

Iowa Electric Light and Power Company

September 1, 1992  
DAEC-92-0303

U.S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington, DC 20555

Subject: Duane Arnold Energy Center  
Docket No. 50-331  
Op. License DPR-49  
10 CFR Part 26, Appendix A  
Unsatisfactory Performance Test Result  
File: A-202

Gentlemen:

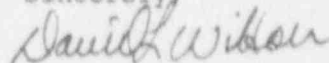
In accordance with Section 2.8(e)(4) of Appendix A to 10 CFR Part 26 please find enclosed the results of the investigation of an unsatisfactory performance test result obtained by MedTox Laboratories on August 6, 1992.

Appendix I, MedTox to St. Luke's letter dated August 13, 1992, transmitted the laboratory's initial notification, investigation and corrective actions.

Appendix II, MedTox to St. Luke's letter dated August 21, 1992 provides additional detail regarding the conduct of the test and the corrective actions to prevent reoccurrence. Please note that no document 3 exists in Appendix II, other documents as listed are attached.

If you have any questions regarding this submittal, please contact D. Engelhardt at 319/851-7280.

Sincerely,



David L. Wilson  
Plant Superintendent - Nuclear

DLW/DE/hj

Enclosures: As Stated

cc: L. Liu  
L. Root  
R. McGaughy  
J. Franz  
K. Young  
A. Bert Davis (NRC Region III)  
C. Shiraki (NRC-NRR)  
NRC Resident Inspector

9209210210 920901  
PDR ADDCK 05000331  
PDR

150106

A073

August 13, 1992

Ms. Kathy Epley  
St. Luke's Hospital  
1026 A. Avenue N E.  
Cedar Rapids, IA 52402

Dear Ms. Epley:

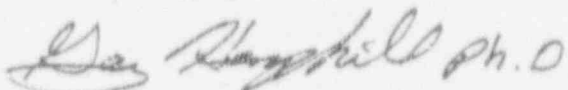
This letter is in response to your inquiry concerning a specimen submitted to MEDTOX under the identification of 461-88-0191. This specimen was received on 8/1/92 and assigned the MEDTOX number of G069499. The specimen tested positive for amphetamines by both Emit immunoassay and FPIA immunoassay and was then analyzed by gas chromatography/mass spectrometry (GC/MS) for confirmation. The confirmation results showed an amphetamine value of 16 ng/ml and a methamphetamine value of 1688 ng/ml. In accordance with NIDA guidelines the specimen was called negative because the amphetamine did not exceed 200 ng/ml. The results were released on 8/3/92. After your phone call of 8/4/92 indicating that the specimen should be positive for amphetamine and methamphetamine, all of the data was gathered for review. At this time a calculation error was discovered which corrected the amphetamine value to 1572 ng/ml. The report was amended on 8/5/92.

The protocol for reporting results requires that a second analyst check all of the work including the calculations generated by the original analyst. The results are then reviewed by the certifying scientist before release. All of these steps were documented as being followed for this specimen. Obviously, there was a breakdown in this procedure.

The corrective action initiated for this problem consisted of discussing the situation with those individuals involved and reemphasizing the need for detailed review. This was also linked to a continuing education seminar for all of the technical staff dealing with the review and checking of results. This incident has also been submitted to the Quality Control Committee.

We thank you for the confidence you have shown in MEDTOX to perform your testing. Be assured that we are very concerned about this incident and have taken steps to safeguard against its recurrence. If you need additional information or data, I can be reached at 1-800-832-3244.

Sincerely yours,

A handwritten signature in cursive script that reads "Gary Hemphill Ph.D." The signature is written in dark ink and is positioned above the typed name.

Gary Hemphill, Ph.D.  
Director of Occupational Toxicology

GH:ch

August 21, 1992

Ms. Kathy Epley  
St. Luke's Hospital  
1026 A. Avenue N.E.  
Cedar Rapids, IA 52402

Dear Ms. Epley:

In response to your recent inquiry concerning specimen number G469499 I am enclosing additional documentation that includes the custody and control form, raw data from the Emit immunoassay, raw data from the fluorescence polarization immunoassay (FPIA), data from the gas chromatography-mass spectrometry assay, and an outline of the seminar presented by Dr. Kingsley Labrosse, Director of MEDTOX Laboratories.

As indicated in the first letter, the Emit immunoassay was positive for amphetamines as noted in document 1B (AMPH 61H). The FPIA immunoassay was also elevated as noted in document 2. The specimen was then tested by gas chromatography-mass spectrometry as seen in document 4A-G.

Document 4A represents the data summary for the batch of specimens that included G469499. This data represents the original data and the amended data as noted by the cross out and initials in data columns 7 and 9 for G469499. Documents 4B and 4C represent the blank that was injected before specimen G469499 to document that no carryover occurred from previous samples. Documents 4D-4G represent the documentation for specimen G469499. Document 4D and E represent the chromatograms from the run. The data calculated by the GC/MS computer system for the amphetamine is shown on 4E. The instrument is programmed to choose the proper peak from the retention time (RT), integrate the peak height, and calculate the ion ratios for the analyte, in this case amphetamine. Occasionally due to the complexity of the urine specimen with the many compounds residing in it, a second peak emerges close to the peak of interest, and the instrument chooses the wrong one. This was the case with specimen G469499. On 4E the retention times (RT) are very similar, but ion 118 has a retention of 0.21 minutes different. When this occurs, the ion ratios must be calculated manually from the data on 4F for those ratios involving ion 118. The correct integration number for ion 118 should have been 188970 from retention time 5.103 rather than 3465 from retention time 5.31. This calculation changes ion ratio 117/118 to 0.18, 140, 118

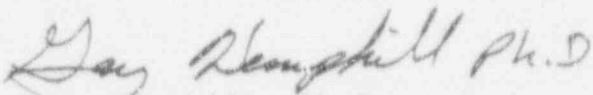
to 1.24, and 118/123 (the ion ratio used to calculate the quantitation of amphetamine) to 2.76 (188970/68305). The first two ion ratios were changed and transferred to the data sheet (4A), but the 118/123 was inadvertently not changed from 0.05 to 2.76. This was also missed in subsequent checks of the data. Since the 0.05 was used to calculate the amphetamine concentration instead of the 2.76, a value of 16 ng/ml was calculated rather than 1572 ng/ml. The data for the methamphetamine was correctly calculated by the instrument and transferred to the data sheet correctly.

The corrective action as indicated in my previous letter involved a discussion with the individuals running these tests, those checking the data, and the supervisory staff in the forensic laboratory. The importance of the correct handling of data and the accurate checking was emphasized. It was also decided that the computer data that is wrong will be crossed out and initialed in order to more graphically emphasize the manual correction needed. This will call additional attention to the problem so that the data handler and checker can insure that the calculation was correct and accurately transferred to the summary sheet.

I have enclosed a summary of our technical staff seminar presented by Dr. Labrosse that dealt directly with the proper method of calculating results and the obligation of the technologist checking the results to review and recalculate all results.

If you need additional documentation or interpretation, I can be reached at 1-800-832-3244.

Sincerely yours,



Gary Memphill, Ph.D.  
Director of Occupational Toxicology

GH:ch

enc.

**7 PART URINE CUSTODY AND CONTROL FORM**

P.N.MT.00101.11.91



402 West County Road D  
Saint Paul, Minnesota 55112  
(612) 636-7466 • (800) 832-3244

591019

CHAIN OF CUSTODY # **G469499**

Employer: **ST. LUKE'S HOSPITAL, IOWA LABORATORY**  
1026 A AVENUE NORTHEAST  
CEDAR RAPIDS, IA 52402

STEP 1 - To be completed by collector  
SUBJECT ID: **461-88-0191**  
Social Security No., Employee No. or other identifier No.  
DC DIV ID: \_\_\_\_\_

INDICATE TEST  
 **NIDA TEST #223:** Amphetamine, Cocaine, Marijuana, Opium, Phencyclidine and TMA  
 OTHER: \_\_\_\_\_

MRO: **ST. LUKES HOSPITAL, IOWA**  
MRO: **DR. BUCK**  
1026 A AVENUE NORTHEAST  
CEDAR RAPIDS, IA 52402

STEP 2 - To be completed by collector  
 Pre-Employment  
 Post-Accident  
 Random  
 Periodic Medical  
 Reasonable Suspicion-For Cause  
 Other (specify): \_\_\_\_\_

STEP 3 - To be completed by collector  
The temperature of the specimen was read within 4 minutes of collection.  Yes  No  
The temperature of the specimen is within the range of 90.5 - 99.8°F / 32.5 - 37.7°C.  Yes  No  
IF NOT - record the actual temperature here \_\_\_\_\_

Account # **2008**

STEP 4 - Before completing this step turn up COPY NO. 3 and have the subject complete the pink areas in STEP 7.  
To be completed by the person collecting the specimen

Collector's Name: **Rizzio, Amy L.** Date of Collection: **7/31/92** Collection Site Phone #: **(319) 3697311**  
Collection Site: **St. Lukes Hospital** Remarks Concerning Collection: \_\_\_\_\_  
I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on COPY NO. 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as in accordance with applicable Federal requirements.  
A split specimen was collected.  Yes  No  
If yes, was it collected in accordance with applicable Federal requirements?  Yes  No  
Signature of Collector: **Amy Rizzio**

STEP 5 - To be initiated by the person collecting the specimen and complete as necessary thereafter  
**DO NOT PUT THE SUBJECT'S NAME IN STEP 5.**

Date	Released By Printed Name Signature	Received By Printed Name Signature	Purpose of Change
7-31-92	<b>SUBJECT/DONOR</b>	<b>Amy Rizzio</b>	Provide Specimen for Testing
7-31-92	<b>Amy Rizzio</b>	<b>Amy Rizzio</b>	For Transport To MEDTOX
1 Aug 92	<b>COURIER</b>	<b>[Signature]</b>	For Accessioning at MEDTOX
	Released by Printed Name	Received by Printed Name	SEAL INTACT
	Released by Signature	Received by Signature	
	Released by Printed Name	Received by Printed Name	
	Released by Signature	Received by Signature	

STEP 6 - To be completed by MEDTOX

I certify that the specimen identified by this accession number is the same specimen that bears the subject's identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth below are for that specimen.  
Accession Number: **G469499**  
Remarks: \_\_\_\_\_  
 D. Gary Hemphill, Ph.D.  David A. Breutzmann, M.S.  
 Kingsley R. Labrosse, Ph.D.  Cynthia K. Veit, MT (ASCP)  
 Harry G. McCoy, Pharm.D.  Barbara S. Mayer, MT (ASCP)  
Signature: \_\_\_\_\_ Date: \_\_\_\_\_

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE SCREENING AND CONFIRMATION CUTOFF LEVELS ESTABLISHED BY THE HHS MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS.

**NEGATIVE**  **POSITIVE**, for the following:  
 Cannabinoids as Carboxy - THC  Opiates  Amphetamines  
 Cocaine Metabolite as Benzoyllecgonine  Codeine  Amphetamine  
 Phencyclidine  Morphine  Methamphetamine

STEP 8 - To be completed by Medical Review Officer  
I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. (Check One)  NEGATIVE  POSITIVE  
Signature of Medical Review Officer: \_\_\_\_\_ Date: \_\_\_\_\_

DATA MONITOR

02/01/92 15:10

URINE 00097-0076-2

G469493

01/92	AMPH	COC	OPIAT	PCP	T-100	CREAT
15:10	-3	-29	89-	-82	-45	52

PANIC

URINE 00098-0076-3

G469494

01/92	AMPH	BARB	BENZO	COC	METHA	METHO	OPIAT	PCP	PROPX
15:10	-12	-45	-26	-34	-63	-29	-45	-88	-38
	T-100	CREAT							
	-54	150							

URINE 00099-0076-4

G469495

01/92	UETCH	AMPH	BARB	BENZO	COC	METHA	METHO	OPIAT	PCP
15:11	-0.201	-3	-49	-23	-29	-68	-28	-41	-88
	PROPX	T-100	CREAT						
	-28	-46	29						

URINE 00100-0076-5

G469496

01/92	AMPH	BARB	BENZO	COC	METHA	METHO	OPIAT	PCP	PROPX
15:11	-8	-49	-24	-38	-61	-28	-43	-85	-38
	T-100	CREAT							
	-49	58							

URINE 00101-0081-1

G469497

01/92	AMPH	COC	OPIAT	PCP	T-100	CREAT
15:11	-9	-33	-44	-87	-58	136

URINE 00102-0081-2

G469498

01/92	AMPH	BARB	BENZO	COC	METHA	METHO	OPIAT	PCP	CREAT
15:12	-5	-49	-23	-29	-61	-27	-42	-82	52
	T-100								
	-33								

URINE 00103-0081-3

\* G469499

01/92	AMPH	COC	OPIAT	PCP	T-100	CREAT
15:12	614	-29	-41	-81	-46	53

PANIC



RESUN LIST

02/01/92 15:39

URINE \*\*\*

SAMPLE #	ID #	1	10	15	20	25	30
00011-00120-1	0469447	---	---	---	---	---	---
00034-0044-1	0469448	---	---	---	---	---	---
00035-0043-1	0469449	---	---	---	---	---	---
00044-0047-1	0469450	---	---	---	---	---	---
00045-0047-1	0469451	---	---	---	---	---	---
00047-0054-2	0469453	---	---	---	---	---	---
00055-0042-5	0469451	---	---	---	---	---	---
00056-0027-1	0469452	---	---	---	---	---	---
00080-0097-5	0469476	---	---	---	---	---	---
00097-0075-2	0469483	---	---	---	---	---	---
00103-0081-3	0469489	---	---	---	---	---	---
00108-0048-1	0469490	---	---	---	---	---	---
00114-0075-1	0469490	---	---	---	---	---	---
00123-0025-3	0469491	---	---	---	---	---	---

TEST COUNT

02/01/92 15:39

CHANNEL	TEST NAME	TEST	REMARKS	VALUE	COUNT
1	AMPH	0	1.0	1.0	0
2	COC	0	1.0	1.0	0
3	ORIPAT	0	1.0	1.0	0
4	PCP	0	1.0	1.0	0
5	THC	0	1.0	1.0	0
6	THCSD	0	1.0	1.0	0
7	PK	0	1.0	1.0	0
8	CREAT	0	1.0	1.0	0
9	BARR	0	1.0	1.0	0
10	BENZ	0	1.0	1.0	0
11	LETCR	0	1.0	1.0	0
12	TRIC	0	1.0	1.0	0
13	METED	0	1.0	1.0	0
14	METED	0	1.0	1.0	0
15	PROCK	0	1.0	1.0	0
16	NICOT	0	1.0	1.0	0
17	TEST	0	1.0	1.0	0

BATCH # 3742      TECH RY  
 LOAD # 65      CHECKED ☆  
 CERTIFIED Wes



PURP

### FORENSIC TDX WORKSHEET

FOR TDX WORKSHEET

ANALYST: DAB ASSAY: B (TDX)  
 VERIFIED BY: PF DATE: 060292  
 CERTIFIED BY: [Signature]

CONTROLS:	T	H <sub>2</sub>
	1194 - 1594	3410 - 4590
LOW		
MEDIUM		
1 HIC:1	3905	OK
2 TCT	1478	OK
3 NEGATIVE	Lo	
UNKNOWN:		
4 G 467557	69	
5 G 469067	73	✓
6 G 469072	3656	>T
7 G 469143	279	
8 G 469282	387	
9 G 469441	7	
10 G 469451	1	
11 G 469476	Lo	
* 12 G 469499	H <sub>2</sub>	>T
13 G 469504	767	
14 G 469538	H <sub>2</sub>	>T
15 G 469549	0	
16 G 469619	0.80	Lo
17 G 469705	349	

*[Faint, illegible text and markings on the right side of the page, possibly bleed-through from the reverse side.]*



Sample Name: BLANK

Misc Info:

Operator: DAB/MS044

Date: 2 Aug 92 11:01 pm

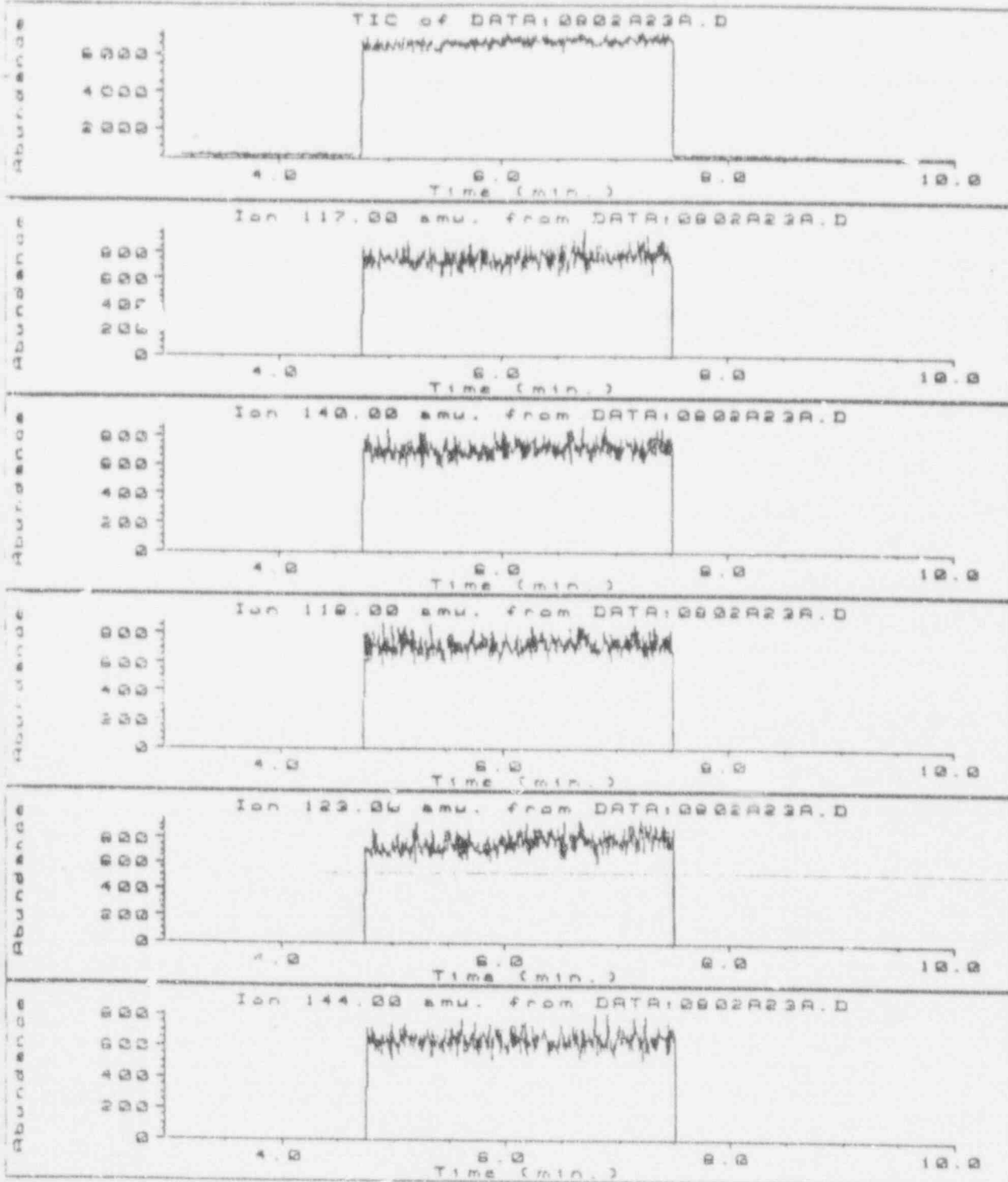
Instrument: MS\_5970

Inlet: GC

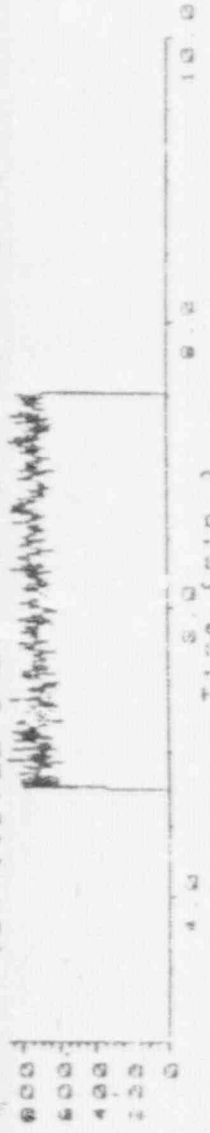
Sequence index: 1

ALS bottle num: 23

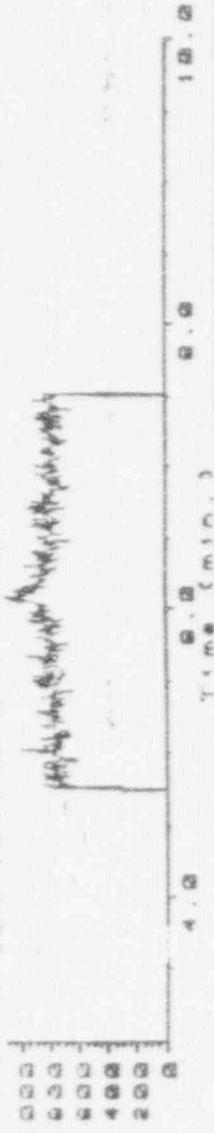
Replicate num: 1



Ion 118.00 amu. from DATA:0602A23A.D



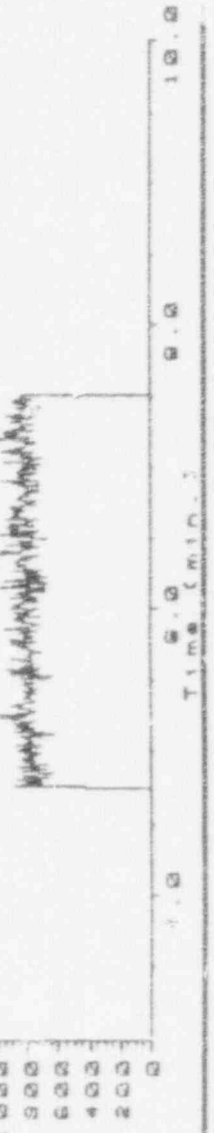
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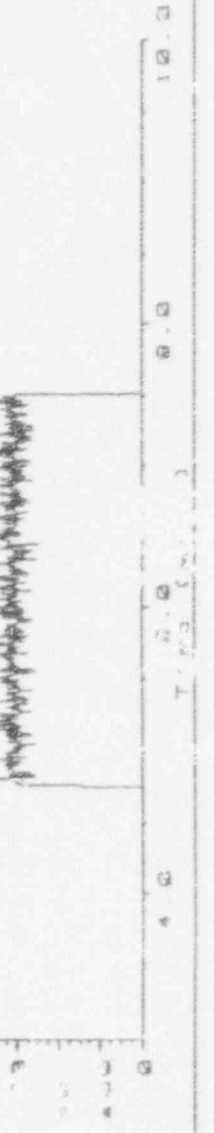
Ion 110.00 amu. from DATA:0602A23A.D



Ion 113.00 amu. from DATA:0602A23A.D



Ion 156.00 amu. from DATA:0602A23A.D



AMPHETAMINE CONFIRMATION ION RATIOS :

ION RATIO 117/118 = 1.00  
 ION RATIO 140/118 = 1.00  
 ION RATIO 123/144 = 1.00  
 ION RATIO 118/123 = 1.00

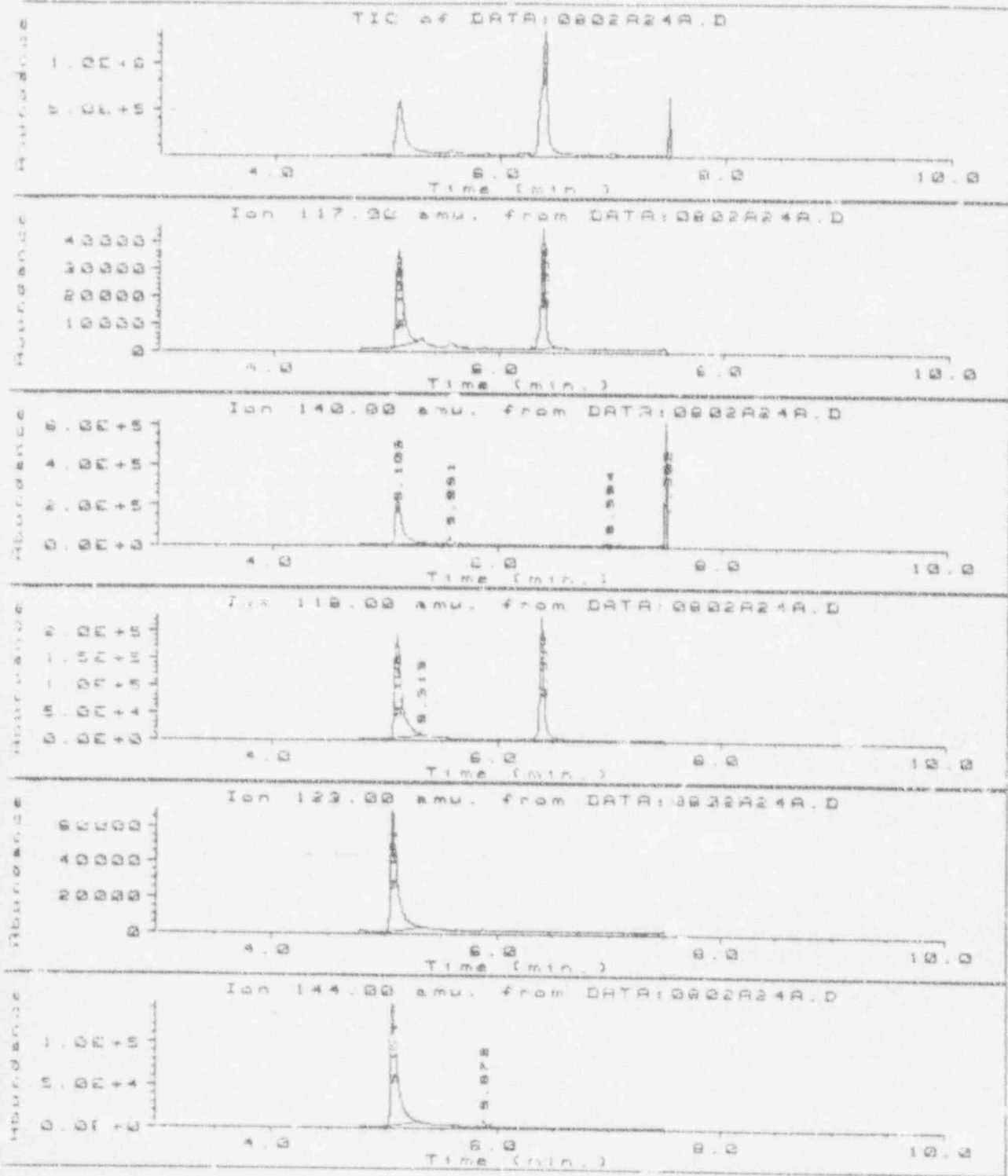
AMPHETAMINE ION PEAK HEIGHTS :

PEAK HEIGHT FOR ION 117 = 1 R.T. = 1.00  
 PEAK HEIGHT FOR ION 140 = 1 R.T. = 1.00  
 PEAK HEIGHT FOR ION 118 = 1 R.T. = 1.00  
 PEAK HEIGHT FOR ION 123 = 1 R.T. = 1.00  
 PEAK HEIGHT FOR ION 144 = 1 R.T. = 1.00

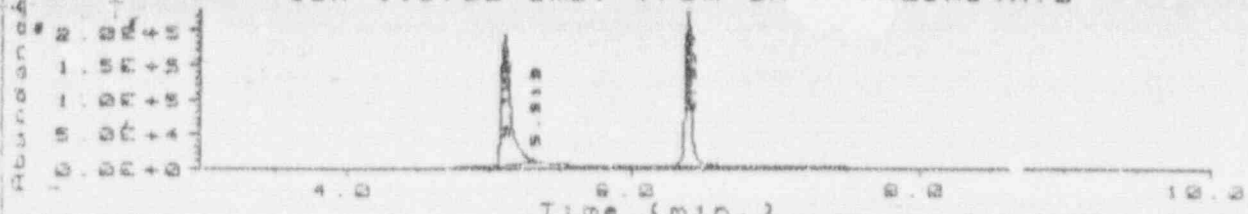
(\*) Document 42

Sample Name: G469499 X2  
Misc Info:  
Operator : DRB/MSD#4  
  
Date : 2 Aug 92 11:23 pm  
Instrument: MS\_5970  
Inlet : GC

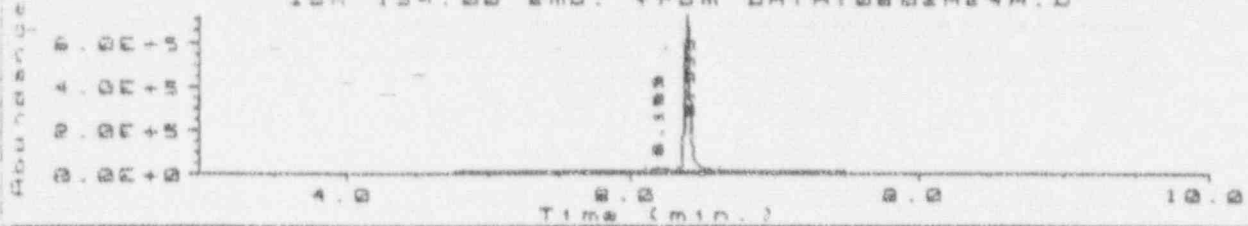
Sequence Index : 1  
ALS bottle num : 24  
Replicate num : 1



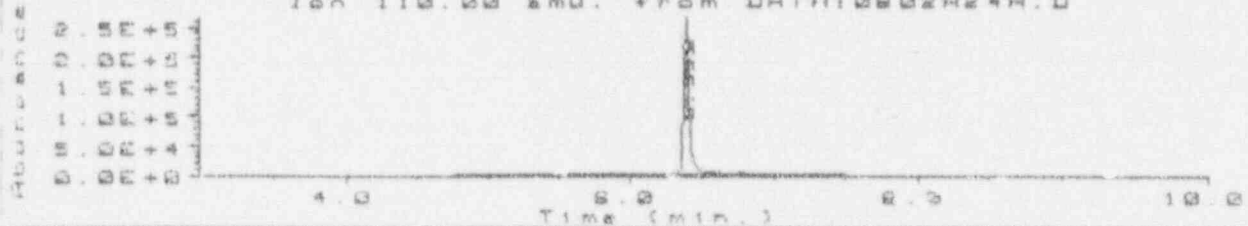
Ion 118.00 amu. from DATA:0002024A.D



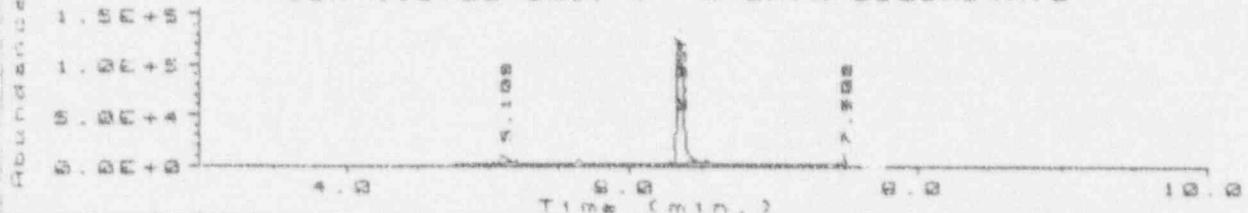
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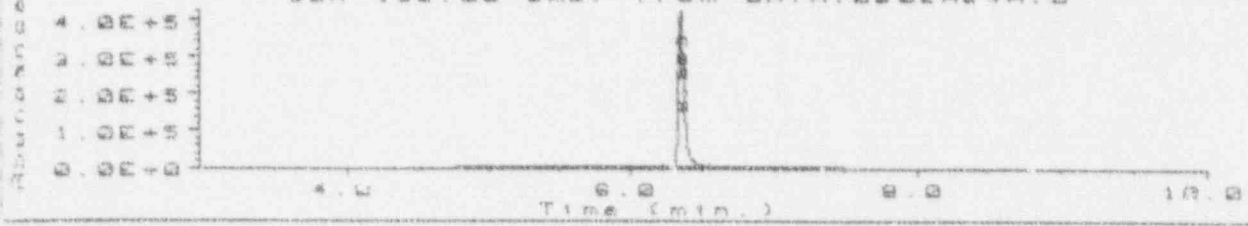
Ion 110.00 amu. from DATA:0002024A.D



Ion 114.00 amu. from DATA:0002024A.D



Ion 150.00 amu. from DATA:0002024A.D



AMPHETAMINE CONFIRMATION ION RATIOS :

- ION RATIO 117/118 = 10.32 \*
- ION RATIO 140/118 = 67.69 \*
- ION RATIO 123/144 = 0.47
- ION RATIO 118/123 = 0.05 \*

AMPHETAMINE ION PEAK HEIGHTS :

- PEAK HEIGHT FOR ION 117 = 35759 R.T. = 5.10
- PEAK HEIGHT FOR ION 140 = 234550 R.T. = 5.10
- PEAK HEIGHT FOR ION 118 = 3465 \*
- PEAK HEIGHT FOR ION 123 = 68305 R.T. = 5.31 \*
- PEAK HEIGHT FOR ION 144 = 146130 R.T. = 5.07



METHAMPHETAMINE CONFIRMATION ION RATIOS :

ION RATIO 118/110 =0.86  
ION RATIO 154/110 =2.70  
ION RATIO 113/158 =0.36  
ION RATIO 110/113 =1.74

METHAMPHETAMINE ION PEAK HEIGHTS :

PEAK HEIGHT FOR ION 118 = 229181 R.T. = 6.40  
PEAK HEIGHT FOR ION 154 = 719339 R.T. = 6.40  
PEAK HEIGHT FOR ION 110 = 266487 R.T. = 6.39  
PEAK HEIGHT FOR ION 113 = 153305 R.T. = 6.35  
PEAK HEIGHT FOR ION 158 = 424055 R.T. = 6.36

\*\*\* Height Percent \*\*\*

Report by Signal

Operator: DAB/MSD#4  
Method File Name : AMPH.M  
Sample Info : G469499 X2  
Misc Info:  
Integration File Name : DATA:0802A24A.I  
Method Index : 1 Bottle Number : 24  
2 Aug 92 11:23 pm

Ret Time	Type	Area	Height	Ht. %	Ratio %
5.103	BV	1425146.6047	35759.206857	44.315	100.00
6.394	BB	1297132.5561	44733.655461	55.685	125.66

Ret Time	Type	Area	Height	Ht. %	Ratio %
5.103	BV	10390807.633	234550.23338	27.167	100.00
5.561	BV	1476794.0358	39370.185319	4.560	16.79
6.994	BV	395957.57995	11217.997697	1.299	4.78
7.502	BB	4952772.9416	578222.63521	66.973	246.52

Ret Time	Type	Area	Height	Ht. %	Ratio %
5.103	BV	7982053.2994	188970.13542	44.820	100.00
5.313	VV	53184.641665	3465.2123416	0.822	1.83
6.394	BV	6243340.5374	220100.53034	51.250	121.00



Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
5.071	BV	123.00 amu	2650735.3870	68705.058874	100.000	100.00

Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
5.071	BV	144.00 amu	5644136.7872	146129.91336	95.233	100.00
5.872	BB	144.00 amu	184738.69757	7315.4953708	4.767	5.01

Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
5.103	BV	118.00 amu	7982053.2994	188970.13542	44.820	100.00
5.313	VV	118.00 amu	53184.661665	3465.2123416	0.822	1.83
6.394	BV	118.00 amu	6243340.5376	229180.53834	54.358	121.28

Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
6.193	PV	154.00 amu	11955.120827	499.93268759	0.069	0.07
6.395	BV	154.00 amu	18562449.999	719338.92992	99.931	100.00

Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
6.390	BV	110.00 amu	7101709.2959	26.487.42779	100.000	100.00

Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
5.108	BV	113.00 amu	271809.75341	7916.4763851	4.608	5.16
6.350	BV	113.00 amu	4215569.1558	153304.51025	89.243	100.00
7.502	BB	113.00 amu	107330.20568	10562.069740	6.148	6.89

Ret Time	Type	Mass	Area	Height	Ht. %	Ratio %
6.355	BV	158.00 amu	11806598.969	424055.32084	100.000	100.00

*This is the outline of the education seminar presented by Dr. Labrosse.*

### CONFIRMATION VERIFICATION

1. Check  $\pm 20\%$  ion ratio range of threshold standard.
2. Check lines with linear regression calculator (Excludes TARGET). Ensure standard quant values within limits.
3. Check that ion ratios are within the  $\pm 20\%$  ion range for standards, controls, and positive patient specimens.
4. Check that controls are within range.
5. Check chain of custody and worksheet initials.
6. Check chromatogram identification numbers with specimen number on worksheet.
7. Re-calculate the quant ion ratio and verify quantitation in the linear regression line.
8. Check chromatography; i.e., peak shape, interfering peak, baseline and abundances.
9. Check retention times of the drug ( $\pm 0.04$  min from internal std retention time).
10. Verify that all positive specimens have quant values greater than the threshold cut-off limit.
11. Verify that all quant confirmation drug levels are above the LOQ.
12. Verify that all "retests" are quantitated to LOD. Report as "presence of drug is confirmed".
13. Check and initial requisition confirmation forms.
14. Initial verifier spot on worksheet (both pages).
15. For opiate confirmation-verify the presence or absence of 6 MAM.
16. For d, & L - methamphetamine - report quantitations.
17. For THC confirmations on clinical mother and baby specimens report to LOQ.