F356: Follow-Up Pad Test and Voiding Diary Summary, version 08/28/06 (A)

UITN TOMUS

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: ___ ___ / ___ ___ / ___ ___ ___ ___ B2a. Initials: ___ ___ ___
Month Day Year

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

Affix ID Label Here

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 ↓	↓ POST-WEIGHTS ↓
B9. DATE PRE-WEIGHTS RECORDED ↓ ____ ____ / ____ ____ / ____ ____ ____ ____ Month Day Year	**B11. DATE POST-WEIGHTS RECORDED ↓** ____ ____ / ____ ____ / ____ ____ ____ ____ Month Day Year
B10. INITIALS: ____ ____ ____	**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 B13b and record in B15

Add entire column of B14a and record in B16 ↓

B15.	Sum of all pre-weights ____ ____ ____ . ____ ____ gms	B16.	Sum of all post-weights ____ ____ ____ . ____ ____ gms

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

B18. Is B17 ≥ 15.00 grams? YES ..... 1 **➔FAILURE; COMPLETE FAILURE PROTOCOL**

NO 2

Affix ID Label Here

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: ____ ____ / ____ ____ / ____ ____ ____ ____ (Month / Day / Year) C2a. Initials: ____ ____ ____

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: _____ _____

Affix ID Label Here

C6. Did the woman report <u>any</u> 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 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)