



Section A: General Study Information for Office Use Only:

A1. STUDY ID#:

LABEL

A2. Visit # F/U 6 Months TF06
 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

SECTION B: PAD TEST

B1. Are there Pad Test measures to record below?

YES 1
 NO..... 2 → **SKIP TO SECTION C**

B2. Date Pad Test Kit distributed:

___/___/___
 Month Day Year

B2a. Initials: _____

B3. Number of pads distributed in the Kit: _____

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

B6. Was the patient menstruating when the Pad Test was conducted? YES..... 1

NO 2

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

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

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

Affix ID Label Here

↓ PRE-WEIGHTS ↓

B9. DATE PRE-WEIGHTS RECORDED ↓
 _____ / _____ / _____
 Month Day Year

B10. INITIALS: _____

↓ POST-WEIGHTS ↓

B11. DATE POST-WEIGHTS RECORDED ↓
 _____ / _____ / _____
 Month Day Year

B12. INITIALS : _____

B13.	PAD # a.	PRE-WEIGHT b.
1.	_____	_____ . _____ grams
2.	_____	_____ . _____ grams
3.	_____	_____ . _____ grams
4.	_____	_____ . _____ grams
5.	_____	_____ . _____ grams
6.	_____	_____ . _____ grams
7.	_____	_____ . _____ grams
8.	_____	_____ . _____ grams
9.	_____	_____ . _____ grams
10.	_____	_____ . _____ grams

B14.	POST-WEIGHT a.	CONTAMINATION CODE* b.
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____
	_____ . _____ gms	_____

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

* See contamination codes in Appendix

B15. Sum of all pre-weights _____ . _____ gms	B16. Sum of all post-weights _____ . _____ gms
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Total Difference and Pre- and Post- Weights	Worksheet															
<p>1st Calculation:</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%;">B16</th> <th style="width: 10%;"></th> <th style="width: 25%;">B15</th> <th style="width: 10%;"></th> <th style="width: 30%;">B17</th> </tr> <tr> <td>(Post-weights)</td> <td style="text-align: center;">-</td> <td>(Pre-weights)</td> <td style="text-align: center;">=</td> <td>Total difference in weights</td> </tr> <tr> <td> </td> <td style="text-align: center;">-</td> <td> </td> <td style="text-align: center;">=</td> <td> </td> </tr> </table>	B16		B15		B17	(Post-weights)	-	(Pre-weights)	=	Total difference in weights		-		=	
B16		B15		B17												
(Post-weights)	-	(Pre-weights)	=	Total difference in weights												
	-		=													
<p>2nd (QC) Calculation: <small>(should be done by another UITN staff member)</small></p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%;">B16</th> <th style="width: 10%;"></th> <th style="width: 25%;">B15</th> <th style="width: 10%;"></th> <th style="width: 30%;">B17</th> </tr> <tr> <td>(Post-weights)</td> <td style="text-align: center;">-</td> <td>(Pre-weights)</td> <td style="text-align: center;">=</td> <td>Total difference in weights</td> </tr> <tr> <td> </td> <td style="text-align: center;">-</td> <td> </td> <td style="text-align: center;">=</td> <td> </td> </tr> </table>	B16		B15		B17	(Post-weights)	-	(Pre-weights)	=	Total difference in weights		-		=	
B16		B15		B17												
(Post-weights)	-	(Pre-weights)	=	Total difference in weights												
	-		=													

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

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

SECTION C: THE VOIDING DIARY

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

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

Day One

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

C3a. Day of the week: Sunday..... 1 Monday 2 Tuesday 3 Wednesday..... 4
 Thursday..... 5 Friday 6 Saturday 7

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

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

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

Day Two

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

C4a. Day of the week: Sunday..... 1 Monday 2 Tuesday 3 Wednesday..... 4
 Thursday..... 5 Friday 6 Saturday 7

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

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

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

Day Three

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

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

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

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

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

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

YES 1 → **FAILURE; COMPLETE FAILURE PROTOCOL**

NO..... 2

C7. Was the Voiding Diary completed per protocol? YES..... 1 → **SKIP TO C8**

NO..... 2

C7a. Was it a... Patient deviation?..... 1

Staff deviation? 2

Other type?..... 3

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**

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)