



Section A: General Study Information for Office Use Only:

A1. STUDY ID#: LABEL	A2. VISIT # BASELINEBASE
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

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: _____

↓ PRE-WEIGHTS ↓		↓ POST-WEIGHTS ↓	
B4. DATE PRE-WEIGHTS RECORDED ↓ _____ / _____ / _____ Month Day Year		B7. DATE POST-WEIGHTS RECORDED ↓ _____ / _____ / _____ Month Day Year	
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	_____
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

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

From the Diary

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

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

B13. Was the Pad Test completed per protocol requirements? YES..... 1 →SKIP TO B14
NO..... 2

B13a. Was it a..... Patient deviation?..... 1
Staff deviation?..... 2
Other type?..... 3

B13b. Describe: _____

B14. Do you judge the test to be valid or invalid? Valid 1
Invalid..... 2 → REPEAT THE MEASURE

SECTION C: THE VOIDING DIARY

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

C2. Date Voiding Diary distributed: ___/___/___ C2a. Initials: ___

Day One

C3. Date of Diary Day 1: ___/___/___

C3a. Day of the week: Sunday.....1 Monday 2 Tuesday 3 Wednesday..... 4
Thursday5 Friday 6 Saturday 7

C3b. Number of accidents: ___

C3c. Toilet voids during **waking** hour: ___

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

C4. Total Toilet voids Day 1 (C3c + C3d): ___ (Do not count accidents in this tally)

Day Two

C5. Date of Diary Day 2: ___/___/___

C5a. Day of the week: Sunday.....1 Monday 2 Tuesday 3 Wednesday..... 4
Thursday5 Friday 6 Saturday 7

C5b. Number of accidents: ___

C5c. Toilet voids during **waking** hour: ___

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

C6. Total Toilet voids Day 2 (C5c + C5d): ___ (Do not count accidents in this tally)

Day Three

C7. Date of Diary Day 3: ___/___/___

C7a. Day of the week: Sunday.....1 Monday 2 Tuesday 3 Wednesday..... 4
Thursday5 Friday 6 Saturday 7

C7b. Number of accidents: ___

C7c. Toilet voids during **waking** hour: ___

C7d. Toilet voids during **bedtime** hours: ___

C8. Total Toilet voids Day 3 (C7c + C7d): ___ (Do not count accidents in this tally)

Total Voids in the 3-Day Diary period

Worksheet

C4		C6		C8		C9
(Day 1)	+	(Day 2)	+	(Day 3)	=	Total voids in 3 Days
	+		+		=	

C9. Total voids: C4+C6+C8 = _____

C10. Is C9 ≥ 36? YES..... 1 **→INELIGIBLE**
 NO 2

C11. Was the Voiding Diary completed per protocol? YES..... 1 **→SKIP TO C12**
 NO 2

C11a. Was it a... Patient deviation? 1
 Staff deviation? 2
 Other type? 3

C11b. Describe: _____

C12. Do you judge the Voiding Diary to be valid or invalid? Valid 1
 Invalid..... 2 **→ MEASURE MUST BE REPEATED FOR RANDOMIZATION**

C13. Please provide any information obtained from the patient that may have affected the interpretation of the Voiding Diary data:

SECTION D: ELIGIBILITY SUMMARY

D1. DOES THE PATIENT MEET ALL ELIGIBILITY CRITERIA AS REQUIRED IN THIS FORM?
 (REVIEW CODES TO ITEMS C9, C10 AND C12.)

YES 1 **→ CONTINUE SCREENING**
 NO 2 **→ INELIGIBLE; END SCREENING**
 Cannot determine, Diary must be repeated..... 3

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 <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)