

Specimen Collection

GEN.40100/COM.06000 Specimen Collection Manual Elements

The purpose of this manual is to provide written procedures describing methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, specimen and requisition labeling, and conditions for transportation and storage before testing in accordance with the College of American Pathologists.

Test Requisition

Patient Testing

All patient testing will originate from a written or electronic request authorized by a physician. An electronic authorization may be solicited within 30 days of an oral request.

Direct-to-Consumer (DTC)

All DTC testing will originate from a written or electronic request authorized by the consumer to be tested. All policies are followed in accordance with CAP requirements.

Required Information for Patient Testing

- Patient's name
- Sex
- DOB
- Test(s) to be performed
- List of current medications
- ICD-10 codes
- Attending physician
- Type of specimen
- Data and time of specimen collection
- Unique random number (in the form of a barcode)
- Insurance and payment information

Required Information for Direct-to-Consumer Testing

- Patient's name
- Sex
- DOB
- Test(s) to be performed
- List of current medications
- Type of specimen
- Data and time of specimen collection
- Unique random number (in the form of a barcode)
- Insurance and payment information

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GEN.40490 Patient Identification

Below details the procedure to reflect Dynamic DNA Laboratories policy that the individual collecting the specimen positively identifies the patient before collecting a specimen.

Patient Preparation and Management

- 1) Identify the patient. Address all patients by the proper prefix (Miss, Mrs., Ms. and surname. Children and personal friends are exceptions.)
- 2) Ask the patient to identify himself/herself to assure proper identification in the form of a state-issued photo-ID.
- 3) Ask when the last time the patient had any food or drink was:
 - a. Last food or drink other than water must have been consumed a minimum of thirty minutes prior to specimen collection.
- 4) Inform him/her of what you are going to do.
- 5) Always follow Universal Precautions.

Location of Specimen Collection

Sample collection may occur in-house at DDNA or at a remote location.

- 1) In-House
 - a. Performed or observed by a trained testing personnel
- 2) Remote Collection
 - i. Performed at a location other than DDNA by a trained healthcare professional.

Proper Specimen Collection

Regardless of who collects the specimen, it will be collected according to the following protocol supplied along with the collection materials.

Buccal Swabs

Samples will be collected using buccal swabs. The quality of the genetic results depends largely on the condition of the DNA submitted for examination. Proper specimen collection and procedural techniques must be followed to ensure the most accurate results possible. Specimens should not be collected following eating or drinking. Sterile, DNA-free swabs should always be used. Swabs need to be collected using Puritan® UltraFlock™ swabs (Cat. 25-3306-U BT) for in-house collections and Puritan HydraFlock™ swabs (Cat. 25-3406-H) for collections that will be mailed.

Protocol for In-House DNA Collections:

- 1) Label the specimen collection tube with at least 2 unique identifiers (Accession number, Patients name, D.O.B., etc.)

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- 2) Twist the red cap of the swab tube, breaking the sterility seal. If the seal is broken prior to handling, discard the swab.
- 3) Remove the swab from the tube, taking care not to touch the white swab head with your fingers.
- 4) Under adequate lighting, apply the swab to the inside of the cheek and swab vigorously for 30 seconds on each side of the cheek or underneath the upper and/or lower lip. Use reasonable, firm pressure when swabbing. Collect a total of two swabs per patient.
- 5) After swabbing, carefully rest the end of the swab over the collection tube in a clean area. Allow the swab to dry for a minimum of 2 hours before reinserting the swab back into the collection tube. Do not touch the end of the swab with bare fingers or to any other surface.
- 6) Seal the tube securely with the cap provided.
- 7) Note: Always use safety devices and follow Universal Precautions. Discard all expired materials.

Protocol for Remote DNA Collections:

- 1) Locate the White Paper Envelope and print a minimum of two unique patient identifiers, including the Patient's name and date of birth where indicated.
- 2) Remove the swab from the plastic sleeve using gloved hands. Be careful to not touch the head of the swab to any foreign surface. If the swab needs to be laid down, replace it into the plastic sleeve.
- 3) Under adequate lighting, apply the swab to the inside of the cheek and swab vigorously for 30 seconds on each side of the cheek or underneath the upper and/or lower lip. Use reasonable, firm pressure when swabbing.
- 4) After swabbing, break the swab at the perforated mark and place the head of the swab into the White Paper Envelope.
- 5) Repeat steps 2-4. Collect a total of two swabs per patient.
- 6) Do not seal the paper envelope, simply fold the seal down.
- 7) Complete additional paperwork (i.e. test requisition form, copies of patient's insurance information) and place these documents along with White Paper Envelope containing the two swab heads into the White Poly Mailer. Two desiccant packets should already be contained inside the poly mailer.
- 8) Seal the poly mailer and send back to Dynamic DNA Laboratories using Priority Mail.
- 9) Note: Always use safety devices and follow Universal Precautions. Discard all expired materials.

MOL.32365 - Sample Preservation/Storage

Buccal swabs that are collected, dried, and sealed in-house using a Dry Transport System (Puritan® Cat. 25-3306-U BT) are stable at ambient temperature for the maximum

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duration of 10 business days that may elapse between sample testing at Dynamic DNA Laboratories. Once extracted, nucleic acids extracted at Dynamic DNA are suspended in Tris-EDTA (TE) buffer which virtually eliminates nuclease activity, subsequently reducing sample degradation. Following the completion of testing, samples will be stored at -20°C.

Samples that are remotely collected will be dried by the desiccant packets and paper envelope during shipment. This drying will serve to preserve the sample during shipment. After being received at Dynamic DNA Laboratories, the samples will be removed from the poly mailer and stored in the paper envelope at ambient temperature until processing. Once extracted, nucleic acids extracted at Dynamic DNA are suspended in Tris-EDTA (TE) buffer which virtually eliminates nuclease activity, subsequently reducing sample degradation. Following the completion of testing, samples will be stored at -20°C.

MOL.32390 – Specimen Processing/Storage

Buccal swabs that are collected, dried, and sealed in-house using a Dry Transport System (Puritan® Cat. 25-3306-U BT) are stable at ambient temperature for the maximum duration of 10 business days that may elapse between sample testing at Dynamic DNA Laboratories. Once extracted, nucleic acids extracted at Dynamic DNA are suspended in Tris-EDTA (TE) buffer which virtually eliminates nuclease activity, subsequently reducing sample degradation. Following the completion of testing, samples will be stored at -20°C.

Samples that are remotely collected will be dried by the desiccant packets and paper envelope during shipment. This drying will serve to preserve the sample during shipment. After being received at Dynamic DNA Laboratories, the samples will be removed from the poly mailer and stored in the paper envelope at ambient temperature until processing. Once extracted, nucleic acids extracted at Dynamic DNA are suspended in Tris-EDTA (TE) buffer which virtually eliminates nuclease activity, subsequently reducing sample degradation. Following the completion of testing, samples will be stored at -20°C.

Extracted nucleic acid samples received by Dynamic DNA Laboratories will be entered into the sample testing log and stored at -20°C and thawed for testing. Residual samples will be stored at -20°C in case further testing is required.

GEN.74500 Sample Transportation

Once properly packaged, buccal swabs may be transported to the testing laboratory through a 3-5 day priority mail service or hand-delivered to the laboratory by a healthcare professional. If samples are collected in-house no sample transport will be necessary.

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Primary Specimen Container Labeling

Identification

All test specimens will be identified using the following:

- Patient/consumer name *
- Date of Birth (DOB)*
- Date Collected
- Unique numerical identifier (in the form of a barcode)*

*Required

Labeling

All specimens will be labeled with at least the patient's name, chart number/unique numerical identifier and date of collection. Additional labeling will be added as appropriate. Reference specimens will be labeled according to that laboratory's instructions.

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