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.

## Sample Collection Information

1. \*Date and time of sample collection:

(M M/D D/Y Y Y Y):

(HH:MM, 24 hr clock):

Unknown

Not applicable

1. Urine time point:

First

Second

Other, specify

1. Date and time of participant’s/subject’s last meal:

(M M/D D/Y Y Y Y):

(HH:MM, 24 hr clock):

Unknown

Not applicable

1. \*Urine collection method

Catheter

Clean Catch

1. Duration of urine collection:

(hours):

(minutes):

1. \*Volume of urine collected (mL):

## Sample Processing Information

1. \*Was sample centrifuged?

Yes

No

Unknown

* 1. If yes:
     1. Time centrifuge started:

(HH:MM, 24 hr clock):

Unknown

* + 1. \*Speed of centrifugation xG (times gravity):
    2. \*Duration of centrifugation (minutes):

1. How many vials of urine were collected?

\*Most important items to specify in protocol