The Great Plains Laboratory, LLC

DNA Methylation Pathway Profile
International Collection Instructions

11813 West 77th Street, Lenexa, KS 66214 | (913) 341-8949 | Fax: (913) 341-6207 | GP-Labs.com

KIT COMPONENTS

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1. Cardboard box
2. Biohazard ziplock bag
3. Saliva collection tubes
4. Gel pack
5. Silver thermo bag
6. FedEx Clinical Pak
7. FedEx Airway Bill
8. Test requisition form and paperwork

BEFORE YOU BEGIN COLLECTIONS

1. Samples may only be sent off to the lab on **Monday or Tuesday.** If samples are sent a different day, extra shipping charges may apply and the sample may become compromised. Send completed kit as soon as possible – ideally the day after collection.
2. Fill out all sections of the Test Requisition Form and the Informed Consent Form.
3. Complete the information on the Swab Collection Return Envelope.
4. 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.
5. If you have any questions, please contact us at +1 (913) 341-8949 or CustomerService@gp-labs.com.

SALIVA COLLECTION

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.

For questions about the collection of samples, call Customer Service at +1 (913) 341-8949.

Instructions continue on the reverse side

PREPARING AND SHIPPING SPECIMENS

In some countries FedEx requires control numbers or pickups to be prearranged. Before you collect samples, please verify with your local FedEx to see if pickups need to be arranged or if a control number is needed. If a control number is needed please send an email to customerservice@gp-labs.com with your name, your address, your phone number and the date/time of pickup at least 3 days before the day you intend to ship the samples.

PREPARING THE SAMPLE

1. **Complete the following documents (PLEASE FOLLOW):**
   - **FedEx "Airway Bill".** Following the example on the last page of the instructions. Please take note of the tracking number in case you want to know the tracking details of your package.
   - **Commercial Invoice.** Make 3 copies of the commercial invoice. THIS IS VERY IMPORTANT FOR CUSTOMS PURPOSES.
   - **Biological Declaration (India & Australia only).** Fill out consignee information (The Great Plains Laboratory), mark sample for lab research/human non-infectious, and please specify what kind of sample. On the second page, please fill out: Declarant name, contact information, and email. (This is your information). Place with the commercial invoices in the plastic pouch attached to the outside of the FedEx Clinical Pak.
2. Complete Test Requisition Form and Informed Consent Form.
3. Remember to put name, date of collection, and date of birth on the Swab Collection Return Envelope and date of collection on requisition form. Missing information may cause a delay in testing and/or interpretation.
4. Place completed Test Requisition Form, completed Informed Consent Form, and the sealed Swab Collection Return Envelope containing the swabs in the FedEx Clinical Pak.
5. Remove the purple FedEx Billable Stamp from the inside of the FedEx Clinical Pak for your records.
6. Place the cardboard box in the FedEx Clinical Pak. Please note that the samples MUST be in the cardboard box; otherwise the shipment will be rejected by FedEx. Close the FedEx Clinical Pak.

SHIPPING INSTRUCTIONS

1. Peel off the adhesive backing of the enclosed plastic pouch and attach to the outside of the FedEx Clinical Pak. Place 4 copies of the completed commercial invoice in the pouch. Place the completed Airway Bill on top of the commercial invoices.
2. Call FedEx to pick up your package. You will receive the discounted shipping rates shown on the last page of these test instructions if you ship your sample using the FedEx Airwaybill included in the kit.
3. We charge for the test and the return shipping when we receive the samples. Shipping charges vary depending on the country.

   IMPORTANT NOTES:

   - Shipping rates are per package. **Please ship all your samples in a single package to avoid multiple shipping charges.**
   - GPL will charge the shipping costs upon sample reception. If you pay FedEx the shipping cost could be higher.
   - Additional charges may apply if your package exceeds **900 grams.**
   - GPL will not be liable for refunds if the delivery is delayed due to customs or any other reason.
   - Shipping charges are subject to change without notice.

The Great Plains Laboratory, Inc.

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, Inc. and Kashi Clinical Laboratories, Inc to test my (or my child's) sample for designated genetic mutations/condition(s). My signature below constitutes my acknowledgement 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 or cause a specific disease tested for. 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 (or my child) have 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 with your consent. Your sample (tissue, blood, fluid, and/or DNA) shall be discarded 60 days after testing or permanently de-identified, i.e. stripped of any identifiers that may be linked to you, and kept for test control/research purposes. You may also decline to allow your DNA to be de-identified and used for control/research purposes by **initialing here:**_____ patient/guardian initials.

6. The performance characteristics of this test(s) were validated by Kashi Clinical Laboratories, Inc. The U.S. Food and Drug Administration (FDA) have not approved this test(s); however, FDA approval is currently not required for clinical use of this test(s). The Great Plains Laboratory, Inc. 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 context 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: