

COLLECTOR TRAINING MANUAL

Policies and Procedures for
Collecting DNA Samples via Buccal (Cheek) Swab
Under Chain-of-Custody Guidelines

Collector Training Manual

Table of Contents

INTRODUCTION	1
How to Use the Collector Training Manual	1
Definitions	2
PRIVACY AND CONFIDENTIALITY	2
NEW YORK STATE COLLECTIONS	2
PARTICIPANT IDENTIFICATION	4
Photo Identification	4
Chain-of-Custody Form	4
Sample Envelopes	5
SAMPLE COLLECTION	5
PACKAGING AND SHIPPING	6

INTRODUCTION

IDENTIGENE maintains DNA testing laboratory accreditations in good standing with the AABB, the Laboratory Accreditation Bureau (LAB), and the New York State Department of Health (NYSDOH). Accreditation guidelines for court-admissible DNA test results require DNA Sample Collection to be witnessed and documented by a disinterested (independent) third party, the Collector.

Only someone with no interest in the outcome of the test should witness sample collection. If a conflict of interest arises for the Collector, a second impartial individual should witness and document the collection, thus maintaining proper chain of custody.

This DNA Sample Collection Manual describes the witness and documentation procedures for buccal (cheek) swab collection compliant with accreditation guidelines. To ensure test accuracy and court-admissible documentation, all Collectors and other Collection Site personnel must strictly follow the chain-of-custody procedure outlined in this manual. Find the most recent updates to this manual at DNAtesting.com/collectors.



IMPORTANT: If you have any questions about this manual, the collection process, or a specific collection appointment, please call our Collector Hotline at 1-866-395-3737 (Monday through Friday, 8 AM to 9 PM, ET).

How to Use the Collector Training Manual

This manual describes the following policies and procedures:

- Privacy and Confidentiality
- New York State Requirements
- Participant Identification
- DNA Sample Collection
- Packaging and Shipment of Samples to the Laboratory

Read the entire manual and become familiar with all policies and procedures. When finished, sign and return the Collector Affiliate Agreement to IDENTIGENE, indicating that you understand and agree to abide by the policies and procedures outlined in this manual. (Find the Collector Affiliate Agreement at

the end of this manual, or download a copy from DNAtesting.com/collectors.)

Court-admissible test results depend entirely on correct participant identification, quality of the samples collected, correct labeling, and complete and accurate paperwork. Please read and follow all procedures carefully.

Definitions

“DNA Testing Services” means the provision of laboratory analysis of biological samples the Participant provides to IDENTIGENE.

“Collector” means the disinterested third party providing collection services in accordance with accreditation guidelines; specifically, the Collector witnesses the DNA sample collection for each Participant and documents the chain-of-custody procedure.

“Participant” means any test participant who submits biological samples to IDENTIGENE for DNA Testing Services or the legal guardian of a test participant who may be a minor or a legally incompetent adult.

PRIVACY AND CONFIDENTIALITY

IDENTIGENE holds all information relating to our customers in the strictest of confidence. All individuals collecting DNA samples must keep all customer information confidential. Participant and case information can only be discussed with IDENTIGENE. For more information about IDENTIGENE privacy policies and practices, visit DNAtesting.com.

NEW YORK STATE COLLECTIONS



*Collections in New York State include additional steps as required by the New York State Department of Health (NYSDOH). If you do not plan to offer collection services in New York State, please skip to the next section (**“Participant Identification”**).*

For collections performed in the state of New York: All DNA collections must comply with New York State Department of Health (NYSDOH) regulations. As a Collector in New York State, you accept sole responsibility to stay well informed of NYSDOH regulations and remain in compliance with New York State law.

In addition to following the chain-of-custody procedure outlined in this manual, New York Residents (Participants) must present a written referral (or prescription) from an authorizing agent, such as a physician or attorney, prior to DNA collection. IDENTIGENE requires a copy of the referral (or prescription) along with the authorizing agent's state ID number before testing can begin.

We designed the IDENTIGENE DNA Paternity Test Collection Kit for New York Residents specifically to comply with NYSDOH guidelines. Under most circumstances, the Participant will purchase the kit at their local pharmacy and obtain testing authorization from their physician or attorney. IDENTIGENE then schedules a collection appointment as needed (though in some cases Participants may schedule their own collection appointment).

At the collection appointment, the Participant should bring the completed order form (with the signature and New York State license number of the authorizing agent) and a sealed collection kit that should only be opened by you, the Collector.



If the tamper evident seal appears broken or if you find any evidence of tampering with the collection kit in any way, please call the Collector Hotline (1-866-395-3737) to request a new kit.

Verify that the order form contains all of the necessary information, including the Participant's payment information and the signature and license number for the physician or attorney licensed in New York State. (You do not need to verify the license number or other information for the authorizing agent; IDENTIGENE verifies all authorizing agent information when samples arrive at the laboratory. Just verify that this section has been completed.)

If the order form appears to be completed properly, proceed with DNA Sample Collection as outlined in the next sections.

PARTICIPANT IDENTIFICATION

Photo Identification

To ensure that participants do not misrepresent their identity, the Collector must obtain proof of identity from each participant, or their legal guardian.

Acceptable means of identification include:

- A government issued photo ID, such as a driver's license or passport.
- A recent, clear photograph suitable for identification purposes.
- A photo taken at the time a collection or otherwise suitable for identification (determined by the collector).
- A single photograph of all the participants together is acceptable and preferred.



Make a visual comparison between the photo ID and the Participant. If the ID seems at all questionable or suspicious, you may request additional identification. Please inform IDENTIGENE if any identification provided by the Participant seems questionable or suspect.

Photocopy the provided identification for each Participant. Ask each Participant, or legal guardian, to sign and date the photocopy of their identification. As Collector, sign and date each photocopy. All copies must be signed and dated by the Participant (or their legal guardian) and the Collector. Ensure that the photograph of the participant is **clearly visible** in the photocopy of the identification.



IMPORTANT: If the Participant is under 18 years of age or legally incompetent, an individual with legal authority to provide consent must sign and date photocopies and forms. A minor mother may sign consent for her child, but may not sign or provide consent for herself.

Chain-of-Custody Form

IDENTIGENE provides a Chain-of-Custody form for each participant. **Both the Participant and the Collector must sign and date the Chain-of-Custody form.** Verify that the Chain of Custody form is filled out completely and legibly. Where possible, make sure that names and spellings appear on the Chain-of-Custody form exactly as they appear on the Participant's identification.

Ask each Participant (or their legal guardian) to do the following:

- Read the Terms and Conditions (located on the back of the Chain-of-Custody form).
- Complete the Participants section of the form.
- Sign and date the consent statement found on the Chain-of-Custody form.

As Collector, do the following:

- Complete the Collector section at the bottom of each form.
- Review the completed paperwork to verify all questions have been answered and requested information is filled in.
- Sign and date each Chain-of-Custody form.

Sample Envelopes

IDENTIGENE provides a Sample Envelope for each Participant. **Both the Participant and the Collector must sign and date the Sample Envelope.** Verify that the Participant's name is written exactly as it appears on their photo ID. Verify that the Sample Envelope is filled out completely and legibly. Where possible, make sure that names and spellings appear on the Sample Envelope exactly as they appear on the Participant's identification (and Chain-of-Custody form).

As Collector, do the following:

- Complete the required information on the Sample Envelope.
- Review the Sample Envelope to verify all the questions have been answered and all the requested information has been filled out.
- Sign and date each Sample Envelope.



IMPORTANT: All documents, including copies of photo ID (or photographs), the Chain-of-Custody form, and Sample Envelopes must be signed and dated by both the Participant and the Collector.

SAMPLE COLLECTION

IDENTIGENE provides a packet of cheek swabs (3 swabs) for each Participant. When using the swabs, be careful to avoid contamination. The swab may be contaminated by touching the end of the swab to any foreign surface such as a tabletop, paperwork, the Collector's skin, or other samples.

Though each Participant generally swabs their own mouth, the Collector may assist as needed with collection, especially when collecting samples from younger children or infants, or when placing swabs into the Specimen Envelopes. To avoid contamination, the Collector should wear clean gloves during the Sample Collection process and witness sample collection from each Participant, one at a time.

For one Participant at a time, remove a single packet of swabs from the IDENTIGENE collection kit. Open the packet of cheek swabs, being careful to avoid contamination. Using one swab at a time, gently scrape the inside of the cheek to collect loose skin cells. (DNA testing uses DNA extracted from human cells, not saliva.)



IMPORTANT: Collect loose cheek cells by rubbing the swab back and forth against the cheek, or between the cheek and gums, for about 20 seconds.

Immediately after sample collection, place the swab directly into the Sample Envelope labeled specifically for the Participant. Do not place the swabs back in their original plastic packaging or any other packaging. Be sure to use all three swabs for one Participant, placing all three into one Sample Envelope.

Repeat the entire sample collection process for each Participant.

PACKAGING AND SHIPPING

IDENTIGENE provides materials for packing and shipping the DNA samples and paperwork.

Be sure to completely and legibly fill out all paperwork, including the date of collection and the signatures of both the Participant and Collector where required. Pack all paperwork and Sample Envelopes (containing cheek swab samples) into the mailer provided by IDENTIGENE.

The following should be placed inside the provided return shipping mailer:

- Photo copies of Identification (or photographs) for each Participant.
- Chain-of-Custody form for each Participant.
- Sample Envelope (with Cheek swabs inside) for each Participant.
- (if required) complete Order Form and payment (provided by the Participant)



IMPORTANT: Do not allow the participants to handle or ship samples or completed documents. These items must be personally mailed or shipped to IDENTIGENE by the Collector.

The mailer may be a postage-paid return envelope (labeled Business Reply Mail) to be shipped via the United States Postal Service (USPS). Business Reply Mail should be deposited into a USPS secure location such as a drop box or dropped off at a post office location. Business Reply Mail takes approximately 3-7 working days to reach IDENTIGENE.

The Participant may choose to pay for express shipping to IDENTIGENE via an express courier service such as FedEx or UPS. For some cases, IDENTIGENE may provide an express shipping label with the DNA Sample Collection Kit. If using an express shipping label, make sure the label is clearly marked and carefully applied to the packaging. Drop the package off at the express courier's official drop box or office location or call to schedule a pickup from your location. Express shipments reach IDENTIGENE in 1-2 working days, depending on the express shipping option indicated.



IMPORANT: If you need any assistance with packaging or shipping samples, or any part of the collection process, please call our Collector Hotline at 1-866-395-3737 (Monday through Friday, 8 AM to 9 PM, ET).

COLLECTOR AFFILIATE AGREEMENT

I have read and fully understand the information contained in the Collector Training Manual provided by IDENTIGENE. I hereby affirm that I will abide by these policies and procedures and understand that deviations must not be made without prior approval by IDENTIGENE.

If I represent a collection facility (collection site) or multiple collectors, I will be responsible for their training and compliance with IDENTIGENE policies and procedures.

Furthermore, I understand that all information received via DNA Testing Services for 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 IDENTIGENE.

Name

Facility Name

Address

City

State

Zip

Phone

Tax ID

Fax

Email Address

Collection Fee

Yes/No

Camera

Yes/No

Cancellation Fee

Signature

Date