

## Form 56: Follow-Up Pad Test and Voiding Diary Summary, Version 09/06/02 (A)\_revised 03/16/05

|               |              | Section                  | A: General S   | tudy Infor | mation for (  | Office Use Only  | :                         |    |
|---------------|--------------|--------------------------|----------------|------------|---------------|------------------|---------------------------|----|
| <b>A1.</b> S7 | ΓUDY ID#:    | LABEL                    |                |            | A2. VISIT#    | F/U 6 MON        | THS FU06                  |    |
|               |              |                          |                |            |               | F/U 12 MO        | NTHS FU12                 |    |
|               |              |                          |                |            |               |                  | NTHS FU24                 |    |
|               |              |                          |                |            |               | F/U 36 MON       | NTHS FU36                 |    |
|               |              |                          |                |            |               | F/U 48 MO        | NTHS FU48                 |    |
|               |              |                          |                |            |               | F/U 60 MO        | NTH FU60                  |    |
|               |              |                          |                |            |               | F/U 72 MO1       | NTHS FU72                 |    |
|               |              |                          |                |            |               | F/U 84 MO        | NTHS FU84                 |    |
|               |              |                          |                |            |               | FAILURE          | FAIL                      |    |
|               |              |                          |                |            | A4 IS THIS    | A REPEAT MEASI   | JRE DUE TO AN INVALID TES | т? |
| <b>A3.</b> D  | ATE FORM (   | COMPLETED: MONTH         | DAY            | YEAR       | 144. 15 11115 |                  |                           |    |
|               |              | MONTH                    | DAT            | TEAK       |               | YES              |                           |    |
|               |              |                          |                |            |               | NO               |                           |    |
|               |              |                          |                |            |               |                  |                           |    |
| SEC           | ΓΙΟΝ B: P.   | AD TEST                  |                |            |               |                  |                           |    |
|               |              |                          |                |            |               |                  |                           |    |
| B1.           | Are there    | Pad Test measures to 1   | ecord below?   |            | YES           | 1                |                           |    |
|               |              |                          |                |            | NO            | 2 <b>→</b> \$KII | P TO SECTION C            |    |
|               |              |                          |                |            | NO            | 2 <b>-2</b> 5KH  | TO SECTION C              |    |
| D2            | D . D 1/     | T                        | ,              | ,          |               | 7.4              | T 1.1.1                   |    |
| B2.           | Date Pad     | Test Kit distributed:    | / _<br>Month   | /<br>Day   |               | B2a.             | Initials:                 |    |
|               |              |                          | William        | Duy        | 1 Cui         |                  |                           |    |
| D2            | Number       | f nada diatributad in th | o Vite         |            |               |                  |                           |    |
| В3.           | Number o.    | f pads distributed in th | e Kit.         |            |               |                  |                           |    |
|               |              |                          |                |            |               |                  |                           |    |
| B4.           | Date Pad     | Test Kit returned:       |                | /          | /             |                  |                           |    |
|               |              |                          | Month          | Day        |               | Year             |                           |    |
|               |              |                          |                |            |               |                  |                           |    |
| Fron          | the Diary    |                          |                |            |               |                  |                           |    |
|               |              |                          |                |            |               |                  |                           |    |
| B5.           | Date P       | ad Test started:         |                |            | _ /           | /                |                           |    |
|               |              |                          |                | Month      | Day           | Year             | <del></del>               |    |
|               |              |                          |                |            |               |                  |                           |    |
|               | B5a.         | Hour started:            |                | :          | B5b.          | AM 1             | PM2                       |    |
|               |              |                          |                |            | _ <del></del> |                  |                           |    |
|               | B5c.         | Hour ended:              |                |            | R5d           | AM 1             | PM2                       |    |
|               | <b>D</b> 50. | from onded.              |                | - `        |               | / 11v1 1         | 1 171                     |    |
|               |              |                          |                |            |               |                  |                           |    |
| D/            | W/ 41        | a nationt                | ryshon 4k - D  | d Tost     | aand          | VEC 1            |                           |    |
| B6.           | wastr        | ne patient menstruating  | , when the Pac | u rest was | conducted?    | 1 ES l           |                           |    |
|               |              |                          |                |            |               | 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 j  | udge the test to be valid or invalid?  |  | Valid 1   | → SKIP TO B9               |  |  |  |  |
|     |   |  |  | Invalid 2 | → MEASURE MUST BE REPEATEI |  |  |  |  |
|     | B8a.  | Describe why the Pad Test was judged t | ibe why the Pad Test was judged to be invalid: |           |                            |  |  |  |  |
|     |   |  |  |           |                            |  |  |  |  |
|     |   |  |  |           |                            |  |  |  |  |
|     |   |  |  |           |                            |  |  |  |  |
|     |   |  |  |           |                            |  |  |  |  |

Affix ID Label Here

| <b>♥</b> PRE-WEIGHTS <b>♥</b> |                                    |                               |                |                                   | ♥ POST-WEIGHTS ♥                         |       |                             |            |  |
|-------------------------------|------------------------------------|-------------------------------|----------------|-----------------------------------|--|-------|-----------------------------|------------|--|
| B9.                           | DATE PRE-WEIGHTS RECORDED <b>♥</b> |                               |                | B11. DATE POST-WEIGHTS RECORDED ♥ |  |       |                             |            |  |
|                               | /                                  | /                             |                |                                   |  | _ /   | /                           |            |  |
| D10                           | Month Day  INITIALS:               | Year                          |                | ъ                                 | Month  12. INITIAL                       | С.    | Day Year                    |            |  |
| B10.                          |                                    |                               |                |                                   |  |       |                             |            |  |
| B13.                          | PAD#<br>a.                         | PRE-WEIGHT<br>b.              |                | В                                 | 14. POST-WE a.                           | IGH   | CONTAMINAT                  | ION CODE*  |  |
| 1.                            |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
| 2.                            |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
| 3.                            |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
| 4.                            |                                    | •                             | _ grams        |                                   | <u>.</u>                                 |       | gms                         |            |  |
| 5.                            |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
| 6.                            |                                    | •                             | _ grams        |                                   | ·  |       | gms                         |            |  |
| 7.                            |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
| 8.                            |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
| 9.                            |                                    | •                             | _ grams        | gms                               |  |       |                             |            |  |
| 10.                           |                                    | •                             | _ grams        |                                   | •  |       | gms                         |            |  |
|                               | •                                  | Add entire co                 |                |                                   | d entire column of<br>a and record in B1 |       | * See contamination codes i | n Appendix |  |
| B15.                          | Sum of all pre-weights             | •_                            | gms            | B16.                              | Sum of all po                            | ost-v | veights •                   | gms        |  |
|                               |                                    |                               | _              |                                   |  |       |                             |            |  |
| Total                         | Difference and Pre- and I          | Post- Weights                 |                |                                   | Work                                     | shee  | t                           |            |  |
|                               |                                    |                               | B16            |                                   | B15                                      |       | B17                         |            |  |
|                               |                                    |                               | (Post-weights) | -                                 | (Pre-weights)                            | =     | Total difference in weights |            |  |
|                               | 1st                                | Calculation:                  |                | -                                 |  | =     |                             |            |  |
|                               |                                    |                               | B16            |                                   | B15                                      |       | B17                         | -<br>      |  |
|                               |                                    |                               | (Post-weights) | +                                 | (Pre-weights)                            | =     | Total difference in weights | -          |  |
|                               | 2.1(00)                            |                               | (Fost-weights) |                                   | (Fie-weights)                            |       | Total difference in weights |            |  |
|                               | (should be done by another UIT     | Calculation: TN staff member) |                | -                                 |  | =     |                             |            |  |
| B17.                          | What is the difference of          | B16-B15?                      |                |                                   | grams                                    |       |                             |            |  |
| B18.                          | Is B17 $\geq$ 15.00 grams?         | Y                             | ES             | 1                                 | <b>→</b> FAILURE;                        | CO    | MPLETE FAILURE PROTO        | COL        |  |
|                               |                                    | N                             | О              | 2                                 |  |       |                             |            |  |

| SEC' | TION C: | THE VOIDING DIARY  |
|------|---------|--|
| C1.  | Are the | re Voiding Diary data to record below? YES 1                                 |
|      |         | NO 2 →SKIP TO C9   |
| C2.  | Date Vo | ding Diary distributed: / C2a. Initials:                                     |
| Day  | One     |  |
| C3.  | Date of | Diary Day 1: /   |
|      | C3a.    | Day of the week: Sunday  |
|      |         | 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 <b>bedtime</b> hours:                                    |
| Daw  | T       |  |
| Day  |         |  |
| C4.  | Date of | Diary Day 2: /   |
|      | C4a.    | Day of the week: Sunday  |
|      |         | 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 <b>bedtime</b> hours:                                    |
|      |         |  |
| Day  | Three   |  |
| C5.  | Date of | Diary Day 3: / / Year  |
|      | C5a.    | Day of the week: Sunday  |
|      |         | 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 <b>bedtime</b> hours:                                    |

|       | YES             |                            | 1 <b>≯FAIL</b> U               | JRE; COMPLET                  | ΓE FAILURE F          | PROTOCO         | L |
|-------|-----------------|----------------------------|--------------------------------|-------------------------------|-----------------------|-----------------|---|
|       | NO              |                            | 2                              |                               |                       |                 |   |
| Was   | the Voiding D   | iary completed per proto   | col? YES                       | 1                             | <b>→</b> SKIP TO (    | C <b>8</b>      |   |
|       |                 |                            | NO                             | 2                             |                       |                 |   |
| C7a.  | Was it a        | Patient deviation?         | 1                              |                               |                       |                 |   |
|       |                 | Staff deviation?           | 2                              |                               |                       |                 |   |
|       |                 | Other type?                | 3                              |                               |                       |                 |   |
| C7b.  | Describe:       |                            |                                |                               |                       |                 |   |
|       | _               |                            |                                |                               |                       |                 |   |
| Do yo |                 | oiding Diary to be valid o | or invalid?                    | Valid 1                       | → SKIP TO C           | 29              |   |
|       | ou judge the Vo |                            | or invalid?                    | Valid 1 Invalid 2             | → SKIP TO C           | C9<br>E MUST BE |   |
| Do yo | ou judge the Vo | oiding Diary to be valid o | or invalid?                    | Valid 1 Invalid 2             | → SKIP TO C           | C9<br>E MUST BE |   |
|       | ou judge the Vo |                            | or invalid?                    | Valid 1 Invalid 2             | → SKIP TO C           | C9<br>E MUST BE |   |
|       | ou judge the Vo |                            | or invalid?                    | Valid 1 Invalid 2             | → SKIP TO C           | C9<br>E MUST BE |   |
|       | ou judge the Vo |                            | or invalid?                    | Valid 1 Invalid 2             | → SKIP TO C           | C9<br>E MUST BE |   |
| C8a   | a. Describ      |                            | or invalid?<br>y was judged to | Valid 1 Invalid 2 be invalid: | → SKIP TO C → MEASURE | E MUST BE       |   |
| C8a   | a. Describ      | be why the Voiding Diar    | or invalid?<br>y was judged to | Valid 1 Invalid 2 be invalid: | → SKIP TO C → MEASURE | E MUST BE       |   |

## **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                  | CONTAMINANT UNKNOWN  |  |  |  |  |  |

| CODES FOR MISSING PADS |              |   |  |  |  |  |  |
|------------------------|--------------|---|--|--|--|--|--|
| 10                     | MISSING PAD: | PATIENT REPORTS NEVER USED                  |  |  |  |  |  |
| 11                     | MISSING PAD: | PATIENT REPORTS USED (INVALIDATES THE TEST) |  |  |  |  |  |