UITN

TOMUS

Section A: General Study Information for Office Use Only:

A1. STUDY ID#: | LABEL |

A2. VISIT   BASELINE ....TBAS

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: THE 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   **➜ SKIP TO C1**

    Invalid......... 2   **➜ MEASURE MUST BE REPEATED FOR RANDOMIZATION**

    B14a.   Describe why the Pad Test was judged to be invalid:_____
_____
_____
_____

SECTION C: THE VOIDING DIARY

C1.   Are there Voiding Diary data to record below?   Yes 1

                                                                       No..................... 2   ➔ **SKIP TO C8**

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: _____ _____

          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: _____ _____

          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: _____ _____

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

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

C6.   Was the Voiding Diary completed per protocol?   YES.................. 1   ➔**SKIP TO C7**

                                                        NO................... 2

    C6a.   Was it a...   Patient deviation?........... 1

                                       Staff deviation? 2

                                        Other type?..................... 3

    C6b.   Describe: _____

                           _____

C7.   Do you judge the Voiding Diary to be valid or invalid?   Valid.......... 1   ➔ **SKIP TO C8**

                                                               Invalid........ 2   ➔ **MEASURE MUST BE REPEATED FOR RANDOMIZATION**

    C7a.   Describe why the Voiding Diary was judged to be invalid: _____

               _____

               _____

               _____

C8.   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	
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)