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 Collection

1. What was the last date and time of medication dosing prior to urine sample collection?

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

(HH:MM, 24 hr clock):

1. How much urine was collected? (cc):
2. Was the urine stored in pre-cooled tubes and stored at -80˚C?

Yes

No

Unknown

1. Was the urine sample shipped to a central laboratory?

Yes

No

Unknown

* 1. If yes, under what conditions was the sample shipped (select all that apply)?

Dry Ice

Overnight

Other, specify