

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

ARMS#

13345



7 - PROCEDURES

000001

MD

PATIENT: [REDACTED]
AGE: 22 Y SEX: F
DATE OF BIRTH: [REDACTED]
PATIENT ID NO.: [REDACTED]
COLLECTION TECH: [REDACTED]
CHART/INSUR NO: [REDACTED]

SAMPLE ID: [REDACTED]
DRWN: 01/04/1999 00:00
RCVD: 01/06/1999 08:14
PRNT: 01/06/1999 14:35
STATION: [REDACTED]

** COMPLETE REPORT **

ATTENDING PHYS:

CYTOLOGY REPORT

P99-38 Pregnancy
All previous pap smears at IMC are negative.

GYN CYTOLOGY

SOURCE: Cervical and Vaginal
EXAMINED BY: [REDACTED]
PATHOLOGIST: [REDACTED] M.D.

Specimen Adequacy

Satisfactory for interpretation.

DESCRIPTIVE DIAGNOSIS

*NEGATIVE (WITHIN NORMAL LIMITS) *

Additional Comments

Inflammatory (very many wbc's)

Recommendations

Repeat Pap smear as per current recommendations
of the American College of Family Physicians

DIRECTOR : Dr. [REDACTED]

[REDACTED]
1-899
[REDACTED]

[REDACTED]

000003

	(STAMP)
	NAME LAST, FIRST, MI
	MR NUMBER: / D.O.B. SEX F
RADIOLOGICAL CONSULTATION	

USE TYPEWRITER OR
PRESS FIRMLY WITH FINE POINT PEN

I.P. HOSPITAL CLINIC
 NURSING HOME E.R.

ANATOMICAL PART TO BE X-RAYED		X-RAY NO
<i>OB ultrasound</i>		
ADMISSION DIAGNOSIS AND/OR CLINICAL INFORMATION		
<i>dates</i>		<i>11-3-98</i> <i>8-9-99</i> <i>13w 0d</i>
DATE TAKEN	DATE READ	ATTENDING PHYSICIAN
<i>2/2/99</i>		

FINDINGS:

2-2-1999

medWatch Report #13345
 Follow-Up Adverse Report
 Thomas S. Donaldson 03-19-99
 Exhibit *6* page *14* of *22* TSD
TD

OB ULTRASOUND

Pt. was examined with transabdominal and transvaginal transducers.

A single intrauterine embryo is present. It measures 23 mm. in length, corresponding to a menstrual age of 9 weeks. No embryonic cardiac activity was seen during the prolonged observation with the transvaginal transducer.

The gestational sac is somewhat irregular in contour. A small amount of subchorionic fluid is seen posteriorly.

INTERPRETATION: Findings indicate embryonic demise at approximately 9 menstrual weeks.

D & C done

02-2/T2-3

CHARGE CODES:

SIGNED _____ RADIOLOGIST

000004

02/03/99

Phone: [REDACTED]
Fax #: [REDACTED]

PT Adrs:

Exam performed by: [REDACTED]

Patient Phone#:

CLINICAL HISTORY: MISSED AB

1 76857TC US PELVIS

LIMITED PELVIC ULTRASOUND 2-3-99:

This exam was completed portably in the operating room by the ultrasound technologist with Dr. [REDACTED] in attendance.

The submitted images demonstrate that initially there is endometrial thickening with a 5 mm. fluid collection in the endometrium near the internal cervical os. The size of the endometrial cavity on this single view is approximately 1.5 by 4 cm., and there is heterogeneous echogenicity. After instrumentation, this area of endometrial thickening was essentially completely removed with the endometrial thickness being between 5 and 10 mm. on the final view.



File

medWatch Report #13345
Follow-Up Adverse Report
Thomas S. Donaldson 03-19-99
Exhibit 6 page 15 of 22 *TS*

D:02/03/99 T: 02/03/99 14:31

[REDACTED] M.D.

MR#: [REDACTED] Age: 22 Sex: F
Family Physician: [REDACTED]
Ordering Physician: [REDACTED]

Visit Type: I Room #: [REDACTED]
Seq#: [REDACTED] DOS: 02/03/99
Image#: [REDACTED]

02/03/99

Phone: [REDACTED]

Fax #: [REDACTED]

Exam performed by [REDACTED]

Patient Phone#: [REDACTED]

CLINICAL HISTORY: MISSED AB

1 76857TC US PELVIS

LIMITED PELVIC ULTRASOUND 2-3-99:

This exam was completed portably in the operating room by the ultrasound technologist with Dr. [REDACTED] in attendance.

The submitted images demonstrate that initially there is endometrial thickening with a 5 mm. fluid collection in the endometrium near the internal cervical os. The size of the endometrial cavity on this single view is approximately 1.5 by 4 cm., and there is heterogeneous echogenicity. After instrumentation, this area of endometrial thickening was essentially completely removed with the endometrial thickness being between 5 and 10 mm. on the final view.

Information contained on this copy may not be released without the permission of the patient.

medWatch Report #13345
Follow-Up Adverse Report
Thomas S. Donaldson 03-19-99
Exhibit 3 page 02 of 03 JSD

D:02/03/99 T: 02/03/99 14:31

[REDACTED] M.D.

MR#: [REDACTED] DOB: [REDACTED] Age: 22 Sex: F
Family Physician: [REDACTED]
Ordering Physician: [REDACTED]

Visit Type: [REDACTED] Room #: [REDACTED]
Seq#: [REDACTED] DOS: 02/03/99
Image#: [REDACTED]

907

000007

SURGICAL PATHOLOGY	SURGICAL PATHOLOGY NO. [REDACTED]
[REDACTED]	PATIENT NAME: [REDACTED]
	DATE OF BIRTH: [REDACTED] SEX: Female
	HOSPITAL#: [REDACTED] LOC: [REDACTED]

DATE OF SURGERY: February 3, 1999

DATE RECEIVED: February 3, 1999

HOSPITAL/CLINIC: [REDACTED]

ATTENDING PHYSICIAN(s): [REDACTED], M.D.

PREOP. DIAGNOSIS: FETAL DEMISE

SPECIMEN SUBMITTED: UTERINE CONTENTS

GROSS:

The specimen is labeled uterine contents and consists of 200 - 300 cc.'s of blood clot and tissue fragments collected in a suction device. These fragments are examined and some intact tissue found. It is grossly villous and membranous. Representative sections. [REDACTED]

MICRO:

Sections show decidua, blood clot and a few villi. There is some degree of hydropic change with no trophoblastic proliferation.

DIAGNOSIS: UTERINE CONTENTS: PRODUCTS OF CONCEPTION WITH HYDROPIK CHANGE

[REDACTED]
Flags [REDACTED] 2-4-1999

[REDACTED]
[REDACTED] M.D./PATHOLOGIST

medWatch Report #13345
Follow-Up Adverse Report
Thomas S. Donaldson 03-19-99
Exhibit 3 page 03 of 03 TSD
HD

Information contained on this report may not be used for legal action without the permission of the patient.

NAME: [REDACTED]

ADDRESS: [REDACTED]

HOSP. NO.: [REDACTED]

TELEPHONE: [REDACTED]

000008

SURGICAL PATHOLOGY	SURGICAL PATHOLOG NO. [REDACTED]
[REDACTED]	PATIENT NAME: [REDACTED] DATE OF BIRTH: [REDACTED] SEX: Female HOSPITAL#: [REDACTED] LOC. [REDACTED]

DATE OF SURGERY: February 3, 1999

DATE RECEIVED: February 3, 1999

HOSPITAL/CLINIC: [REDACTED]

ATTENDING PHYSICIAN(s): [REDACTED], M.D.

PREOP. DIAGNOSIS: FETAL DEMISE

SPECIMEN SUBMITTED: UTERINE CONTENTS

GROSS:

The specimen is labeled uterine contents and consists of 200 - 300 cc.'s of blood clot and tissue fragments collected in a suction device. These fragments are examined and some intact tissue found. It is grossly villous and membranous. Representative sections. [REDACTED]

MICRO:

Sections show decidua, blood clot and a few villi. There is some degree of hydropic change with no trophoblastic proliferation.

DIAGNOSIS: UTERINE CONTENTS: PRODUCTS OF CONCEPTION WITH HYDROPIK CHANGE

[REDACTED]
 Flags: [REDACTED]-4-1999

Needs quantitative HCG's weekly until "0"

[REDACTED] M.D./PATHOLOGIST

pt. informed to come for blood test

medWatch Report #13345
 Follow-Up Adverse Report
 Thomas S. Donaldson 03-19-99
 Exhibit 6 page 10 of 22 ISD
tb

RECEIVED
 FEB 08 1999

NAME: [REDACTED]
 ADDRESS: [REDACTED]

HOSP. NO.: [REDACTED]
 TELEPHONE: [REDACTED]

000009

PATIENT: [REDACTED]
AGE: 22 Y SEX: F
DATE OF BIRTH: [REDACTED]
PATIENT ID NO.: [REDACTED]
COLLECTION TECH: [REDACTED]
CHART/INSUR NO: [REDACTED]

SAMPLE ID: [REDACTED]
DRWN: 02/11/1999 00:00
RCVD: 02/11/1999 14:16
PRNT: 02/11/1999 15:26
STATION: [REDACTED]

** COMPLETE REPORT **

ATTENDING PHYS: [REDACTED] MD

TEST NAME	NORMAL	OUT OF RANGE	UNITS	REFERENCE RANGE
BETA HCG		823 H	mIU/ml	0-5
	WEEKS POST LMP	APPROX hCG RANGE		
	3-4 weeks	9-130 mIU/ml		
	4-5 weeks	75-2600 mIU/ml		
	5-6 weeks	850-20800 mIU/ml		
	6-7 weeks	4000-100200 mIU/ml		
	7-12 weeks	11500-289000 mIU/ml		
	12-16 weeks	18300-137000 mIU/ML		
	2nd trimester	1400-53000 mIU/ML		
	3rd trimester	940-60000 mIU/ML		

NOTE: Failure to see a normal gestational sac on ultrasonography with serum BhCG levels >6500 is suggestive of ectopic pregnancy.

*** REFERENCE COPY ONLY ***

DIRECTOR : Dr. [REDACTED]

file
[REDACTED]

needs weekly quant HCGs
[REDACTED]

000010