The Great Plains Laboratory, LLC

DNA Methylation Pathway Profile
Saliva Sample Collection Instructions

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1 Before You Begin Collection

- Please fill out all sections of the Test Requisition Form provided in your kit.
- Complete the Informed Consent for Molecular Genetic Testing.
- Complete the information on the Swab Collection Return Envelope.
- Rinse your mouth with cold water before you begin collecting your sample. If the patient cannot perform the rinse, have the patient drink a small glass of water.

2 Collection Instructions

1. Each paper sleeve contains two swabs. A total of four swabs are to be collected.
2. Open a sleeve and remove one Sterile Cotton Tipped Applicator (swab) at a time. Keep the paper sleeve to return swab after collecting.
3. Swallow to remove excess saliva. Using a circular motion, rub the first swab on the inside of one cheek about 20 times, with enough pressure so that the cheek is pushed outward.
4. Gently wave the swab through the air to dry it for three minutes. Then place the first swab back into the sleeve. Remove the second Sterile Cotton Tipped Applicator (swab) from the sleeve and repeat steps using the same cheekside .
5. Repeat using the second set of swabs in the second sleeve, repeat the same process using the other cheek side.
6. Place the two sleeves containing the four dry swabs in the Swab Collection Return Envelope and seal envelope.

3 Mailing Instructions

Place completed Test Requisition Form, completed Informed Consent Form, and the Swab Collection Return Envelope containing the swabs into the FedEx Small Envelope. Remove adhesive sticker and then place into the FedEx envelope.

Be sure to seal. In the United States, call FedEx at 1-800-463-3339 for pick up. Mention you need to schedule a pick-up using a billable stamp. Do not put kits in a FedEx drop box.

Turn Around Time

Please note that most test results take a minimum of **5-6 weeks** to become available after the sample arrives at our facility.

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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 The Great Plains Laboratory 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
    e) be indeterminate due to technical limitations or familial genetic patterns
    f) 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). The Great Plains Laboratory 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:**