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

ARMS#

12609

7 - PROCEDURES

NAME: [redacted] LOC: [redacted] ROOM: [redacted]
DOB: SEX: F
MED REC#: ADMIT: 09/09/97
ACCT #: DR: [redacted]

******** ROUTINE & MICROSCOPIC URINALYSIS [redacted] HEM LAB ********

| TEST: | SOURCE | COLOR | APPEAR | SP GR | pH | GLU | KET | ALBU | HGB |
|---|---|---|---|---|---|---|---|---|---|
| UNITS: | | | | | | | | | |
| LO-HI: | | | | 1.003-1.029 | 4.5-7.8 | NEG | NEG | NEG | NEG |
| 09/09 + 0935 | RAND | YELLOW | CLEAR | 1.008 | 6.0 | NEG | 1+* | NEG | NEG |

======== ROUTINE & MICROSCOPIC URINALYSIS [redacted] HEM LAB ========

| TEST: | NITR | LEUKOCYTE ESTERASE |
|---|---|---|
| UNITS: | | |
| LO-HI: | | |
| 09/09 + 0935 | NEG | NEG |

********** HEMATOLOGIC PROFILE [redacted] HEM LAB **********

| TEST: | WBC | RBC | HGB | HCT | MCV | MCH | MCHC | PLAT CT |
|---|---|---|---|---|---|---|---|---|
| UNITS: | THO/CMM | MIL/CMM | GM/DL | % | U3 | MMG | GM % | K/CMM |
| LO-HI: | 4.1-9.3 | 4.0-5.1 | 12.1-14.9 | 37.0-44.0 | 82.2-94.5 | 27.5-32.2 | 32.5-35.1 | 130-350 |
| 09/09 + 0640 | 7.1 | 4.05 | 12.9 | 37.9 | 93.4 | 31.9 | 34.1 | 252 |

========== HEMATOLOGIC PROFILE [redacted] HEM LAB ==========

| TEST: | MPV | RDW |
|---|---|---|
| UNITS: | U3 | % |
| LO-HI: | | |
| 09/09 + 0640 | 7.9 | 12.9 |

********** DIFFERENTIAL WBC [redacted] HEM LAB **********

| TEST: | NEUT 5PD | LYMPH 5PD | MONO 5PD | EOS 5PD | BASO 5PD |
|---|---|---|---|---|---|
| UNITS: | % | % | % | % | % |
| LO-HI: | 41-67 | 28-42 | 4-8.5 | 0-5 | 0-1 |
| 09/09 + 0640 | 42 | 43* | 10* | 4 | 1 |

H90051 (9/90)

[redacted]

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CONTINUED

NAME: [redacted] LOC: ROOM: [redacted]
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ACCT #: [redacted] DR: [redacted]

********** GENERAL CHEMISTRY [redacted] CHEM LAB **********

| TEST: | GLUCOSE | NA | K | CL | CO2 | UREA N | CREAT |
|---|---|---|---|---|---|---|---|
| UNITS: | MG/DL | MEQ/L | MEQ/L | MEQ/L | MMOL/L | MG/DL | MG/DL |
| LO-HI: | 65-115 | 135-145 | 3.5-5.2 | 99-109 | 21-30 | 7-22 | 0.6-1.2 |
| 09/09 + 0640 | 79 | 140 | 4.0 | 103 | 24 | 6* | 0.6 |

========== GENERAL CHEMISTRY [redacted] CHEM LAB ==========

| TEST: | PROTEIN | ALBUMIN | CALCIUM | PO4 | URIC ACID | CHOL | BILI-T |
|---|---|---|---|---|---|---|---|
| UNITS: | GM/DL | GM/DL | MG/DL | MG/DL | MG/DL | MG/DL | MG/DL |
| LO-HI: | 6.0-8.0 | 3.5-5.2 | 8.6-10.6 | 2.5-4.5 | 2.6-5.8 | 0-200 | 0.1-1.2 |
| 09/09 + 0640 | 6.9 | 4.5 | 8.9 | 4.0 | 3.3 | 169 | 0.6 |

========== GENERAL CHEMISTRY [redacted] CHEM LAB ==========

| TEST: | CK | LD | ALK PHOS | GGT | AST |
|---|---|---|---|---|---|
| UNITS: | IU/L | IU/L | IU/L | IU/L | IU/L |
| LO-HI: | 30-225 | 90-225 | 30-115 | 0-45 | 5-45 |
| 09/09 + 0640 | 46 | 138 | 71 | 34 | 60* |

********* PREGNANCY EVALUATION [redacted] SEROL/IMMUN LAB **********

TEST: BETA-HCG (QUAL) (URINE)

QUANTITATIVE HCG TESTING
EXPECTED HCG RANGE DURING NORMAL PREGNANCY

| TIME AFTER CONCEPTION | TIME AFTER LAST PERIOD | HCG RANGE (MIU/ML) |
|---|---|---|
| WK 1 | 3RD WK | UP TO 50 |
| WK 2 | 4TH WK | UP TO 400 |
| WK 3 | 5TH WK | 100-4000 |
| WK 4 | 6TH WK | 1000-20000 |
| MONTH 2 | | 4000-130000 |
| MONTH 3 | | 30000-200000 |
| 2ND TRIMESTER | | 7000-120000 |
| 3RD TRIMESTER | | 1000-80000 |

09/09 + 0935 NEG

********* ENDOCRINE (THYROID FUNCTION) [redacted] CHEM LAB *********

| TEST: | FREE T4 | T3 | TSH |
|---|---|---|---|
| UNITS: | NG/DL | NG/DL | UIU/ML |
| LO-HI: | 0.7-2.0 | 60-181 | 0.6-4.8 |
| 09/09 + 0640 | 1.4 | 123 | 1.4 |

[redacted]
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********** URINE DRUG SCREEN **********

| TEST: / LO-HI: | AMPHETAMINE | BARBITURATE | COCAINE | OPIATE | PHENCYCLIDINE | METHADONE |
|---|---|---|---|---|---|---|
| 09/09 + 0935 | NEGD | NEGD | NEGD | NEGD | NEGD | NEGD |

========== URINE DRUG SCREEN ==========

| TEST: / LO-HI: | BENZODIAZEPINES | CANNABINOIDS |
|---|---|---|
| 09/09 + 0935 | PEND | NEGD |

********** MISC TOXICOLOGY [redacted] CHEM LAB **********

09/09 + 0640 TRICYCLIC DRUG SCREEN
[NEGD]
NEGATIVE FOR DRUG(S) TESTED

********** MICROBIAL ANTIBODIES **********

09/09 + 0640 RPR [NREA] TITER
NONREACTIVE

---FOOTNOTES---
NEGD NEGATIVE FOR DRUG(S) TESTED

[redacted]

[redacted]

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END OF REPORT

# Memorandum to ARMS # 12609 COPY

Date: 26 Aug 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 |
|---|---|
| 27 | Nursing notes |
| | Dietitian notes |
| | Respiratory therapy/occupational therapy/physical therapy notes |
| | Clergy notes |
| | Medication records |
| 4 | Physician's orders |
| | Vital signs, fluids, input/output records |
| | Ventilator records |
| 12 | Hospital administrative records (e.g., insurance information, living will, etc) |
| | |
| | |
| | |