Validity Testing Information Part I

Laboratory Name: Associated Pathologists Laboratories
Address: 4230 S. Burnham Ave # 350, Las Vegas, NV. 89119

Responsible Person: Raymond C. Kelly, 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).

Raymond C. Kelly, Ph.D. — Signature, Responsible Person

10/3/00 — Date

Raymond C. Kelly, Ph.D., DABFT

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).

Raymond C. Kelly, Ph.D.
Signature, Responsible Person

10/16/00
Date

Raymond C. Kelly, Ph.D., DABFT
Printed Name, Responsible Person

ASSOCIATED PATHOLOGISTS LABORATORIES
4230 S. [redacted] SUITE 200
[redacted]

11-0148

Spec. ID#	Accn#	Rcd.	Report	Reported Result	Quant	Quant

ASSOCIATED PATHOLOGISTS LABORATORIES
4230 S. BURNHAM AVE., SUITE 250
LAS VEGAS, NEVADA 89119

#0148

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 17, 2000

0148

Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

The enclosed critique was developed from the inspection report associated with the October 25-27, 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt148

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0148
Document No. Final

Laboratory: Associated Pathologists Laboratories, Inc.

Location: Las Vegas, NV

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 25 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

Section O. Overall

APL
ASSOCIATED PATHOLOGISTS LABORATORIES

4230 Burnham Ave.
Las Vegas, Nevada 89119-5480
(702) 733-3790

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology
Nevada State Lab License No. 4
CAP. No. 89109-004-011

December 19, 2000

Susan Crumpton
NLCP Technical Analyst
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

I am writing in response to your communication of November 17, 2000 concerning our special specimen validity inspection of October 25-27, 2000. Here are our responses:

Please contact Dr. Jim Bourland if you require further information.

Sincerely,

ASSOCIATED PATHOLOGISTS LABORATORIES

Raymond C. Kelly, Ph.D.

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology and Responsible Person, NLCP Testing

RCK:me

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

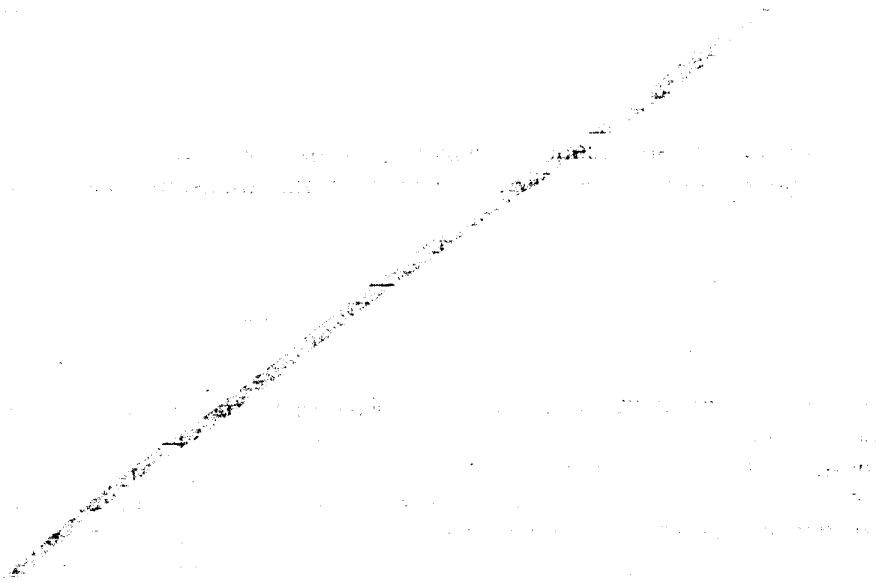
January 8, 2001

0148
Dr. James Bourland
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Bourland:

We have reviewed the material provided in your laboratory's correspondence of December 19, 2000, submitted in response to issues raised during the October 25-27, 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 have been completed to address most issues raised. However, the following issues remain or were raised during our review of submitted material:

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

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0148

APL
ASSOCIATED PATHOLOGISTS LABORATORIES

4230 Burnham Ave.
Las Vegas, Nevada 89119-5480
(702) 733-3790

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology
Nevada State Lab License No. 4
CAP. No. 89109-004-011

received
1/22/01 SDC

January 18, 2001

Susan Crumpton
NLCP Technical Analyst
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

I received your letter dated January 8, 2001 and am responding to your requests concerning the specimen validity inspection and validation materials we previously submitted. What follows is a point by point response to the issues raised. For further clarification I have included, in bold, the headings of the relevant sections of the November 2000 NLCP Guidance Document for Laboratories and Inspectors:

APL
ASSOCIATED PATHOLOGISTS LABORATORIES

4230 Burnham Ave.
Las Vegas, Nevada 89119-5480
(702) 733-3790

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology
Nevada State Lab License No. 4
CAP. No. 89109-004-011

APL
ASSOCIATED PATHOLOGISTS LABORATORIES

4230 Burnham Ave.
Las Vegas, Nevada 89119-5480
(702) 733-3790

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology
Nevada State Lab License No. 4
CAP. No. 89109-004-011

If you require further clarification or information, please contact me at (702)-733-7866 ext. 769.

Sincerely,

James A. Bourland, Ph.D.
Technical Director of Toxicology
Temporary Responsible Person for NLCP Testing

JAB:me

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 24, 2001

0148
Dr. James Bourland
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Bourland:

We have reviewed the material provided in your correspondence of January 18, 2001, submitted in response to our correspondence of January 8, 2001, concerning remaining issues raised during the 25 October 2000 specimen validity testing inspection of your laboratory. 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 laboratory's second specimen validity testing inspection scheduled for January 30, 2001.** 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,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0148

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

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 6, 2001

0148
Dr. James Bourland
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Bourland:

We have reviewed the inspector's report from the January 30, 2001, specimen validity testing inspection of your laboratory. The information submitted by the inspector appears to demonstrate that appropriate corrective actions have been completed to address the issues raised in the laboratory's October 25, 2000, specimen validity testing inspection. The laboratory must take steps 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

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance.

The laboratory must take corrective actions to address the issues outlined above. 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 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) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT2_148