

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

ARMS#

12733



7 - PROCEDURES

000001

12-22-97
8:41P



CARDIAC PROFILE

11:45:08 12-22-1997

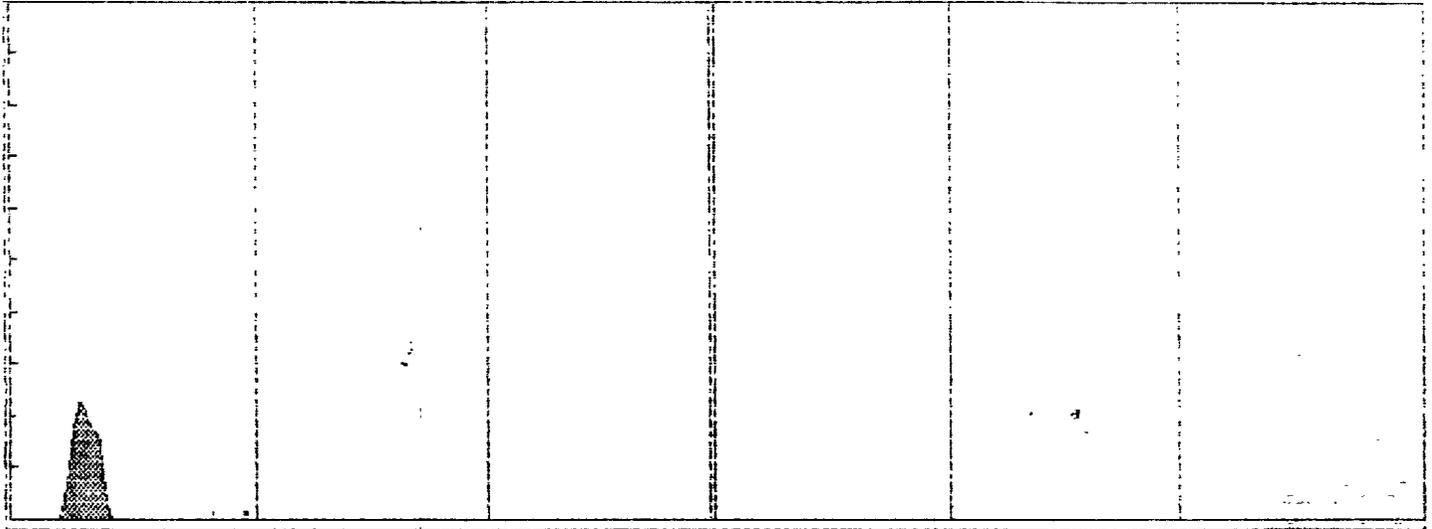
FINAL REPORT

NAME :
ID # :
ROOM # :
AGE-YEARS : 47

SEX : M
PHYSICIAN :
TECH ID :
ACC # :

CPK

LDH ISOENZYMES



CPK

LDH

DATE DRAWN: 12-22-97
TIME DRAWN: 0040

Frac	%	IU/L
MM	100.00	512.00
MB	0.00	0.00
BB	0.00	0.00

Frac
1
2
3
4
5

Totals 512.00

Totals
LDH 1:2 Ratio

Reference ranges (IU/L):
Total CPK 50.00-170.00 MM
Total LDH

CARDIAC PROFILE COMMENTS:
SEE COMPUTERIZED REPORT FOR HIS INTERPRETATION.



000002

REVIEWED BY

47 yrs Male White

22 DEC 1997 BP 16/

4:29:47

PR	167
QRSD	90
QT	373
QTc	430
--AXES--	
P	28
QRS	-20
T	116

Normal sinus rhythm, rate 80
 Late transition
 Consider left atrial enlargement
 Nonspecific lateral T wave abnormalities
 Cannot exclude ischemia

- ABNORMAL ECG -

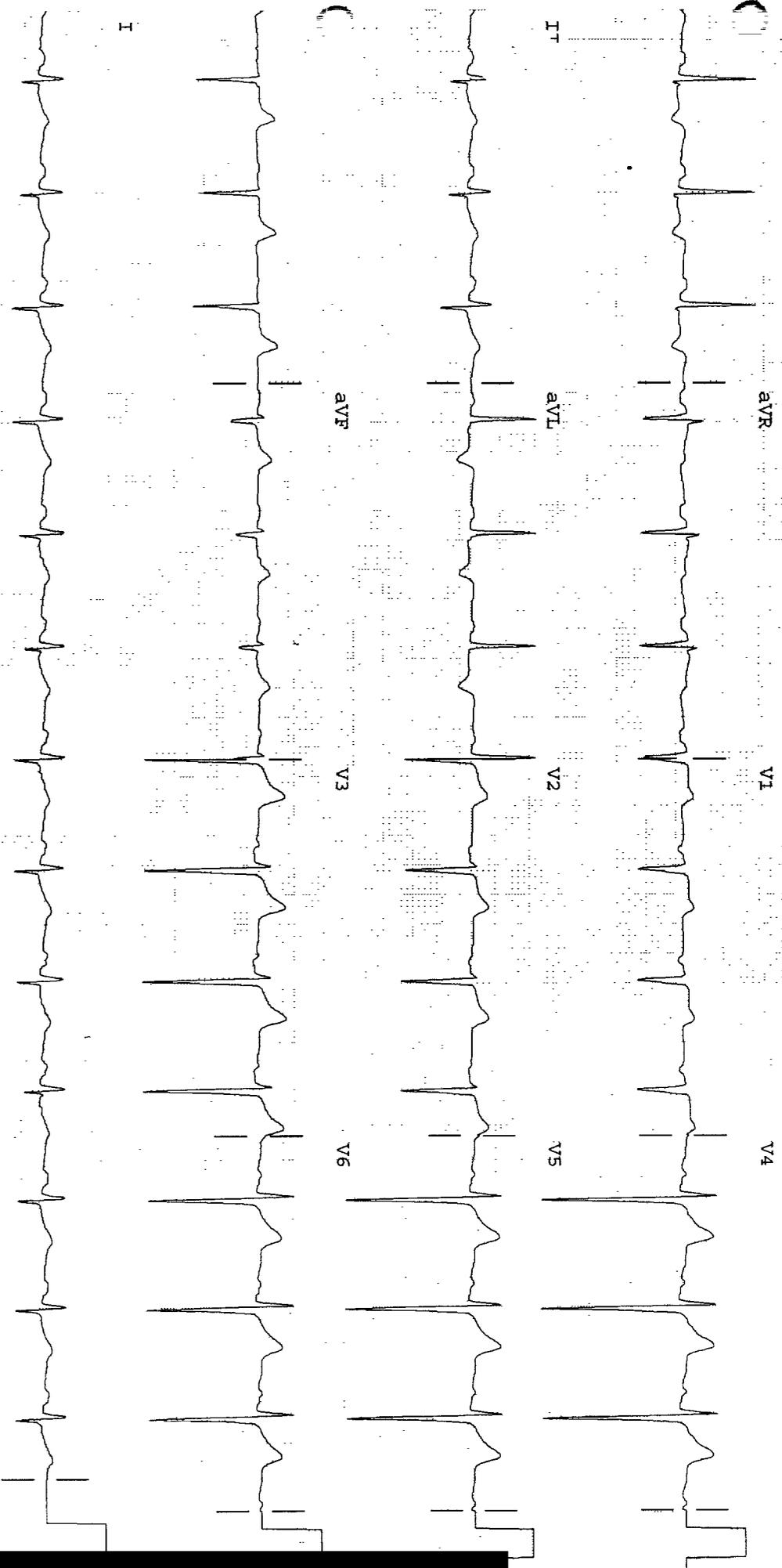
FIN: [redacted]
 PRIORITY 2

Requested by

Tech [redacted]
 Room [redacted]
 Edited [redacted]

- 22 DEC 1997 15:43:18

000003



Loc [redacted]

25 mm/sec 10.0 mm/mV

F ~ W 0.50-150

12/16/97 08:00

PAGE 001

MR#: [REDACTED] ACCT#: M 47 DIAGNOSTIC RADIOLOGY RESULTS
SERV: [REDACTED]
MD: [REDACTED] ADM: [REDACTED] REQ#: [REDACTED]
DX: [REDACTED]

CONSULTING MD: [REDACTED]

ORDER: CHEST, PORTABLE 58 [REDACTED]
INDICATIONS: --R/O INFILTRATE.

RADIOLOGIST: [REDACTED] STENO: [REDACTED]

12/15/97

PORTABLE CHEST

HX: SHORTNESS OF BREATH

THE HEART SIZE IS ENLARGED. THE TRACHEA IS MIDLINE. PULMONARY VASCULARITY IS NORMAL. THERE ARE NO ACTIVE INFILTRATES. NO PLEURAL FLUID IS SEEN.

OPINION:

- 1. CARDIOMEGALY.
- 2. NO ACTIVE INFILTRATES.

Dictated 12-15-97

[REDACTED]

LAST PAGE

-*-

000004

12/13/97 12:01

MR#: [REDACTED] M 47
SERV: [REDACTED] ACCT#: [REDACTED]
MD: [REDACTED] ADM: 12/13/97
DX: INTER CERBRAL BLEED

VERIFIED RADIOLOGY RESULTS

CONSULTING MD: [REDACTED]

ENTERED FOR: [REDACTED]

REQ#: [REDACTED]

EXAM: OUTSIDE FILM PROCESSING [REDACTED]

INDICATIONS: ORDERED BY RADIOLOGY

RADIOLOGIST: [REDACTED] STENO: [REDACTED]

OUTSIDE FILM PROCESSING
12-13-97

OUTSIDE FILM PROCESSING

HX LEFT HEMIPARESIS

OFFERED FOR INTERPRETATION IS A CT SCAN OF THE HEAD FROM [REDACTED]
[REDACTED] IN [REDACTED] DATED 12-12-97.

THE STUDY WAS DONE WITHOUT CONTRAST AND DEMONSTRATES A 4 X 2.5 CM
HYPERTENSIVE HEMORRHAGE IN THE RIGHT BASAL GANGLIAR REGION. IT IS IN
THE LENTIFORM NUCLEUS. IT HAS SOME LOCALIZED MASS EFFECT WITH MILD
MIDLINE SHIFT BUT NO TRANSTENTORIAL HERNIATION. THERE IS EFFACEMENT
OF THE RIGHT LATERAL VENTRICLE.

THERE ARE NO OTHER AREAS OF INTRACRANIAL HEMORRHAGE AND THERE IS NO
EVIDENCE OF ANY NON-HEMORRHAGIC INFARCTION.

WHAT IS SEEN OF THE SINUSES ARE CLEAR.

THE CHEST X-RAY SHOWS THAT THE PATIENT IS OBESE AND HAS CARDIOMEGALY.
THE LUNG FIELDS ARE CLEAR. THERE ARE NO INFILTRATES OR
CONSOLIDATIONS.

IMPRESSION;

- 1. CARDIOMEGALY WITH A HYPERTENSIVE BLEED IN THE RIGHT LENTIFORM
NUCLEUS.

DICT: 12-13-97 [REDACTED]

LAST PAGE

000005

DIAG RADIOLOGY

12/15/97 13:41

MR#: [REDACTED] ACCT#: [REDACTED] M 47
SERV: [REDACTED]
MD: [REDACTED] ADM: 12/13/97
DX: INTER CERBRAL BLEED

~~~~~  
VERIFIED C.T. / M.R.I. RESULTS  
~~~~~

CONSULTING MD: [REDACTED]

ENTERED FOR: [REDACTED]

REQ#: [REDACTED]

EXAM: CT, HEAD WITHOUT CONTRAST [REDACTED]

INDICATIONS: --F/U HEMORRHAGE; PT SLEEPY NOW. R/O SHIFT OR PROGRESSION.
RADIOLOGIST: [REDACTED] STENO: [REDACTED]

CT, HEAD WITHOUT CONTRAST [REDACTED]
12/15/97

CT, HEAD WITHOUT CONTRAST

IND: STATUS POST INTRACRANIAL HEMORRHAGE WITH SOMNOLENCE

COMMENT:

UNENHANCED CT EXAMINATION OF THE HEAD WAS PERFORMED AND COMPARED TO AN OUTSIDE CT OBTAINED AT [REDACTED] DATED 12-12-97.

AGAIN NOTED IS A LARGE PARENCHYMAL HEMORRHAGE IN THE RIGHT BASAL GANGLIA REGION WITH SURROUNDING VASOGENIC EDEMA AND MASS EFFECT. THERE IS STABLE MASS EFFECT ON THE RIGHT LATERAL VENTRICLE WITH NO SIGNIFICANT MIDLINE SHIFT. THERE IS NO HYDROCEPHALUS OR INTRAVENTRICULAR HEMORRHAGE.

IMPRESSION:

STABLE PROMINENT PARENCHYMAL HEMORRHAGE IN THE RIGHT BASAL GANGLIA REGION WITH MASS EFFECT. NO SIGNIFICANT INTERVAL CHANGE. NO SIGNIFICANT MIDLINE SHIFT.

Dictated 12-15-97

[REDACTED]

LAST PAGE

000006

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C.T./M.R.I.  
~~~~~

12/17/97 11:48

M 47

MR#: [REDACTED] ACCT#: [REDACTED]
SERV: .. [REDACTED]
MD: [REDACTED] ADM: 12/13/97
DX: INTER CERBRAL BLEED

~~~~~  
VERIFIED RADIOLOGY RESULTS  
~~~~~

CONSULTING MD: [REDACTED]

ENTERED FOR: [REDACTED]

REQ#: [REDACTED]

EXAM: PORTABLE ABDOMEN NG/FEEDING TUBE 7 [REDACTED]

INDICATIONS: --FEEDING TUBE PLACEMENT

RADIOLOGIST: [REDACTED] STENO: [REDACTED]

PORTABLE ABDOMEN NG/FEEDING TUBE 7

12/16/97.

ABDOMEN FEEDING TUBE

RADIOPAQUE TIP OF THE NASOGASTRIC FEEDING TUBE APPEARS IN SATISFACTORY POSITION WITHIN THE STOMACH.

IMPRESSION:

SATISFACTORY POSITION OF FEEDING TUBE.

12/17/97

LAST PAGE

000007

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[REDACTED]  
DIAG RADIOLOGY

12/18/97 14:14

M 47

MR#: [REDACTED] ACCT#: [REDACTED]  
SERV: .. [REDACTED]  
MD: [REDACTED] ADM: 12/13/97  
DX: INTER CERBRAL BLEED

===== VERIFIED RADIOLOGY RESULTS =====

CONSULTING MD: [REDACTED]

ENTERED FOR: [REDACTED]

REQ#: [REDACTED]

EXAM: VIDEOfLUROSCOPIC SWALLOW [REDACTED]

INDICATIONS: --SIGNS OF DYSPHAGIA NOTED AT BEDSIDE

RADIOLOGIST: [REDACTED] STENO: [REDACTED]

VIDEOfLUROSCOPIC SWALLOW

12-18-97

VIDEOfLUROSCOPIC SWALLOW

THE PATIENT SWALLOWED 3 AND 10 CC'S OF THICK BARIUM, 3 AND 10 CC'S OF THIN BARIUM, 3 AND 10 CC'S OF BARIUM PUDDING, BARIUM COATED CRACKER, THIN BARIUM FROM A STRAW AND THIN BARIUM FROM A CUP. SWALLOWING MECHANISM WAS INTACT AND THERE WAS NO EVIDENCE OF PENETRATION OR ASPIRATION.

IMPRESSION:

- 1. NORMAL VIDEO SWALLOW WITH NO EVIDENCE OF PENETRATION OR ASPIRATION.

DICTATED 12-18-97

LAST PAGE

===== DIAG RADIOLOGY =====

000008

[REDACTED]

ELECTROENCEPHALOGRAPHY - ELECTROMYOGRAPHY

Patient: [REDACTED]  
Age....: 47

Date: 12/16/97  
Fin #: [REDACTED]  
MR #: [REDACTED]  
Room: [REDACTED]

REPORT OF ELECTROENCEPHALOGRAM

EEG #: [REDACTED]

\*REFERRING PHYSICIAN: [REDACTED] M.D.

\*REASON FOR THIS REQUEST:

A 47 year old male with a history of left-sided weakness and drowsiness.

This is a digitally-acquired portable (EEG) electroencephalogram performed using a modified 1020 system for the evaluation of mental status changes.

The waking background rhythm consists of predominantly posterior, 9-10 Hz, 40-60 microvolt activity. During drowsiness, the background rhythm increases by 2-3 Hz. Prominent irregular, 2-3 Hz activity is noted over the right frontotemporal region. No sleep is recorded. Hyperventilation was not attempted. Photic stimulation failed to induce any abnormality in the tracing. No epileptiform discharges are noted.

\*IMPRESSION:

This is an abnormal (EEG) electroencephalogram because of the presence of focal slowing over the right hemisphere. This abnormality is consistent with focal central nervous system dysfunction and correlation with radiographic studies and clinical history suggested.

[REDACTED] M.D.

I AUTHORIZE MY TYPED NAME TO SIGNIFY THAT I AUTHENTICATED THIS REPORT.

[REDACTED]  
D: 12/16/97  
T: 12/16/97

000009

# Memorandum to ARMS # 12733

Date: 6/12/98

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

Subject: Medical Records Place 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                                                                 |
|--------------|---------------------------------------------------------------------------------|
| 71           | Nursing notes                                                                   |
|              | Dietitian notes                                                                 |
| 38A          | Respiratory therapy/occupational therapy/physical therapy notes                 |
|              | Clergy notes                                                                    |
|              | Medication records                                                              |
| 18           | Physician's orders                                                              |
|              | Vital signs, fluids, input/output records                                       |
|              | Ventilator records                                                              |
| 6            | Hospital administrative records (e.g., insurance information, living will, etc) |
|              |                                                                                 |
|              |                                                                                 |
|              |                                                                                 |

*V. Cheeseman*  
for Lisa Ginn, MD

000010