



Pre-Randomization  
ID: \_\_\_\_\_

### Central Lab Collection Form – Baseline 24-Hour Urine

**Data from worksheet (best of initial sample or repeat)**

**Collect start date** ..... \_\_\_ / \_\_\_ / \_\_\_\_\_

**Start time** ..... \_\_\_ : \_\_\_ AM or PM

**Collect stop date** ..... \_\_\_ / \_\_\_ / \_\_\_\_\_

**Stop time** ..... \_\_\_ : \_\_\_ AM or PM

**Time Sufficient (22-26 hours)** ..... Yes  1  
No  2

**Total Volume** ..... \_\_\_ \_\_\_ cc

**Volume Sufficient (≥500 cc)** ..... Yes  1  
No  2

**Sample obtained correctly** ..... Yes  1  
 discarded initial void    ≤1 voiding missed    not menstruating   No  2

**Was participant able to refrigerate sample?** ..... Yes  1  
No  2

**Sample Collection Outcome** ..... Ready to ship to lab\*  1  
Failed  2

**Extra Collection Outcome** ..... Ready to ship to storage\*  1  
Failed  2

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

\*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.



## Overview

This form will be used to track the collection and shipping of 24-hour urine specimens during screening. Use forms 62 and 64 for specimens collected at 6 and 18 months. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a 24-hour urine specimen.

## Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

## Coding Instructions

Page	Field	Special Instructions
2	1	Record the start date and start time as recorded on the label attached to the urine collection jug. For the date, use leading zeros as appropriate. Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that Noon is 12 PM.
	2	Record the stop date and stop time as recorded on the label attached to the urine collection jug.
	3	Subtract stop time from start time. Record answer in hours (rounded to the nearest whole number). This is a two-digit field. Use leading zeros as appropriate.
	4	Mark Yes if number of hours is at least 22 but not more than 26 hours. Mark No if number of hours is fewer than 22 or more than 26.
	5	Record total volume in cubic centimeters of urine as measured using a graduated cylinder. This is a four-digit field. Use leading zeros if necessary.
	6	Mark Yes if total volume is at least 500 cc. Otherwise, mark No.
	7	Mark Yes only if all three boxes below are checked.
	8	Mark Yes if the participant was able to refrigerate the sample. Note that this is <u>not</u> a requirement for Q9.
	9	Mark Adequate if answers are Yes to #4, 6, and 7.
	10-18	Only go on to repeat sample if Q9 is coded as inadequate. Instructions for Q10-18 are the same as for Q1-9.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to

### **Review Instructions**

Make sure that if the sample collection outcome is “ready to ship to lab” that you have two tubes of urine (1 with HCl and 1 without) in the freezer. If the extra collection outcome is “ready to ship to storage”, you should have four additional tubes of urine in the freezer (2 with HCl and 2 without).

Check that the data were correctly transcribed from page 2 to page 1.

### **Additional Instructions**

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.