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

ARMS#

13167

4 - ER URGENT

[redacted] PRESS HARD - 5 COPIES ER REGISTRATION FO

FINANCIAL TYPE	RELIGION	ARRIVAL	REGISTRATION DATE	TIME
COMMERCL	OTHER	[redacted]	09/09/98	13:48

AGE	DATE OF BIRTH	SEX	MARITAL STATUS	SOCIAL SECURITY NO
45	[redacted]	FEMALE WHITE	SINGLE	[redacted]

MAILING ADDRESS	COUNTY OF RESIDENCE	NOTIFY IN CASE OF EMERGENCY	RELATIONSHIP
[redacted]	[redacted]	[redacted]	

HOME ADDRESS	PHONE NUMBER	EMERGENCY CONTACT'S ADDRESS	STATE	ZIP CODE
	[redacted]			

CITY	STATE	ZIP CODE	ADMIT TYPE	EMPLOYMENT	PHONE
[redacted]	[redacted]	[redacted]	URGENT	[redacted]	[redacted]

FATHER'S NAME (IF MINOR)	ADMIT SOURCE	MOTHER'S NAME (IF MINOR)
	EMER ROOM	

GUARANTOR'S NAME	PATIENT'S RELATIONSHIP TO GUARANTOR	EMPLOYMENT STATUS	EMPLOYEE I D NO
[redacted]	SELF	FULL TIME	

GUARANTOR'S MAILING ADDRESS	GUARANTOR'S HOME PHONE	EMPLOYER'S NAME	EMPLOYER'S PHONE
[redacted]	[redacted]	[redacted]	[redacted]

GUARANTOR'S HOME ADDRESS	GUARANTOR'S SOCIAL SECURITY NO	EMPLOYER'S LOCATION STREET, CITY, STATE AND ZIP CODE
	[redacted]	[redacted]

GUARANTOR'S CITY	STATE	ZIP CODE	GUARANTOR NO
[redacted]	[redacted]	[redacted]	[redacted]

GUARANTOR'S EMPLOYER'S NAME	GUARANTOR'S EMPLOYMENT PHONE
[redacted]	[redacted]

GUARANTOR'S EMPLOYER'S LOCATION STREET, CITY, STATE AND ZIP CODE
[redacted]

SPOUSE INFO

NAME	SOCIAL SECURITY NO
ADDRESS	**RES PHONE**
EMPLOYMENT	**JOB PHONE**

PRIMARY INS CO NAME	POLICY HOLDER	INSURED RELATION	POLICY NO
[redacted]	[redacted]	SELF	[redacted]

GROUP POLICY NAME	GROUP POLICY NO	COMMENTS
[redacted]		

SECONDARY INS CO NAME	POLICY HOLDER	INSURED RELATION	POLICY NO

GROUP POLICY NAME	GROUP POLICY NO	COMMENTS

TERTIARY INS CO NAME	POLICY HOLDER	INSURED RELATION	POLICY NO

GROUP POLICY NAME	GROUP POLICY NO	COMMENTS

AGE TIME 1330 | ☐ EMERGENT 1 | ☑ URGENT 2 | ☐ NON EMERGENT 3 | CHIEF COMPLAIN[T] H.A. & T.B.P

[redacted]

Current Medications ☐ None ☐ Unknown ~~☐ See~~ Triage/Flowsheet

Name	Dose	Freq	Name	Dose	Fre

[redacted]

AMBU[redacted] ☐ COMBATIVE
STRETCHER ☐ ARMS ☑ ORIENTED ☐ ARREST/CPR
ASSISTED ☐ W/C ☐ DISORIENTED ☐ DOA
WITH Self ☐ UNCONSCIOUS

PMD OR [redacted]

NOTIFIED ☐ POLICE ☐ SHERIFF ☐ HWY PATROL ☐ CLERGY ☐ PARENTS ☐ OTHER

[redacted]	[redacted]ATION / TREATMENTS	TIME	NURSE	[redacted] RESPONSE
	ENT #20 Jelco L. wrist x 2		[redacted]	
	Hiprine Drip AT 1mg/kg/min 1330 pt to 45cc/hr.			
	Vinergan 12.5mg IV 1330		[redacted]	
	Tylenol ✓ 30cc/hr 1630		[redacted]	

LAB	X	TESTS	X-RAY	
	X	CBC		
	X	U/A	X	CHEST
		CHEM-7		SKULL
	X	CHEM-12		KNEE
		OCCULT BLD		ANKLE
		ABG		HAND/WRIST
		UCG/BHCG		FOREARM
		COAGS		IVP
		CULTURE & SENSITIVITY		ACUTE ABD SERI
		DIG LEVEL		CERVICAL SPI
		THEO LEVEL		LUMBAR SPINE
		DRUG SCREEN		
	X	CARDIAC		CT.
	X	EKG	☐ OLD RECORDS	
		AMYLASE		
		STREP		

RESULTS

[redacted]ING TESTS REVIEWED BY E D PHY

REVIEWED BY E D PHY

Adverse Event Project # 13167

[redacted]

3/26/99 HRB

000002

Exhibit # 1 Pg 1 of 16

[redacted]

MEDICAL RECORDS

PRESS HARD:
5 COPIES

[redacted]

HYSICIAN'S ASSESSMENT

ME SEEN: 2:00 pm. CHIEF COMPLAINT: ALLERGIES: NKDA

HPI: 45 y/o WF c/o occip ton H/A which she awoke with yesterday "worst H/A I have ever had". Progressively worse. (-) CP (-) SOB. Took percocet yesterday

SIG. PAST HX: (+) HRT murmur (+) s/p CVA (+) s/p hyst.

SIG. SOC. HX:

SIG. FAM HX

VS: T: 97.4 P: 80 BP: (R) 181/122 (L) 161/76.

CVS: RR 5(m) (-) carotid bruits

LUNG: CTA

ABD: Benign

NEURO: Alert, OX3, PERRLA, conj, (-) papilledema

No cross motor/sensory deficit.

DTR's all +3/4 CN II-XII grossly intact.

3:15 pm - H/A ↓↓ c̄ ↓ in BP (171/80) + IV Demerol.

CK: 93
MB: 393
AST: 25

139	102	8	
4.8		0.6	117

CT HEAD: (-) PA Dr [redacted] (2:35 pm).

CXR:

EKG: Possible Ant. ischemia? (T-wave inversion)

9.3	13.9	39	246	132	102	39	108	4.9	1.3	132	103	39	ALKP 146	4.9	1.3	108	

P.M.D./BACK-UP PHYSICIAN CALLED: [redacted]

TIME CALLED: 3:45 P.M.; 3:55 pm

RESPONSE: 3:55 pm - Admit ICU - CTP Dr. [redacted]

[redacted]

DIAGNOSIS

Hypertensive encephalopathy

SIGNATURES.

E.D. PHY. #1 [redacted]

E.D. PHY. #2

CHARGE INSTRUCTIONS AND RX

Admitted ICU.
CTP Dr. [redacted] (spoke c̄ him at 4:05 pm.)

CHARGE TIME 1700

CHARGE CONDITION
GOOD ☐ SAME
FAIR ☐ CRITICAL
SERIOUS ☐ EXPIRED

DISPOSITION
☐ HOME ☐ [redacted] ☐ Coroner/Funeral Home
☑ ADMITTED TO RM: (ICU)
☐ TRANSFERRED TO:
☐ REFERRED TO:

ACCOMPANIED BY: nurse
MODE: stretcher
VALUABLES: ☐ YES ☐ NO
GIVEN TO:

000003

CT NO	MEDICAL RECORD NO	FINANCIAL TYPE	RELIGION	MODE OF ARRIVAL	REGISTRATION DATE	TIME	REGISTERED BY
[redacted]	[redacted]	COMMERCL	OTHER		09/09/98	13:48	[redacted]

PATIENT NAME	AGE	DATE OF BIRTH	SEX	RACE	MARITAL STATUS	SOCIAL SECURITY NO
[redacted]	45	[redacted]	FEMALE	WHITE	SINGLE	[redacted]

MAILING ADDRESS	COUNTY OF RESIDENCE	NOTIFY IN CASE OF EMERGENCY	RELATIONSHIP
[redacted]	[redacted]	[redacted]	

HOME ADDRESS	HOME PHONE	EMERGENCY CONTACT'S ADDRESS	STATE	ZIP CODE
	[redacted]			

CITY	STATE	ZIP CODE	ADMIT TYPE	EMPLOYMENT	PHONE
[redacted]	[redacted]	[redacted]	URGENT	[redacted]	[redacted]

FATHER'S NAME (IF MINOR)	ADMIT SOURCE	MOTHER'S NAME (IF MINOR)
	EMER ROOM	

Adverse Event Project # 13161 [redacted] 3/26/99 HRB

Exhibit # 1 Pg 2 of 16

[redacted]

PATIENT [redacted]

EMERGENCY DEPARTMENT NURSING FLOW SHEET

DATE: 9/9 TIME TRIAGED: 1330 TRIAGED NURSE: [redacted] ED BED/TIME: 1330 EMERGENT

TRMT IN PROGRESS ON ARRIVAL: O2 L/MIN ORAL AIRWAY SAND BAGS SPLINT MONITOR COLLAR BACKBOARD ET URGENT

IV ICE PRESSURE DRESSING NONE NON-URGENT ✓

SUBJECTIVE

INFORMATION OBTAINED FROM PATIENT/TIME. FAMILY/FRIEND/TIME. TRANSPORTED BY: [redacted]

CHIEF COMPLAINT: H.A. since yesterday / Pain behind [redacted] Sensitive to light. ONSET:

MEDICATIONS: ☐SEE FRONT SHEET
Excedrin
Metabolife ?? yesterday
been taking for 5 days.

PAST MEDICAL HISTORY: CARDIAC:

HYPERTENSION
DM
SEIZURES
ASTHMA/COPD

OTHER Heart murmur
☐ ETO# Surgeries: Hysterectomy (Ch. lapsed)
☐ SMOKER PPD

PED. IMMUNIZATIONS UTD ☐Y ☐N

TETANUS STATUS: YR LMP: hysterectomy WT: 250

ALLERGIES: ☐NKDA ☐SEE FRONT SHEET
none.

TIME: OBJECTIVE

TIME	T	P	R	BP	BP	PULS OX
1330	97.4	80	20	181/120	161/74	95%
1400		84	18	202/107	146/73	

VISION: COMMENTS:
WITH GLASSES: OD OS OU
WITHOUT GLASSES [redacted] OU
TRIAGE NURSE: [redacted]

GROWTH/DEVELOPMENT APPROPRIATE FOR AGE YES/NO
COLOR: WNL PALE FLUSHED CYANOTIC JAUNDICED
SKIN: WARM DRY RASH DIAPHORETIC
RESPIRATIONS: NORMAL ABN TACHY RETRACTIONS DIAPHRAMATIC
BREATH SOUNDS: BILATERAL NORMAL/ABN WHEEZE CRACKLES
PULSES: REG/IRR TACHY/BRADY HEARTSOUNDS: NOR/ABN
ABD: FLAT DISTENDED BOSO: PRESENT/ABSENT HYPO HYPER
PAIN: LOCATION H.A. GRADE (0-10)

NURSING DIAGNOSIS

ALTERATION IN SKIN INTEGRITY R/T
ALTERATION IN COMFORT R/T ✓
ALTERATION IN TISSUE PERFUSION R/T
POTENTIAL FOR INJURY R/T
IMPAIRED BREATHING PATTERN R/T
ALTERATION IN THERMO REGULATION R/T/RISK OF INFECTION
ALTERATION IN FLUID VOLUME R/T
ALTERATION IN COPING MECH R/T

MENTAL ASSESS.

MIS: FIVE "R'S" ASSESSED: NORMAL/ABN
LOC: ALERT VERBAL/APPROPRIATE VERBAL/INAPPROPRIATE OTHER
MOOD/AFFECT: APPROPRIATE INAPPROPRIATE BLUNT/FLAT FEARFUL
NERO: PERL SPEACH: WNL ABN
THOUGHTS: ORIENTED DISORIENTED APPR. AGE MEMORY: INTACT / IMPAIRED

PLAN

✓ IDENTIFY PATIENT NEEDS. PHYSICAL ___ SOCIAL ___
✓ PSYCHOSOCIAL ___ SPIRITUAL ___ OTHER ___
___ ASSESS LEVEL OF BASIC KNOWLEDGE
___ ASSESS & PROVIDE FOR APPROPRIATE SAFETY MEASURES
___ PROVIDE COMFORT MEASURES, EMOTIONAL SUPPORT, DISCH.

GOAL: Pain ✓ THE PATIENT WILL: be ✓ pain.

INTERVENTIONS

TIME SEEN BY M.D. 1340
O2
1441 MONITOR RHYTHM: NSR.
NG
FOLEY / ST. CATH.

WOUND CLEANSED
BETADINE SOAK
DRESSING APPLIED
ELEVATION
ICE
TIME TO X-RAY/RESULTS
TIME LAB DRAWN/RESULTS
1441 SPLINT

TIME EKG DONE/RESULTS
TIME ABG DONE/RESULTS
TIME UA DONE/RESULTS

1441 IV #1 D5W to KVO #2 Reglan @ 40 cc/hr. 1620 #3 Reglan 2 50 cc/hr.

NURSING NOTES

Yo H.A. (has never had before) Sensitive to light. Works @ [redacted] Gone ? procedure subl. this Dr. - Started taking Metabolife on Friday. At 1340 Ketorolac dose. 1345 C.T. Scan being done. 1445 back from X-ray & Reglan Injection started @ 40 cc/hr. & D5W to KVO started. & #20 Jelco L wrist X-1 stick. 1500 Demerol 125 mg IV slowly for yo H.A. Jelco drawn. EKG done [redacted]
1600 Sleepy "Feels better," when awoken [redacted] Dr. [redacted] talked & Dr. [redacted] and Dr. [redacted] & orders to admit to ICU under [redacted]
1620 BPV. 1/26/99. Reglan 2 50 cc/hr as instructed by Dr. [redacted] [redacted]
1730 Pt. admitted to ICU & report given to [redacted] BPV. Dr. Denis C.P. Denies H.A. "it's gone now." Laughing. Cheerful. Personal belongings & Pt. [redacted]

GOAL: MET ☐ UNMET ☐

ADMISSION SUMMARY

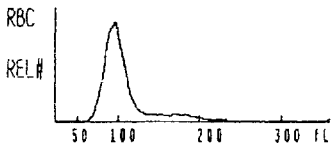
CALLED FOR BED 1600 AVAILABLE @
REPORT CALLED @ [redacted] TO 1730.
PT TOA @ BY
STATUS STABLE UNSTABLE UNCHANGED
NURSING SIG: [redacted]
NURSING SIG: [redacted]
NURSING SIG:

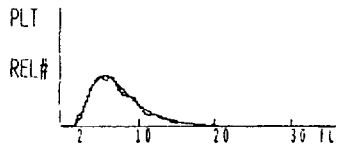
Adverse Event Project # 1310
[redacted] HRB 3/26/99
Exhibit # 1 Pg 3 of 16

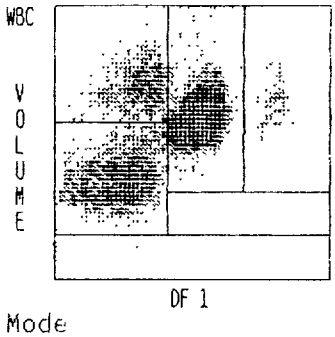
000004

[redacted]

09/09/98 15:18:07 DR [redacted]







Mode P CBC+Diff ID# [redacted] DATE: 09/09/98 TIME: 15:17:49

ID# [redacted]

Location [redacted]
Physician [redacted]
Date of Birth [redacted] Sex F
Comments

Sequence #
Date & Time 09/09/98 15:05
Drawn By: [redacted]
Run By: [redacted]
Reviewed By: [redacted]

Normal WBC Pop			Normal RBC Pop			Normal PLT Pop	
WBC	9.3		RBC	4.05	L	PLT	246
NE%	59.2		HGB	13.9		MPV	7.7
LY%	29.0		HCT	39.7			
MO%	9.2		MCV	98.0			
EO%	1.5		MCH	34.3	H		
BA%	1.1	H	MCHC	35.0			
NE#	5.5	H	RDW	12.4			
LY#	2.7						
MO#	0.9	H					
EO#	0.1						
BA#	0.1						

NORMAL RANGES

WBC	MF	4.8- 10.8	RBC M	4.70- 6.10	F	4.20- 5.40	PLT MF	130- 400
NE%	MF	43.0- 65.0	HGB M	14.0- 18.0	F	12.0- 16.0	MPV MF	7.4- 10.4
LY%	MF	20.5- 45.5	HCT M	42.0- 52.0	F	37.0- 47.0		
MO%	MF	5.5- 11.7	MCV M	80.0- 94.0	F	81.0- 99.0		
EO%	MF	0.9- 2.9	MCH MF	27.0- 31.0				
BA%	MF	0.2- 1.0	MCHC MF	32.0- 36.0				
			RDW MF	11.5- 15.5				
NE#	MF	2.2- 4.8						
LY#	MF	1.3- 2.9						
MO#	MF	0.3- 0.8						
EO#	MF	0.0- 0.2						
BA#	MF	0.0- 0.1						

Microscopic

WBC Diff
Neut _____ Meta _____
Band _____ Myelo _____
Lymph _____ Pro _____
Mono _____ Blast _____
Eos _____ Atyp _____
Baso _____ NRBC _____
Toxic Gran _____

RBC Morph
Aniso _____ Baso Stip _____
Macro _____ Sphero _____
Micro _____ Target _____
Hypo _____
Poly _____ PLT Est _____
Poik _____

Comments _____
Sig/Rev _____ Date _____

[redacted]

9-9-98
19 45 [redacted]

Ica

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

000005

Exhibit # 1 Pg 11 of 16

[redacted]

LABORATORY DIRECTOR: [redacted]

PATIENT: [redacted] [redacted]
Sample ID: [redacted]
SEX: F AGE: 45 ROOM: [redacted]
DRAWN BY: [redacted]

PHYSICIAN: [redacted]
CUP NO: [redacted] TRACK NO: [redacted]
COMMENT:
TECH: [redacted]

TEST	RESULT	UNIT	STATUS	NORMAL RANGE
GLUCOSE	117.	mg/dL	HI	65. - 110.
BUN	8.	mg/dL		7. - 18.
CREATININE	.6	mg/dL	LO	.7 - 1.5
SODIUM	139.	mmol/L		137. - 145.
POTASSIUM	4.8	mmol/L		3.6 - 5.0
CHLORIDE	102.	mmol/L		98. - 107.
ALBUMIN	3.6	g/dL		3.1 - 4.7
ALKP	97.	U/L		38. - 126.
AST	25.	U/L		5. - 40.
TOTAL BILI	.5	mg/dL		.2 - 1.0
CALCIUM	10.7	mg/dL	HI	8.4 - 10.2
CK [redacted]	93.	U/L		30. - 170.
LDH	393.	U/L		313. - 618.
TOTAL PROTEIN	6.6	g/dL		6.1 - 8.1
A/G RATIO	1.2			1.0 - 2.2
BUN/CREATININE	13.3			7.0 - 25.0

TIME RUN: 15:29:14
DATE RUN: Sep 09 98

REPORT TIME: 15:37:48
REPORT DATE: 09/09/98

Chem 12
[redacted]
1945 h
9-9-98
ICU

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

000006

Exhibit # 1 Pg 9 of 16

[redacted]

LABORATORY DIRECTOR: [redacted]

PATIENT: [redacted]
Sample ID: [redacted]
SEX: F AGE: 45 ROOM: [redacted]
DRAWN BY: [redacted]

PHYSICIAN: [redacted]
CUP NO: [redacted] TRACK NO: [redacted]
COMMENT:
TECH: [redacted]

TEST	RESULT	UNIT	STATUS	NORMAL RANGE
ALBUMIN	3.6	g/dL		3.1 - 4.7
ALKP	99.	U/L		38. - 126.
ALT	36.	U/L		7. - 56.
AST	26.	U/L		5. - 40.
TOTAL BILI	.5	mg/dL		.2 - 1.0
UNCONJ. BILI	0.0	mg/dL		0.0 - 1.1
DIRECT BILI	.4	mg/dL		

TIME RUN: 20:42:30
DATE RUN: Sep 09 98

REPORT TIME: 20:49:58
REPORT DATE: 09/09/98

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

000007

Exhibit # 1 Pg 10 of 16

[redacted] 9 SEP 1998 15:21:08 [redacted]

000008

. NORMAL SINUS RHYTHM, RATE 82
. DIFFUSE NONSPECIFIC T WAVE ABNORMALITIES

-ABNORMAL ECG-

NSR
Anterior Tw D

[redacted]

HORIZONTAL

RATE	82
PR	149
QRSD	91
QT	383
QTC	447

Adverse Event Project # 13167

[redacted]

3/26/99 HRB

--AXIS--

P	47
QRS	21
T	-25

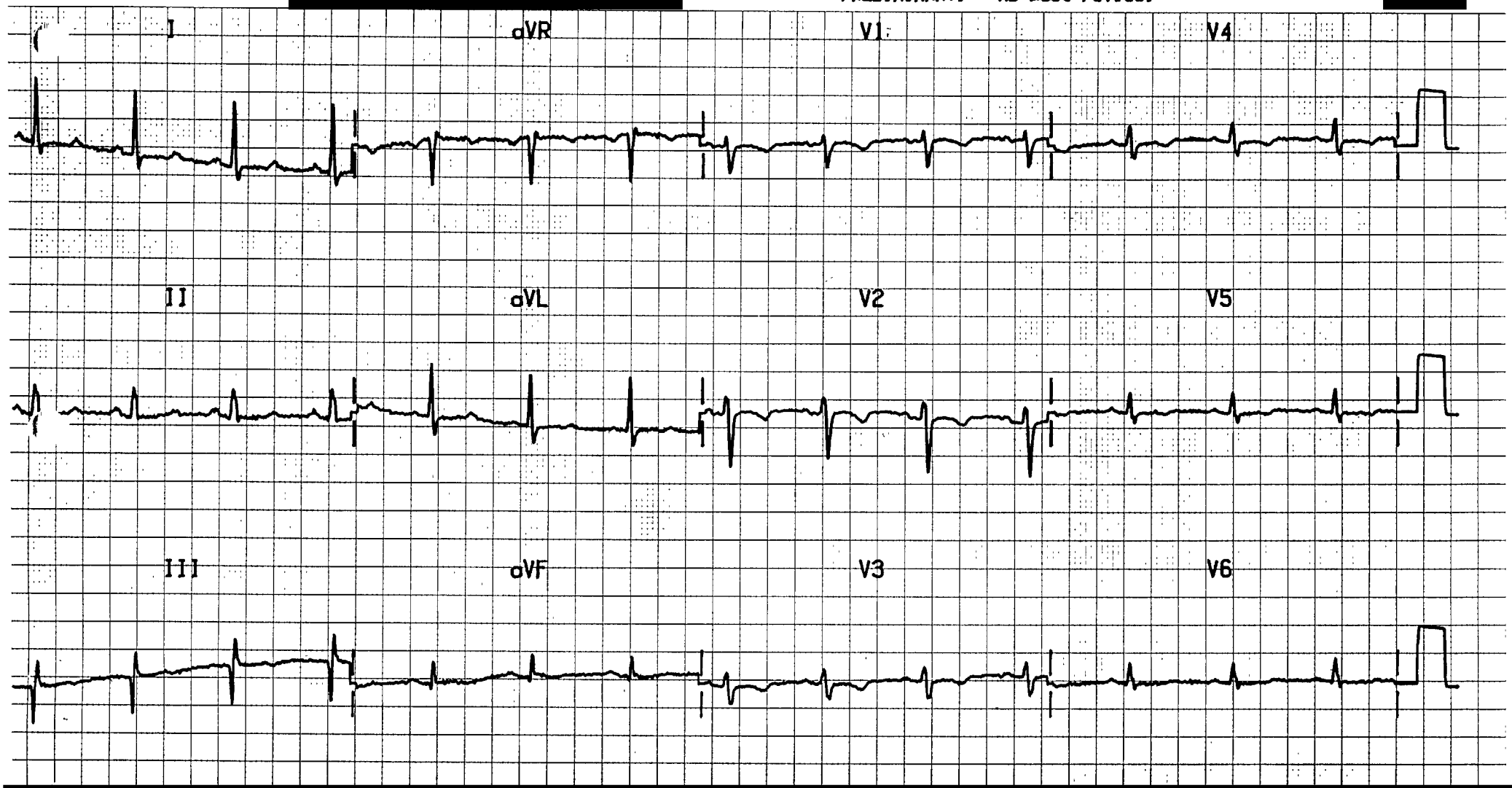
Exhibit # 1 Pg 16 of 16

FRONTAL

[redacted]

PRELIMINARY. MD must review.

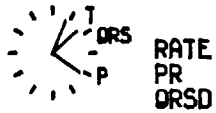
[redacted]



[redacted] 9 SEP 1998 15:21:08 [redacted]

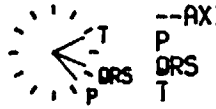
. NORMAL SINUS RHYTHM, RATE 82
. DIFFUSE NONSPECIFIC T WAVE ABNORMALITIES

-ABNORMAL ECG-



RATE	82
PR	149
QRSD	91
QT	383
QTC	447

HORIZONTAL



--AXIS--

P	47
QRS	21
T	-25

FRONTAL

Adverse Event Project # 13167 [redacted]

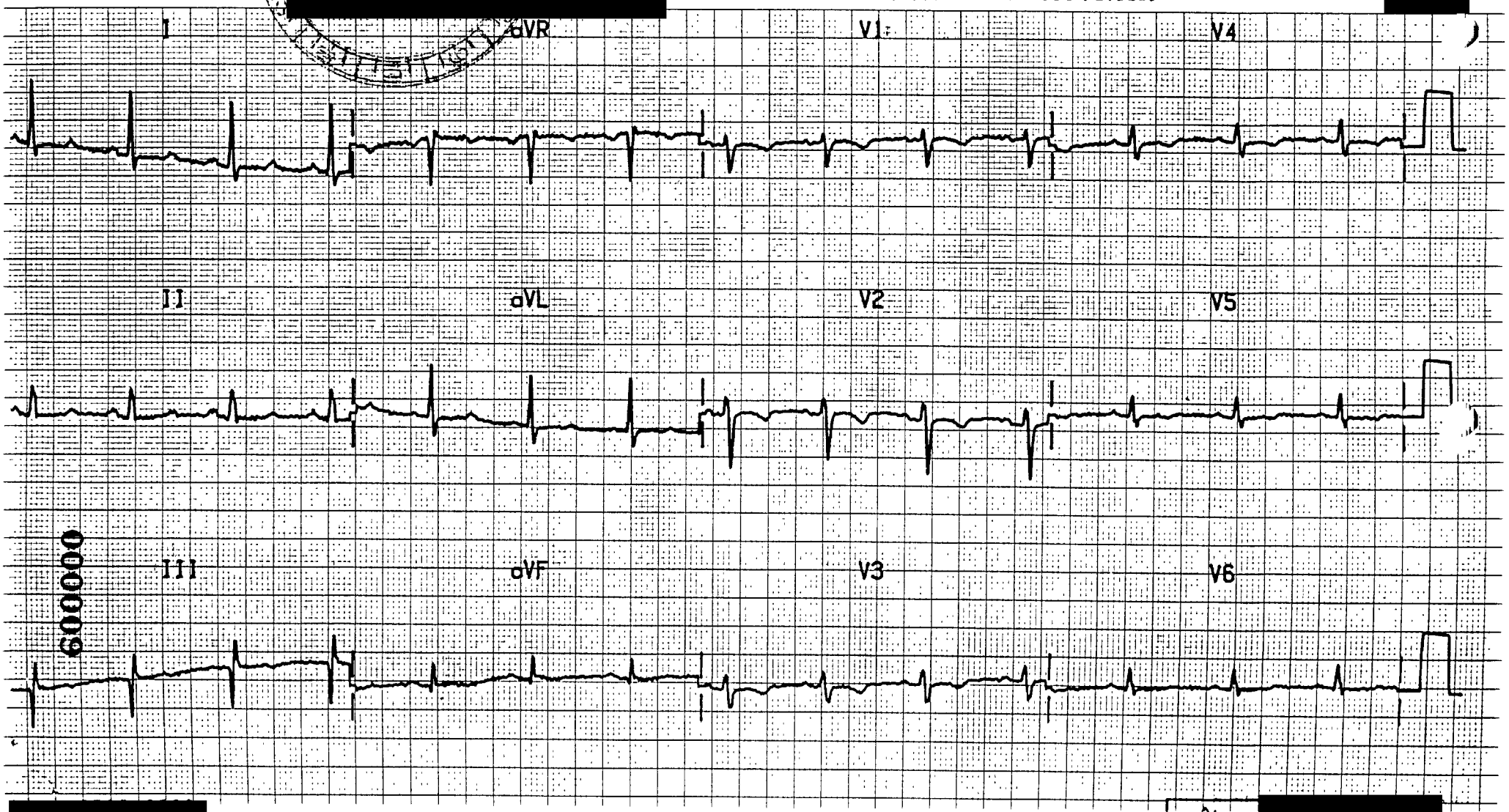
[redacted] 3/26/99 HRB

[redacted] Exhibit # 2 Pg 17 of 36

[redacted]

PRELIMINARY. MD must review.

[redacted]



[redacted]

53 years Female

Room: [redacted]
Oper: [redacted]

Rate	75
PR	161
QRSD	93
QT	361
QTc	403

. Normal sinus rhythm, rate 75
. Nonspecific Inferior T abnormalities

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

Exhibit # 4 Pg 19 of 19

PT. [redacted]
DOB [redacted]
Requested by: [redacted]

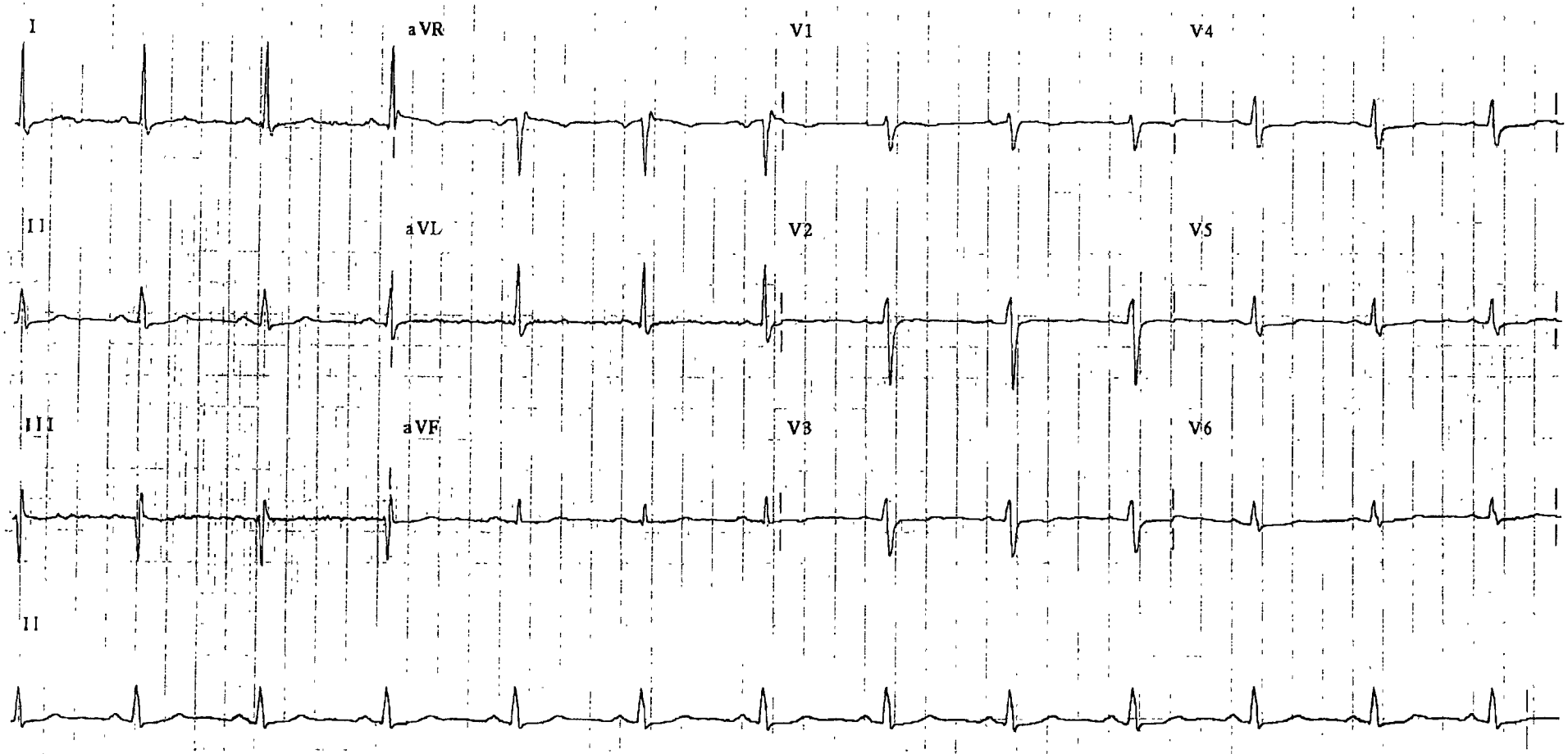
000010

--AXIS--

P	43
QRS	16
T	-6

- BORDERLINE ECG -

REVIEWED BY.



LOC [redacted] Speed:25 mm/sec Limb:10 mm/mV Chest:10 mm/mV

F 60∿ 0.5-150 Hz W HP708 287?

[redacted]

[redacted]