Validity Testing Information Part I

Laboratory Name: Universal Toxicology Laboratories, LLC
Address: 9930 W. Hwy 80 Midland, TX 79706

Responsible Person: Ronald C. Backer (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).

Ronald C. Backer, Ph.D
Signature, Responsible Person

10-5-00
Date

Ronald C. Backer, Ph.D.
Printed Name, Responsible Person

HP OfficeJet
Personal Printer/Fax/Copier

Fax Log Report

Oct-05-00 12:33 PM

Last Fax

Identification	Result	Pages	Type	Date	Time	Duration	Diagnostic

1.3.0 2.8

Universal Toxicology Laboratories
0210

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).

Ronald C Backer, Ph.D. — Signature, Responsible Person

10-17-00 — Date

Ronald C. Backer, Ph.D. — Printed Name, Responsible Person

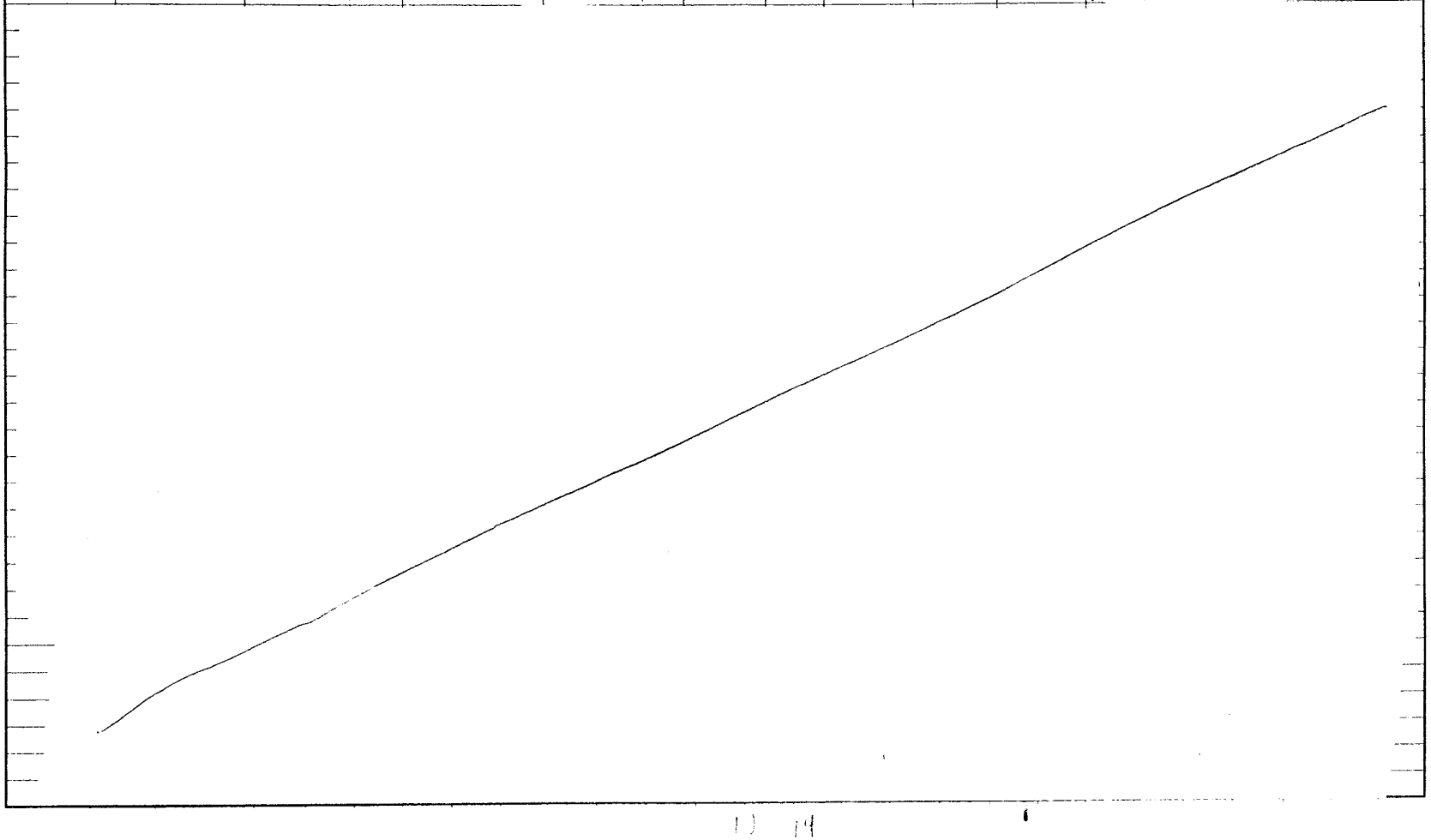
the DATA Available was from Sept 1, 1998 thru Oct 5, 2000

RCB
10-17-00

UTL VALIDITY TESTING

(9/ 98 to 10/5/00)

	ID #	LAB ACC NO:	DATE REC'D	DATE REP'D	ADULT	SUB	UNSUIT	CREAT	S.G.	pH	ADULT ID	CONC



Adul = Adulterated
SUB = Substituted
UNSUIT = Unsuitable
POS = Qualitative result

Ronald C. Backer

UTL VALIDITY TESTING

(9/ 98 to 10/5/00)

ID #	LAB ACC NO:	DATE REC'D	DATE REP'D	ADULT	SUB	UNSUIT	CREAT	S.G.	pH	ADULT ID	CONC

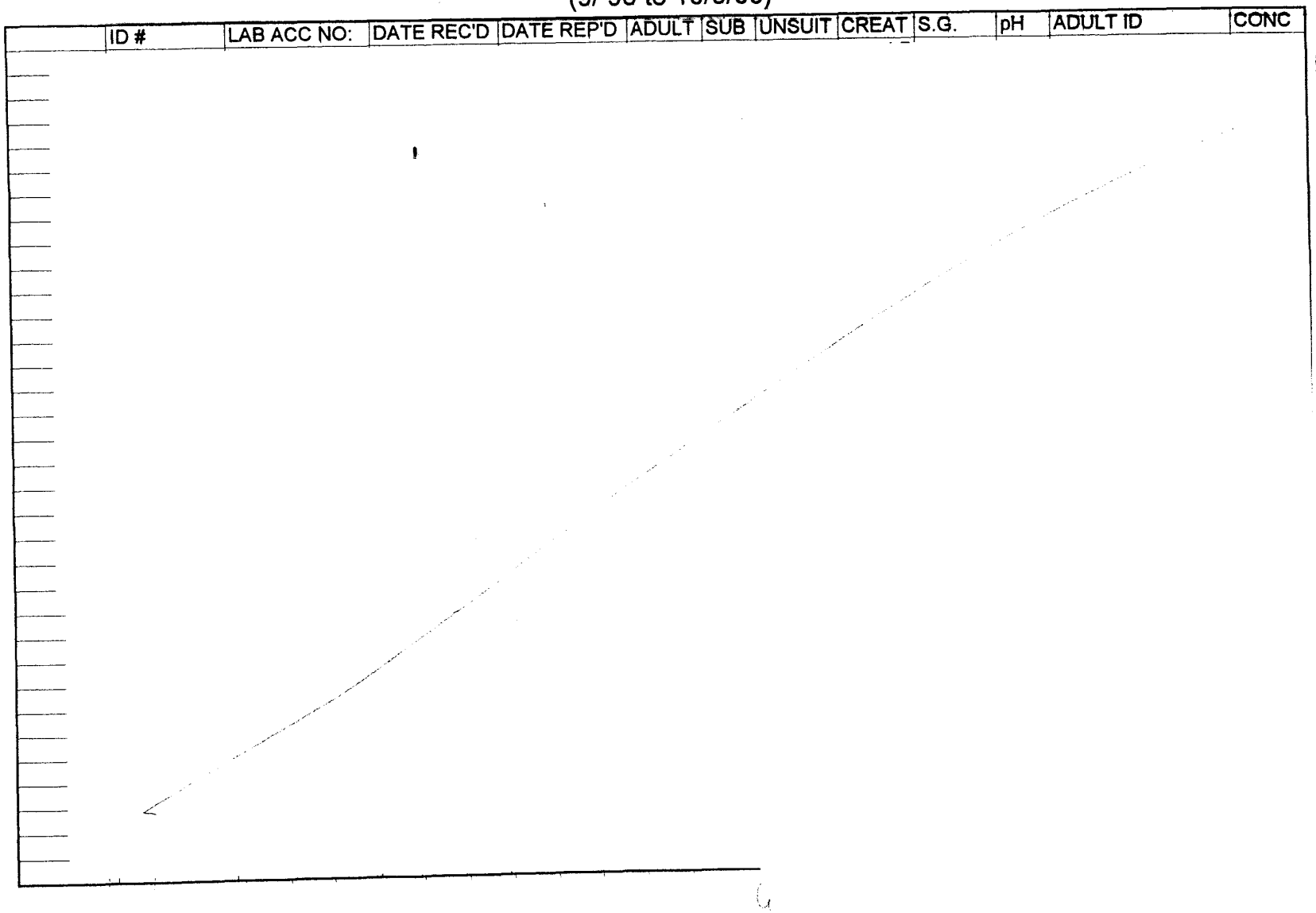
Adul = Adulterated
SUB = Substituted
UNSUIT = Unsuitable
POS = Qualitative result

Ronald C. Backer
11-17-00

UTL VALIDITY TESTING

(9/ 98 to 10/5/00)

	ID #	LAB ACC NO:	DATE REC'D	DATE REP'D	ADULT	SUB	UNSUIT	CREAT	S.G.	pH	ADULT ID	CONC



Adul = Adulterated
SUB = Substituted
UNSUIT = Unsuitable
POS = Qualitative result

Nancy C. Barker
10-17-00

UTL VALIDITY TESTING

(9/ 98 to 10/5/00)

	ID #	LAB ACC NO:	DATE REC'D	DATE REP'D	ADULT	SUB	UNSUIT	CREAT	S.G.	pH	ADULT ID	CONC

Adul = Adulterated
SUB = Substituted
UNSUIT = Unsuitable
POS = Qualitative result

Ronald C Backer

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 29, 2001

0210
Dr. Ron Backer
Universal Toxicology Laboratories, LLC
9930 West Highway 80
Midland, TX 79706

Dear Dr. Backer:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory appeared to meet most of the minimum technical criteria. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

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. 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M6

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0210
Document No. Final

Laboratory: Universal Toxicology Laboratories, LLC

Location: Midland, TX

Document Reviewed:
[ ] Application Form
[XX] Inspection Report # M6 Date: 30 November 2000
[ ] Other _____

Status:
[XX] 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

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