

Test Kit Contents

Start by identifying these six elements of your test kit.

Four cotton tipped applicator swabs (in 2 sleeves)

Informed Consent Form

Test Requisition Form

Swab collection return envelope

Test Kit Box or Envelope

Return Shipping Materials will include one of the following:

- Purple Bubble Mailer
- Shipping Laboratory Pak

Preparing for Your Test

- **For patients residing within the United States**, collecting your sample on a Monday – Thursday is important so that the specimen can get to our lab before the weekend.
- **For patients residing outside of the United States**, collect and ship your sample on a Monday or Tuesday.
- Complete the **Informed Consent Form**, prior to collecting.

Let's Get Started

1. Rinse your mouth with cold water prior to collection of your sample.
2. Each paper sleeve contains two swabs. A total of four swabs are to be collected.
3. Open one of the sleeves and remove one swab at a time. Keep the paper sleeve to return the swab after collecting.
4. Swallow to remove excess saliva. Using a circular motion, rub the swab on the inside of one cheek about 20 times, with enough pressure so that the cheek is pushed outward.
5. Gently wave the swab through the air to dry it for 3 minutes. Then place the swab back into the sleeve and remove the second swab from the same sleeve.
6. Repeat steps 4 and 5 using the same cheek side.
7. Open the second sleeve and repeat the same process using the other cheek side for both of those swabs.
8. Place the two sleeves containing the four dried swabs in the Swab collection return envelope and seal.

After You Collect the Samples

Locate and complete the barcode sheet in your test kit. Place a barcode sticker onto the swab collection return envelope. Be sure that the information is legible and includes the collection date, time, and that the name matches what was provided on the test order.

Preparing for Package

Place the swab collection return envelope, the Informed Consent Form, and Test Requisition Form (if using) into the purple bubble mailer and seal. Locate the shipping instruction card included in your test kit for details on how to ship your collection(s).

! Ensure all samples are labeled. Unlabeled samples will be rejected.

What's Next?

Your test results will be delivered to your doctor or health advisor generally within 5-6 weeks after they are received at the Mosaic Diagnostics labs.

It will be up to your doctor or health advisor to review the results with you, identify any areas of interest or concern, and work with you to lay out the appropriate next steps.

Any Questions?

If you have questions about any aspect of the specimen collection or shipping process, please feel free to contact us:

Phone | Our friendly customer service team is available Monday through Friday 8am – 5pm CST at 800-288-0383

Email | CustomerService@MosaicDX.com

For questions about test outcomes or their implications for your health, please speak with your doctor or health and wellness advisor. Mosaic Diagnostics personnel cannot discuss test results directly with test patients or their family members.



Informed Consent for Molecular Genetic Testing

Tests/profiles covered by consent form (see reverse for information): **DNA Methylation Pathway Profile**

Intended purpose is: Screening Carrier status Predictive Diagnosis Other:

I request and authorize Mosaic Diagnostics and Kashi Clinical Laboratories, Inc. to test my (or my child's) sample for genetic mutations/ condition(s). My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by my physician or genetic counselor.

Genetic testing is used to determine if a person has genetic differences, known as mutations that caused or contributed to a disorder they have, puts them at risk for a disorder in the future, or may be used for screening purposes to look for mutations that are not currently associated with a specific disease or predisposition. This means that a genetic difference is found, but it is unclear whether this particular difference can contribute to or cause a specific disease. In addition, the test may uncover mutations that are not well-understood. In some instances, there is not enough information to determine if a mutation is associated with disease or not, and more research will need to be done before a definite answer is known. In other cases, a mutation may be associated with a different condition than the one your doctor ordered the test for.

1. DNA test results associated with specific condition(s) may:
 - a) diagnose whether or not I have (or my child) this condition or am at risk for developing this condition
 - b) indicate whether or not I (or my child) am a carrier for this condition
 - c) predict another family member is a carrier or is at risk for developing this condition
 - d) be indeterminate due to technical limitations or familial genetic patterns
 - e) reveal non-paternity
2. Genetic counseling is recommended prior to, as well as following, genetic testing. The decision to consent or to refuse the testing is entirely your (or your legal guardian's) choice.
3. Although DNA testing usually yields precise information, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, laboratory method limitations, and inaccurate information regarding family relationships. DNA testing will not detect all causative mutations.
4. Genetic tests are handled in a confidential manner, like all other personal health information. Test results are released to the ordering health care provider, and to those parties entitled to them by state and local laws, or to a person whom you have specifically authorized by signing a written release. Genetic test results are part of your medical record. If a genetic test is performed, your insurance company may have access to the result. Federal law extends some protections regarding genetic discrimination (www.genome.gov/10002328).
5. No other tests than the tests specifically authorized will be performed on your identifiable sample, unless specifically authorized by you/your guardian. The sample will not be used in any identifiable manner for research purposes without your consent. Your sample (tissue, blood, fluid and/or DNA) shall be discarded 60 days after testing.
6. The performance characteristics of this test(s) were validated by Kashi Clinical Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test(s); however, FDA approval is currently not required for clinical use of this test(s). Mosaic Diagnostics and Kashi Clinical Laboratories, Inc. are authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing. The results are not intended to be used as the sole means for clinical diagnosis or patient management decision. If a specific genetic diagnosis is suspected, please consult with a certified clinical geneticist for additional testing that may be recommended.

The patient/legal guardian has read or has been read the above and fully understands the significance, risk and benefits of having the test completed and wishes to proceed with testing. Genetic counseling is recommended prior to, as well as following, genetic testing.

Patient Name(print)	Date of Birth:
Patient/Legal Guardian Signature:	Date Signed: