

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

ARMS#

13167



7 - PROCEDURES

000001

HOSPITALIZATION #1

000002

LAB REQUEST / REPORT

Add on

NURSE'S INITIAL	DATE <u>9/9</u>	DESIRED TIME	AM/PM
TECH'S INITIALS	DATE <u>9/9</u>	COLLECTED TIME	AM/PM
TECH'S INITIALS	DATE <u>9/9</u>	COMPLETED TIME	AM/PM



STAT ASAP				OUT PATIENT				PRE-OP				PNWHH				EMERGENCY ROOM			
GAP				HOSPICE				FA HC											
X	TEST	RESULTS	UNITS	NORMAL	X	TEST	RESULTS	UNITS	NORMAL	X	TEST	RESULTS	UNITS	NORMAL					
PROFILES					CREATININE					MG/dL	0.7-1.5	VALPORIC ACID (DEPAKOT)							
	CBC & AUTO DIFF	SEE REPORT				CREATININE CLEARANCE	SEE REPORT				VANCOMYCIN		UG/ML	50-100					
	CHEM-7	SEE REPORT				DIGOXIN	SEE REPORT	NG/ML	0.8-2.0				UG/ML	THROUGH 5-10 PEAK: 20-40					
	ELECTROLYTES	SEE REPORT				DILANTIN	SEE REPORT	UG/ML	10-20	EKG									
	BCP - 21	SEE REPORT				DRUG SCREEN	SEE REPORT			EKG									
	CARDIAC PROFILE (CPK, LDH, SGOT) IF CK > 120 PERFORM CK-MB	SEE REPORT				FERRITIN		NG/ML	F: 10-120 M: 20-300	SEROLOGY									
X	LIVER FUNCTION (BCP-21 & SGPT)	SEE REPORT				FOLATE (FOIC ACID)	SEE REPORT				PREGNANCY TEST (SERUM)								
	ANEMIA PROFILE	SEE REPORT				GENTAMYCIN		UG/ML	TROUGH: 1-2 PEAK: 5-10		PREGNANCY TEST (URINE)								
	LIPID PROFILE	SEE REPORT				GLUCOSE		MG/dL	65-110		MONO TEST			NEGATIVE					
	TIBC	SEE REPORT				HGB A1C (GLYCOHEMOGLOBIN)		%	4.2-6.3		RPR			NON-REACTIVE < 0.5 NEG > 1.6 POS					
HEMATOLOGY / COAG.					HIV HTLV-III					SEE REPORT									
	BLEEDING TIME		MIN.	3-9		LDH		U/L	313-618		STREP SCREEN								
	HEMOGLOBIN (HGB)		GM/100ML	11.3-15.5		LDH ISO ENZYMES	SEE REPORT				BACTERIOLOGY								
	HEMATOCRIT (HCT)		%	32.4-45.4		LEAD					SOURCE:								
	RETIC COUNT		%	0.5-2.7		LIPASE		U/L	23-300		BACTERIAL CULTURE	SEE REPORT							
	MANUAL DIFF					LITHIUM	SEE REPORT				BLOOD CULTURE	SEE REPORT							
	SED RATE (ESR) (WEST)		MM/HR	F: 0-20 M: 0-15		MAGNESIUM		MG/dL	1.7-2.2		CHLAMYDIA/GC GEN PROBE	SEE REPORT							
	APTT		SEC.	21-35		MYOGLOBIN		NG/ML	F: 12-76 M: 19-92		GRAM STAIN	SEE COMMENTS							
	PROTIME		SEC.	10.8-12.8		PHENOBARBITAL		UG/ML	15-40		STOOL								
	THERA. INDEX					PHLEBOTOMY (THERAPEUTIC)	ML DRAWN =				C. DIFFICILE TOXIN			NEGATIVE					
	INR					PHOSPHORUS		MG/dL	2.5-4.5		CULTURE	SEE REPORT							
CHEMISTRY						PKU					GIARDIA ANTIGEN			NEGATIVE					
	ACETONE SERUM (KETONE)	SEE REPORT		NEG.		POTASSIUM		mmol/L	3.6-5.0		OCCULT BLOOD			NEGATIVE					
	ALBUMIN		G/dL	3.9-5.0		PROCAINAMIDE	SEE REPORT				OVA & PARASITE	SEE REPORT							
	ALCOHOL (MEDICAL)		MG/dL	TOXIC > 200		PROLACTIN	SEE REPORT				WBC			NONE SEEN					
	ALCOHOL (LEGAL)	GIVE BLOOD TO POLICE				PROTEIN, TOTAL		G/dL	6.3-8.2		MISC. TEST & COMMENTS								
	DRUG & ALCOHOL KIT (LEGAL)					PSA	SEE REPORT				<p><i>T3</i></p> <p>ILLS</p> <p>BILLED BY [REDACTED]</p> <p>Adverse Event Project # 13167</p> <p>[REDACTED]</p> <p>3/26/99 HRB</p> <p>000003</p> <p>Exhibit # <u>1</u> Pg <u>13</u> of <u>16</u></p>								
	ALKALINE PHOS.		U/L	38-126		QUINIDINE		MG/L	2.0-5.0										
	AMMONIA		UMOL/L	9-33		SALICYLATES		MG/L	50-100										
	AMYLASE		U/L	30-110		SEMI ANALYSIS (COMPLETE)	SEE COMMENTS												
	ANA	SEE REPORT				SEMI ANALYSIS (POST SURGERY)	SEE COMMENTS												
	B-12	SEE REPORT				SGOT (AST)	SEE REPORT	U/L	5-40										
	BETA - HCG (QUANTITATIVE)		mIU/ML	< 10 NON-PREGNANT		SGPT (ALT)	SEE REPORT	U/L	7-56										
	BILIRUBIN (TOTAL)		MG/dL	0.2-1.0		SODIUM	SEE REPORT	mmol/L	137-145										
	BUN		MG/dL	7-18		SURG. SPEC. HANDLING FEE													
	CALCIUM		MG/dL	8.4-10.2		T UPTAKE	<u>25.4</u>	%	25-37										
	CEA		NG/ML	< 5.0		T4	<u>8.30</u>	UG/dL	4.4-12.2										
	CELL COUNT (BODY FLUID)	SEE COMMENTS				THYROXINE INDEX	<u>2.11</u>		1.2-3.4										
	CHOLESTEROL		MG/dL	139-200		TSH	<u>8.73</u>	mIU/L	0.4-4.2										
	CLO TEST			NEGATIVE		TEGRETOL		UG/ML	8.0-12.0										
	CPK (CK)		U/L	30-170		THEOPHYLLINE		UG/ML	10-20										
	CK-MB		NG/ML	< 5.0		TRIGLYCERIDES		MG/dL	35-										
	CORTISOL	SEE REPORT				TRIAGE DRUG SCREEN			NEG.										
						TYLENOL (ACETAMINOPHEN)		UG/ML	10										
						URIC ACID		MG/dL	2.5-7.5										

9-10-98

RECEIVED		COMPLETED		TECH. INT.	
DATE	TIME	DATE	TIME		
		9/9	2050		
CHARTED		INITIALS		REQUESTED	
DATE	TIME			DATE	TIME
				9/9	2050
I.D. [REDACTED] Color: Yellow Clarity: Clear GLU Negative BIL Negative KET Negative SG <=1.005 PH 6.5 PRO Negative URO 0.2 EU/dL NIT Negative BLD Negative LEU Negative				<input checked="" type="checkbox"/> ROUTINE URINALYSIS <input type="checkbox"/> MICROSCOPIC ONLY	
RANDOM <input checked="" type="checkbox"/>		CLEAN CATCH <input type="checkbox"/>		CATHERIZED <input type="checkbox"/>	
RESULTS CALLED					
DATE	TIME	INITIALS			
WBC	/HPF				
RBC	/HPF				
CASTS	/LPF				
TYPE					
SQUAMOUS CELLS					
RENAL CELLS					
BACTERIA					
CRYSTALS					
TRICHOMONAS					
YEAST					
AMORPH					
MUCOUS					
BILE					
OTHER					

URINALYSIS

DOCTOR'S COPY

Adverse Event Project # 13167

3/26/99 HRB

000004

Exhibit # 2 Pg 22 of 36



RADIOLOGY REPORT

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]

DATE OF STUDY: 09-09-98

ATTENDING PHYSICIAN: [REDACTED] MD

CHEST

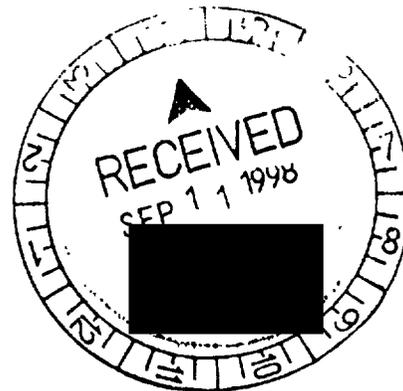
PA and lateral films were obtained.

The lungs are clear and fully expanded. The heart is normal in size and shape. No mediastinal masses or pleural effusions are seen.

IMPRESSION: No acute process.



D: 09-09-98
T: 09-09-98



Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

000005

Exhibit # 2 Pg 19 of 36

[REDACTED]

RADIOLOGY REPORT

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]

DATE OF STUDY: 09-09-98

ATTENDING PHYSICIAN: [REDACTED] MD

CT HEAD

CT head scan was performed without contrast.

Multiple axial cuts show the ventricular system of the brain to be normal in size and configuration without effacement or midline shift. There are no abnormal areas of increased or decreased attenuation or extra-axial fluid collections.

IMPRESSION: Normal head CT. [REDACTED]

[REDACTED] MD

D: 09-09-98
T: 09-09-98



Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

000006

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HOSPITALIZATION #2

000007

03/15/99
6:19 PM

PAGE: 1



FINAL REPORT

MEDICAL RECORD #: [REDACTED]
ID: [REDACTED] NAME: [REDACTED]
LOC: [REDACTED] ADMITTING DR: [REDACTED]
ORDERING DR: [REDACTED]

SEX: F AGE: 46
ADMITTING DATE: 3/15/99

ACCESSION: [REDACTED] ORDERED: 3/15/99 5:37 PM ORDERED BY: [REDACTED]
COLLECTED: 3/15/99 5:45 PM DRAWN BY: [REDACTED]
COMPLETED: 3/15/99 6:19 PM

COMMENT:

TEST	RESULT	ABNORMAL	---EXPECTED---	UNITS
CBC/DIFFERENTIAL				
WBC	8.2		4.0-10.8	x10 ³
RBC	4.5		4.1-5.4	x10 ⁶
HEMOGLOBIN	14.8		12.0-16.0	G/DL
HEMATOCRIT	43		37-47	%
MCV	96		81-99	fL
MCH		33	27-31	pg
MCHC	34		31-37	G/DL
PLATELET	263		130-400	x10 ³
LYMPHS %		53.90	10.00-50.00	%
SEGS %		35.70	37.00-60.00	%
MONOS %	8.70		0.00-12.00	%
EOS%	0.90		0.00-7.00	%
BASO%	0.90		0.00-2.50	%
SEGS, COUNT	2.9		2.0-6.9	K/ μ L
LYMPHS, COUNT		4.4	0.6-3.4	K/ μ L
MONOS, COUNT	0.7		0.0-0.9	K/ μ L
EOS, COUNT	0.1		0.0-0.7	K/ μ L
BASOS, COUNT	0.1		0.0-0.2	K/ μ L

Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

000008

Exhibit # 4 Pg 14 of 19

03/15/99
6:47 PM

PAGE: 1



FINAL REPORT

MEDICAL RECORD #: [REDACTED]
ID: [REDACTED] NAME: [REDACTED]
LUC [REDACTED] ADMITTING DR: [REDACTED]
ORDERING DR: [REDACTED]

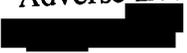
SEX: F AGE: 46
ADMITTING DATE: 3/15/99

ACCESSION: [REDACTED] ORDERED: 3/15/99 5:43 PM ORDERED BY: [REDACTED]
COLLECTED: 3/15/99 5:45 PM DRAWN BY: [REDACTED]
COMPLETED: 3/15/99 6:47 PM

COMMENT:

TEST	RESULT	ABNORMAL	--EXPECTED--	UNITS
CHEM 7				
SODIUM	137		136-145	MMOL/L
POTASSIUM	3.9		3.5-5.1	MMOL/L
CHLORIDE	100		98-107	MMOL/L
CO2	25		23-29	MMOL/L
GLUCOSE	97		65-110	MG/DL
BUN	14		8-21	MG/DL
CREATININE, SERUM	0.8		0.7-1.3	MG/DL
ANION GAP	16		9-25	

Adverse Event Project # 13167



3/26/99 HRB

000009

Exhibit # 4 Pg 11 of 19

03/15/99
6:17 PM

PAGE: 1



FINAL REPORT

MEDICAL RECORD #: [REDACTED]
ID: [REDACTED] NAME: [REDACTED] SEX: F AGE: 46
LOC: [REDACTED] ADMITTING DR: [REDACTED] ADMITTING DATE: 3/15/99
ORDERING DR: [REDACTED]

ACCESSION: [REDACTED] ORDERED: 3/15/99 5:38 PM ORDERED BY: [REDACTED]
COLLECTED: 3/15/99 5:45 PM DRAWN BY: [REDACTED]
COMPLETED:

COMMENT:

TEST	RESULT	ABNORMAL	--EXPECTED--	UNITS
LIPASE	116		0-190	u/L
TOTAL CPK	67		24-173	U/L

Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

000010

Exhibit # 4 Pg 13 of 19

03/15/99
6:54 PM

PAGE: 1



FINAL REPORT

ID: [REDACTED] NAME: [REDACTED] SEX: F AGE: 46
LUC: [REDACTED] ADMITTING DR: [REDACTED] ADMITTING DATE: 3/15/99
ORDERING DR: [REDACTED]

ACCESSION: [REDACTED] ORDERED: 3/15/99 5:45 PM ORDERED BY: [REDACTED]
COLLECTED: 3/15/99 5:45 PM DRAWN BY: [REDACTED]
COMPLETED: 3/15/99 6:52 PM

COMMENT:

TEST	RESULT	ABNORMAL	--EXPECTED--	UNITS
PTT PROTIME		25.6	25.8-35.8	SEC.
PROTHROMBIN TIME INR	12.2 1.0		11.1-14.0	SEC.

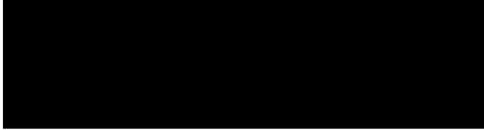
Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

Exhibit # 4 Pg 15 of 19

000011

03/16/99
11:21 AM



FINAL REPORT

PATIENT ID: [REDACTED]
MEDICAL RECORD #: [REDACTED]
LOC: [REDACTED]

PATIENT NAME: [REDACTED]
ADMITTING DR: [REDACTED]

SEX: F AGE: 46
ADMITTING DATE: 3/15/99

ORDERED: | 3/15/99 9:33 PM | 3/15/99 9:34 PM | |
COLLECTED: | 3/16/99 2:25 AM | 3/16/99 9:45 AM | |
COMPLETED: | 3/16/99 4:20 AM | 3/16/99 11:20 AM | |
| | | | |

TEST | [REDACTED] | [REDACTED] || EXPECTED RANGE | UNITS

CPK IMMUNOASSAY | 0.6 | 0.6 | | 0.0-5.0 NG/ML

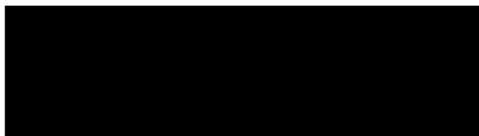
Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

Exhibit # 4 Pg 8 of 19

000012

03/16/99
4:21 AM



FINAL REPORT

PATIENT ID: [REDACTED]
MEDICAL RECORD #: [REDACTED]
LOC: [REDACTED]

PATIENT NAME: [REDACTED]
ADMITTING DR: [REDACTED]

SEX: F AGE: 46
ADMITTING DATE: 3/15/99

ORDERED: | 3/15/99 9:33 PM ||
COLLECTED: | 3/16/99 2:25 AM ||
COMPLETED: | 3/16/99 4:20 AM ||

TEST				EXPECTED RANGE		UNITS
CALCIUM		10.9 H		8.8-10.2		MG/DL
TOTAL CPK		59		24-173		U/L

Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

Exhibit # 4 Pg 9 of 19

000013

RADIOLOGY REPORT

NAME OF PATIENT:
HOSPITAL NUMBER:
ROOM NUMBER:
ADMITTING PHYSICIAN:
ORDERING PHYSICIAN:

[REDACTED]

[REDACTED]

X-RAY NUMBER:
PROCEDURE DATE:

[REDACTED]

03/15/99

[REDACTED]

REASON FOR REQUEST: LEFT ARM PAIN

PORTABLE CHEST:

Study performed 03/15/99 at 18:03. Clinical Indication: Left arm pain.

There are no prior chest films available for comparison.

A single frontal portable view of the chest demonstrates a normal heart and mediastinum.

The lungs are clear. The pulmonary vasculature is within normal limits.

The regional skeleton and soft tissues are unremarkable.

IMPRESSION:

NORMAL CHEST.

Adverse Event Project # 13167

[REDACTED]

3/26/99 HRB

Exhibit # 4 Pg 17 of 19

[REDACTED] M.D.
RADIOLOGIST

[REDACTED]
D: 03/16/99
T: 03/16/99
[REDACTED]

CHART COPY
RADIOLOGY REPORT



[REDACTED]

RADIOLOGY REPORT

[REDACTED]

NAME OF PATIENT:
HOSPITAL NUMBER:
ROOM NUMBER:
ADMITTING PHYSICIAN:
ORDERING PHYSICIAN:

[REDACTED]
03/17/99

EXAMINATION NUMBER:
PROCEDURE DATE:

REASON FOR REQUEST: CHEST PAIN, RULE OUT MYOCARDIAL INFARCTION.

NUCLEAR CARDIOLOGY

DUAL-ISOTOPE STRESS TEST:

INDICATION: Chest pain, rule out coronary artery disease.

PROCEDURE: The patient was given an injection of 3.1 mCi of thallium-201 chloride IV and resting SPECT images were obtained. The patient was then given an infusion of 60 mg of Persantine IV over 4 minutes. During this time, the baseline heart rate of 66 increased to a maximum of 90. The baseline blood pressure of 116/62 decreased to a minimum of 99/66. Patient did complain of chest discomfort and there was noted up to a millimeter of ST depression in the inferolateral leads. Please refer to Dr. [REDACTED] for complete description of the stress test. Three minutes following the Persantine infusion, the patient was injected with 27.5 mCi of technetium 99m sestamibi and approximately one hour later, gated SPECT images were obtained.

On review of these images, there is noted to be normal tracer uptake throughout the myocardium on both resting and stress images. Gated wall motion study is normal in the short axis, horizontal axis, and vertical axis with a calculated ejection fraction of 56 percent.

IMPRESSION:

1. NO EVIDENCE OF ISCHEMIA OR PRIOR MYOCARDIAL INFARCTION.
2. NORMAL GATED WALL MOTION STUDY WITH CALCULATED EJECTION FRACTION OF 56 PERCENT.

[REDACTED]
[REDACTED], M.D.
CARDIOLOGIST

Adverse Event Project # 13167

D: 03/18/99
T: 03/18/99

CHART COPY
RADIOLOGY REPORT

3/26/99 HRB

Exhibit # 4 Pg 14 of 19

ID:

16-Mar-1999 4:59:20

Female Caucasian

Room: [REDACTED]

Vent. rate 58 bpm
 PR interval 154 ms
 QRS duration 86 ms
 QT/QTc 420/412 ms
 P-R-T axes 48 30 27

Sinus bradycardia
 Nonspecific T wave abnormality
 Abnormal ECG

[REDACTED]

Adverse Event Project # 13167
 [REDACTED]
 3/26/99 HRB

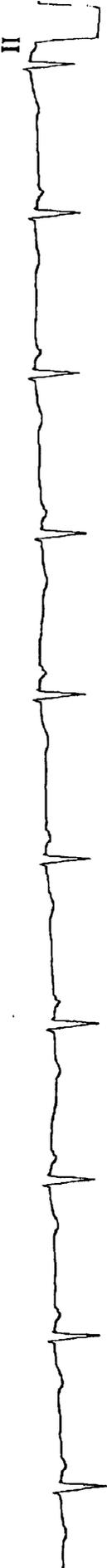
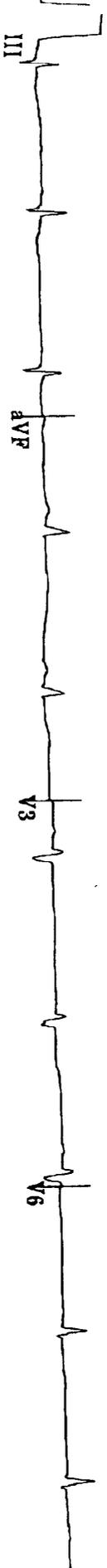
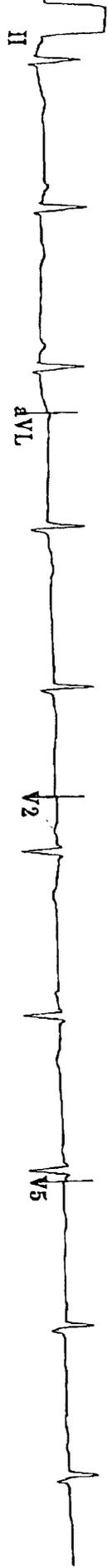
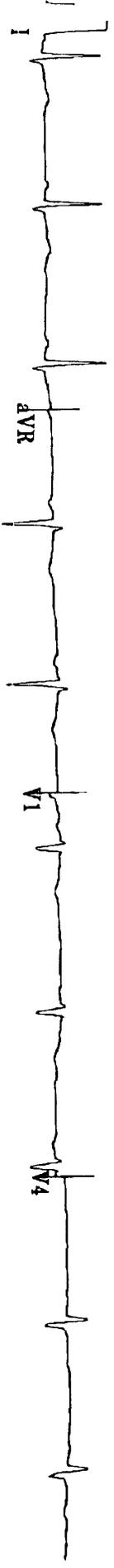
Exhibit # 4 Pg 18 of 19

000016

Technician [REDACTED]

[REDACTED]

Unconfirmed



40 Hz 25.0 mm/s 10.0 mm/mV

4 by 2.5s + 1 rhythm 1d

[REDACTED]

12SL km v250