F306: Baseline Pad Test and Voiding Diary Summary, version 03/27/06 (A)

TOMUS

Section A: General Study Information for Office Use Only:

A1. STUDY ID#: LABEL

A2. VISIT BASELINE .....TBAS

A3. DATE FORM COMPLETED: ___ ___ / ___ ___ / ___ ___ ___ ___
MONTH DAY YEAR

A4. IS THIS A REPEAT MEASURE?

YES 1

NO..... 2 ➔**SKIP TO SECTION B**

A5. WHY IS THIS MEASURE BEING REPEATED?

MEASURES EXPIRED 1

PRIOR TEST(S) INVALID..... 2

repeat_meas_pt	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	51	8.59	51	8.59
2	543	91.41	594	100.00

Frequency Missing = 3

why_repeat_pt	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
-2	543	91.41	543	91.41
1	2	0.34	545	91.75
2	49	8.25	594	100.00

Frequency Missing = 3

SECTION B: THE PAD TEST

B1 Are there Pad Test measures to record below? Yes..... 1

No ..... 2 ➔**SKIP TO SECTION C**

PT_DATA	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	594	100.00	594	100.00

Frequency Missing = 3

B2. Date Pad Test Kit distributed: ____ ____ / ____ ____ / ____ ____ ____ ____ B2a. Initials: ____ ____ ____
Month Day Year

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Analysis Variable : PT_DIST_Daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	37.5	29.4	2.0	19.0	31.0	48.0	259.0

PT_DIST_Daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

B3. Number of pads distributed in the Kit: _____ _____

Analysis Variable : TOT_PADS								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	5.0	2.1	1.0	4.0	5.0	6.0	15.0

TOT_PADS	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

↓ PRE-WEIGHTS ↓

B4. DATE PRE-WEIGHTS RECORDED ↓

____ ____ / ____ ____ / ____ ____ ____ ____
Month Day Year

↓ POST-WEIGHTS ↓

B7. DATE POST-WEIGHTS RECORDED ↓

____ ____ / ____ ____ / ____ ____ ____ ____
Month Day Year

Analysis Variable : pre_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	37.8	29.5	2.0	19.0	31.0	48.0	259.0

pre_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

Analysis Variable : post_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	20.3	22.7	0.0	6.0	13.0	26.0	158.0

post_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

B5. INITIALS: ____ ____ ____

B8. INITIALS: ____ ____ ____

B6.	**PAD # a.**	**PRE-WEIGHT b.**	**B9.**	**POST-WEIGHT a.**	**CONTAMINATION CODE * b.**
1.	_____	____ ____ . ____ ____ grams		____ ____ ____ . ____ ____ gms	_____ _____
2.	_____	____ ____ . ____ ____ grams		____ ____ ____ . ____ ____ gms	_____ _____
3.	_____	____ ____ . ____ ____ grams		____ ____ ____ . ____ ____ gms	_____ _____

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4.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____
5.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____
6.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____
7.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____
8.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____
9.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____
10.	____ ____ . ____ ____ grams _____	____ ____ ____ . ____ ____ gms _____ _____

Sum of pre_weights:

Analysis Variable : sumprewt								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	74.8	40.1	22.0	47.8	71.7	96.1	294.2

sumprewt	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

Sum of post weights :

Analysis Variable : sumpstwt								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	110.6	94.9	24.4	55.9	83.1	127.2	750.9

sumpstwt	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

Difference in pre and post weight:

Analysis Variable : diffwt								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	35.8	66.6	0.0	6.0	12.5	33.5	546.4

diffwt	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

*See contamination codes in Appendix

B10. Date Pad Test Kit returned: _____ _____ / _____ _____ / _____ _____ _____ _____
Month Day Year

Analysis Variable : return_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	20.5	22.8	0.0	6.0	13.0	27.0	158.0

return_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

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From the Diary

B11. Date Pad Test started: ____ ____ / ____ ____ / ____ ____ ____ ____
Month Day Year

Analysis Variable : ptstart_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	24.2	22.9	1.0	10.0	17.0	31.0	159.0

ptstart_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

B11a. Time started: ____ ____ : ____ ____ B11b. AM..... 1 PM.....2

B11c. Time ended: ____ ____ : ____ ____ B11d. AM..... 1 PM.....2

B12. Was the patient menstruating when the Pad Test was conducted? Yes..... 1

No..... 2

Because the frequency of at least one category is very low, this variable was not included in the dataset

B13. Was the Pad Test completed per protocol requirements? YES..... 1 **➔SKIP TO B14**

NO..... 2

PT_PROTO	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	303	51.01	303	51.01
2	291	48.99	594	100.00

Frequency Missing = 3

B13a. Was it a..... Patient deviation?..... 1

Staff deviation?..... 2

Other type?..... 3

Because the frequency of at least one category is very low, this variable was not included in the dataset

B13b. Describe: _____

_____

B14. Do you judge the test to be valid or invalid? Valid..... 1 **➔ SKIP TO C1**

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Invalid..... 2 ➔ **MEASURE MUST BE REPEATED FOR RANDOMIZATION**

PT_VALIDITY	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	594	100.00	594	100.00

Frequency Missing = 3

B14a. Describe why the Pad Test was judged to be invalid: _____

_____

_____

_____

SECTION C: THE VOIDING DIARY

C1. Are there Voiding Diary data to record below? Yes..... 1

No ..... 2 ➔**SKIP TO C8**

VD_DATA	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	594	100.00	594	100.00

Frequency Missing = 3

C2. Date Voiding Diary distributed: ____ ____ / ____ ____ / ____ ____ ____ ____ C2a. Initials: ____ ____ ____
Month Day Year

Analysis Variable : vd_dist_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	38.2	29.1	4.0	20.0	32.0	48.0	259.0

vd_dist_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

Day One

C3. Date of Diary Day 1: ____ ____ / ____ ____ / ____ ____ ____ ____
Month Day Year

Analysis Variable : day1_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	25.9	22.8	3.0	12.0	19.0	32.0	161.0

day1_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

C3a. Day of the week: Sunday.....1 Monday ..... 2 Tuesday.....3 Wednesday..... 4

Thursday.....5 Friday..... 6 Saturday 7

DAY1_DAY	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	94	15.82	94	15.82
2	149	25.08	243	40.91
3	81	13.64	324	54.55
4	72	12.12	396	66.67
5	102	17.17	498	83.84
6	57	9.60	555	93.43
7	39	6.57	594	100.00

Frequency Missing = 3

C3b. Number of accidents: _____ _____

C3c. Toilet voids during **waking** hours: _____ _____

C3d. Toilet voids during **bedtime** hours: _____ _____

TOT_VOID_1: Total voids during waking or bedtime hours

Analysis Variable : tot_void1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
593	0	9.3	3.4	3.0	7.0	9.0	11.0	27.0

tot_void1	Frequency	Percent	Cum Freq	Cum Percent
.	4	100.00	4	100.00

Day Two

C4. Date of Diary Day 2: ____ ____ / ____ ____ / ____ ____ ____ ____
Month Day Year

Analysis Variable : day2_date_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	24.9	22.8	2.0	11.0	18.0	31.0	160.0

day2_date_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

C4a. Day of the week: Sunday.....1 Monday ..... 2 Tuesday.....3 Wednesday..... 4

Thursday.....5 Friday..... 6 Saturday 7

DAY2_DAY	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	39	6.57	39	6.57
2	95	15.99	134	22.56

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DAY2_DAY	Frequency	Percent	Cum Freq	Cum Percent
3	149	25.08	283	47.64
4	79	13.30	362	60.94
5	72	12.12	434	73.06
6	102	17.17	536	90.24
7	58	9.76	594	100.00

Frequency Missing = 3

C4b. Number of accidents: _____ _____

C4c. Toilet voids during **waking** hours: _____ _____

C4d. Toilet voids during **bedtime** hours: _____ _____

TOT_VOID_2: Total voids during waking or bedtime hours

Analysis Variable : tot_void2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	9.2	3.4	2.0	7.0	9.0	11.0	24.0

tot_void2	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

Day Three

C5. Date of Diary Day 3: ____ ____ / ____ ____ / ____ ____ ____ ____
Month Day Year

Analysis Variable : day3_date_daysnew								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	23.9	22.8	1.0	10.0	17.0	30.0	159.0

day3_date_daysnew	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

C5a. Day of the week: Sunday.....1 Monday ..... 2 Tuesday..... 3 Wednesday..... 4
Thursday.....5 Friday..... 6 Saturday 7

DAY3_DAY	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
-9	1	0.17	1	0.17
1	57	9.60	58	9.76
2	39	6.57	97	16.33
3	96	16.16	193	32.49
4	147	24.75	340	57.24
5	78	13.13	418	70.37
6	72	12.12	490	82.49
7	104	17.51	594	100.00

Frequency Missing = 3

C5b. Number of accidents: _____ _____

C5c. Toilet voids during **waking** hours: _____ _____

C5d. Toilet voids during **bedtime** hours: _____ _____

TOT_VOID_3: Total voids during waking or bedtime hours

Analysis Variable : tot_void3								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	9.0	3.2	2.0	7.0	9.0	11.0	22.0

tot_void3	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

tot_void = "Diary: NumVoids (in 3dy)"

Analysis Variable : tot_void								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	27.5	9.0	7.0	21.0	26.0	32.0	72.0

tot_void	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

ave_void = "Diary: ave #voids per dy"

Analysis Variable : ave_void								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	9.2	3.0	2.3	7.0	8.7	10.7	24.0

ave_void	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

Diary: total #accidents of three days"

Analysis Variable : tot_acc								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
593	0	10.0	8.9	0.0	4.0	8.0	14.0	77.0

tot_acc	Frequency	Percent	Cum Freq	Cum Percent
.	4	100.00	4	100.00

ave_acc = "Diary: ave #accidents per dy"

Analysis Variable : ave_acc								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
593	0	3.3	3.0	0.0	1.3	2.7	4.7	25.7

ave_acc	Frequency	Percent	Cum Freq	Cum Percent
.	4	100.00	4	100.00

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C6. Was the Voiding Diary completed per protocol? YES..... 1 ➔**SKIP TO C7**

NO..... 2

VD_PROTO	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	461	77.61	461	77.61
2	133	22.39	594	100.00

Frequency Missing = 3

C6a. Was it a... Patient deviation? 1

Staff deviation? 2

Other type? 3

VD_DEV_TYPE	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
-2	461	77.61	461	77.61
1	129	21.72	590	99.33
2	4	0.67	594	100.00

Frequency Missing = 3

C6b. Describe: _____

_____

C7. Do you judge the Voiding Diary to be valid or invalid? Valid ..... 1 ➔ **SKIP TO C8**

Invalid..... 2 ➔ **MEASURE MUST BE REPEATED FOR RANDOMIZATION**

VD_VALIDITY	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	594	100.00	594	100.00

Frequency Missing = 3

C7a. Describe why the Voiding Diary was judged to be invalid: _____

_____

_____

_____

Affix ID Label Here

C8. Please provide any information obtained from the patient that may have affected the interpretation of the Pad Test or Voiding Diary data: _____

_____

_____

_____

_____

Appendix

CONTAMINATION CODES	
01	USED PAD: NOT CONTAMINATED WITH A SUBSTANCE OTHER THAN URINE
02	SOAKED THROUGH WITH URINE
03	CONTAMINATED / BLOOD
04	CONTAMINATED / STOOL
05	SOAKED THROUGH AND CONTAMINATED WITH BLOOD
06	SOAKED THROUGH AND CONTAMINATED WITH STOOL
07	SOAKED THROUGH AND CONTAMINATED WITH BLOOD AND STOOL
08	CONTAMINATE UNKNOWN

CODES FOR MISSING PADS	
10	MISSING PAD: PATIENT REPORTS **NEVER USED**
11	MISSING PAD: PATIENT REPORTS **USED** (INVALIDATES THE TEST)