

Biospecimen Collection 3 Month

A. Whole Blood

1

Date of collection:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	BloodDate	<i>Name: BloodDate SASFmt:</i> BloodDate <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		DATETIME		No range checks
Val	Text	Culture Suppression									
-1	--										

2

Time of collection:

:

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	BloodTime	<i>Name: BloodTime SASFmt:</i> BloodTime <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		NVARCHAR	100	No range checks
Val	Text	Culture Suppression									
-1	--										

3

Date patient last ate solid food:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	BloodFastingDate		DATETIME		No range checks

4

Time patient last ate solid food:

:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	BloodFastingTime		NVARCHAR	250	No range checks

5 | Time processed:
:

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	TimeProcessed	<i>Name:</i> TimeProcessed <i>SASFmt:</i> TimeProcessed <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		NVARCHAR	100	No range checks
Val	Text	Culture Suppression									
-1	--										

6 | Time placed in freezer:
:

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	TimeInFreezer	<i>Name:</i> TimeInFreezer <i>SASFmt:</i> TimeInFreezer <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		NVARCHAR	100	No range checks
Val	Text	Culture Suppression									
-1	--										

B. UrinePrimary

1 | What was the method of collection for the urine sample?
 --
 Mid-stream clean catch
 Straight Catheterization
 Both

#	Field Name	Lookup Set	Type	Length	Range Checks
1	UrineMethod	<i>Name:</i> UrineMethod <i>SASFmt:</i> UrineMethod	SMALLINT		No range checks

Val	Text	Culture Suppression
-1	--	
1	Mid-stream clean catch	
2	Straight Catheterization	
3	Both	

2 Clean catch date of urine collection:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanDateUrine		DATETIME		No range checks

3 Clean catch time of urine collection:
 :

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanTimeUrine		NVARCHAR	100	No range checks

4 Date patient last ate solid food:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanFastingDate		DATETIME		No range checks

5 Time patient last ate solid food:
 :

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanFastingTime		NVARCHAR	250	No range checks

6 Clean catch total volume obtained:

- Not Done
-
- oz
- mL
- Not Done

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	CleanUrineVol	<i>Name: OZML SASFmt: OZML</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>oz</td> <td></td> </tr> <tr> <td>2</td> <td>mL</td> <td></td> </tr> <tr> <td>99</td> <td>Not Done</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	oz		2	mL		99	Not Done		FLOAT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
1	oz																			
2	mL																			
99	Not Done																			
2	CleanUrineVolUnit	<i>Name: OZML SASFmt: OZML</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>oz</td> <td></td> </tr> <tr> <td>2</td> <td>mL</td> <td></td> </tr> <tr> <td>99</td> <td>Not Done</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	oz		2	mL		99	Not Done		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
1	oz																			
2	mL																			
99	Not Done																			

7

Clean catch time of last prior void:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanTimeLastVOid		NVARCHAR	100	No range checks

8

Clean catch time placed in refrigerator (if not immediately processed):

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanTimeInFridge		NVARCHAR	100	No range checks

9

Clean catch time processed:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanTimeProcessed		NVARCHAR	100	No range checks

10

Clean catch time placed in freezer:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CleanTimeInFreezer		NVARCHAR	100	No range checks

11

Straight catheter date of urine collection:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightDateUrine		DATETIME		No range checks

12

Straight catheter time of urine collection:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightTimeUrine		NVARCHAR	100	No range checks

13

Date patient last ate solid food:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightFastingDate		DATETIME		No range checks

14

Time patient last ate solid food:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightFastingTime		NVARCHAR	250	No range checks

15

Straight catheter total volume obtained:

- Not Done
-
- oz
- mL
- Not Done

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	StraightUrineVol	<i>Name: OZML SASFmt: OZML</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>oz</td> <td></td> </tr> <tr> <td>2</td> <td>mL</td> <td></td> </tr> <tr> <td>99</td> <td>Not Done</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	oz		2	mL		99	Not Done		FLOAT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
1	oz																			
2	mL																			
99	Not Done																			
2	StraightUrineVolUnit	<i>Name: OZML SASFmt: OZML</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>oz</td> <td></td> </tr> <tr> <td>2</td> <td>mL</td> <td></td> </tr> <tr> <td>99</td> <td>Not Done</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	oz		2	mL		99	Not Done		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
1	oz																			
2	mL																			
99	Not Done																			

16

Straight catheter time of last prior void:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightTimeLastVOid		NVARCHAR	100	No range checks

17

Straight catheter time placed in refrigerator (if not immediately processed):

#	Field Name	Lookup Set	Type	Length	Range Checks
---	------------	------------	------	--------	--------------

1	StraightTimeInFridge		NVARCHAR	100	No range checks
---	----------------------	--	----------	-----	-----------------

18

Straight catheter time processed:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightTimeProcessed		NVARCHAR	100	No range checks

19

Straight catheter time placed in freezer:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	StraightTimeInFreezer		NVARCHAR	100	No range checks

C. Saliva

1

Date of Day 1 Morning salivary cortisol:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D1DateMorningCortisol	<i>Name:</i> D1DateMorningCortisol <i>SASFmt:</i> D1DateMorningCortisol <table border="1" data-bbox="636 1394 1068 1562"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		DATETIME		No range checks
Val	Text	Culture Suppression									
-1	--										

2

Time of Day 1 Morning salivary cortisol:

#	Field Name	Lookup Set	Type	Length	Range Checks
1	D1TimeMorningCortisol	<i>Name:</i> D1TimeMorningCortisol	NVARCHAR	100	No range checks

		<i>SASFmt:</i> D1TimeMorningCortisol								
		<table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--			
Val	Text	Culture Suppression								
-1	--									

3

Barcode ID of Day 1 AM Salivary Sample

#	Field Name	Lookup Set	Type	Length	Range Checks
1	SalivaDay1AMBC		NVARCHAR	50	No range checks

4

Date of Day 1 Night salivary cortisol:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D1DateNightCortisol	<i>Name:</i> D1DateNightCortisol <i>SASFmt:</i> D1DateNightCortisol <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		DATETIME		No range checks
Val	Text	Culture Suppression									
-1	--										

5

Time of Day 1 Night salivary cortisol:

 :

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D1TimeNightCortisol	<i>Name:</i> D1TimeNightCortisol <i>SASFmt:</i> D1TimeNightCortisol <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		NVARCHAR	100	No range checks
Val	Text	Culture Suppression									
-1	--										

6

Barcode ID of Day 1 PM Salivary Sample

#	Field Name	Lookup Set	Type	Length	Range Checks
1	SalivaDay1PMBC		NVARCHAR	50	No range checks

7

Date of Day 2 Morning salivary cortisol:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D2DateMorningCortisol	<i>Name:</i> D2DateMorningCortisol <i>SASFmt:</i> D2DateMorningCortisol <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		DATETIME		No range checks
Val	Text	Culture Suppression									
-1	--										

8

Time of Day 2 Morning salivary cortisol:

 :

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D2TimeMorningCortisol	<i>Name:</i> D2TimeMorningCortisol <i>SASFmt:</i> D2TimeMorningCortisol <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		NVARCHAR	100	No range checks
Val	Text	Culture Suppression									
-1	--										

9

Barcode ID of Day 2 AM Salivary Sample

#	Field Name	Lookup Set	Type	Length	Range Checks
1	SalivaDay2AMBC		NVARCHAR	50	No range checks

10

Date of Day 2 Night salivary cortisol:

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D2DateNightCortisol	<i>Name:</i> D2DateNightCortisol <i>SASFmt:</i> D2DateNightCortisol <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		DATETIME		No range checks
Val	Text	Culture Suppression									
-1	--										

11

Time of Day 2 Night salivary cortisol:

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	D2TimeNightCortisol	<i>Name:</i> D2TimeNightCortisol <i>SASFmt:</i> D2TimeNightCortisol <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		NVARCHAR	100	No range checks
Val	Text	Culture Suppression									
-1	--										

12

Barcode ID of Day 2 PM Salivary Sample

#	Field Name	Lookup Set	Type	Length	Range Checks
1	SalivaDay2PMBC		NVARCHAR	50	No range checks

D. ProtocolDeviations312EV

1

Did the participant smoke tobacco in the 3 hours prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks
---	------------	------------	------	--------	--------------

1	EVsmokeTab	<i>Name: \$Edema SASFmt: \$Edema</i>	SMALLINT	No range checks															
		<table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown			
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		
2	Unknown																		

If yes, specify which samples (check all that apply):

2



Blood

Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	EVsmokeTabSpecify	<i>Name: SampleProtDevShort</i> <i>SASFmt: SampleProtDevShort</i> <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

Did the participant exercise in the 3 hours prior to providing any sample?

3

--

No

Yes

Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks			
1	EVexercsize	<i>Name: \$Edema SASFmt: \$Edema</i> <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> </table>	Val	Text	Culture Suppression	SMALLINT		No range checks
Val	Text	Culture Suppression						

		-1	--			
		0	No			
		1	Yes			
		2	Unknown			

4

If yes, specify which samples (check all that apply):



Blood

Urine

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	EVexercsizeSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																	
-1	--																		
1	Blood																		
2	Urine																		

5

Did the participant have caffeine in the 6 hours prior to providing any sample?

--

No

Yes

Unknown

#	Field Name	Lookup Set			Type	Length	Range Checks															
1	EVcaffeine	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																				
-1	--																					
0	No																					
1	Yes																					
2	Unknown																					

6

If yes, specify which samples (check all that apply):



- Blood
 Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	EVcaffeineSpecify	<p><i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort</p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

7

Did the participant have probiotics (except yogurt or drinks) in the 24 hours prior to providing any sample?

- No
 Yes
 Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	EVprobiotics	<p><i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema</p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

8

If yes, specify which samples (check all that apply):



- Blood
 Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	EVprobioticsSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

9

Did the participant wear a pad in their underwear or wear pull-ups in the 48 hours prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	EVwearpad	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

10

If yes, specify which samples (check all that apply):

-
- Blood
 - Urine

#	Field Name	Lookup Set	Type	Length	Range Checks

1	EVwearpadSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort	NVARCHAR	100	No range checks												
		<table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine				
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

11

Did the participant use a spermicide in the 7 days prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	EVspermicide	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

12

If yes, specify which samples (check all that apply):

-
- Blood
 - Urine

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	EVspermicideSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table>	Val	Text	Culture Suppression				NVARCHAR	100	No range checks
Val	Text	Culture Suppression									

		-1	--				
		1	Blood				
		2	Urine				

E. ProtocolDeviations312WM

- This section suppressed if database function al.fn_GetGender returns 1

1 Did the participant have active menstrual bleeding in the 48 hours prior to providing any sample?

--
 No
 Yes
 Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	WMmenstr	<i>Name: \$Edema SASFmt: \$Edema</i> <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

2 If yes, specify which samples (check all that apply):

Blood
 Urine

#	Field Name	Lookup Set	Type	Length	Range Checks			
1	WMmenstrSpecify	<i>Name: SampleProtDevShort SASFmt: SampleProtDevShort</i> <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </table>	Val	Text	Culture Suppression	NVARCHAR	100	No range checks
Val	Text	Culture Suppression						

		-1	--		
		1	Blood		
		2	Urine		

3

Did the participant use a tampon or menstrual cups in the 48 hours prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	WMtampon	<p><i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema</p> <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

4

If yes, specify which samples (check all that apply):

-
- Blood
 - Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	WMtamponSpecify	<p><i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort</p> <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

Did the participant use douches, feminine sprays, or wipes in the 48 hours prior to providing any sample?

5

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	WMfemspray	<p><i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema</p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

If yes, specify which samples (check all that apply):

6

-
- Blood
 - Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	WMfemspraySpecify	<p><i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort</p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

7

Did the participant have vaginal sex in the 48 hours prior to providing any sample?

-
- No
- Yes

Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	WMvagsex	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

8

If yes, specify which samples (check all that apply):



- Blood
- Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	WMvagsexSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

9

Did the participant use vaginal medications in the 7 days prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks
1	WMvagmed	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema	SMALLINT		No range

					checks
	Val	Text	Culture Suppression		
	-1	--			
	0	No			
	1	Yes			
	2	Unknown			

10

If yes, specify which samples (check all that apply):



- Blood
- Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	WMvagmedSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

F. ProtocolDeviations312MN

- This section suppressed if database function al.fn_GetGender returns 2

1

Did the participant use medications, antifungal powder, or cream on or near their genitals in the 48 hours prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks
---	------------	------------	------	--------	--------------

1	MNmedantifung	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema	SMALLINT	No range checks															
		<table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown			
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		
2	Unknown																		

If yes, specify which samples (check all that apply):

2

-
- Blood
- Urine

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	MNmedantifungSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression															
-1	--																
1	Blood																
2	Urine																

Did the participant have sex (any kind - vaginal, oral, anal) in the 48 hours prior to providing any sample?

3

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks			
1	MNsex	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema	SMALLINT		No range checks			
		<table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> </table>	Val	Text	Culture Suppression			
Val	Text	Culture Suppression						

		-1	--			
		0	No			
		1	Yes			
		2	Unknown			

If yes, specify which samples (check all that apply):

4



Blood

Urine

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	MNsexSpecify	<i>Name:</i> SampleProtDevShort <i>SASFmt:</i> SampleProtDevShort <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Blood</td> <td></td> </tr> <tr> <td>2</td> <td>Urine</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		1	Blood		2	Urine		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																	
-1	--																		
1	Blood																		
2	Urine																		

G. ProtocolDeviationsSW

Did the participant eat any food, drink any liquid, or brush their teeth after waking up and prior to providing any sample?

1

--

No

Yes

Unknown

#	Field Name	Lookup Set			Type	Length	Range Checks						
1	SWeatdrink	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		SMALLINT		No range checks
Val	Text	Culture Suppression											
-1	--												

	0	No			
	1	Yes			
	2	Unknown			

If yes, specify which samples (check all that apply):



- Day 1 AM sample
- Day 1 PM sample
- Day 2 AM sample
- Day 2 PM sample

2

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	SWeatdrinkSpecify	<i>Name:</i> SampleProtDevSwab <i>SASFmt:</i> SampleProtDevSwab <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>1</td> <td>Day 1 AM sample</td> <td></td> </tr> <tr> <td>2</td> <td>Day 1 PM sample</td> <td></td> </tr> <tr> <td>3</td> <td>Day 2 AM sample</td> <td></td> </tr> <tr> <td>4</td> <td>Day 2 PM sample</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	1	Day 1 AM sample		2	Day 1 PM sample		3	Day 2 AM sample		4	Day 2 PM sample		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																		
1	Day 1 AM sample																			
2	Day 1 PM sample																			
3	Day 2 AM sample																			
4	Day 2 PM sample																			

Did the participant smoke tobacco in the 3 hours prior to providing any sample?

-
- No
- Yes
- Unknown

3

#	Field Name	Lookup Set	Type	Length	Range Checks			
1	SWsmokeTab	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> </table>	Val	Text	Culture Suppression	SMALLINT		No range checks
Val	Text	Culture Suppression						

		-1	--			
		0	No			
		1	Yes			
		2	Unknown			

If yes, specify which samples (check all that apply):



4

- Day 1 AM sample
- Day 1 PM sample
- Day 2 AM sample
- Day 2 PM sample

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	SWsmokeTabSpecify	<i>Name:</i> SampleProtDevSwab <i>SASFmt:</i> SampleProtDevSwab <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Day 1 AM sample</td> <td></td> </tr> <tr> <td>2</td> <td>Day 1 PM sample</td> <td></td> </tr> <tr> <td>3</td> <td>Day 2 AM sample</td> <td></td> </tr> <tr> <td>4</td> <td>Day 2 PM sample</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	1	Day 1 AM sample		2	Day 1 PM sample		3	Day 2 AM sample		4	Day 2 PM sample		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																		
1	Day 1 AM sample																			
2	Day 1 PM sample																			
3	Day 2 AM sample																			
4	Day 2 PM sample																			

Did the participant exercise in the 3 hours prior to providing any sample?

5

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks
1	SWexercsize	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema	SMALLINT		No range checks

	Val	Text	Culture Suppression			
	-1	--				
	0	No				
	1	Yes				
	2	Unknown				

If yes, specify which samples (check all that apply):



- Day 1 AM sample
- Day 1 PM sample
- Day 2 AM sample
- Day 2 PM sample

6

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	SWexercsizeSpecify	<i>Name:</i> SampleProtDevSwab <i>SASFmt:</i> SampleProtDevSwab <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>1</td> <td>Day 1 AM sample</td> <td></td> </tr> <tr> <td>2</td> <td>Day 1 PM sample</td> <td></td> </tr> <tr> <td>3</td> <td>Day 2 AM sample</td> <td></td> </tr> <tr> <td>4</td> <td>Day 2 PM sample</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	1	Day 1 AM sample		2	Day 1 PM sample		3	Day 2 AM sample		4	Day 2 PM sample		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																		
1	Day 1 AM sample																			
2	Day 1 PM sample																			
3	Day 2 AM sample																			
4	Day 2 PM sample																			

Did the participant consume caffeine in the 6 hours prior to providing any sample?

-
- No
- Yes
- Unknown

7

#	Field Name	Lookup Set	Type	Length	Range Checks

1	SWcaffeine	<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema	SMALLINT	No range checks															
		<table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown			
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		
2	Unknown																		

8

If yes, specify which samples (check all that apply):



- Day 1 AM sample
- Day 1 PM sample
- Day 2 AM sample
- Day 2 PM sample

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	SWcaffeineSpecify	<i>Name:</i> SampleProtDevSwab <i>SASFmt:</i> SampleProtDevSwab <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>1</td> <td>Day 1 AM sample</td> <td></td> </tr> <tr> <td>2</td> <td>Day 1 PM sample</td> <td></td> </tr> <tr> <td>3</td> <td>Day 2 AM sample</td> <td></td> </tr> <tr> <td>4</td> <td>Day 2 PM sample</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	1	Day 1 AM sample		2	Day 1 PM sample		3	Day 2 AM sample		4	Day 2 PM sample		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																		
1	Day 1 AM sample																			
2	Day 1 PM sample																			
3	Day 2 AM sample																			
4	Day 2 PM sample																			

9

Did the participant have probiotics (except yogurt or drinks) in the 24 hours prior to providing any sample?

-
- No
- Yes
- Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	SWprobiotics	<i>Name: \$Edema SASFmt: \$Edema</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> <tr> <td>2</td> <td>Unknown</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		2	Unknown		SMALLINT		No range checks
Val	Text	Culture Suppression																		
-1	--																			
0	No																			
1	Yes																			
2	Unknown																			

If yes, specify which samples (check all that apply):



- Day 1 AM sample
- Day 1 PM sample
- Day 2 AM sample
- Day 2 PM sample

10

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	SWprobioticsSpecify	<i>Name: SampleProtDevSwab</i> <i>SASFmt: SampleProtDevSwab</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Day 1 AM sample</td> <td></td> </tr> <tr> <td>2</td> <td>Day 1 PM sample</td> <td></td> </tr> <tr> <td>3</td> <td>Day 2 AM sample</td> <td></td> </tr> <tr> <td>4</td> <td>Day 2 PM sample</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	1	Day 1 AM sample		2	Day 1 PM sample		3	Day 2 AM sample		4	Day 2 PM sample		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																		
1	Day 1 AM sample																			
2	Day 1 PM sample																			
3	Day 2 AM sample																			
4	Day 2 PM sample																			

H. Questionnaire Complete

-
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks									
1	CenterComplete	<i>Name:</i> QuestComp <i>SASFmt:</i> QuestComp <table border="1" style="margin-top: 10px;"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression												
-1	--													
1	Yes													
