This document provides guidance on the types of specifications that should be documented in the protocol if the study involves collection of urine. As the majority of the items that follow will be dictated on the protocol level and NOT collected for each and every specimen, CDEs are not associated with these guidelines.

## Urine Sample Collection Information

1. Date and time of urine sample collection: // (m m/dd/yyyy) : (hh:mm, 24 hour clock)
2. Date and time participant/ subject last ate: // (m m/dd/yyyy) : (hh:mm, 24 hour clock)
3. Urine Time Point:

[ ]  First [ ]  Second [ ]  Other, specify

1. Method of urine collection:

[ ]  Catheter [ ]  Clean catch [ ]  Other, specify

1. Duration of urine collection: [ ]  Timed collection, hours [ ]  Spot collection
2. If timed collection, frequency of collection:

[ ]  Collection of all urine per specified duration in question #5

[ ] Other, specify number of times urine was collected per duration in question #3

1. Total volume collected: mL

## Urine Sample Processing Information

1. Number of vials:
2. Volume of vials: mL
3. Volume of last vial, if different from other vials: mL [ ]  N/A – same as other vials
4. Sample centrifuged? [ ]  Yes [ ]  No (Skip to Question 8) [ ]  Unknown (Skip to Question 8)

If Yes, type of centrifuge used: [ ]  Refrigerated [ ]  Non-refrigerated

1. Date sample centrifuged: // (m m/dd/yyyy) : (hh:mm, 24 hr clock)
2. End Time sample centrifuged: : (hh:mm, 24 hr clock)
3. Speed at which sample centrifuged: x g
4. Number of aliquots:
5. Volume of aliquots: mL
6. Volume of last aliquot, if different from other aliquots: mL [ ]  Not Applicable
7. Time sample aliquoted: : (hh:mm, 24 hr clock)
8. Time aliquots put on dry ice: : (hh:mm, 24 hr clock)
9. Were aliquots on ice prior to freezing? [ ]  Yes [ ]  No [ ]  Unknown
10. Long term sample storage temperature: [ ]  -800C [ ]  -20 0C [ ]  4 0C [ ]  Other, specify 0C
11. Was sample stored locally prior to long term storage (e.g. home refrigerator)?

[ ]  Yes [ ]  No (End)[ ]  Unknown(End)

1. Total time in local storage : (hh:mm)
2. Temperature of local storage: [ ]  -800C [ ]  -20 0C [ ]  4 0C [ ]  Other, specify 0C