not hesitate to call me at (858) 677-7970, extension 117.

Sincerely,



Kenneth C. Wahl
Responsible Person

Enclosure

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 17, 2000

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

The enclosed critique was developed from the inspection report associated with the October 31, 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:



Mr. Wahl
Page 2 of 2
11/17/00

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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt220

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0220
Document No. Final

Laboratory: San Diego Reference Laboratory

Location: San Diego, CA

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 31 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

San Diego Reference Laboratory

6122 Nancy Ridge Drive, San Diego, CA 92121
ph: (858) 550-7344 fax: (858) 677-7998

December 13, 2000

Ms. Susan Crumpton
RESEARCH TRIANGLE INSTITUTE
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

received
SJC 12/19/00

Re: Specimen Validity Testing Inspection Response

Dear Ms. Crumpton;

The following is a response to your letter of November 17, 2000 regarding the Validity Testing inspection. -
The following items correspond to your letter.

The response to the laboratory critique is as follows:

If there are any additional question please do not hesitate to contact me at (858) 677-7970 extension 117.
Thank you.

Sincerely,

Kenneth Wahl
Kenneth C. Wahl
Responsible Person

Attachments:

SOP 3091
SOP 3100
SOP 3316
SOP 3400

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 8, 2001

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

We have reviewed the material provided in your correspondence of December 13, 2000, submitted in response to issues raised during the October 31, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 17, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions were completed to address the issues raised. However, the following issues were raised during our review of submitted material:

Mr. Wahl
Page 2 of 2
01/08/01

The laboratory must further revise its procedures to address the above issues, to ensure compliance with this program guidance and submit documentation of corrective actions **within 10 calendar days of receipt of 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.*** 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 R. Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT220

San Diego Reference Laboratory
6122 Nancy Ridge Drive, San Diego, CA 92121
ph: (858) 550-7344 fax: (858) 677-7998

received
11/18/01 spc

January 16, 2001

Ms. Susan Crumpton
RESEARCH TRIANGLE INSTITUTE
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

Re: Adulteration Inspection Response Corrections

Dear Ms. Crumpton;

This letter is a response to your letter dated January 8 and received on January 9, 2001.

If you have any questions please do not hesitate to call me at (858) 677-7970, extension 117.

Sincerely,



Kenneth C. Wahl
Responsible Person

File: Crumpton010116

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 23, 2001

0220
Mr. Kenneth Wahl
San Diego Reference Laboratory
6122 Nancy Ridge Drive
San Diego, CA 92121

Dear Mr. Wahl:

We have reviewed the material provided in your correspondence of January 16, 2001, submitted in response to our correspondence of January 8, 2001, concerning remaining issues from the specimen validity testing inspection. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions 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) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Crumpton".

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT220