Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13370

7 - PROCEDURES

[redacted]

FINAL REPORT

ORDER NUMBER [redacted]

PATIENT NAME [redacted]

DRAWN DATE AND TIME 02/01/1999 AM

RECEIVED DATE 02/01/1999

REPORT DATE AND TIME 02/03/1999 9:30A

DATE OF BIRTH [redacted] AGE 19

SEX M

CLIENT NAME AND ADDRESS [redacted]

ACCT NO [redacted]

PATIENT ID [redacted]

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TESTS	RESULT		UNITS	RANGE
GLUCOSE	89		MG/DL	65-125
SMA AECCT				
PROTEIN, TOTAL	8.0		G/DL	6.0-8.7
ALBUMIN	5.1	H	G/DL	3.5-5.0
GLOBULIN, CALCULATED	2.9		G/DL	2.0-3.7
A/G RATIO	1.8		RATIO	1.1-2.7
SODIUM	142		MEQ/L	134-146
POTASSIUM	3.7		MEQ/L	3.5-5.4
CHLORIDE	105		MEQ/L	95-110
CARBON DIOXIDE	21		MEQ/L	18-30
UREA NITROGEN	10		MG/DL	5-25
CREATININE	1.0		MG/DL	0.5-1.5
BUN/CREATININE RATIO	10.0		RATIO	10-30
URIC ACID	5.6		MG/DL	3.0-8.0
CALCIUM	9.7		MG/DL	8.6-10.2
PHOSPHATE	3.7		MG/DL	2.4-4.9
ALKALINE PHOSPHATASE	102		U/L	25-130
BILIRUBIN, TOTAL	0.7		MG/DL	0.2-1.5
BILIRUBIN, DIRECT	0.1		MG/DL	0.0-0.2

**NOTE SLIGHT CHANGE IN REFERENCE RANGE

BILIRUBIN, INDIRECT	0.6	MG/DL	0.1-1.0
AST	29	U/L	0-45
ALT	15	U/L	0-53
LD	238	U/L	100-250
TRIGLYCERIDES	80	MG/DL	<200

REFERENCE RANGE VALID FOR 12 HOUR FASTING:

NORMAL	<200
BORDERLINE HIGH	200-399
HIGH	400-1000
VERY HIGH	>1000

CHOLESTEROL	186	MG/DL	<200

DESIRABLE	<200
BORDERLINE HIGH RISK	200-239
HIGH RISK	>=240

DL CHOLESTEROL	36	MG/DL	>34

HDL CHOLESTEROL CONCENTRATION OF <35 CONSTITUTES A CHD RISK FACTOR.
A CONCENTRATION > OR = 60 CONSTITUTES A "NEGATIVE" RISK FACTOR.

HOLESTEROL/HDL RATIO	5.2	RATIO	4.0-6.7

CHD RISK MALE FEMALE

REPORT CONTINUED ON NEXT FORM

Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP Exh D7

[redacted]

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[redacted]

[redacted]

DATE OF BIRTH [redacted] AGE 19 SEX M

PATIENT ID [redacted]

DRAWN DATE AND TIME 02/01/1999 AM

RECEIVED DATE 02/01/1999

REPORT DATE AND TIME [redacted] 02/03/1999 9:31A

CLIENT NAME AND ADDRESS [redacted]

ACCT NO [redacted]

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TESTS	RESULT		UNITS	RANGE
	AVERAGE		4.0- 6.7	3.7-5.6
	ABOVE AVERAGE		6.7-14.0	5.6-8.3
	BELOW AVERAGE		2.7- 4.0	2.5-3.7
IRON-TIBC				
IRON	95		UG/DL	27-185
TIBC	364		UG/DL	170-410
% SATURATION	26		PERCENT	12-53
T3 UPTAKE	28.6		PERCENT	25.0-37.0
T4, TOTAL	10.2		UG/DL	4.2-10.5
T4, FREE, CALCULATED	2.9			1.20-3.70
TSH	2.840		MU/L	0.70-6.40
CBC W/ DIFF & PLT				
WBC	10.4		THOU/CUMM	3.9-11.7
RBC	4.94		MILL/CUMM	4.1-5.8
HEMOGLOBIN	15.2		G/DL	13.4-16.9
HEMATOCRIT	44.0		%	38.5-50.0
MCV	89.0		FL	79-93
MCH	30.8		PG	27.0-33.5
MCHC	34.6		%	32.0-36.0
PLATELET COUNT	215		THOU/CUMM	140-390
RDW	12.2		%	11.0-15.0
MPV	10.6		FL	7.5-11.5
TOTAL NEUTROPHILS, %	83.3	H	%	40-75
TOTAL LYMPHOCYTES, %	10.8	L	%	15-50
MONOCYTES, %	3.9		%	0-10
EOSINOPHILS, %	0.7		%	0-6
BASOPHILS, %	1.3		%	0-2
NEUTROPHILS, ABSOLUTE	8.66	H	THOU/CUMM	1.80-8.00
LYMPHOCYTES, ABSOLUTE	1.12		THOU/CUMM	1.0-5.2
MONOCYTES, ABSOLUTE	0.41		THOU/CUMM	0.04-0.90
EOSINOPHILS, ABSOLUTE	0.07		THOU/CUMM	.03-.60
BASOPHILS, ABSOLUTE	0.14		THOU/CUMM	0.00-0.200
DRUG SCR 10 DRUG,W/O CONF				
CREATININE	1.51			

URINE CREATININE IS USED TO EVALUATE SAMPLE COLLECTIONS FOR ADULTERATION. A RESULT GREATER THAN OR EQUAL TO 0.20 GM/L IS NORMAL. A RESULT LESS THAN 0.20 GM/L MAY INDICATE POSSIBLE ADULTERATION.

AMPHETAMINE	NEGATIVE	CUTOFF 1000 NG/ML
CANNABINOIDS (THC)	NEGATIVE	CUTOFF 100 NG/ML

REPORT CONTINUED ON NEXT FORM

Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP Exh DX

[redacted]

[redacted]

[redacted]

DRAWN DATE AND TIME: 02/01/1999 AM

RECEIVED DATE: 02/01/1999 REPORT DATE AND TIME: 02/03/1999 9:31A

[redacted]

DATE OF BIRTH: [redacted] AGE: 19 SEX: M

CLIENT NAME AND ADDRESS: [redacted]

PATIENT ID: [redacted]

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TESTS	RESULT	UNITS	RANGE
PHENCYCLIDINE (PCP)	NEGATIVE		CUTOFF 25 NG/ML
COCAINE	NEGATIVE		CUTOFF 300 NG/ML
OPIATES	NEGATIVE		CUTOFF 300 NG/ML
BARBITURATE	NEGATIVE		CUTOFF 200 NG/ML
BENZODIAZEPINE	NEGATIVE		CUTOFF 200 NG/ML
METHADONE	NEGATIVE		CUTOFF 100 NG/ML
METHAQUALONE	NEGATIVE		CUTOFF 300 NG/ML
PROPOXYPHENE	NEGATIVE		CUTOFF 300 NG/ML
NITRITE, URINE	NEGATIVE		CUTOFF 500 UG/ML

THIS IS A SCREEN ONLY, AS ORDERED. TESTING OF INDIVIDUAL DRUGS BY [redacted] WILL BE PERFORMED UPON REQUEST. SPECIMEN WILL BE HELD FOR 14 CALENDAR DAYS BEFORE DISPOSAL.

****
NON-FEDERAL DRUG TESTING RESULTS
****

DRUG SCREEN 5(THC50) CP

CREATININE 1.51

URINE CREATININE IS USED TO EVALUATE SAMPLE COLLECTIONS FOR ADULTERATION. A RESULT GREATER THAN OR EQUAL TO 0.20 GM/L IS NORMAL. A RESULT LESS THAN 0.20 GM/L MAY INDICATE POSSIBLE ADULTERATION.

AMPHETAMINE	NEGATIVE		CUTOFF 1000 NG/ML
PHENCYCLIDINE (PCP)	NEGATIVE		CUTOFF 25 NG/ML
COCAINE	NEGATIVE		CUTOFF 300 NG/ML
OPIATES	NEGATIVE		CUTOFF 300 NG/ML
CANNABINOIDS (THC50)	NEGATIVE		CUTOFF 50 NG/ML
NITRITE, URINE	NEGATIVE		CUTOFF 500 UG/ML

****
NON-FEDERAL DRUG TESTING RESULTS
****

SUMMARY OF RESULTS OUTSIDE ESTABLISHED REFERENCE RANGE

ALBUMIN	5.1	H	G/DL	3.5-5.0
TOTAL NEUTROPHILS, %	83.3	H	%	40-75
TOTAL LYMPHOCYTES, %	10.8	L	%	15-50
NEUTROPHILS, ABSOLUTE	8.66	H	THOU/CUMM	1.80-8.00

[redacted] 2/3/99.

[redacted]

Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP Exh D7

[redacted]

FINAL REPORT

ORDER NUMBER [redacted]

PATIENT NAME [redacted]

DRAWN DATE AND TIME 01/09/1998

RECEIVED DATE 01/09/1998

REPORT DATE AND TIME 01/12/1998 7:44A

DATE OF BIRTH [redacted] AGE 18 SEX M

CLIENT NAME AND ADDRESS [redacted]

ACCT NO [redacted]

PATIENT ID [redacted]

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TESTS	RESULT	UNITS	RANGE
GLUCOSE	90	MG/DL	70-115
CBC W PLATELET			
WBC	7.1	THOU/CUMM	3.9-11.7
RBC	5.19	MILL/CUMM	4.1-5.8
HGB	15.9	G/DL	13.4-16.9
HCT	45.3	PERCENT	38.5-50.0
MCV	87.0	FL	79-93
MCH	30.7	PG	27.0-33.5
MCHC	35.2	PERCENT	32.0-36.0
PLATELET COUNT	177	THOU/CUMM	140-390
RDW	12.1	PERCENT	11.0-15.0
MPV	10.4	FL	7.5-11.5
NEUTROPHILS	65.1	PERCENT	40-75
LYMPHOCYTES	24.1	PERCENT	15-50
MONOCYTES	7.1	PERCENT	0-10
EOSINOPHILS	2.9	PERCENT	0-6
BASOPHILS	0.8	PERCENT	0-2
NEUT ABS	4.62	THOU/CUMM	1.80-8.00
LYMPH ABS	1.71	THOU/CUMM	1.0-5.2
MONO ABS	0.50	THOU/CUMM	0.04-0.90
EOS ABS	0.21	THOU/CUMM	.03-.60
BASO ABS	0.06	THOU/CUMM	0.00-0.200

[redacted] 1/12/98

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3/24,25,30/99 ARP Exh 1)12

[redacted] PAGE 1

[redacted]

ORDER NUMBER

DRAWN DATE AND TIME

RECEIVED DATE

REPORT DATE AND TIME

DATE OF BIRTH AGE

SEX

CLIENT NAME AND ADDRESS

ACCT NO

PATIENT ID

[redacted]

12/17/96

Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP Exh. D1

000006

[redacted]

ROUTINE CHEMISTRIES

TIME COLLECT:	03/01/99 0655	REFERENCE	UNITS
PROCEDURE			
GLUCOSE	89	(70-105)	MG/DL
BUN	11	(7-22)	MG/DL
CREATININE	0.8	(0.5-1.5)	MG/DL
BUN/C RATIO	13.8	(12.0-20.0)	
CALCIUM	2.44	(2.13-2.63)	mM/L
TOTAL PROTEIN	7.1	(6.0-8.0)	G/DL
ALBUMIN	4.3	(3.5-5.0)	G/DL
A/G RATIO	1.5	(1.1-2.2)	
BILIRUBIN TOTAL	0.7	(0.2-1.3)	MG/DL
ALK PHOS	78	(38-126)	U/L
SGOT	34	(8-40)	U/L

ELECTROLYTES

TIME COLLECT:	03/01/99 0655	REFERENCE	UNITS
PROCEDURE			
SODIUM	138	(134-145)	mM/L
POTASSIUM	4.0	(3.5-5.0)	mM/L
CHLORIDE	102	(96-107)	mM/L
CO2	31H	(24-30)	mM/L
ANION GAP	5L	(7-14)	mM/L

THERAPEUTIC DRUG TESTING

TIME COLLECT:	03/07/99 0650	03/05/99 0627	03/03/99 0722	02/28/99 0717	REFERENCE	UNITS
PROCEDURE						
LITHIUM	0.6	1.0	1.0		(0.6-1.2)	MEQ/L
ANTICONVULSANTS						
CARBAMAZEPINE	6	5	5		(4-10)	UG/ML
VALPROIC ACID				78.7	(50.0-100.0)	G/ML

Legend:
L = Low, H = High

Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP Exh EZ-1

Pt.: [redacted]
MR [redacted]
ADM: 02/28/99 Sex: M
Dr: [redacted]

Acct.# [redacted]
Age: 19 YRS DOB: [redacted] Loc: [redacted]
[redacted]

INPATIENT FINAL REPORT

LABORATORY

Print Date: 03/08/99 0305
Page: 1 CONTINUED...
[redacted]

[redacted]

DRUG OF ABUSE TESTING

02/28/99
TIME COLLECT: 0809

PROCEDURE		REFERENCE	UNITS
URINE TOXICOLOGY			
AMPHETAMINES	NEGATIVE	(NEGATIVE)	
BARBITURATES	NEGATIVE	(NEGATIVE)	
COCAINE METAB	NEGATIVE	(NEGATIVE)	
MARIJUANA MET	NEGATIVE	(NEGATIVE)	
OPIATES	NEGATIVE	(NEGATIVE)	
BENZODIAZEPINE	NEGATIVE	(NEGATIVE)	
PCP	NEGATIVE	(NEGATIVE)	

Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP ExhEZ

[redacted]

LABORATORY

Print Date: 03/08/99 0305
Page: 3 END OF REPORT

[redacted]

Memorandum to ARMS # 13370

Date: 10Aug99

From: Medical Officer, Clinical Research and Review Staff, Office of Special Nutritionals, HFS-452

Subject: Medical Records Placed in Permanent Storage.

The following types and amounts of records (more than 20 pages total) were place in permanent storage on this date because they were not considered essential for interpretation of this adverse event.

Approx Pages	Type of Records
1/8"	Nursing notes
	Dietitian notes
1/8"	Respiratory therapy/occupational therapy/physical therapy notes
	Clergy notes
9	Medication records
11	Physician's orders
	Vital signs, fluids, input/output records
	Ventilator records
17	Hospital administrative records (e.g., insurance information, living will, etc)

V Cheeseman for
LA Love