



FRAMATOME TECHNOLOGIES

155 Mill Ridge Road
P.O. Box 10935
Lynchburg, VA 24502-0935
Telephone: 804-832-4000
Telecopy: 804-832-4029

December 10, 1996

Nuclear Regulatory Commission
Attn: Document Control
11545 Rockville Pike
North Bethesda, MD 20852

Dear Sir:

On November 8, 1996, blind proficiency urine specimens were forwarded for testing to our approved laboratory, American Medical Laboratories, Inc. in accordance with Framatome Technologies 10CFR26 Fitness For Duty Program. On November 12, 1996, the sample in question, patient identification number 517716912, did not result in the expected cutoff level range as specified by the vendor from which we purchased the samples (Drug testing Consultants, Inc.). The deviations fell below the expected range by slightly more than 30%.

Drug Testing Consultants, Inc. was alerted to the deviation and requested to address the possible issues that may have caused the out of range results. Attached is documentation from American Medical Laboratories, Inc. discussing the deviation with the blind sample.

The attached letter is enclosed for your review; the letter will remain on file in FTI Access Control for audit purposes. Should you require further information, please contact me at (804) 832-4010.

Sincerely,

Amy L. Hanse, Manager
FTI Access Control

attachments

9612170435 961210
PDR TOPRP EMVFRAMA
PDR

RD-8-2 Framatome

A022



American Medical Laboratories, Inc.*
14225 Newbrook Drive
P.O. Box 10841
Chantilly, Virginia 22021-0841
703 802-8900

Anthony G. Costantino

December 9, 1996

Ms. Tara Werner
Fitness for Duty
Framatome Technologies, Inc.
3315 Old Forest Rd
PO Box 10935
Lynchburg, VA 24506-0935

Dear Ms. Werner:

This letter is in reference to the internal investigation of the GCMS analysis performed on the sample submitted with the patient ID 517-71-6912 and the accessioning number 22642275. This sample was a blind sample submitted by FTI. The sample screened correctly positive for opiates and was correctly reported positive for morphine and codeine. The reported concentrations were 420 and 410 ng/mL respectively. I was verbally informed that the concentrations should have been 699 and 698 ng/mL respectively. Repeat GCMS analysis yielded results for morphine and codeine of 685 and 654 ng/mL respectively. The quality control for these analytes was near the mean on both assays.

Review of the initial GCMS data did not reveal an obvious cause for the difference in the quantitative values. The chromatography was acceptable and showed proper integration. There was no evidence of interfering compounds. There is no evidence to suggest transposition of the aliquots. The blind and open quality control values were close to the mean. The drug free control was negative.

My conclusion is that this was a random error. The staff has been instructed to verify that all samples are well mixed before each aliquot is poured from a sample. Any other deviations in the method should have been detectable by examination of the open and blind quality control samples.

If I can be of further assistance please call me.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Anthony G. Costantino'.

Anthony G. Costantino, Ph.D., DABFT

Director of Toxicology

cc: Robert Schoening

Patient ID # 517-71-6912

Mor

$$\begin{aligned} \text{QL of Cof A} &= 698 \times .80 = 558.4 \\ &698 \times 1.20 = 837.6 \end{aligned}$$

Result Range = 400

Cod

$$\begin{aligned} \text{QL of Cof A} &= 699 \times .80 = 559.2 \\ &699 \times 1.20 = 838.8 \end{aligned}$$

Result Range = 400

AMERICAN MEDICAL LABORATORIES, INC.®

P.O. Box 10841 • 14225 Newbrook Drive

Chantilly, VA 22021-0841

Telephone: (703) 802-6900

7716912

Page 1 From Chantilly

COLLECTED: 11/08/96

RECEIVED: 11/09/96

REPORTED: 11/12/96

1996/ 0/ 16498/ 0/9983

PATIENT ID: 517716912

SITE CODE: INS

Please note: FTI INS

22642275/0 (ADULT ASSUMED)

FOR NOT PROVIDED

16498 RICHARD LANE, M.D.*

FTI/ACCESS CONTROL

155 MILL RIDGE ROAD

LYNCHBURG VA 24502

TEST REASON: RAN

COLL. SITE: LYNCHBURG, VA

T16498:A

-----TESTS-----RESULTS---REF. RANGE-----UNITS----

180577/Chantilly

Medicolegal Toxicology

MEDICOLEGAL CHAIN-OF-CUSTODY REPORT.

Chain of Custody document received and specimen
seal intact.

43167/Chantilly

Progressive Drug Screen #121, Urine

Test results

MARIJUANA METABOLITES	negative	Screen cutoff	@50 ng/mL
MARIJUANA METABOLITES	negative		@100 ng/mL
PCP (PHENCYCLIDINE)	negative		@25 ng/mL
AMPHETAMINES	negative		@1000 ng/mL
COCAINE METABOLITES	negative		@300 ng/mL
OPIATE METABOLITES	* POSITIVE		@300 ng/mL
Creatinine, Urine	57		mg/dL
pH	within acceptable range of 4.5-9		

Confirmatory Tests

Opiates, Confirmation by GCMS, Urine

MORPHINE	+	420	<300	ng/mL
CODEINE	+	400	<300	ng/mL

*** FINAL REPORT ***

[P 68300]-[S 577]

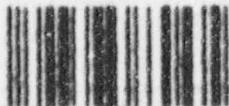


FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

American Medical Laboratories, Inc.
1225 Newbrook Drive
O. Box 10841
Falls Church, Virginia 22041-0841
703-261-6900 • 800-852-9528

016498

22642275



1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

LABORATORY ACCESSION NO.

A. Employer Name, Address and I.D. No.

FTI, INS
Lynchburg, VA

B. MRO Name and Address

16498- 9983
RICHARD LANE, N.D.
FTI/ACCESS CONTROL
155 MILL RIDGE ROAD
LYNCHBURG, VA 24502
804-832-4014

T16498:A

CODE

INS

(04316) (01805)

24 JUL 1996

C. Donor SSN or Employee I.D. No.

5, 7, 71-6912

D. Reason for Test:

- ☐ Pre-employment ☒ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ OTHER (specify) _____

E. Tests to be performed:

☐ THC, Cocaine, PCP, Opiates and Amphetamines

☐ Only THC and Cocaine

☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☒ Yes, 90° - 100° F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION:

FTI / INS

Collection Facility

(804) 832-4014
Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION

☒ YES ☐ NO

REMARKS:

that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labeled and sealed as in accordance with applicable Federal requirements.

Tara W. Werner

Tara W. Werner

11/8/96 8:47am

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
11 8 96	DONOR - NO SIGNATURE	Collector Signature: Tara W. Werner Name: Tara W. Werner	PROVIDE SPECIMEN FOR TESTING
11 8 96	Collector Signature: Tara W. Werner Name: Tara W. Werner	Signature: _____ Name: _____	COC
11 9 96	Signature: _____ Name: _____	Signature: JILL LATHROP Name: JILL LATHROP	COC Room/Accession
	Signature: _____ Name: _____	Signature: _____ Name: _____	

STEP 7: TO BE COMPLETED BY THE LABORATORY

Specimen Bottle Seal(s) Intact: ☒ YES ☐ NO, Explain in Remarks Below.

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

- ☐ NEGATIVE ☒ POSITIVE, for the following: ☐ Cannabinoids as Carboxy - THC ☐ Cocaine Metabolites as Benzoylcegonine ☐ Phencyclidine
☒ Opiates ☐ Amphetamines
☐ TEST NOT PERFORMED ☒ Codeine ☐ Amphetamine ☐ OTHER _____
☐ Morphine ☐ Methamphetamine

REMARKS

TEST LAB (if different from above)

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen 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 are for that specimen.

ZENAIDA B. BARRERO
(PRINT) Certifying Scientist's Name (First, MI, Last)

Signature of Certifying Scientist

11/12/96
Date (Mo. / Day / Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable federal requirements. My determination / verification is:

- ☐ Negative ☒ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS

Signature of Medical Review Officer

11/15/96
Date (Mo. / Day / Yr.)