

Criteria for Redo Collection (Instructions for Study Staff)

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road, NE, M/S D74, Atlanta, GA 30333, ATTN: PRA 0920-xxxx.

When the urine sample is returned to the clinic, assessment will be made to determine if the sample is acceptable. If any of the following scenarios apply, the urine sample is deemed as incomplete or invalid:

a. Time of urine collection was not recorded –

If the length of collection time cannot be ascertained, the urine sample cannot be used. If the participant is unable or unwilling to redo the collection, no additional follow-up interview or dietary recall will be administered. This case will be counted as “non-response” and coded as “Not Done” with comment “Participant failed to follow protocol”.

b. The length of collection time is <22 hours or >26 hours -

In order for this to truly qualify as a 24 hour collection, the length of collection time should be 22-26 hours. Although this urine sample may still be used, it is preferable to get a new sample falling in the required timeframe.

- If the participant is unable or unwilling to redo the collection and the length of the collection is more than 20 hours, the interviewer will continue to complete the rest of follow-up questionnaire and dietary recall interview.
- If the participant is unable or unwilling to redo the collection but the length of the collection is less than 20 hours, no additional follow-up interview or dietary recall will be administered. This case will be counted as “non-response” and coded as “Not Done” with comment “Participant failed to follow protocol”.

c. Missing or losing urine for once or more during the collection –

This is determined by the combined responses to FQ2, FQ5, and FQ7. Although this urine sample may still be used, it is preferable to get a more completed sample for analysis.

- If the participant only missed or lost urine for one time, but he/she is unable or unwilling to redo the collection, the interviewer will continue to complete the rest of follow-up questionnaire and dietary recall interview.
- If the participant missed or lost urine for more than one time, and he/she is unable or unwilling to redo the collection, no additional follow-up interview or dietary recall will be administered. This case will be counted as “non-response” and coded as “Not Done” with comment “Participant failed to follow protocol”.

When the urine sample met the above criteria, the participant will be asked if he/she is willing to redo the collection. If the participant agrees to redo the collection, the interviewer will go over the procedure with him/her again and schedule another collection appointment.