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Assisted Buccal Specimen Collection Chain of Custody Procedure (Revised and adapted as a result of the COVID-19 Pandemic)

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A. Introduction

This process is effective May 1, 2020 and will continue indefinitely in order to conduct buccal swab specimen collections with little to no direct physical customer contact. It is intended for use within the governmental agency facility and may be performed by either the IV-D agency staff or DNA Diagnostics (DDC) staff, referred to throughout as "collector". The process must be in adherence with all local- and/or state-mandated safety and social distancing requirements, and must meet the accreditation standards for the American Association of Blood Banks (AABB). AABB is the accrediting body that dictates laboratory requirements and standards for parentage testing. No deviation from this procedure is acceptable that may result in direct physical contact with the customer and/or within a six foot distance.

"Assisting" the customer involves giving proper instruction to ensure collection of a suitable buccal sample for paternity testing, while directly witnessing the collection. The intention is to:

- 1. Eliminate physical contact between the "collector" and the customer; while adhering to social distancing requirements, and
- 2. Eliminate any paperwork exchange where possible.

Chain of custody must be maintained and documented, while providing instructions to the customer for the buccal swab collection procedure and witnessing the entire process.



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B. Supplies Needed

- 1. The collector will need to provide:
 - a. Face covering-home made cloth mask, scarf, bandanna or disposable mask;
 - b. Pen
- 2. DDC to provide:
 - a. Gloves
 - b. Chain of Custody forms
 - c. Buccal swabs & sample envelopes
- 3. Local agency to provide:
 - a. Appropriate space as outlined in section C;
 - b. Sanitizing surface cleaner in accordance with facility accepted procedures;

Note: Gloves must be removed and discarded in regular trash between customers, and surfaces should be sanitized using the protocols that are in place for that local facility.

- 4. The customer will need to arrive with:
 - a. Face covering;
 - b. Pen:
 - c. Government issued photo id

The following sections C, D, and E are the responsibility of the IV-D agency

When planning for collections one must take into account, but not limited to the following considerations:

C. Prepare the Space

- Coordinate designated seating in advance so that it is clear where the customers should sit during the collection process. Maintain social distancing between the collector and other customers.
- Identify a location to place paperwork to ensure a distance of 6 feet between the staff member/collector and customers. It will be necessary to establish a routine that follows the agency/facility protocols for outside visitors and meeting with



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customers on-site. It may be helpful to install a Plexiglas shield with a cutout at the bottom to pass paperwork under.

3. If the facility lends itself to conducting collections outdoors and/or in a drive-up setting there must be an agreed upon procedure and proper planning in place in order to facilitate outdoor/drive-up collection. Such a procedure will require the agency completing 100% of the paperwork in advance, with the exception of the customer consent. DDC can work with you to determine if this is an option and to customize an acceptable protocol if appropriate.

D. Schedule Customers

- 1. Communicate in advance to all customers, instructing them to remain home in the event they are experiencing any symptoms of illness.
- 2. Schedule customers that do not reside together at separate times; customers must have individual appointment times to avoid a gathering of people in any waiting areas. Emphasize the importance of being prompt.
- 3. Inform customers that they must wear a covering over their nose and mouth to enter the building. This covering may be a homemade mask, scarf, bandana, or handkerchief. Also instruct customers to bring their own pen.

E. Prepare for Customer Arrival

- 1. Complete facility sanitizing protocols before the arrival of customers and in between customers.
- 2. Wherever possible, pre-populate as much of the known information on the Chain of Custody form in advance of the customer arrival. This will reduce contact time during the process. DDC can provide an electronic version of the Chain of Custody form, if needed.

Note: It will be helpful if the agency can pre-populate the Chain of Custody form even if DDC is supplying a collector for the "Collector Assisted Process." This could be done by phone much like a "pre-registration" for a medical procedure and provide the completed or partially completed form at the time of collection.

- 3. Depending on the circumstances, you may establish a process where you can call or text customers when you are ready for them to enter the building.
- 4. Put on clean gloves prior to the customers entering the space. Observe social distancing and/or have a Plexiglass divider between yourself and the customer.

F. Verify the ID and Complete Paperwork



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- 1. Verify the identity of individual(s) by viewing a government- issued photo ID. Children typically do not have a photo ID. Instruct the customer to place the ID in the designated location and have them return to their seat while you view the ID and confirm their identity.
- Complete all or any remaining sections of the Chain of Custody form by asking questions to the customer. Obtain basic information (such as first and last name) for parties who are absent. Fingerprints will **not** be obtained for this procedure, leave this section blank.
- 3. Ask the parties to lower their face coverings and take a photo of all parties.
- 4. Write the first and last name of the tested party at the bottom of the photo, along with the date. Repeat the name back to the party to ensure that it is correct.

G. Specimen Collection Procedure

1. Open the wrapper at the end opposite from the swab tip. You can peel apart the paper ends or break the paper using the stick end of the swabs. Leave the stick exposed for the customer and place them in the designated location. It is also acceptable to instruct the customer to open the swab packets while receiving proper instruction from the collector.



Note: The actual cotton portion of the swab should not be touched or placed on any surface. If they are, discard them and use a new swab. Work with one customer at a time until their collection is completed.

2. Let the customer remove one swab from the opened swab sleeve. Ask them to swab the inside of their cheek taking precaution to stay away from the gum line and keep the swab in the middle section of the cheek. Conduct swabbing while counting to at least 10 for each swab. Ensure you can visibly see the



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swab pushing out their cheek. They should be rotating the swab and moving up and down. Use 2 swabs for each side of the cheek.

- Have the customer place each swab in the appropriate color-coded envelope after swabbing until four swabs are in the envelope. The mother or custodial parent should swab the child.
- 4. Once all four swabs are placed in the envelope, have the customer seal the envelope by pressing down on the self-adhesive flap.
- 5. Have the customer label the specimen envelope with the collected party/customer name, date of birth, and collection date. Ask each customer and the Mother or custodial parent of the child to review the sample envelope and write his/her initials to confirm the information. Have them place completed labeled envelope with swabs in the designated location. Initial and date the swab envelope and place it into the plastic sleeve.

H. Prepare to Send the Specimen and Paperwork

- 1. Once samples have been collected, have customers sign and date the Chain of Custody consent statement.
- Ask the customer to place the completed sample envelope and signed consent statement in the designated paperwork area while maintaining appropriate social distance.
- 3. Obtain the sample envelope and consent statement, review for completion, and sign and date the back of the Chain of Custody form.
- 4. Place the Chain of Custody form front-side down. Lay the photos and specimen envelopes in the center section of the back side of the Chain of Custody form. If customers are ordered to pay, place the money order here.
- 5. Fold up the bottom third of the Chain of Custody form, then fold down the top third over the bottom third.
- 6. Slide the Chain of Custody form with the samples and photo into the zippertype plastic bag.
- Ensure that the top "Requesting Agency" information is visible on one side of the bag and the M/CH/AF info is visible when the other side of the bag is viewed.
- 8. Remove the excess air and seal the bag.



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- 9. Sign/Date the tamper tape and place it over the zipped closure of the bag. Once the tamper-proof seal has been placed over the bag, the customer is free to leave.
- 10. Place each sealed bag inside the return shipping courier bag. Maintain security for these samples. Once all specimens have been collected for the day, remove the strip for the adhesive seal for the courier bag and seal it securely.

I. Shipping Procedure

- 1. Prepare the package for courier pick-up depending upon site-specific procedures. If a pick-up is needed, call FedEX at 800-463-3339. Call DDC at 800-310-9868 if you have questions.
- 2. Record the tracking number.