

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

ARMS#

13256



3 - OUTPATIENT

000001

ALLERGIES: See H & P

NAME

BIRTHDATE:

SEX: M-F

DATE

OCT 02 1998

CLINICAL RECORD

DIAGNOSIS

LAB X-RAY

MAY LEAVE

Age 38 Ht. ___ Wt. ___ Tob. ___ Dr. ___
BP ___ T ___ P ___ R ___ Adv. ___ Rm# ___

1. ~~UPT~~
2. Basic metabolic
3. CPK
4. CXR ✓
5. EKG.
6. _____

NURSING ORDERS

38y/o F present in C/O chest
pain @ suprasternal notch. He
began 3 days ago while she was
at work at [redacted] she
given morphine (Toradol) / G.I.
colic which relieved the
pain. The pain came back again
today is radiating to @ Arms
& back. ~~perforated~~ SOB
while driving over home.
@ PULS.

Q/E: bronchitis & NAD
Arteries

Heels are 5 m/mc r/s. 5 se

Low COX B

check normal symmetry, & parasternal
movement but marked tenderness
in palpation of sternal bone esp
@ manubrium

2Lh () ischemic dis

Assoc costochondritis

- Pls (1) Toradol 30mg
(2) Motin 50mg p.o qd for pain
(3) ✓ EKG / SNA 7, CBC, CKP

733.6
[redacted]
786.50
09/30/98

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October 5, 1998

A 38 year old woman referred by Dr. [REDACTED] [REDACTED] is under the care of Dr. [REDACTED] for Graves disease and she was diagnosed in February of 1997. She has been well controlled since July, 1998, and is taking PTU.

The patient has been under the care of Dr. [REDACTED] for infertility evaluation and treatment. She has had 4 pregnancies, 3 miscarriages in 1980, 1984 and 1986, all in the first trimester. She gave birth to a healthy male infant in 1982. This summer she was found to have anticardiolipin antibody IgM at 91.6 and was encouraged, at that time, to see a rheumatologist. We had not been able to schedule her appointment due to scheduling conflicts. She has no history of deep vein thrombophlebitis and has had no arthralgias or arthritis until the past month when she has noted slight pain in her knees with morning stiffness which is fairly short lived. None of the joints have been acutely red, hot or tender. She has no history of nasal or mouth ulcers, Raynauds, renal disease. She feels that there is thinning of her frontal scalp but has not had areas of discreet alopecia. There is no history of seizures, dry eyes or dry mouth.

On September 30, 1998, the patient developed a relative acute upper anterior chest pain which was aggravated with coughing, sneezing and deep breathing. She was seen in the Emergency Room at [REDACTED] and had a chest x-ray and EKG which were within normal limits. A troponin was within normal limits. She was treated with Toradol, Vicodin, Motrin and eventually with morphine sulfate. She was discharged home and during that night developed some nausea and vomiting. She took off work the next day, was able to work on October 2, 1998, but while at work, had a return of heaviness in her chest radiating into her back and into the left arm which was markedly pleuritic. She was seen in the Emergency Room at the [REDACTED] and she was informed that she had inflammation in the sternum and a rib. She feels that the pain is worse when she lies in the supine position and when she lies on her right side. She has had to sleep either upright or in the left lateral decubitus position. She has not had any coughing, chills, fevers, may have had a night sweat on the evening of September 30, 1998. She is not sure if this was related to the morphine sulfate.

Over the past 3 months, the patient has been taking a product known as Metabolife. She has found that her sleep has become extremely restless and her legs are in constant motion over the last month. She has been able to lose 30 pounds in the past 3 months. She usually retires at 10:00 p.m., arises at 5:00 a.m. and awakens numerous times during the night. She is certain that she awakens 2 or 3 times per night for pain. The components of Metabolife include royal jelly, spirulina, algae, gofu-kola, nettles, golden seal, sarsaparilla, damina, bovine complex, lectin, ginseng, bea pollen and Ma-huang. There is also chromium picolinate, zinc and magnesium. In approximately the past week the patient has developed a raised, annular, nonpruritic lesions over the forearms bilaterally. She has not had excessive sun exposure.

PAST MEDICAL HISTORY: Essentially unremarkable for chronic illnesses. She has had no hypertension, heart disease, hepatitis, jaundice, tuberculosis, diabetes or asthma. She has no known allergies. Surgeries have included a tonsillectomy and a C-section. She has had all of her immunizations.

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FAMILY HISTORY: Negative for inflammatory arthropathy.

SOCIAL HISTORY: Patient is married. She has a 16 year old son. She drinks alcohol on an occasional basis and does not smoke. Does not use intravenous drugs.

PHYSICAL EXAMINATION: Examination shows a 5 feet, 5 3/4 inches tall woman who weighs 199 pounds. Blood pressure is 138/84. Pulse is 76 and regular. **HEENT:** Conjunctivae are clear. Pupils are round and reactive to light and accommodation. Extraocular movements are intact. Ears and nose are unremarkable. Mouth: Tongue in the midline, there is a good saliva pool. Teeth are in good repair and there are no oral ulcerations. Neck shows no adenopathy or thyromegaly. Chest expands well and there are no rales, rubs, rhonchi or wheezes. Heart shows a normal S1-S2, with no murmur, gallop or click. No rub is heard lying supine or sitting upright and in a forward position. She is modestly tender on palpating costosternal junction numbers 2 through 4 bilaterally. The abdomen is soft and benign, without organomegaly. Extremities show no cyanosis, clubbing or pitting of the fingernails and pulses are full. Skin evaluation shows several raised, annular, papules which are slightly darker than her skin, which is tanned, over the forearms bilaterally. Joint examination shows no synovial pathology in the small hand joints, wrists, elbows, shoulders, knees, ankles or MTPs.

Limited lab studies from [REDACTED] show the positive anticardiolipin antibody Igm at 91.6. Her FANA is positive in a homogenous pattern 1:40.

ASSESSMENT:

1. Upper chest wall pain which appears to have a pleuritic component but no rub is heard.
2. Anticardiolipin antibody syndrome--conceivably related to the numerous miscarriages in the past.
3. Suspect that we are dealing with marked toxicity from the Metabolife which she is taking. Her sleep has been markedly disturbed, her legs are restless and the skin lesions over her forearms may be a side effect from this medication.

PLAN:

1. Cardiac echo to rule out a pericardial effusion.
2. Discontinue Metabolife and force fluids.
3. Continue PTU and Motrin.
4. Maintain contact with the office in the next 1 to 2 weeks for her progress report

[REDACTED], M. D.

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Dr. [REDACTED] Patient Name [REDACTED] Person Calling *pt.*
 Rec'd By [REDACTED] Date *12/14/98* Time _____ Phone #1 [REDACTED]
 Message *has been having a lot of problems until 3 or after 6
 and would like to have lab work done at [REDACTED]
 stiffness + pain in ankles + knees before appt
 @ thumb, ankle, knee med
 Wants bloodwork done for lupus / is going through in vitro + carbonyl*
 Reply [REDACTED] *repeat ANA, sched appt*

DEC 23 1998

B/P: 116/78

[REDACTED] indicates that she has been having pain in her left knee for the past three or four weeks. She has also had a very transient and low-grade aching in a number of the small hand joints including the right fourth PIP and the left third MCP. The left wrist has also been mildly achy. There has been no obvious swelling in the hands or wrists, but she feels that the left knee is obviously swollen. She has discomfort particularly when ascending and to a lesser extent descending stairs and is aware of crepitation in the knee. There is no history of knee injury and the knee is not locking or buckling. It has not been red or warm. She is not taking anti-inflammatory medication other than occasional Ibuprofen.

Her sleep disorder and restless leg syndrome resolved when she discontinued Metabolife. She has had no further episodes of pleuritic type chest pain. There have been no nasal or mouth ulcers, alopecia or palpitations. No dyspnea on exertion, cough, sputum production or chills. The skin lesions over the dorsum of her forearms have resolved completely. She remains on low-dose Aspirin 81mg per day to treat her anti-cardiolipin antibody disease.

Remains under the care of Dr. [REDACTED] for infertility and plan is to have another in vitro in January.

EXAMINATION: Blood pressure on the left in the sitting position 116/78, pulse is 74 and regular. HEENT shows very mild pupillary irregularity with the left pupil approximately 1mm larger than the right. The pupils react to light and accommodation and conjunctivae are clear. Extraocular movements are full. Mouth is unremarkable. Neck shows no adenopathy or thyromegaly. Chest is clear without rales, rubs, rhonchi or wheezes. Heart sounds are crisp and normal with no murmur, gallop or clicks. No accentuation of the second heart sound or split. Abdomen is soft and there is no organomegaly. Extremities show no cyanosis, clubbing or pitting of the fingernails. Pulses are 2+ at the radial, dorsalis pedis and posterior tibial arteries. There are no skin rashes. Joint examination shows no synovial pathology in the small hand joints, wrists, elbows or shoulders. Right knee is normal. The left knee shows a grade 1 effusion without thickening. No Baker's cyst. Negative McMurray's test but there is marked patellofemoral crepitation. No medial or lateral instability and negative anterior and posterior drawer sign. The ankles and MTPs are unremarkable.

PA of both knees and lateral of left knee are normal with no evidence of joint space narrowing, erosion or demineralization. No evidence of fracture.

After sterile prep, 10cc of clear, thick, mucoid, yellowish synovial fluid was aspirated from the left knee and 1cc of Aristospan was injected. CESAN #13256

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December 23, 1998 cont.

PLAN:

- 1. ESR, ANCA to be performed at [REDACTED]
- 2. Synovial fluid analysis-crystal analysis is clear and there are 1-2 WBC/hpf.
- 3. Return in one month.

[REDACTED] - *never Reproductive - ~~has~~*
new fert. specialist - has appt to see 1/27.

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Xray & Lab Reports Sheet

Printed Report:
10/02/98 22:26

[REDACTED]

Lab Director: Dr. [REDACTED]

Last Name: [REDACTED]
 First Name: [REDACTED] Sex: F
 Birthdate: [REDACTED] Age: 38Y
 Collection: 10/02/98 22:00
 Sample Comment:

Loc: [REDACTED]
 Dr: [REDACTED]
 Dr: [REDACTED]
 SID: [REDACTED]

Send by Mail
 Send form only
 Send lab copy
 Call
 (Signature) (time)
 Advise in office
 Dictated letter
 Other
 10/02/98
 (date)

-----Reference Range-----
 Test Name Result Flags Low - High Units Comments

BASIC METABOLIC PROF

Test Name	Result	Flags	Low	High	Units	Comments
GLUCOSE	113	H	70	110	mg/dL	
UREA NITROGEN	17		7	18	mg/dL	
CREATININE	1.0		0.6	1.3	mg/dL	
BUN/CREAT RATIO	17		7	23		
SODIUM	145		136	146	mmol/L	
POTASSIUM	4.8		3.6	5.2	mmol/L	
CHLORIDE	109	H	100	108	mmol/L	
CARBON DIOXIDE	26.5		21.0	32.0	mmol/L	
ANION GAP	14		9	19	mmol/L	
CREATINE KINASE	98		21	232	U/L	

RUN DATE/TIME 10/02/98 22:07
 SPECIMEN ID [REDACTED]
 PATIENT [REDACTED]
 SEX F [REDACTED]
 Dr [REDACTED] DOB [REDACTED]
 OP ID [REDACTED] SEQ [REDACTED]

TEST	RESULT	EXPECTED RANGE
WBC:	10.3 K/uL	4.0-10.0
RBC:	4.45 M/uL	4.04-5.30
HGB:	13.4 g/dL	12.0-16.5
HCT:	38.9 %	36.0-50.0
MCV:	87.6 fL	78.0-99.0
MCH:	30.1 pg	26.5-31.0
MCHC:	34.3 g/dL	31.5-37.0
RDW:	13.4 %	11.6-14.8
PLT:	248. K/uL	150.-450.

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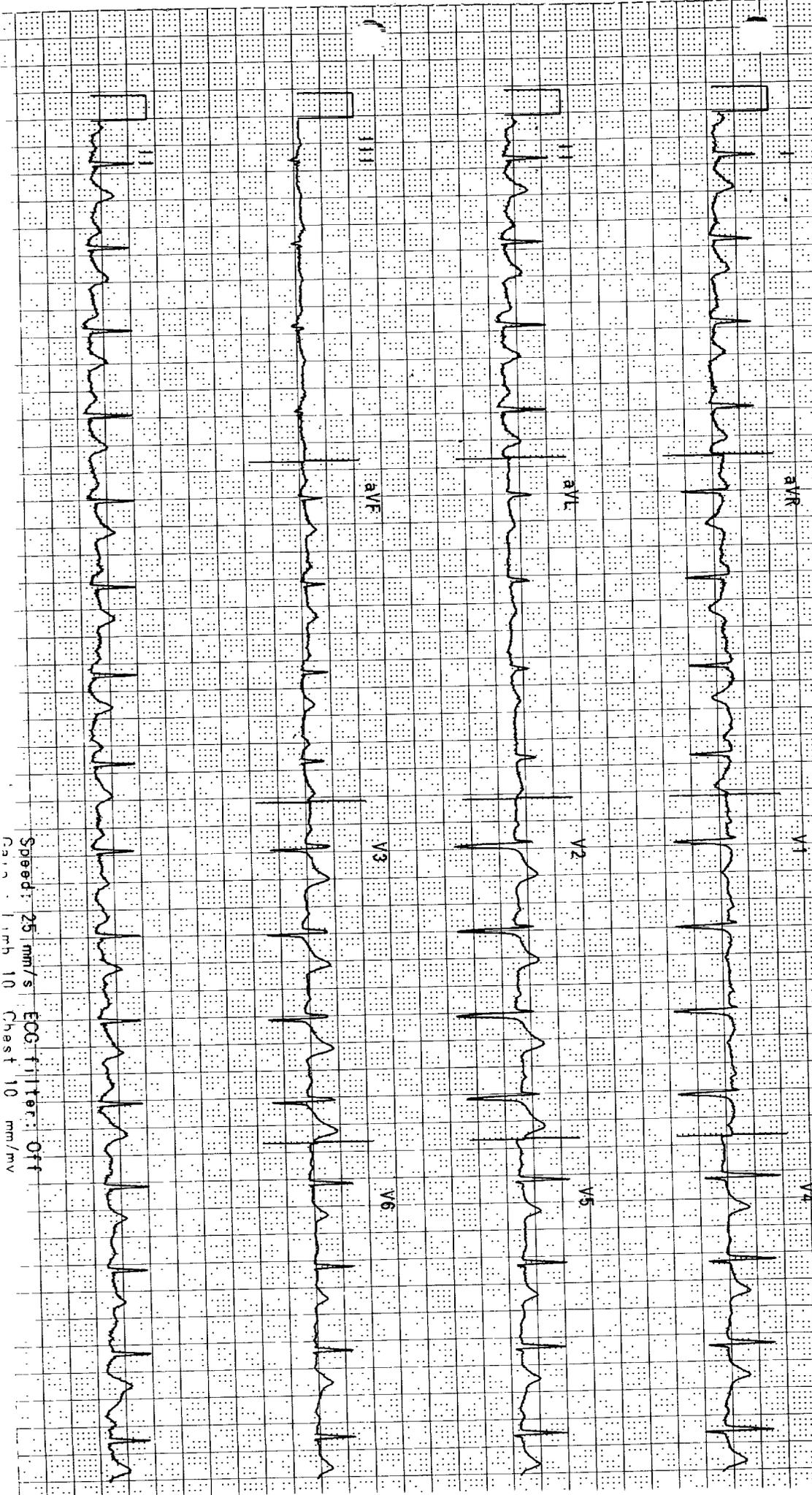
AUTO-DIFFERENTIAL

NEU:	72.4 %	36.0-65.0
LYM:	17.8 %	24.0-44.0
MONO:	6.7 %	0.0-10.0
EOS:	2.3 %	0.0-6.0
PLT:	248	

MD [REDACTED]
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 Exhibit 2 pg 2 of 4

SINUS RHYTHM
NORMAL ECG

Name: [REDACTED]
ID: [REDACTED]
Age: 38 Sex: Female
Hgt: 65 Wgt: 160
B/P: 142/88 Race: Caucasian
Optn:
Med1: Unknown
Med2: None
Tech: [REDACTED] Dr.: [REDACTED]
Site: [REDACTED] Unit: [REDACTED]
Date: 10/02/98 Time: 20:38
Vent Durations Axes
PR QRS QT/QTc P--QRS--T
Rate 96 136 80 344/397 53 26 42



Speed: 25 mm/s
Gain: 1 mmh 10
ECG filter: Off
Chest 10 mm/mv

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