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



A4. IS THIS A REPEAT MEASURE? YES								TOMUS	
A3. DATE FORM COMPLETED: MONTH			Section A: G	eneral Study I	nformation	for Office U	Jse Only:		
A4. IS THIS A REPEAT MEASURE? YES	A1. STUDY ID#:	L			i			TBAS	
A4. IS THIS A REPEAT MEASURE? YES	A3 DATE FORM		TED: /	/					
MEASURES EXPIRED 1	A3. DATE FORM	MONTH DAY YEAR							
NO	A4. IS THIS A REP	A4. IS THIS A REPEAT MEASURE? A5. WHY IS THIS MEASURE BEING REPEATED?							
repeat_meas_pt	YES		1		M	EASURES EX	PIRED	. 1	
repeat_meas_pt	NO		2 →SKIP TO SECT	TION R	PI	RIOR TEST(S)	INVALID	2	
1 51 8.59 51 8.59 2 543 91.41 594 100.00								· -	
1 51 8.59 51 8.59 2 543 91.41 594 100.00		_						-	
1 51 8.59 51 8.59 2 543 91.41 594 100.00 Frequency Missing = 3		-	repeat_meas_pt		Percent	Cum Freq	Cum Percent		
Frequency Missing = 3 why repeat pt				51					
why repeat pt			2	543	91.41	594	100.00]	
why repeat pt						_			
3 -2 543 91.41 543 91.45 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				Frequei	ncy Missing = 1	3			
3 -2 543 91.41 543 91.45 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				F	Danaant	Com Franc	Com Dansont		
1			wny_repeat_pt		Percent .	cum Freq	· Cum Percent		
SECTION B: THE PAD TEST			-2						
SECTION B: THE PAD TEST B1 Are there Pad Test measures to record below? Yes			2						
SECTION B: THE PAD TEST B1 Are there Pad Test measures to record below? Yes		'							
B1 Are there Pad Test measures to record below? No				Freque	ncy Missing =	3			
B1 Are there Pad Test measures to record below? No	GE GETTON B.	7777 D.	D WD0W		V /				
No	SECTION B:	ГНЕ РА	DTEST				/		
PT_DATA Frequency Percent Cum Freq Cum Percent . 3 . . . 1 594 100.00 594 100.00 Frequency Missing = 3	B1 Are there	Pad Tes	t measures to record	l below?	Yes	J 1			
PT_DATA Frequency Percent Cum Freq Cum Percent . 3 . . . 1 594 100.00 594 100.00 Frequency Missing = 3				/ /]	No	2	→ SKIP TO SE	CTION C	
3					110	2	ZSKII TO SE	CHONE	
3			PT DATA	A Frequency	Percent	Cum Frea	Cum Percent		
Frequency Missing = 3				3					
			1	594	100.00	594	100.00		
					Frequency Mis	ssing = 3			
B2. Date Pad Test Kit distributed: / / B2a. Initials:	B2. Date Pad	Tost Vit	distributed:	/	/		D2a Initiala		
B2. Date Pad Test Kit distributed: / B2a. Initials: B2a. Initials:	DZ. Date Fau	ı esi Kil		onth Day		Year	DZa. IIIIIIais	·	

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Analy	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

В3.	Number of pa	ads distributed in the Kit:
		L
		Analysis Variable : TOT_PADS
		N Lower Upper
		N Miss Mean SD Minimum Quartile Median Quartile Maximum 594 0 5.0 2.1 1.0 4.0 5.0 6.0 15.0
		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
	1	PRE-WEIGHTS ♥ POST-WEIGHTS ♥
B4.		WEIGHTS RECORDED ♥ B7. DATE POST-WEIGHTS RECORDED ♥
D	DITTETRE	
	/	
	Month	Day Year Month Day Year
		Analysis Variable : pre daysnew
		N Lower Upper
		N Miss Mean SD Minimum Quartile Median 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 Lower Upper
		N Miss Mean SD Minimum Quartile Median 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#	PRE-WEIGHT B9. POST-WEIGHT CONTAMINATION CODE* b. b.
1.		gms
	_	grams
		gms
2.		grams
3.		grams gms

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4.				_ •	8	grams				•	gn	ns			
5.				_ •	g	grams				•-	:	gms			
6.				_ •	8	grams				•	gn	ns			
7.				_ •	8	grams				•	gn	ns			
8.				_ •	§	grams				•	gn	ns			
9.				_ •	g	grams				•	gn	ns			
10.		_		_ •	g	grams				•	gn	ns			
Sum	f nno woid	htae													
Sum (of pre_weig	nts:													
						Analy	cic Vor	iable : sun	nrosst						
			N			Anary	515 V a1	Lower	ipiewi	I	Jpper				
		N	Miss	Mean	SD	Minimu	m	Quartile	Median		uartile	Maximur	n		
		594	0	74.8	40.1	22.0		47.8	71.7		96.1	294.2			
											1				
	sumprewtFrequencyPercentCum FreqCum Percent.3100.003100.00														
Sum o	of post weig	hts :							/ /						
						Analy	cic Var	riable : sur	netwt						
			N			Anary	515 V a1	Lower	ipstwt		Upper				
		N	Miss	Mean	SD	Minim	ım	Quartile	Median		Quartile	Maximu	m		
		594	0	110.6	94.9	24.4		55.9	83.1		127.2	750.9			
			٢												
			sur	npstwt	Freq	uency	Per	cent	Cum Freq	Cu	ım Percen	t			
						3	100	0.00	3		100.00				
				\		/ /									
Differ	ence in pre	and po	ost wei	ght: \											
						Ana	lysis V	ariable : d	iffwt			ı			
		NI	N	Mann	CD	Minimum		Lower	Madian		Jpper	Manimum			
		N 594	Miss 0	Mean 35.8	SD 66.6	Minimu 0.0	m	Quartile 6.0	Median 12.5		uartile 33.5	Maximur 546.4	n		
		334		33.6	00.0	0.0		0.0	12.3		33.3	340.4			
			d	iffwt	Frequ	encv	Perce	nt C	um Freq	Cur	n Percent				
					3		100.0		3		00.00				
									l-						
											*See	contamina	ation cod	les in Apper	ndix
B10.	Date Pad T	oct Vit	raturn	ad:		,	,	/							
D 10.	Date I ad I	CSt IXIt	return	cu.	Mo	onth	D	ay	Y	ear					
						Analysis	Variah	le : return	daysnew						
			N					Lower		J	Jpper				
		N	Miss	Mean	SD	Minimu	m	Quartile	Median	Q	uartile	Maximur	n		
		594	0	20.5	22.8	0.0		6.0	13.0		27.0	158.0			
						_									
			return	_daysnew	1	Frequenc	У	Percent	Cum Fr	eq	Cum Po	ercent			
				•		3		100.00	3		100.	.UU			

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From the Diary	From
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B11.	Date	Pad	Test started:	

/	′	/
Month	Day	Year

	Analysis Variable : ptstart_daysnew								
	N Lower Upper								
-	N Miss Mean SD Minimum Quartile Median Quartile Maximum							Maximum	
ĺ	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

No.....2

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



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.	Desc	ribe wł	y the P	ad Test	was judge	ed to be inv	valid:			
SEC"	TION C: THI	Z VOII	OING F	IADV							
SEC	HONC. IIII	VOII	JING L	IAKI							
G1	4 .1 77		o: 1			0	**	_1			
C1.	Are there Vo	olding	Diary da	ata to red	cord belo	w?	Yes	1			
							No	2	→SKIP TO C	28	
			VD	DATA	Freque	nev E	Percent	Cum Freq	Cum Percent	- ()	
			VD		3			•			
				1	594	1	100.00	594	100.00		
			ſ								
			1			Freque	ency Missing	g = 3			
C2.	Date Voiding	Diary	distribu	ted: \	Month	Day	/	Year	C2a.	Initials:	
				`							
			N		A	nalysis Var	iable : vd_di	st_daysnew	Linnar		
		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	1

Date of Diary Day 1: C3.

vd_dist_daysnew

,	/	/
Month	Day	Year

Frequency

3

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

Percent

100.00

Cum Freq

Cum Percent 100.00

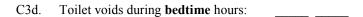
day1_daysnew	Frequency	Percent	Cum Freq	Cum Percent
	3	100.00	3	100.00

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:



TOT_VOID_1: Total voids during waking or bedtime hours

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

1	tot_void1	Frequency	Percent	Cum Freq	Cum Percent	
Ī		4	100.00	4	100.00	
_						

Day Two

C4. Date of Diary Day 2

ay 2:		/	/
	Month	Day	Year

	Analysis Variable : day2_date_daysnew									
N Lower						Lower		Upper		
	N	Miss	Mean	SD	Minimum	Quartile	Median	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

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

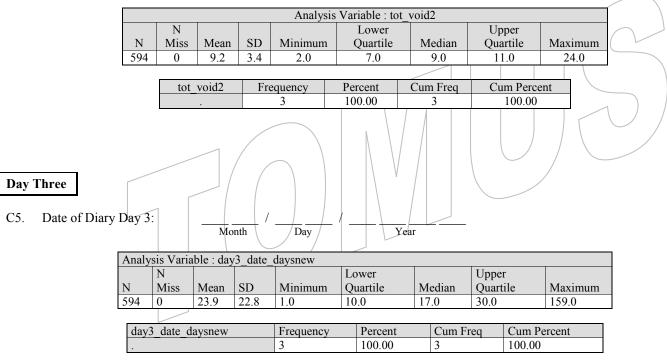
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DAY2_DAY	Frequency	Percent	Cum Freq	Cum Percent
3	149	25.08	283	47.64
4	79	13.30	362	60.94
5	72	12.12	434	73.06
6	102	17.17	536	90.24
7	58	9.76	594	100.00

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



C5a.	Day of the week:	Sunday1	Monday 2	Tuesday3	Wednesday 4
		Thursday5	Friday 6	Saturday7	

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

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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 Lower Upper											
N Miss Mean SD Minimum Quartile Median Quartile Maxin											
594											

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 Lower Upper								
N	N Miss Mean SD Minimum Quartile Median Quartile								
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					Lower				Upper		
N	Miss	Mean	SD	Minimun	n	Quartile		Media	n	Quartile	Ma	ximum
594	0	9.2	3.0	2.3		7.0		8.7		10.7	2	24.0
		\										
	ave	void	Fre	quency		Percent	Cı	ım Fred	1	Cum Percei	nt	
				3		100.00		3		100.00		l

Diary: total #accidents of three days"

	Analysis Variable : tot_acc									
N	N Miss	Mean	SD	Minimum	Lower Ouartile	Median	Upper Ouartile	Maximum		
1.4	171133				.		(
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				Lower		Upper	
N	Miss	Mean	SD	Minimum	Quartile	Median	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 I	Diary completed per	protocol?	YES	1 → SK	ПР ТО С7	
			1	NO	2		
		VD_PROTO	Frequency	Percent	Cum Freq	Cum Percent	
		1	3 461	77.61	461	77.61	
		2	133	22.39	594	100.00	
			Free	quency Missing	= 3		
	C6a. Was it a	. Patient deviation					
		Stail deviation	? Z				
		Other type?	3				
		VD_DEV_TYPE	Frequency	Percent	Cum Freq	Cum Percent	
		-2	3 461	77.61	461	77.61	
		1	129	21.72	590	99.33	
	C6b. Describe:	2	Free	quency Missing	594	100.00	
		_					
07	Decree in terms	7.11: Diam. (-1	1:1 : /	. 10	1 .	S CIZID TO CO	
C7.	Do you judge the	Voiding Diary to be	vand or invan			SKIP TO C8	
				Invali	d 2 🛨	FOR RANDO	UST BE REPEATED MIZATION
		VD_VALIDITY	Frequency 3	Percent	Cum Freq	Cum Percent	
		1	594	100.00	594	100.00	_
							_
			Free	quency Missing	= 3		
	C7a. Desc	ribe why the Voidin	ng Diary was j	udged to be in	valid:		

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Diary data:	any information obtained fro	om the patient that may hav	ve affected the interpretation of the Pad T	est or v
Diary data				



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Appendix

CON	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 <u>AND</u> CONTAMINATED WITH BLOOD				
06	SOAKED THROUGH <u>AND</u> CONTAMINATED WITH STOOL				
07	SOAKED THROUGH <u>AND</u> CONTAMINATED WITH BLOOD <u>AND</u> STOOL				
08	CONTAMINATE UNKNOWN				

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

F306 codebook Attachment