

Instructions for Completing the Federal Drug Testing Custody and Control Form for Oral Fluid Specimen Collection

When making entries on a paper CCF, use black or blue ink pen and press firmly

- Collector marks the **Oral Fluid** box above STEP 2.
- Collector ensures that the name and address of the HHS-certified laboratory are on the top of the Federal CCF.
- Collector verifies that the Specimen Identification (I.D.) number on the top of the Federal CCF matches the Specimen I.D. number on the labels/seals.

STEP 1:

- Collector ensures that the required information is in STEP 1. Collector enters a remark in STEP 2 if Donor refuses to provide his/her SSN, Employee I.D., or CDL state and number.
- Collector notes any unusual behavior or appearance of Donor in the Remarks line in STEP 2. If the Donor's conduct at any time during the collection process clearly indicates an attempt to tamper with the specimen, Collector notes the conduct in the Remarks line in STEP 2 and takes action as required.

STEP 2:

- Collector checks the Split or Single Collection box in STEP 2. For split specimen collections, Collector checks the appropriate split type box (i.e., Serial, Concurrent, or Subdivided).
- Collector checks that each collection device is within its expiration date before use and marks the appropriate box in STEP 2. For ECCFs: Collector may scan or enter the expiration date for each device into the ECCF system before use, for the system to check that the collection device is within its expiration date and to mark STEP 2 (i.e., when both A and B devices are within date for a split collection). Collector visually verifies the expiration date on each tube vs. that in the ECCF system immediately prior to use.
 - For serial split collections:
 - Collector records times in STEP 2 when Donor removes the A specimen device from their mouth and when Donor places the B specimen device in their mouth (time between A and B collections must not exceed two minutes).
 - If two minutes is exceeded, Collector discards the first specimen, collects the second specimen as the A specimen, and collects a third specimen as the B specimen. Collector enters explanatory remarks in STEP 2.
- Collector observes volume indicator(s) for A and B specimens during collection and marks the appropriate box in STEP 2. If the volume is less than required by the federal agency, Collector takes action as required, and enters remarks in STEP 2.
- Collector inspects the specimen and notes any unusual findings (e.g., unusual color, presence of foreign objects or material) in the Remarks line in STEP 2 and takes action as required.
- If no oral fluid specimen is collected by the end of the collection process, Collector checks the None Provided box, enters a remark in STEP 2, discards Copy 1, and distributes remaining copies as required.

STEP 3:

- Donor watches Collector cap each specimen tube and affix the label/seal on each specimen tube. NOTE: Collector places the label/seal so the expiration date remains visible on the tube.
- Collector dates the specimen tube label(s)/seal(s) after placement on the specimen tube(s).
- Donor initials the specimen tube label(s)/seal(s) after placement on the specimen tube(s).
- Collector instructs Donor to read and complete the certification statement in STEP 5 on Copy 2 (signature, printed name, date, email address, phone numbers, and date of birth). If Donor refuses to sign the certification statement, Collector enters a remark in STEP 2 on Copy 1. For ECCFs: if the donor refuses to sign electronically but is willing to sign a paper CCF, Collector prints ECCF Copies 1-5. Donor signs in STEP 5 of Copies 2-5 using a wet-ink signature and Collector signs in STEP 4 of Copies 1-5 using a wet-ink signature.

STEP 4:

- Collector completes entries in STEP 4 on Copy 1:
 - Collector chain of custody (signature, printed name, date, time of collection, and name of delivery service).
 - Manufacturer's expiration date for each device used (date on A tube as the Primary/Single Specimen Device Expiration Date, date on B tube as the Split Specimen Device Expiration Date). For ECCFs: Collector may scan or enter the expiration date for each device into the ECCF system before use, for the system to check that the collection device is within its expiration date and to enter the expiration date into STEP 4 when the device is within date.
- Collector verifies the expiration date in STEP 4 on Copy 1 of the CCF vs. that on the tube (i.e., both A and B tubes), then places the sealed specimen tube(s) in a leak-proof plastic bag.
- Paper CCF: Collector places Copy 1 in separate compartment of the leak-proof plastic bag. Electronic CCF: Collector places printed copy of Copy 1 in separate compartment of the leak-proof plastic bag and/or places package label (with Specimen I.D. number, test facility name and contact information, and collection site name and contact information) on the outside of the bag.
- Collector seals the bag, prepares the specimen package for shipment, and distributes the remaining CCF copies as required.