



Section A: General Study Information for Office Use Only:

A1. STUDY ID#:

A2. Visit # F/U 6 MonthsTF06
 F/U 12 Months.....TF12
 F/U 24 Months.....TF24
 Failure.....TFAI

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

A4. IS THIS A REPEAT MEASURE?
 YES 1
 NO 2

VISIT	Frequency	Percent	Cum Freq	Cum Percent
TF06	493	34.40	493	34.40
TF12	497	34.68	990	69.09
TF24	439	30.64	1429	99.72
TFAI	4	0.28	1433	100.00

repeat_meas_vd	Frequency	Percent	Cum Freq	Cum Percent
.	11	.	.	.
1	59	4.15	59	4.15
2	1363	95.85	1422	100.00

Frequency Missing = 11

SECTION B: 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
.	67	.	.	.
1	1366	100.00	1366	100.00

Frequency Missing = 67

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

B3. Number of pads distributed in the Kit: ____

Analysis Variable : TOT_PADS									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
1366	0	2.9	1.0	1.0	2.0	3.0	3.0	12.0	

TOT_PADS	Frequency	Percent	Cum Freq	Cum Percent
.	67	100.00	67	100.00

B4. Date Pad Test Kit returned: _____ / _____ / _____
 Month Day Year

From the Diary

B5. Date Pad Test started: _____ / _____ / _____
 Month Day Year

B5a. Hour started: _____ : _____ B5b. AM..... 1 PM.....2

B5c. Hour ended: _____ : _____ B5d. AM..... 1 PM.....2

Analysis Variable : pt_time_hr								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1365	0	24.2	1.0	22.0	24.0	24.0	24.0	40.8

pt_time_hr	Frequency	Percent	Cum Freq	Cum Percent
.	68	100.00	68	100.00

Analysis Variable : pt_time_min								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1365	0	1450.7	57.4	1320.0	1440.0	1440.0	1442.0	2447.0

pt_time_min	Frequency	Percent	Cum Freq	Cum Percent
.	68	100.00	68	100.00

B6. Was the patient menstruating when the Pad Test was conducted? YES 1
 NO 2

MENST	Frequency	Percent	Cum Freq	Cum Percent
.	67	.	.	.
2	1366	100.00	1366	100.00

Frequency Missing = 67

B7. Was the Pad Test completed per protocol requirements? YES..... 1 →SKIP TO B8
 NO..... 2

PT_PROTO	Frequency	Percent	Cum Freq	Cum Percent
.	67	.	.	.
1	691	50.59	691	50.59
2	675	49.41	1366	100.00

Frequency Missing = 67

B7a. Was it a..... Patient deviation?..... 1
 Staff deviation?..... 2
 Other type?..... 3

B7b. Describe: _____

B8. Do you judge the test to be valid or invalid? Valid 1 → SKIP TO B9
 Invalid..... 2 → MEASURE MUST BE REPEATED

PT_VALIDITY	Frequency	Percent	Cum Freq	Cum Percent
.	67	.	.	.
1	1366	100.00	1366	100.00

Frequency Missing = 67

B8a. Describe why the Pad Test was judged to be invalid: _____

↓ PRE-WEIGHTS ↓		↓ POST-WEIGHTS ↓	
B9. DATE PRE-WEIGHTS RECORDED ↓ _____ / _____ / _____ Month Day Year B10. INITIALS: _____	B11. DATE POST-WEIGHTS RECORDED ↓ _____ / _____ / _____ Month Day Year B12. INITIALS : _____		
B13.	PAD # a.	PRE-WEIGHT b.	B14. POST-WEIGHT a.
			CONTAMINATION CODE * b.
1.	_____	_____ . _____ grams	_____ . _____ gms
2.	_____	_____ . _____ grams	_____ . _____ gms
3.	_____	_____ . _____ grams	_____ . _____ gms
4.	_____	_____ . _____ grams	_____ . _____ gms
5.	_____	_____ . _____ grams	_____ . _____ gms
6.	_____	_____ . _____ grams	_____ . _____ gms
7.	_____	_____ . _____ grams	_____ . _____ gms
8.	_____	_____ . _____ grams	_____ . _____ gms
9.	_____	_____ . _____ grams	_____ . _____ gms
10.	_____	_____ . _____ grams	_____ . _____ gms

* See contamination codes in Appendix

↓ Add entire column of Add entire column of ↓
 B13b and record in B15 B14a and record in B16

B15. Sum of all pre-weights _____ . _____ gms	B16. Sum of all post-weights _____ . _____ gms
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Analysis Variable : SUM_PRE								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1366	0	69.3	24.8	15.0	49.7	69.9	72.7	271.2

SUM_PRE	Frequency	Percent	Cum Freq	Cum Percent
.	67	100.00	67	100.00

Analysis Variable : SUM_POST								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1366	0	79.1	55.7	16.4	54.0	73.6	77.8	836.5

SUM_POST	Frequency	Percent	Cum Freq	Cum Percent
.	67	100.00	67	100.00

Total Difference and Pre- and Post- Weights

Worksheet

B16		B15		B17
(Post-weights)	-	(Pre-weights)	=	Total difference in weights

1st Calculation:

	-		=	
--	---	--	---	--

B16		B15		B17
(Post-weights)	-	(Pre-weights)	=	Total difference in weights
	-		=	

2nd (QC) Calculation:

(should be done by another UITN staff member)

B17. What is the difference of B16-B15? _____ • _____ grams

Analysis Variable : WEIGHT_DIFF								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1362	0	9.8	40.8	0.0	2.4	3.7	5.6	625.9

WEIGHT_DIFF	Frequency	Percent	Cum Freq	Cum Percent
.	71	100.00	71	100.00

B18. Is B17 ≥ 15.00 grams? YES..... 1 **→FAILURE; COMPLETE FAILURE PROTOCOL**
 NO..... 2

WEIGHT_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	67	.	.	.
1	89	6.52	89	6.52
2	1277	93.48	1366	100.00

Frequency Missing = 67

NERI VAL RVW:

NERI_VAL_RVW	Frequency	Percent	Cum Freq	Cum Percent
1	219	15.28	219	15.28
2	1214	84.72	1433	100.00

SECTION C: THE VOIDING DIARY

C1. Are there Voiding Diary data to record below? Yes..... 1
 No..... 2 **→SKIP TO C9**

VD_DATA	Frequency	Percent	Cum Freq	Cum Percent
.	11	.	.	.
1	1422	100.00	1422	100.00

Frequency Missing = 11

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

Analysis Variable : DAYSVOID								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	411.0	228.5	20.0	190.0	356.0	699.0	987.0

DAYSVOID	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

Day One

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

Analysis Variable : DAY1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	428.1	228.7	34.0	205.0	372.0	718.0	993.0

DAY1	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	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
.	11	.	.	.
1	251	17.65	251	17.65
2	305	21.45	556	39.10
3	214	15.05	770	54.15
4	240	16.88	1010	71.03
5	226	15.89	1236	86.92
6	109	7.67	1345	94.59
7	77	5.41	1422	100.00

Frequency Missing = 11

C3b. Number of accidents: _____ **ACCIDENT COUNT ≥1 = FAILURE;
 COMPLETE FAILURE PROTOCOL**

Analysis Variable : DAY1_ACC								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	0.5	1.4	0.0	0.0	0.0	0.0	14.0

DAY1_ACC	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

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

Analysis Variable : WAKE_VOID_1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	6.9	2.2	0.0	5.0	7.0	8.0	17.0

WAKE_VOID_1	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

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

Analysis Variable : BED_VOID_1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1419	0	0.8	1.0	0.0	0.0	1.0	1.0	9.0

BED_VOID_1	Frequency	Percent	Cum Freq	Cum Percent
.	14	100.00	14	100.00

Day Two

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

Analysis Variable : DAY2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	429.1	228.7	35.0	206.0	373.0	719.0	994.0

DAY2	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

C4a. Day of the week: Sunday.....1 Monday 2 Tuesday 3 Wednesday..... 4
 Thursday5 Friday 6 Saturday 7

DAY2_DAY	Frequency	Percent	Cum Freq	Cum Percent
.	11	.	.	.
1	79	5.56	79	5.56
2	250	17.58	329	23.14
3	304	21.38	633	44.51
4	215	15.12	848	59.63
5	239	16.81	1087	76.44
6	227	15.96	1314	92.41
7	108	7.59	1422	100.00

Frequency Missing = 11

C4b. Number of accidents: _____ **ACCIDENT COUNT \geq 1 = FAILURE; COMPLETE FAILURE PROTOCOL**

Analysis Variable : DAY2_ACC								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	0.5	1.4	0.0	0.0	0.0	0.0	14.0

DAY2_ACC	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

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

Analysis Variable : WAKE_VOID_2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	7.0	2.3	0.0	6.0	7.0	8.0	25.0

WAKE_VOID_2	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

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

Analysis Variable : BED_VOID_2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1416	0	0.8	1.0	0.0	0.0	1.0	1.0	8.0

BED_VOID_2	Frequency	Percent	Cum Freq	Cum Percent
.	17	100.00	17	100.00

Day Three

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

Analysis Variable : DAY3								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	430.1	228.7	36.0	207.0	374.0	720.0	995.0

DAY3	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	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
.	11	.	.	.
1	107	7.52	107	7.52
2	79	5.56	186	13.08
3	244	17.16	430	30.24
4	308	21.66	738	51.90
5	217	15.26	955	67.16
6	238	16.74	1193	83.90
7	229	16.10	1422	100.00

Frequency Missing = 11

C5b. Number of accidents: _____ **ACCIDENT COUNT ≥1 = FAILURE; COMPLETE FAILURE PROTOCOL**

Analysis Variable : DAY3_ACC								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	0.4	1.4	0.0	0.0	0.0	0.0	12.0

DAY3_ACC	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

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

Analysis Variable : WAKE_VOID_3								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	7.1	2.2	0.0	6.0	7.0	8.0	20.0

WAKE_VOID_3	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

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

Analysis Variable : BED_VOID_3								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1417	0	0.8	1.0	0.0	0.0	1.0	1.0	8.0

BED_VOID_3	Frequency	Percent	Cum Freq	Cum Percent
.	16	100.00	16	100.00

C6. Did the woman report any accidents during the 3-day Voiding Diary?

YES 1 → FAILURE; COMPLETE FAILURE PROTOCOL

NO 2

ANY_ACCID	Frequency	Percent	Cum Freq	Cum Percent
.	12	.	.	.
1	427	30.05	427	30.05
2	994	69.95	1421	100.00

Frequency Missing = 12

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

Analysis Variable : tot_void								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	23.4	6.9	0.0	19.0	22.0	27.0	64.0

tot_void	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	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
1422	0	7.8	2.3	0.0	6.3	7.3	9.0	21.3

ave_void	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

F356 Diary : fail date

Analysis Variable : Dayfail								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
431	0	426.5	236.3	34.0	198.0	372.0	721.0	993.0

Dayfail	Frequency	Percent	Cum Freq	Cum Percent
.	1002	100.00	1002	100.00

Diary: total #accidents of three days"

Analysis Variable : tot_acc								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1422	0	1.4	3.9	0.0	0.0	0.0	1.0	35.0

tot_acc	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	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
1422	0	0.5	1.3	0.0	0.0	0.0	0.3	11.7

ave_acc	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

C7. Was the Voiding Diary completed per protocol? YES..... 1 →SKIP TO C8
NO..... 2

VD_PROTO	Frequency	Percent	Cum Freq	Cum Percent
.	11	.	.	.
1	1147	80.66	1147	80.66
2	275	19.34	1422	100.00

Frequency Missing = 11

C7a. Was it a... Patient deviation? 1
Staff deviation? 2
Other type? 3

VD_DEV_TYPE	Frequency	Percent	Cum Freq	Cum Percent
.	1158	.	.	.
1	274	99.64	274	99.64
2	1	0.36	275	100.00

Frequency Missing = 1158

C7b. Describe: _____

C8. Do you judge the Voiding Diary to be valid or invalid? Valid 1 → SKIP TO C9
Invalid..... 2 → MEASURE MUST BE REPEATED

VD_VALIDITY	Frequency	Percent	Cum Freq	Cum Percent
.	11	.	.	.
1	1422	100.00	1422	100.00

C8a. Describe why the Voiding Diary was judged to be invalid: _____

C9. 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	
00	RETURNED, UNUSED PAD
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)

