

DNA Diagnostics Center

SAMPLE COLLECTION MANUAL

Collection Manual

Applicants to our Collection Providers Program must read this manual thoroughly before taking the Competency Quiz. You may also download a printable copy of the manual (PDF format). You will need Adobe Reader to open the PDF.

Note: Printed copies are considered uncontrolled and may not contain current updates.

TABLE OF CONTENTS	1
Introduction	2
New York State Collections	2
Australian Collections	3
Company Overview	4
Safety	5
Confidentiality Policy	7
Client Identification	7
Chain of Custody	8
Buccal Swab Sample Collection	10
Venous Sample Collection	12
Australian Collection Procedures	14
Packaging and Shipping	18

Introduction

This Sample Collection Manual is intended for the use of all phlebotomists, collectors and personnel at sample collection sites providing services to DNA Diagnostics Center (DDC). DDC strives to establish uniformity and quality in the sample collection procedure for buccal and blood collected for DNA identity testing.

Note: This manual provides instructions on general DNA collections and does not contain specific requirements for government requested child support cases.

This manual describes DDC's policies, procedures and protocols for the following:

- Safety measures
- Confidentiality Policy
- Identification of individuals to be tested
- Completion of the chain of custody
- Collection of samples
- Packaging and shipment of the samples to the laboratory

After reading this manual, new applicants are asked to complete an online competency quiz and a collector's agreement in order to be approved to perform collections.

IMPORTANT

Client identification, quality of the samples collected, correct labeling, and complete paperwork are essential. Please follow all directions carefully.

NEW YORK STATE COLLECTIONS

Collections performed within the state of New York are to be done in compliance with New York State Department of Health regulations. It is the collector's responsibility to be knowledgeable of New York regulations and to be in accordance with them.

Patients must have a written request from a physician or another authorized official (such as courts, immigration departments, US embassies and social services) prior to collection. DDC requests a faxed copy of the referral prior to scheduling the collection appointment and instructs the patients to take the referral to the appointment. If the client has forgotten the referral, contact DDC for a faxed copy before proceeding with the sample collection.

AUSTRALIAN COLLECTIONS

Collections performed in Australia **or for individuals applying for immigration/visa into Australia** must follow NATA guidelines including the use of Form 2 and Form 4.

Collections that are required to be carried out on a person under a parentage testing order made by the court under subsection 69W(1) of the Family Law Regulations 1984 must be performed by a:

- (a) registered medical practitioner or;
- (b) person employed by a hospital, a pathology practice, a parentage testing practice or a registered medical practitioner for the purpose of taking a bodily sample from a donor.

Specific identification requirements and collection instructions are provided on page 10.

COMPANY OVERVIEW

DNA Diagnostics Center

DNA Diagnostics Center (DDC) was founded in 1995 as a full service nationwide paternity & forensic testing laboratory based in Fairfield Ohio. DDC annually tests tens of thousands of cases for the establishment of paternity and for forensics analysis utilizing DNA analysis. DDC operates under the philosophies as stated in its mission statement:

Our mission is to provide the best DNA testing service. We make DNA testing accessible and affordable to people worldwide. We serve and satisfy our customers by working as a strong, integrated team with an innovative, efficient, effective and competitive spirit matched by none.

DNA Diagnostics Center has collection agreements with thousands of collection facilities nationwide. These sites collect DNA samples and for subsequent testing at DDC's laboratory. Our collection sites play an important role in maintaining the quality of our specimens and services.

SAFETY

DNA Diagnostics Center follows those procedures outlined by OSHA (Occupational Safety & Health Administration) for the personal protection of phlebotomists and collectors as well as our clients.

The OSHA standard on bloodborne pathogens can be found in CFR 1910.1030. This standard was designed to protect health workers in preventing the transmission of HIV (human immunodeficiency syndrome) and HBV (hepatitis B) and other pathogens as a result of work place exposures. Bloodborne pathogens are pathogenic microorganisms present in blood and body fluids (i.e.; saliva with blood, amniotic, chorionic villus sample), and any unfixed tissues that may cause disease.

The following sections contain general laboratory practices that should be followed by all sample collectors.

Universal Precautions (UP):

The most important safety precaution while collecting, handling and transporting specimens is to automatically treat all blood or other potentially infectious materials as if they are known to be infectious. This practice is known as the principle of universal precautions. These precautions include the use of personal protective equipment, work practice controls, good hygiene and housekeeping. It is meant to reduce the risks associated with exposure to bloodborne pathogens. UP cannot entirely eliminate these risks.

Personal Protective Equipment (PPE):

Personal protective equipment places a barrier between you and the patient's blood or other potentially infectious materials. The following are useful in protecting against bloodborne pathogens:

Gloves
Safety glasses / face shield
Lab coat

Any direct contact with body fluids (blood, saliva, etc.) must be avoided. Gloves must be worn when in contact with a patient or sample, and should be discarded after collecting samples from each patient. Do not use gloves for more than one collection. Never wash or decontaminate disposable gloves for reuse; discard gloves if torn, punctured, or contaminated, or if their ability to function as a barrier is compromised.

Safety glasses or a face shield may be worn in cases where blood or other infectious materials may spray or splash.

All PPE must be removed prior to leaving the work area. To minimize the potential spread of bloodborne pathogens, PPE should not be worn in public areas.

Engineering and Work Practice controls:

To limit the spread of any pathogen, hand washing should be routinely performed:

- Before and after each patient contact
- Before and after gloving
- Before leaving the collection area
- Before eating
- After hands have touched a possibly contaminated surface

Thoroughly wash hands with soap or an approved antimicrobial solution for a minimum of 20 seconds.

Disposable Sharps (Blood collections)

Any contaminated object that can puncture the skin is considered a contaminated sharp. This included needles, scalpels, broken glass, slides, and any other object capable of penetrating the skin. In blood collections, self-sheathing needles should be used to reduce risk of exposure or puncture. The following are procedure for disposal of sharps and needles.

Sharps Containers

Sharps containers should be used in areas where the risk of generating sharp objects has been assessed. Containers should be labeled and color-coded as well as puncture resistant and leak proof. They should be kept upright at all times, with the lid will be tightly sealed prior to removal of the container.

Once a sharps container is filled to $\frac{3}{4}$ capacity, it should be placed in a regulated medical waste container or disposed of as specified by your own laboratory protocols. If the outside of the container becomes contaminated, the container should be placed into another leak proof container prior to disposal. Never open, empty, clean or attempt to reuse a contaminated sharps container.

Needle Handling

Never recap needles; they should be disposed of in a sharps container. Do not place sharps inside packages for shipment. The proper procedure for picking up any sharp object is the use of a mechanical device such as forceps or tweezers to prevent any accidental punctures, which could increase the likelihood of a contamination.

Good Hygiene and Housekeeping

As a general policy, under no circumstance shall there be any eating, drinking, smoking, applying cosmetics or lip balm and handling of contact lenses in any area where the potential for bloodborne pathogens exist, such as: laboratory, phlebotomy room and waste storage areas.

Any area where the potential for bloodborne pathogens exist, should be decontaminated with a disinfectant solution (such as 10% bleach) known to eradicate bloodborne pathogens as often as practical and feasible. For example, after each blood collection, the table area should be cleaned. The same procedure should be done at the end of each workday in the laboratory or collection site.

Confidentiality Policy

DNA Diagnostics Center (DDC) holds in strict confidence all information relating to client testing. All individuals collecting specimens for DDC are also required to keep all information that is provided by patients confidential. You are not to discuss any testing, or to confirm or deny that any testing is being performed, or has been performed, or may be performed at DNA Diagnostics Center with anyone outside of DDC. Patient and case information is confidential and can only be discussed with DDC employees.

Confidential information, as used in this paragraph, is defined as any information not in the public domain relating to the names or addresses of individuals, test results, processes, formulas and any other information DNA Diagnostics Center may deem confidential.

Client Identification

It is imperative that all individuals are properly identified prior to their samples being collected. The Client Identification and Consent/Chain of Custody Form provided by DDC must be completely and properly filled out and signed by the test participants and the collector. This form must be returned with the samples collected.

Proper identification must be obtained by the phlebotomist/collector prior to collecting the samples. Acceptable means of identification include the following:

- A government issued photo ID such as a driver's license
- State photo ID, passport, current employee photo ID, or student photo ID
- Non-returnable recent photo suitable for identification (**includes infants**)
- Photo taken at the time of collection that is suitable for identification

Identification by the other test participants, known as mutual identification, is acceptable only if it is clearly documented on a chain of custody form (Mutual Identity Form provided by DDC) and signed by test participants and /or guardians. In certain situations and when a photo or camera is not available, the Mutual ID form may replace the need for a photograph when all test participants and the custodians of any minors appear together for the sample collection. **This form cannot be used for New York State collections.** Again, this type of identification should only be used in extraordinary or extenuating circumstances with the approval of DNA Diagnostics Center's customer service.

To properly identify the test participants, the following identification procedures are used. (The step- by- step procedures for completing the Client Identification and Consent Form are found in the next page).

- **Photocopy** all identification materials provided by the test participants. The test participants and collector are to sign and date the copies. A photo is required for all tested parties including infants.
- **Photograph** all tested parties when photo identification or a recent photo is not provided. The tested parties and the collector are to sign and date the photograph.

- **Complete and sign Section II** or the appropriate section of the consent form, verifying proper identification of each client and proper labeling of the specimens. By signing, the sample collector also affirms that the samples have not been tampered with or left unattended, and that the collector has no interest in the outcome of the test being performed. If the collector has a **conflict of interest** (defined below), he or she should **decline the collection**, or an **impartial witness** should be present during the collection. He or she should sign below the collector's signature to verify the proper identification and sample integrity.

A conflict of interest is defined as a situation in which the collector has any of the following relationships with any of the tested parties: spouse, parent/child, sibling, other family relationships, friend.

Chain of Custody

Chain of Custody procedures protect the integrity of client identification and sample collection throughout the DNA testing process.

Note: You may only use collection materials for legal cases that have been sent directly to the collection site by the requesting laboratory. Collection materials must not be in possession of any of the tested parties prior to or after the collection.

Clients should have complete confidence that their samples have been placed into a properly labeled envelopes or containers, sealed and transported to DDC with no possibility of tampering. **Collection materials (kit and samples) must not be in the possession of the tested parties either before or after the collection.**

The DNA Diagnostics Center provides a Client Identification and Consent form that serves as Chain of Custody documentation. This form must be completed in full and signed by the phlebotomist/collector and the individual being collected (for minors, see note in #1 below). Additionally, if a representative photo is not provided, an instant photograph may be taken of those individuals collected.

The collector must verify that the Client Identification and Consent Form is complete and legible. The following are procedures for properly filling out the form and ensuring Chain of Custody.

1. Ask adult patient test participant or minor's legal guardian to do the following:
 - a. Read the back of the Consent form,
 - b. Complete the appropriate section of the form, with the requested tested party's information. The name on the DNA test report will be written as indicated on the consent form.
 - c. Sign the consent form.

Notes:

- Do not fill out the tested participant's information on the form yourself. To ensure correctness of the information, test participants themselves should write in their details in Section 1 or appropriate fields.
- A consent form for each test participant must be completed.
- If the test participant is under 18 years of age or legally incompetent, an individual with the legal authority to provide consent must complete and sign the form. A minor mother may sign the consent for her child, but not for herself.

2. Ask to see the individual's photo ID.
 - At this time, make a visual comparison between the photograph on the ID and the individual being collected.
 - If the identification is questionable, request additional ID. Make a photocopy of the ID and sign and date it as described in the previous page.
 - Verify any name discrepancies between the form and the ID and the individual being collected.
 - Please inform DDC if the identity of any tested party is in question.
3. Check the Consent form to see if the test participant has indicated his/her race on the form.
 - If the race was not indicated, ask the individual for his/her race-do not rely on appearance, as this can often be deceiving.
 - If necessary, please explain to the individual that this information is important in the statistical calculations of the testing.
4. Ask if the test participant has received any blood transfusions within last 90 days or a bone marrow transplant or verify the information has been completed on the form.
 - If so, record the date of the transfusion/transplant.
 - Buccal swabs, rather than a blood sample, must be collected from an individual who has had a bone marrow transplant or a recent blood transfusion.
5. Photograph the test participants if no photo identification is provided. A photograph that is suitable for proper identification can be used.
 - Take an instant picture of the tested parties together if possible. If the parties object, take a picture of the mother and child together and then photograph the alleged father or other individuals separately.
 - Ask the participants to hold up the DDC identification Sheet (provided in the test kit or faxed from DDC for the picture.
 - Have each tested party sign and date the photograph.
 - Return the photo(s) with the samples and completed forms.
6. Complete the collector's section (Section II) at the bottom of the form, recording the specimen type, patient history, form of patient ID presented, collection site information and the collection date and time.

Note: Some forms may have the listed information completed by the test participant. Verify the section has been completed.

 - Date and sign the form as indicated.
 - Check that the collection dates written by the patient and collector match on both the consent forms and the samples.
7. Review the completed form with the test participants to ensure that the form was filled out fully and accurately.
8. Collect the samples according to procedures on pages 8 (buccal) and 9 (blood), sealing them with tamper tape as described.
9. Sign Section II or the bottom of the form, verifying proper labeling and security of samples. Seal and tamper tape samples as outlined in the collection procedures.

Note: To maintain proper chain of custody, it is important that the client identification/chain of custody form and sample is completed in full with utmost accuracy.

Sample Collection Procedures

To provide confidence in the accuracy and validity of test results, it is required that only someone who has no interest in the outcome of the testing performs the sample collection. In the event the collector has a conflict of interest, **provide another collector** or a second impartial individual is to witness and document that the collection was performed correctly maintaining proper chain of custody.

DNA Diagnostics Center (DDC) routinely utilizes cheek cell tissue (buccal swab) in its DNA tests. DDC also occasionally uses blood samples upon request. Although both types of samples are acceptable, buccal swabs are preferred for the following reasons:

- Buccal swabs are non-invasive, safe, and comfortable for the patient.
- The results are accurate even after the patient has received a blood transfusion.
- The procedure has only minimal chance of exposure to bloodborne pathogens.

You will find instructions for both sample collections in this manual. DDC provides a kit with the approved forms and supplies. **Do not use DDC supplies for non-DDC collections.**

Use latex-free supplies, including gloves or tourniquets to collect specimens from those individuals with allergies to latex.

Buccal Swab Sample Collection

Specimen:

4 Dacron buccal swabs-sterile

Patient Preparation

None

Storage/ Transportation:

Buccal swabs may remain at room temperature following collection and during transport.

Supplies:

1 Buccal swabs envelope per patient, each envelope containing 4 buccal swabs (provided)

Latex Free gloves

Tamper Tape (provided)

Procedure:

During buccal swab sample collection, precautions must be observed to avoid contaminating the swab. The swab can be contaminated by touching the end of swab to any foreign surface such as a table top, collector's skin and other samples. Immediately after sample collection, the swab must be taken from the patient's mouth and placed directly into the paper envelope labeled for him/her. Do not place the swabs in plastic.

1. Perform Client identification and Chain of Custody procedures (see pages 6 and 7 of this manual) and complete the required paperwork.

Note: Do not pre-label all the buccal swab envelopes in advance. Pre-labeling the envelopes may lead to errors, such as switching of samples and envelopes.

2. Remove one envelope of buccal swabs from the collection kit.
3. Place the envelope on a clean surface (clean paper towel may be used).
4. Label the swab envelope with the tested individual's full name, date of birth, and the date of collection. Sign your initials on the space provided.

Note:(Do not use the information from DDC identification sheet provided – the spelling has not been verified with patient ID).

- **Always label one swab envelope and collect the sample from one tested person at a time.**
 - **The name on the sample must match the Client ID/Consent form.**
5. Put on clean gloves.
 6. Cut open the buccal wrapper at the end opposite from the cotton tip.
 7. Remove one swab from the package, taking care not to touch the end with the cotton tip.
 - Do not touch the cotton tip to touch any surface (table, skin, etc.), doing so could contaminate the specimen.
 8. Ask the tested party to open their mouth wide.
 9. Insert swab into the patient's mouth and rub it firmly back and forth and up and down while rotating against the inside of the cheek for 10 strokes.
 - It is important to collect enough cheek cells on the entire swab, so be sure to rotate the swab while rubbing.
 - Insufficient specimen may require recollection and will delay test results.
 10. Remove the swab from the mouth and place it directly into the **PAPER** Buccal Swab Collection Kit envelope labeled for that person.
- CAUTION: Do NOT place the swabs back into the plastic wrapper.** Moisture created within the plastic sleeve encourages the growth of mold, which destroys the DNA sample.
11. Repeat the collection process with the remaining swabs.
 - Use 2 swabs on the right cheek and 2 swabs on the left cheek for each tested person.
 - Place swabs into the labeled paper envelope.
 - **Discard the plastic wrapper** when all swabs have been used.
 12. . Seal the paper envelope within view of the patient.
 - **The collected sample should never be left unattended.**
 13. Ask the patient to **verify** that their name and date of birth are correct and **sign or initial** the envelope.
 14. Sign the Client Identification/ Consent form.
 - If appropriate, have the witness sign below the collector's signature.
 15. Repeat steps 1-14 for each patient.
 - Label each sample carefully.
 - The name on the envelope **must** match the name on the client consent form.
 - Please use all four swabs provided to ensure adequate collection of DNA samples.
 16. Take a photo, if a camera is available, of the tested parties holding the DDC Identification Sheet provided in the kit or faxed from DDC.

- This ID sheet has the patient names and a case # printed on the front.
 - Ask client to sign and date the photograph taken.
17. Place the completed sealed collection envelopes, forms, copies of ID and photograph or instant camera into the provided plastic zip lock bag as described in Packaging and Shipping.
 18. Tamper tape the zip lock bag in the presence of the patient.

Venous Blood Collection

DNA Diagnostics Center requires venous collections to be performed by individuals who have previously acquired a certificate in phlebotomy from a nationally accredited organization such as the American Society of Clinical Pathology or have documented relevant experience. Therefore, the phlebotomist will be knowledgeable concerning bloodborne pathogen risks, Universal Precautions and measures to be taken to reduce/eliminate risk. Any needle puncture or bloodborne exposure is to be reported immediately to a physician for evaluation and treatment when indicated.

The veins on the forearm are the preferred sites for collection. There may be instances where this vein is not suitable. An alternate site in the hand may be selected. Do not make more than two attempts to draw samples. If you are unable to obtain a minimum of 1.0 milliliter, collect a buccal swab.

Specimen: 5 ml blood collected in an EDTA vacutainer (purple top tube) Minimum volume 1 ml

Note: Prenatal Paternity Blood Collections require a specific collection kit provided by DDC. The kit includes barcoded forms and vacutainer tubes; 1 EDTA tube for Alleged Father and 2 special application tubes for the Mother. Refer to the specific collection instructions included in the prenatal paternity blood collection kit.

Patient Preparation: None

Storage/Transportation Requirements:

Blood samples may remain at room temperature following collection and during transport. If transport is delayed more than 48 hours-refrigerate in a secure area until transported.

Supplies:

Vacutainer tube (purple top) –EDTA (provided)
 Tourniquet*
 Powder free or latex free gloves
 Alcohol pad
 2"x2" gauze
 Vacutainer needle-**sterile** / holder
 Ammonia inhalants
 Adhesive bandaide*
 Sharps disposal system
 Tamper tape (provided)

* Use latex-free supplies (syringe, tourniquet, and bandage) for latex-sensitive **test participants**.

Procedure:

1. Perform Client identification and Chain of Custody procedures (see pages 6 and 7 of this manual) and complete the required paperwork.

2. Ask if the **tested party if he/she** is allergic to latex; if so, use latex-free supplies
3. Select a suitable site for venipuncture.
4. Position arm downward and assemble necessary supplies.
5. Put on clean gloves.
6. Apply tourniquet 2 to 4 inches above the venipuncture site.

(Note: Gloves and lab coat must be worn. If you anticipate that contamination might occur, such as when drawing blood from an uncooperative individual, wear eye and face protection.)

7. Cleanse with an alcohol swab.
 - Allow the site to dry.
8. Insert the needle into the vein; making sure the needle is bevel up.
9. After sufficient amount of blood has been collected, remove the tourniquet.
10. Position dry gauze over the site and remove needle, applying pressure to venipuncture site.
11. Place a sterile band-aid over the site to complete the procedure.
12. Dispose of the materials used in a biohazard container. Use either of the following procedures for sharps:
 - Eject needle from the holder into the sharps container
 - Dispose of entire blood collection device into the sharps container.

Note: Never recap the needle.

13. Label the tube with the patient's name, date of birth, and collection date. Sign your initials on the tube.
 - Label each tube as it is collected. Do not pre-label tubes.
14. Ask patient to verify that the labeling is correct and sign his/her initials on the label.
15. Take a photo of the tested parties, if a camera is available, holding the DDC Identification Sheet provided in the kit or faxed from DDC. Ask the tested parties to sign the photograph taken or provided.
16. Sign the Client Identification and Consent Form.
 - If appropriate, have the witness sign below the collector's signature.
17. Place the labeled blood tubes into the Styrofoam box provided in the blood collection kit as outlined on the next page (Packaging and Shipping).
 - Seal the samples, documents, photograph or instant camera (if provided) in the zip lock bag in the presence of the patients.

Notes:

- Do Not attempt venipunctures on wrist, ankles or feet.

- Do not attempt a venipuncture using the arm adjacent to a mastectomy site.
- If patient becomes light headed or dizzy, discontinue venipuncture and break ammonia inhalant under the patient's nose.
- If patient does not recover quickly, contact your local EMS immediately. (Do not leave patient alone.)

Australian Collections

Client Identification

It is imperative that all individuals are properly identified prior to their samples being collected. The Donor Identification & Consent Affidavit, Form 2 and the Donor Collection, Form 4, provided by DDC, must be completely and properly filled out and signed. These forms must be returned with the samples collected.

Form 2- The Donor Identification & Consent Affidavit – Completed by Justice of the Peace

The sampler (collector) must verify that Form 2 is complete, legible and completed on the day the donor's sample is taken. The affidavit may be completed prior to the collection appointment or completed at the collection site if a Justice of the Peace or equivalent person eligible to witness a Form 2 Affidavit is available at the collection site and it has been arranged in writing beforehand.

Instructions for Justice of the Peace or Equivalent:

The following instructions are provided to the Justice of the Peace, or equivalent person eligible to witness a Form 2 Affidavit, for properly completing Form 2.

The collector can NOT sign Form 2 unless they are a Justice of the Peace or equivalent.

Use one form for one adult and / or child (test participant) COC-4038.au.

The affidavit for a minor (under 18yrs of age or for a person not capable of affirming the affidavit (eg. suffering from a mental disability) may be completed only by those listed in each category listed below:

a) Minors

- Parent or guardian of the child
- Person, who under a specific issues order, is responsible for the long term or day-to-day care, welfare and development of the child

b) Adult not capable of swearing or affirming the affidavit including mental disorders;

- a trustee or manager in relation to the person under a law of the State or Territory whose laws apply to the person; or
- a person who is responsible for the care, welfare and development of the person suffering from a mental disability.

1. Ask the donor or Parent/Guardian to complete the DDC Form 2 (affidavit).

Note: The form may be previously completed by the donor or Parent/Guardian but must not be signed prior to your witness. If the form has been previously signed a new form will be required.

2. Attach a recent photograph of the donor to the form. The photo shall:
 - Suitable for the identification of the donor
 - Measure approximately 45mm by 35mm (passport size)
 - Show a full face view of the donor's head and shoulders
 - Have a plain background
 - Marked with an "A"
 - Bear a statement, signed by both the person witnessing the sworn affidavit and the deponent, identifying it as the photograph mentioned in the affidavit.
3. Verify that the photograph is a true likeness of the donor.
4. Sign the photograph.
5. Ask the donor or guardian to sign the photograph/ statement.
6. Ask the donor or guardian to sign and date the Form 2 affidavit .
7. Enter your name and sign the form as the witness to the affidavit. Verify that all the data fields have been completed.

Instructions for the Collector:

The sampler (collector) must verify that Form 2 is complete, legible and completed on the day the donor's sample is taken. Form 2 must be provided and complete. Do not add information to the completed form. If Form 2 is not complete, has been signed prior to the date of collection or unsigned, do not proceed with the collection. Advise the client that a new Form 2 will need to be completed. Notify the laboratory.

Completion of Form 4 (Donor Collection)

Form 4 can be used for up to 4 donors if all the donors are being collected at the same appointment at the same time. If the collections are performed at different times, even though they may be in the same case, they must have separate forms completed.

1. Verify the correct donors are being collected. Verify that an acceptable photo taken on the day of collection, representative of the donor, has been provided for Form 4 or will be taken at the time of collection.
2. Verify the correct identification and donor information with a type of identification such as license or passport.
3. A recent photograph is required that is passport sized showing a full face view of the donor's head and the donor's shoulders against a plain background. The collection can not proceed without a suitable photograph.

4. Complete the requested information for collector and donor details. All fields must be completed correctly. Errors may require recollection. Correct errors with a strike out and initial or complete a new form. Do not use white-out.
5. Attach the photo(s) of the donor to the form verifying that it is a true likeness of the donor. If the photo is not representative of the donor, take a photo if possible. Otherwise request additional identification and notify the laboratory.
6. Complete the donor information: name, date of birth, type of sample and identification requested under each photograph.

NOTE: The donor information must match the information on the ID and Form 2.
Verify the spelling and information entered onto Form 4 as correct.

7. Sign your name partly on the photo and partly on the form so that removal would be evident.
8. Collect the sample as instructed in Specimen Collection Procedure below.
9. Sign the form.

Collection of Buccal samples

The labeling, collection and packaging must be performed in the presence of the donors and authorized guardian. **If latex free gloves are not available, verify the donor has no latex allergies.**

Specimen:

4 polyester buccal swabs

Patient Preparation

None

Storage/ Transportation:

Buccal swabs may remain at room temperature following collection and during transport.

Supplies:

Buccal swabs-4 sterile swabs per donor (provided)

Buccal swab sample envelope (provided)

Latex Free gloves

Tamper Tape (provided)

Procedure:

During buccal swab sample collection, precautions must be observed to avoid contaminating the swab. The swab can be contaminated by touching the end of swab to any foreign surface such as a table top, collector's skin and other samples. Immediately after sample collection, the swab must be taken from the patient's mouth and placed directly into the paper envelope labeled for him/her. Do not place the swabs in plastic.

1. Verify the correct donors are being collected. Verify that an acceptable photo taken on the day of collection, representative of the donor has been provided or will be taken at the time of collection (See Form 4 instructions above).
2. Remove one envelope of buccal swabs from the collection kit.

Note: Do not pre-label **all** the buccal swab envelopes in advance. Pre-labeling the envelopes may lead to errors, such as switching of samples and envelopes.

3. Place the envelope on a clean surface (clean paper towel may be used).
4. Label the sample in ink with the following information;
 - Full name of the donor as listed on the affidavit **Form 2 and Form 4**; and
 - The date of birth and the **gender** of the donor; and
 - The date and time at which the sample was taken; and
 - The signature of the sampler and the donor or authorized guardian.

Note: Always label one swab envelope and collect the sample from one tested person at a time.

5. Put on clean gloves.
6. Cut open the plastic wrapper at the end opposite from the cotton tip.
7. Remove one swab from the package, taking care not to touch the end with the polyester tip.
 - **Do not** touch the polyester tip to any surface (table, skin, etc.), doing so could contaminate the specimen.
8. Ask the donor to open their mouth wide.
9. Insert swab into the donor's mouth and rub it firmly back and forth and up and down while rotating against the inside of the cheek for 10 strokes.
 - It is important to collect enough cheek cells on the entire swab, so be sure to rotate the swab while rubbing.
 - Insufficient specimen may require recollection and will delay test results.
10. Remove the swab from the mouth and place it directly into the PAPER Buccal Swab Collection Kit envelope labeled for that person.

CAUTION: Do NOT place the swabs back into the plastic wrapper. Moisture created within the plastic sleeve encourages the growth of mold, which destroys the DNA sample.

11. Repeat the collection process with the remaining swabs.
 - Use 2 swabs on the right cheek and 2 swabs on the left cheek for each tested person.
 - Place swabs into the labeled paper envelope.
 - **Discard the plastic wrapper** when all swabs have been used.
12. Seal the paper envelope or sample container with tamper tape within view of the donor and/or consenting guardian. **Sign.**
 - **The collected sample should never be left unattended or given to a tested party.**
14. Ask the donor to **verify** that their specimen label information is correct and **sign** the envelope.
15. Repeat steps 1-14 for each patient.
 - Label each sample carefully.

- The name on the envelope **must** match the name on the affidavit and **Form 4**.
 - Please use all four swabs provided to ensure adequate collection of DNA samples.
16. Take a photo, if a photograph was not provided, and the donor has arranged the service.
 17. Complete Form 4 entering the required donor information.
 18. Attach the photograph
 19. Sign the photograph with the signature partly on the photograph and partly on the statement.
 20. Place the completed sealed collection envelopes, the affidavit (Form 2), collection statement (Form 4), into the provided plastic zip lock bag as described in Packaging and Shipping.
 21. Tamper tape the zip lock bag in the presence of the patient.

Venous Blood Collection :

Venous blood sample collections are performed as outlined on page 9 completing Forms 2 and 4 as directed in the Buccal Samples Collection procedure.

Packaging and Shipment

DNA Diagnostics Center provides a collection kit for the packaging and shipping samples to our laboratory. The samples must be packed correctly to ensure that they arrive at the laboratory in good condition. Following the procedures below helps maintain the sample's integrity from the time of shipment to its receipt by DDC.

Please notify the courier for pickup at the time of collection. Samples should be shipped on the day they are collected (exception of holidays and weekends).

Packaging

DDC provides shipping bags and materials approved to ship specimens to the laboratory. Follow instructions found on the bag and below.

1. Place the following items inside the clear zip lock bag;
 - All specimens collected (buccal swab envelopes and/or polystyrofoam box containing the labeled blood tubes).
 - All completed Client identification /Consent forms, affidavits (Australia cases).
 - All photocopies of patients' IDs
 - DDC Identification Sheet used in the photograph (showing the case number and patients' names).

- Disposable camera (if one is provided)
 - The Polaroid photograph, if an instant camera was used.
2. Sign and date the tamper tape provided and seal the plastic bag's zip lock closure with the tamper tape.
 - Have clients witness the tamper taping of the specimen bag.
 - Samples and consent forms must be placed into the bag and sealed with tamper tape. **The tamper tape is very important in providing a proper chain of custody.** Although preferable, the other items are not required to be inside the tamper-taped bag.
 - Do not break the seal to add them to the bag. If it is necessary to break the tamper tape, it must be done in the presence of the clients, resealed with both the collector and client's initials on the tamper tape.
 3. Seal Package using the following procedure:
 - If you were provided with the DDC cardboard box, place the clear zip lock bag inside the box.
 - Place the tamper taped zip lock bag or cardboard box inside the large plastic and seal securely.
 4. Complete the Airbill:
 - Complete the "From" address on the air bill on the Shipping Bag if it is blank.
 - Write in the Case Number or the patient's name in the Billing Reference box.

Shipping

For package pick-up within the U.S. please call the phone number of the carrier on the airbill provided. For international shipments, contact your local international carrier for instructions. Take note of the confirmation number for your records.

This is the end of the Sample Collection Manual. If you feel familiar with the material you have just read, please proceed to the Competency Quiz.

Agreements

DNA Diagnostics Center's policy requires that the phlebotomist/collector complete and sign the Statement of Procedures/ Agreement form. This form indicates that the phlebotomist has read and understands the procedures and will adhere to the confidentiality policy.

All completed and signed forms are to be returned to DNA Diagnostics Center electronically or by mail. If you have any questions regarding any of these forms, please don't hesitate to contact our customer service department.

Customer Service:

e-mail address:

DNA Diagnostics Center
Re: Collector Agreement/Competency
205 Corporate Court
Fairfield, Ohio 45014

Collector's Agreement

I have read and fully understand the sample collection manual that has been provided by DNA Diagnostics Center. I hereby affirm that I will abide by these policies and procedures and understand that deviations **MUST NOT** be made without prior approval by DNA Diagnostics Center. If I represent a collection facility or multiple collectors, I will be responsible for their training and compliance to DDC policies and procedures.

Furthermore, I understand that all information received on genetic testing of an individual(s) is subject to confidentiality and that any information, in whatever form it is presented to me, shall be deemed confidential information. I agree that I shall not use or disclose, directly or indirectly, any confidential information during the time I am serving as a collector or after discontinuance of providing services to DDC.

NAME _____

ADDRESS _____

CITY/ST/ZIP _____

PLACE OF
EMPLOYMENT _____

HOME PHONE _____

WORK PHONE _____

SOC. SECURITY# / _____

TAX ID # (if applicable) _____

Signature

Date

DDC Signature

Date

DRAW SITE APPLICATION

Facility Name: _____

Patient Sent to: ☐ Same address ☐ Different Address

Address: _____

if different: _____

Phone: _____

Kits Sent to: ☐ Same Address ☐ Different Address

Fax: _____

if different: _____

Email: ☐ YES ☐ NO

Checks Sent to: ☐ Same Address ☐ Different Address

Email Address: _____

if different: _____

Internet Access ☐ YES ☐ NO

Lab Manager (if applicable): _____

Schedule Appointments with: _____

Hours of Operation:

In Office: Mon. _____ Tues. _____ Wed. _____ Thurs. _____ Fri. _____ Sat. _____ Sun. _____
Mobile Mon. _____ Tues. _____ Wed. _____ Thurs. _____ Fri. _____ Sat. _____ Sun. _____

Collection Fee: In Office (\$15-25pp) Buccal _____ Blood* _____
Mobile (\$15-35pp) Buccal _____ Blood* _____

Minimum Age Requirement for Blood Draw: _____

Billing: ☐ Will send monthly invoice to DDC with date of service, patient's names and case number.

☐ Request check to be sent with each individual case scheduled

*** Phlebotomists collecting blood specimens are required to have a phlebotomy certificate or documentation of relevant experience.**

Instant camera available?

☐ YES

☐ NO

Do you provide specimen collection for other companies?

☐ YES

☐ NO

Are you a vendor/reseller of paternity testing?

☐ YES

☐ NO

Which lab/labs do you outsource paternity testing to?

Please list 2 business references. May we contact those references? ☐ YES ☐ NO

Name

Phone

Relationship

