

## Validity Testing Information Part I

Laboratory Name:

ALLIANCE LABORATORY SERVICES

Address:

3200 BURNET AVE CINCINNATI, OH 45229

Responsible Person:

MARK WVEST (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).

Mark Wuest  
Signature, Responsible Person

10-4-00  
Date

MARK WUEST  
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).

Mark Wuest  
Signature, Responsible Person

10-16-00  
Date

Mark Wuest  
Printed Name, Responsible Person





RESEARCH TRIANGLE INSTITUTE

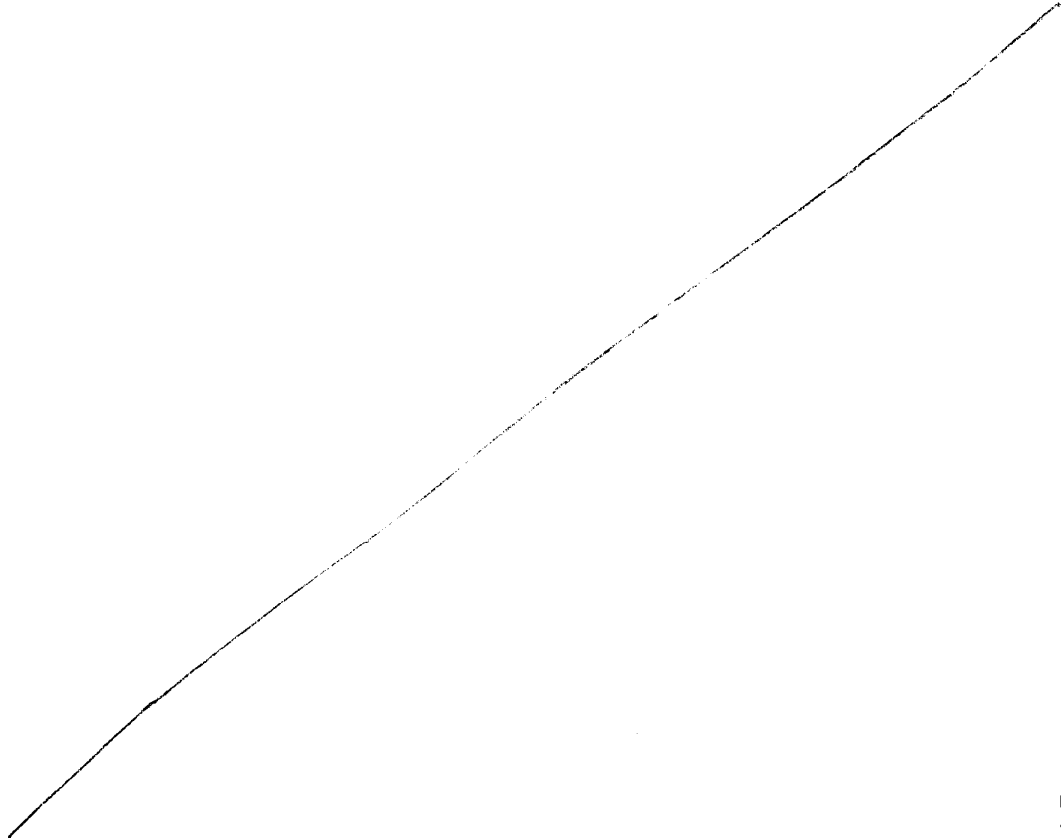
National Laboratory Certification Program

January 24, 2001

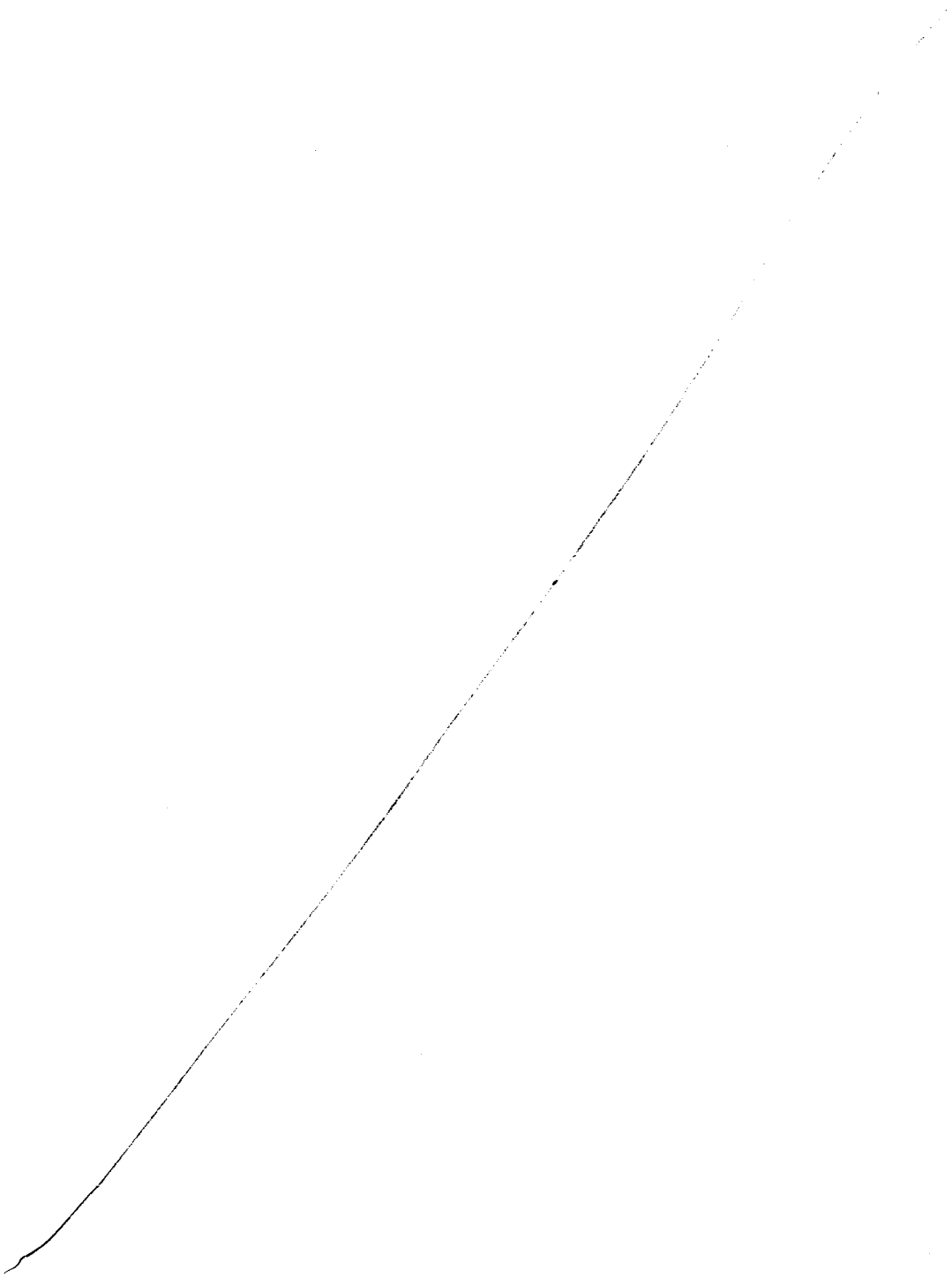
0044  
Mr. Mark Wuest  
Alliance Laboratory Services  
3200 Burnet Avenue  
Cincinnati, OH 45229

Dear Mr. Wuest:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection appeared to meet Minimum Technical Criteria. However, the laboratory must take steps to correct the following issues raised:



Mr. Wuest  
Page 2 of 3  
01/24/01



Mr. Wuest  
Page 3 of 3  
01/24/01

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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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/M16

---

## NATIONAL LABORATORY CERTIFICATION PROGRAM

---

### Document Review and Critique

---

Laboratory I.D. Number: 0044  
Document No. Final

Laboratory: Alliance Laboratory Services

Location: Cincinnati, OH

Document Reviewed:      Application Form  
                               Inspection Report #M16     Date: 9 November 2000  
                               Other \_\_\_\_\_

Status:            Appeared to meet most of the minimum technical criteria  
                       Appeared to meet a number of the minimum technical criteria  
                       Failed to meet a number of the minimum technical criteria  
                       Failed to meet a significant number of the minimum technical criteria

---

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.



The following deficiencies were identified, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

3. NO, the following procedures and/or information were not consistent between different sections of the SOP:

4. NO, the following procedures described in the SOP were not consistent with actual laboratory practice:

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section H. Initial Tests

---

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section K. Records Audit

---

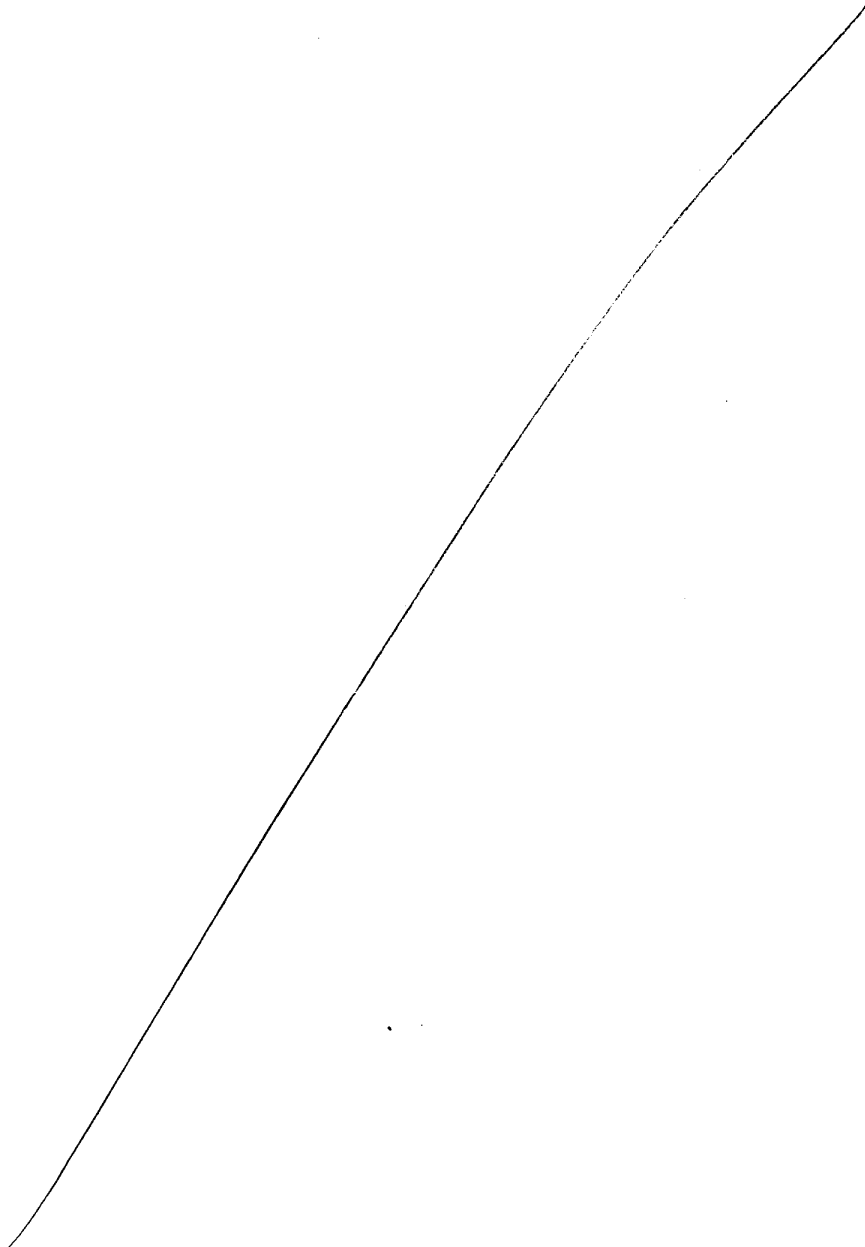
Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

## Validity Testing Information Part I

Laboratory Name: Quest Diagnostics Incorporated  
Address: One Malcolm Avenue, Teterboro, New Jersey 07608  
Responsible Person: Edward A'Zary, 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).

Hashim Othman, Ph.D. (AHRP) v. [Signature]  
for Edward A'Zary, Ph.D.  
Signature, Responsible Person

10/3/2000  
Date

Edward A'Zary, Ph.D.  
Printed Name, Responsible Person