



SAMPLE COLLECTION MANUAL

Revised and Updated
v.2 February 2005

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I. 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 procedures used in buccal and blood sample collection for DNA identity testing.

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 samples to the laboratory

After reading the manual, new applicants should complete an online competency quiz and a collector's agreement in order to be approved to perform collections. The agreement, a copy of which is on page 16 of this manual, must be signed by the collector and returned to DNA Diagnostics Center.

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 the New York regulations and to be in accordance with them.

Patients must have a written request from a physician or other 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.

II. COMPANY OVERVIEW

DNA Diagnostics Center (DDC) was founded in 1994 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 forensic 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 for subsequent testing at DDC's laboratory. Our collection sites play an important role in maintaining the quality of our samples and services.

III. 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), HBV (hepatitis B), and other pathogens as a result of workplace exposures. Bloodborne pathogens are pathogenic microorganisms present in blood and body fluids (i.e., saliva with blood, amniotic, chorionic villi 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 samples 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 patients' 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 pathogens, handwashing 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 antimicrobial solution for a minimum of 10 seconds.

Disposable Sharps (Blood Collections)

Any contaminated object that can puncture the skin is considered a contaminated sharp. This includes 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 procedures 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 tightly sealed prior to removal of the container.

Once a sharps container is filled to 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; these 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 to use a mechanical device such as forceps or tweezers to prevent any accidental punctures, which could increase the likelihood of 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 exists: the laboratory, phlebotomy room, and waste storage areas.

Any area where the potential for bloodborne pathogens exists 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.

IV. CONFIDENTIALITY POLICY

DNA Diagnostics Center (DDC) holds in strict confidence all information relating to client testing. All individuals collecting samples for DDC are required to keep all patient information confidential. You are not to discuss any testing, nor confirm or deny that any testing is being performed, 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 section, 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.

V. 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 for each test participant 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
- 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 both test participants. In certain situations and when a camera is not available, the Mutual ID form may replace the need for a photograph **when all adult test participants appear together for sample collection**. 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 section.)

- **Photocopy** all identification materials provided by the test participants. The test participants and collector are to sign and date the copies.
- **Thumbprint** the test participants. DNA Diagnostics Center provides an ink strip in the sample collection kit for thumbprinting.
- **Photograph** all test participants. The test participants and the collector are to sign and date the photograph.
- **Complete and sign Section II** of the consent form, verifying proper identification of each client and proper labeling of the samples. 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 sample collection. He or she should sign below the collector's signature to verify 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.

VI. CHAIN OF CUSTODY

Chain of Custody procedures protect the integrity of client identification and sample collection throughout the DNA testing process. Clients should have complete confidence that their samples have been placed into properly labeled envelopes or containers, sealed, and transported to DDC with no possibility of tampering.

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 by the individual being collected (for minors, see note in #1 below). Additionally, instant photographs and thumbprints are taken of the test participants.

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 the adult test participant** or minor's legal guardian to do the following:
 - a. Read the back of the consent form.
 - b. Complete Section I of the form. The name on the DNA test report will be written as indicated on the consent form.
 - c. Sign the form.

Notes:

- **Do not** fill out Section I of the form yourself. To ensure correctness of the information, test participants themselves should write in their details in Section I.
 - 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 section (section V).
 - Verify any name discrepancies between the form and the ID with the tested party.
 - Please inform DDC if the identity of any test participant 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 during the DNA test.

4. Ask if the test participant has received any blood transfusion within the last 90 days or a bone marrow transplant.
 - 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, together if possible.
 - If the participants 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 test participant print their name, sign, and date the photograph.
 - Return the photo(s) with the samples and completed forms.
6. Thumbprint each client to be tested as described in section V.
 - Peel the clear plastic ink strip
 - Ink the patient's right thumb.
 - Apply his/her thumbprint in the box on Section II of the Client Identification and Consent Form.
7. Complete the collector's section (Section II) at the bottom of the form, recording the sample type, patient history, form of patient ID presented, collection site information, and the collection date and time.
 - **Do not** sign the form at this step.
 - Check that the collection dates written by the patient and collector match on both the consent forms and the samples.
8. Review the completed form with the test participants to ensure that the form was filled out fully and accurately.
9. Collect the samples according to procedures in section IV of this manual, sealing them with tamper tape as described.
10. Sign Section II of the Consent form, affirming the proper labeling and secure packaging of the samples.

Note: To maintain proper chain of custody, it is important that the Client Identification and Consent Form is completed in full with utmost accuracy.

VII. SAMPLE COLLECTION ---

To provide confidence in the accuracy and validity of test results, only someone who has no interest in the outcome of the testing should perform the sample collection. In the event that the collector has a conflict of interest, a second impartial individual should witness the collection and document that it was performed correctly, maintaining proper Chain of Custody.

DNA Diagnostics Center (DDC) routinely utilizes cheek cell tissue (buccal swab) samples 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 a minimal chance of exposure to bloodborne pathogens.

You will find instructions for both sample collection methods in this section. 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 samples from individuals with allergies to latex.

Buccal Swab Sample Collection

Specimen

4 Dacron buccal swabs

Patient Preparation

None

Storage and Transport

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

Supplies

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

Latex-free or powder-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 tabletop, the collector's skin, other samples, and others. 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 sections V and VI of this manual) and complete the required paperwork.

Note: Do not pre-label the buccal swab envelopes. 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 envelope on a clean surface (clean paper towel may be used).
4. Label the buccal swab envelope with the patient's full name, date of birth, and date of collection. Sign your initials on the space provided.
 - **Always label one swab envelope and collect the sample from one patient at a time.**
 - The name on the sample must match the Client ID/Consent form.
5. Put on clean gloves.
6. Cut open the plastic wrapper at the end opposite from the cotton swab tip.
7. Remove one swab from the package, taking care not to touch the end with the cotton tip.
 - **Do not** allow the cotton tip to touch any surface (table, skin, etc.). Doing so could contaminate the sample.
8. Ask the patient to open his/her mouth wide.
9. Insert the 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 samples may require a recollection and will delay test results.
10. Remove the swab from the patient's mouth and place it directly into the **paper** buccal swab 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 two swabs on the right cheek and two swabs on the left cheek for each patient.
 - 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 client to **verify** that the name and date of birth are correct and **sign** across the envelope flap.
14. Sign the Client Identification and 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 should match the name on the client consent form.
 - Please use all four swabs provided to ensure adequate collection of DNA sample.
16. Take a photo of the test participants holding the DDC Identification Sheet provided in the kit or faxed from DDC.
 - This ID sheet has the patient names and a case number printed on the front.
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 the next section (Packaging and Shipping).
18. Tamper-tape the zip lock bag in the presence of the patient.

Reference:

Butler, John M. 2001. Forensic DNA Typing. San Diego, CA: Academic Press.

Venous Blood Collection

DNA Diagnostics Center requires venous collections to be performed by individuals who have acquired a certificate in phlebotomy from a nationally accredited organization (such as the American Society of Clinical Pathologists) or who have documented relevant experience. Therefore, the phlebotomist will be knowledgeable concerning bloodborne pathogen risks and the universal precautions and measures for reducing/eliminating risk. Any needle puncture or exposure should 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 when 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 mL, collect a buccal swab.

Specimen

5 mL blood collected in an EDTA Vacutainer (purple-top tube); minimum volume 1 mL

Patient Preparation

None

Storage and Transport

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

Supplies

Vacutainer tube (purple top) with EDTA (provided)

Tourniquet*

Powder-free or latex-free gloves

Alcohol pad

2"x2" gauze

Vacutainer needle/holder*

Ammonia inhalants

Adhesive bandage*

Sharps disposal system

Tamper tape (provided)

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

Procedure

1. Perform Client Identification and Chain of Custody procedures (see sections V and VI of this manual) and complete the required paperwork.
2. Ask if the patient is allergic to latex; if so, use latex-free supplies.
3. Select a suitable site for venipuncture.
4. Position the arm downward and assemble necessary supplies.
5. Put on clean gloves.
6. Apply tourniquet 2–4 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 the site with an alcohol swab.
 - Allow the site to dry.

8. Insert needle into the vein, making sure the needle bevel is up.
 9. After a 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 adhesive bandage over the site to complete the procedure.
 12. Dispose of all used materials 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 test participants holding the DDC Identification Sheet provided in the kit or faxed from DDC.
 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 polystyrene box provided in the blood collection kit as outlined in the next section (Packaging and Shipping).
 - Seal the samples, documents, and photograph or instant camera 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.

Reference:

Brown, Barbara. 1976. Hematology: Principles and Procedures. 2nd Edition. Philadelphia: Lea & Febiger.

VIII. Packaging and Shipping

DNA Diagnostics Center provides a collection kit for 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 (except on holidays and weekends).

Packaging

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

1. Place the following items inside the clear zip lock bag:
 - All samples collected (buccal swab envelopes and/or polystyrene box containing the labeled blood tubes)
 - All completed Client Identification and Consent forms
 - All photocopies of patients' IDs
 - DDC Identification Sheet used in the photograph (showing the case number and patient names)
 - Disposable camera (if one was provided)
 - 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 as you tamper-tape the sample 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 the other items to the bag. If it is necessary to break the tamper tape, it must be done in the presence of the clients and 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 tamper-taped zip lock bag inside the box.

- Place the tamper-taped zip lock bag or cardboard box inside the large plastic shipping bag and seal securely.
4. Complete the airbill.
- Complete the “From” address on the shipping bag air bill 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, please 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 by logging on to <http://www.dnacenter.com/drawsites>.



Collection Affiliate Agreement

I have read and fully understand the sample collection manual that has been provided by DNA DIAGNOSTICS CENTER (DDC) 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 with DDC policies and procedures. Furthermore, I understand that all information received on the 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 _____

Facility Name _____

Address _____

City _____ State _____ Zip _____

Phone (Work) _____ Phone (Home) _____

SSN _____ Tax ID # (if applicable) _____

Signature

Date

Signature

Date