Form 56: Follow-Up Pad Test and Voiding Diary Summary, Version 09/06/02 (A)



		Section	A: General Stu	ay informati	on for	Office Use (Only:		
A1. S'	TUDY ID#:	LABEL		A2. VI	SIT# I	F/U 6 MONTH	ISFU06	F/U 12 MONTHS	S FU12
	L				I	F/U 24 MONT	HSFU24	F/U 36 MONTHS	5 FU36
					I	F/U 48 MONT	HSFU48	F/U 60 MONTHS	5 FU60
					I	F/U 72 MONT	HSFU72	F/U 84 MONTHS	5 FU84
					I	FAILURE	FAIL		
							a		
A3. D	ATE FORM C		//	. — A4. IS	THIS A R			TO AN INVALID	TEST?
		MONTH	DAY YEAR			YES			
						NO	2		
SEC	TION B: PA	AD TEST							
B1.	Are there P	Pad Test measures to	record below?	YES	S	1			
				NO		2 →	SKIP TO	SECTION C	
B2.	Date Pad T	est Kit distributed:	/ /	/ Day	Year		B2a. Initi	als:	
			Wionin	Day	1 car				
В3.	Number of	pads distributed in the	he Kit:						
		•							
B4.	Date Pad T	Test Kit returned:	/	,	/				
	Dute I ud I	ost Hit Totalliou.	Month	Day		Year			
Fron	n the Diary								
B5.	Date Pa	nd Test started:	-	/ _ Month	 Day	_ /	 Year		
				Wionth	Day		1 Cai		
	B5a.	Hour started:	:		B5b.	AM	1 PM	1 2	
	B5c.	Hour ended:	:		B5d.	AM	1 PM	I 2	
B6.	Was the	e patient menstruatin	g when the Pad T	est was cond	ucted?	YES	1		
						NO	2		
						110	2		

B7.	Was the	Pad Test compl	leted 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				
				Invalid2	→ MEASURE MUST BE REPEATED				
	B8a.	Describe why	escribe why the Pad Test was judged to be invalid:						

Affix ID Label Here

	♥ PRE-WEIGHTS ♥			4	P	OST-WEIGHTS ♥	
B9. DATE PRE-WEIGHTS RECORDED ↓				B11. DATE POST-WEIGHTS RECORDED ♥			
	/ /				_ /	//	
D10	Month Day Year		ъ.	Month	a	Day Year	
B10.	INITIALS:		В				
B13.	PAD # PRE-WEIGHT a. b.		В	14. POST-WEI a.	IGH'		ATION CODE *
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.						gms	
	Add entire col	<u> </u>	Ad	d entire column of		* See contamination code	s in Appendix
	B13b and recore	d in B15	B14a	a and record in B16	5	+	
B15.	B15. Sum of all pre-weights egms			Sum of all po	st-v	veights •	gms
Total Difference and Pre- and Post- Weights				Works	shee	t	
		B16		D15		B17	
		(Post-weights)	_	B15 (Pre-weights)	=	Total difference in weights	
	14 Calculation	(1 Ost-weights)		(1 ic-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)						
D17	What is the difference of D1C D150						
B17. What is the difference of B16-B15?				grams			
B18. Is B17 \geq 15.00 grams? YES				→ FAILURE;	co	MPLETE FAILURE PROT	OCOL
	No	OC	. 2				

SEC	SECTION C: THE VOIDING DIARY							
C1.	Are the	re Voiding Diary dat	a to record below?	YES				
C2.	Date Voi	ding Diary distribute	ed: / Month	Day / Ye	C2a. Ini ar	tials:		
Day	One							
C3.	Date of I	Diary Day 1:	Month Day	/				
	C3a.	Day of the week:	Sunday1	Monday 2	Tuesday 3	Wednesday 4		
			Thursday5	Friday 6	Saturday7			
	C3b.	Number of acciden	ts:	ACCIDENT COU FAILURE PROT	UNT ≥1 = FAILURE; O'COCL	COMPLETE		
	C3c.	Toilet voids during	waking hours:					
	C3d.	Toilet voids during	bedtime hours:					
Day	Two							
C4.	Date of I	Diary Day 2:	Month Doy	/	· 			
	~.		•					
	C4a.	Day of the week:		Monday 2 Friday 6	-	Wednesday 4		
			Thursday	111day 0	Saturday			
	C4b.	Number of acciden	ts:	ACCIDENT CO FAILURE PRO	OUNT ≥1 = FAILURE OTOCOL	; COMPLETE		
	C4c.	Toilet voids during	waking hours:					
	C4d.	Toilet voids during	bedtime hours:					
Day	Three							
C5.	Date of I	Diary Day 3:	/ Month Day	/	· 			
	C5a.	Day of the week:	Sunday1	Monday 2	Tuesday3	Wednesday 4		
			Thursday5	Friday 6	Saturday7			
	C5b.	Number of acciden	ts:	ACCIDENT CO FAILURE PRO	UNT ≥1 = FAILURE; TOCOL	COMPLETE		
	C5c.	5c. Toilet voids during waking hours:						
	C5d.	Toilet voids during	bedtime hours:					

Did the woman report <u>any</u> accidents during the 3		rt any accidents during the 3	3-day Voiding Diary?				
	YES		1→FAILURE; COMPLETE FAILURE PROTOCOL				
	NO		2				
Was th	ne Voiding D	iary completed per protocol	ol? YES 1 →SKIP TO C8				
			NO 2				
C7a.	Was it a	Patient deviation?	1				
		Staff deviation?	2				
		Other type?	3				
C7b.	Describe: _						
			Invalid 2 → MEASURE MUST BE REPEATED				
C8a.	Descril	be why the Voiding Diary w	was judged to be invalid:				
Please J Diary d		nformation obtained from th	the patient that may have affected the interpretation of the Pad Test or Voi				
		nformation obtained from th					
		nformation obtained from th					

Appendix

CON	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 <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)				