DATAC
Drug & Alcohol Testing Association of Canada

Laboratory - Oral Fluid Procedural

It is possible that the EOA requires you to obtain a split specimen sample for your oral fluid laboratory test; two samples may be collected in one of three ways, those are:

Serially: one right after the other (with the requirement of no more than 2 MINUTES between collections)
Concurrent: at the same time, with two devices in the donor's mouth.
Subdivided: collected using one device that splits the sample into two vials, or after collection the collector splits the sample into two vials.

1. First steps as any collection:
    a. check ID
    b. fill out paperwork,
    c. have donor sign form
2. If the donor will be with you, under your direct observation from now until the entire procedure is completed, INCLUDING the ten minute wait time, you may skip to Step 4, if they will NOT be under your direct observation for the entire time, you should continue on to step 3, here
3. Ask the donor to remove any unnecessary clothing, outerwear such as a coat etc. Ask the donor to empty their pockets of all items so that you can check if there is anything to be used for substituting or adulterating their specimen.
4. Ask the donor to open their mouth so you can inspect the inside of their mouth (oral cavity).
    a. If you find an item that would be used for adulteration or substitution this would be considered a refusal to test. If this occurs you must stop the collection at this point, and report the refusal to test to the EOA as soon as possible. As well you should create an MFR which documents item(s) found and sign and date the MFR.
    b. If an item is found that could be used to adulterate, substitute or dilute specimen but may NOT have be present for that (ie. gum, tobacco, food, candy etc.) instruct the donor to remove the item.
        i. If the donor complies and removes the item, have them rinse with water (up to 4oz), they may swallow the water after rinsing if they choose.
        ii. If the donor refuses to remove the item, this is a refusal to test, inform the EOA and create an MFR to explain the situation.
    c. If the donor states they have "dry mouth" or if their oral fluid is abnormally coloured give the donor water (up to 4oz) to rinse their mouth (they may drink the water).
        i. If the donor refuses to rinse their mouth, this is considered a refusal to test, stop the collection and report the refusal to the DER.
5. Start the 10 minute timer. During the 10 minute wait you should:

a. Explain the collection procedure to the donor, particularly how to use the specific oral fluid collection device you will be using. You may allow the donor to look at the written instructions for the device if wanted.
b. Inform the donor they must remain in the designated wait area for the wait period.
c. You may choose to NOT keep the donor under your direct observation for the rest of the wait period so that you may start the collection process for other donors, but they would still remain in the Rest Area (possibly under another collector's view but not necessarily). NOTE: The collector must ensure that all collections take place privately, and maintain the security and confidentiality of the donor's information on the Federal CCF.

6. Prepare for the collection:
    a. Have the donor wash and dry their hands while in your direct view. Once this has been completed they must stay in your sight until the end of the collection. Advise them to avoid touching surfaces.
    b. Either the collector or the donor can choose a new device for the collection.
        i. The collector must open the device package. Once the package is open both the collector and the donor must have it in sight until the procedure is over.
    c. Review the manufacturer's instructions for the device with the donor.
        i. The donor can use the device to obtain the sample, however if it doesn't work and a second device has to be used to try again, the collector should handle the device to obtain the sample.
    d. Check the device being used for any obvious defects before beginning the collection. If you find any issue with the device you must discard it and use a new device.
        i. If the device you are using has diluent present you must check the volume in both A and B vials against a known proper device to confirm they both have the standard amount for that device. NOTE: it is advised that the collection site has an open device available to collectors for this comparison
        ii. When two devices with diluent are to be used for the A and B specimens (when a split is being collected) the collector is to compare the devices to each other to confirm they both have the same amount of diluent in them (if not this indicates a defective product).
    e. Confirm that the collection device is within its expiry date and indicate this on the form if there is a checkbox to that effect.
    f. Fill out the expiry date for the collection device, there is likely a section for this on your form, but if not, write the expiry date in the remarks.
7. Perform the oral fluid collection.

   a. Follow the device specific instructions, to collect the sample. You must maintain direct visual contact with the donor throughout the entire collection.
   b. If there is a failure to collect enough specimen, discard the device and begin the process again. You must note the failed attempt in the remarks section of the CCF.
   c. Once the volume indicator shows that a sufficient amount of oral fluid has been collected, or the appropriate time has gone by, the collector should take the collection device from the donor and check it for any abnormalities. If all looks correct, follow the manufacturer's instructions for completing the collection.
8. Optional second sample collection.
   a. If required, the process is then repeated a second time for a split-specimen style collection. This normally occurs when a second sample is taken by an identical or alternative device. Direction to do so will be provided by the Program Administrator (PA) or Employer, Organization, or Agency (EOA).
9. Seal the specimen(s) with the labels provided on the federal CCF while the donor watches; confirm that the numbers on the A/B labels match the specimen ID number on the CCF.
   a. Remove the tamper-evident specimen bottle seal from the Custody and Control Form (CCF) and apply it to the specimen bottle.
   b. Date the specimen bottle seal.
   c. Have the donor initial the seal. This certifies that the donor has witnessed the transfer and that the specimen in the bottle is their own.
      i. If the donor will not sign the labels, note this in the remarks of the CCF, it is NOT considered a Refusal to Test. If this step gets missed in the collection process, this is NOT a fatal flaw.
10. Complete your CCF, including:
   a. Record donor information and have the donor sign and date the form (usually found in Step 5 on Copy 2). This is the donor’s attestation to the validity of the specimen as well as their declaration that the specimen has not been adulterated or tampered with in any way.
   b. This is the copy that will be forwarded to the Medical Review Officer (MRO), so ensure that the donor legibly prints his or her name and phone numbers on the form.
   c. Step 5 on Copy 2 of the CCF does not need to be signed by the donor in order for the test to be considered valid. Ensure that the refusal or failure to sign is documented in the “Remarks” section.
   d. Record collector information, sign and date the form (usually Step 4 on Copy 1 of the CCF).This certifies the specimen collection and will also include indicating to which courier company the specimen will be released.
      i. This step initiates the chain of custody for the specimen.

    e. Fill out information about the device which was used, including its expiry date. **Always indicate the expiry date of the device(s) on the CCF!**

11. Prepare the specimen for shipment, while still in view of the donor:
    a. Place the specimen in the front pouch of the shipping bag, with absorbent material.
    b. Place the filled out Copy 1 of the CCF into the back pouch of the bag.
    c. Seal the bag so BOTH compartments are sealed, this means the adhesive on the fold over needs to go right over the hatch marks on the front of the bag.
12. Give the donor Copy 5 of the CCF and let them know they are free to go.
13. Distribute the copies of the multipart CCF
    a. Fax or email Copy 2 of the CCF IMMEDIATELY to the MRO.
    b. The collector copy, Copy 3, should be kept for a minimum of 30 days.
    c. The employer copy should be immediately faxed or emailed to the EOA.