DOT - Oral Fluid Procedural

For a DOT oral fluid collection there is only one acceptable way/device-type used to collect the specimen and that is, **Subdivided:** collected using one device that splits the sample into two vials, or after collection the collector splits the sample into two vials. We will go over the procedure here from start to finish.

1. First steps as any collection:
    a. **Check ID**
    b. Fill out all items in Step 1
2. 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, enter remarks as to what has occurred, and report the refusal to test to the DER immediately.
    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, enter your remarks onto the CCF and inform the DER immediately.
    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).
    d. BEST PRACTICE - offer the donor water after checking their mouth and before starting the 10 minute timer, in case they had a dry mouth but didn't think to mention it, or realize how much oral fluid would be needed for the test. This way you are less likely to waste a device and need to start over again after a QNS.
3. **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. Choose the device and **check the expiration date and check the box in Step 2 indicating that each device is within its expiry date.**.
    c. **Show the donor the expiration date on the device.**
    d. **Have the donor wash and dry their hands** while in your direct view (may use hand sanitizer if not washing available). Once this has been completed they must stay in your sight (or another worker's sight) until the end of the collection. Advise them to avoid touching surfaces.

4. 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.
    a. 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.
    b. If there is not a device to compare with, simply check that both vials look like they have the SAME amount of diluent in them, and that it is not cloudy.
5. 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, have the donor remove the device from their mouth and place specimen collection into the two vials with buffer.
    d. HINT: if you are worried about the vials getting knocked over as you are preparing to put the collection devices in them, you can place them in an open, unused, specimen container to ensure they do not fall over.
6. **Check the Volume Indicator(s) Observed checkbox in Step 2**
7. 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.
8. Complete your CCF, including:
    a. Record donor information and **have the donor sign and date the form** (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. Copy 2 will be forwarded to the Medical Review Officer (MRO), so ensure that the donor legibly prints their name and phone number on the form.

   c. **Record collector information, sign and date the form** (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.

9. **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.
10. **Give the donor Copy 5 of the CCF and let them know they are free to go.**
11. 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 DER.