

### **Informed Consent for Pharmacogenomic and/or Nutrigenomic Testing**

**Important – Please Read Carefully:** This informed consent describes the purpose, procedures, benefits, limitations and possible risks associated with pharmacogenomic and nutrigenomic testing. Please click on the appropriate box to indicate the type of testing to which you are consenting:

Pharmacogenomic

Nutrigenomic

#### **Description and Purpose of The Tests:**

- Pharmacogenomics is the study of how an individual’s genetic makeup affects his or her response to certain drugs. Pharmacogenomic genetic testing is used to help determine your responsiveness to certain medications. Your results may reveal that you process or respond to certain medications more or less effectively than the average person. Your health care provider can use the information from pharmacogenomic testing along with other factors, such as health history, family history and environmental factors, in determining how to best provide and manage your medications.
- Nutrigenomics is the study of the interaction of nutrition and genes, especially with regard to the prevention or treatment of disease. Nutrigenomic genetic testing is used to help understand how your genes affect the way your body responds to certain types of food. Nutrigenomics is used to learn more about how genes and diet together may affect your health and the risk of developing certain diseases.

**Testing Procedures:** You will be asked to provide certain relevant health information to your health care provider. This information may include, but is not necessarily limited to, your age, ethnicity, biological gender, history of certain health conditions, medication history and lifestyle information. You will also be asked to provide a saliva sample or obtain a buccal swab, which is a swabbing of the inside of your cheek with a cotton swab. Both your saliva or buccal sample and the collected health information will be sent to one of Base10’s affiliated laboratories in the United States for processing. DNA will be extracted from your sample and sequenced. Sequence data includes information about your genes and regions on those genes relevant to the specific test (pharmacogenomics or nutrigenomic), as well as other regions, up to and including your entire genome. All sequenced data may be used for regulatory compliance purposes, Base10’s health care operations, or any other purpose required or permitted by applicable law. This data may also be used for internal quality control, validation studies and internal research and development purposes. Analysis and reporting on genes and regions beyond those relevant to the ordered testing will not occur unless you specifically consent to future products or services.

**Test Results and Interpretation:** Upon the completion of test processing, the test results will be made available to you, to your ordering health care provider and, for nutrigenomic testing only, to the registered dietician assigned to you.

- Pharmacogenomic Testing: Your health care provider may use the results of pharmacogenomic testing in conjunction with other factors, such as your health and medication history, to assist in determining how to best provide and manage your medications. **Always consult with your health care provider before stopping or making any other changes to your medications. Stopping or changing medications or dosages without medical consultation can be harmful to your health.**
- Nutrigenomic Testing: Your health care provider may use the results of you nutrigenomic testing to recommend dietary additions or restrictions in order to assist in your management of disease or to promote optimal health. Base10 will assign a registered dietician (“RD”) to you. The RD will review your genetic test results and the health information you have provided and will engage with

you in one or more telephonic and/or digital coaching sessions. The number and content of the coaching sessions will depend upon the type of Base10 nutrigenomic program for which you have signed up. **Always work with your health care provider or other health professional in making changes to your diet. Making significant changes to your diet without medical consultation may be harmful to your health.**

### **Benefits of Testing:**

- **Pharmacogenomic Testing:** The results of your test may show that the genes Base10 analyzed and reported on may affect how you process or respond to certain medications. Knowing this information may help your health care provider make more informed medication prescribing or dosing decisions.
- **Nutrigenomic Testing:** Undergoing nutrigenomic testing may assist your health care providers in recommending dietary changes in order to manage a disease state or to help promote better health. Research has shown that individuals who receive DNA-based dietary advice find the information more motivating in adopting healthier eating habits and make more changes to their diet compared to general population-based dietary advice.

**Risks Associated with Testing:** Both pharmacogenomic and nutrigenomic testing may cause you to discover sensitive information about your health and your genetic makeup. Some individuals worry that their genetic information may be used to discriminate against them in their job or for health insurance coverage. In the United States, the Genetic Information Nondiscrimination Act (GINA) was signed into law in May of 2008. This law offers federal protection against such discrimination. There are, however, exceptions in this law and there are currently no federal laws that prohibit the use of genetic information to discriminate in issuing policies of life insurance, disability insurance or long-term care insurance. Base10 stores your genetic information in a secure database and data is encrypted while at rest. Additional information about how Base10 protects your information is provided on our website.

**Limitations on Testing:** Base10 and its affiliated laboratories implement several safeguards to avoid technical errors, but as with all medical tests, there is a chance of a false positive or a false negative result. A false positive result means that genetic variation was reported which is not actually present. A false negative result means that the test failed to identify a genetic variation that is actually present and within the reportable range. An inconclusive result may occur due to limitations in laboratory methods, limitations in knowledge of the meaning of identified variant(s) or poor sample quality. Other sources of error, while rare, include sample mix-ups, contamination of the sample or inherent DNA sequence properties. Your clinical status at the time the biological sample was taken may also limit the accuracy or relevance of the results or prevent the test from being completed. This includes the presence of certain conditions such as rare biological conditions, hematologic malignancies or the receipt of transfusions or bone marrow or organ transplants. There is always a possibility of error or failure in sample analysis; this is true with complex testing in any laboratory. The analysis of test results is based on currently available information in the medical literature and scientific databases, as well as laboratory informatics and algorithms that may be subject to change. Such analysis requires the exercise of professional judgment and is not an exact science. New information may replace or add to the information that was used to analyze your results.

- **Pharmacogenomic Testing:** Your pharmacogenomic test is intended to detect variants within a specified reportable range of selected genes known to detect gene alleles (two or more versions of a gene) and variants known to impact your ability to process and respond to certain medications. This test may not detect every variant or allele that may affect how you process or respond to medications. The activity of the tested genes is just one of the factors that influence your ability to process and respond to certain medications. Other factors include the influence of other genes, your health history, environmental factors and other medications that you may be taking. Different

genes and other factors may interact in ways that are not completely understood. This test does not diagnose or treat any disease or condition, nor does it predict responses to medications other than those specifically indicated.

- **Nutrigenomic Testing:** Your nutrigenomic test looks at genes that have been shown to modify responses to dietary intake and/or to impact nutrition and physical activity recommendations. This test does not diagnose or treat any disease or condition.

#### **Acknowledgments and Consent:**

- I understand and acknowledge that the results of my testing are confidential to the extent allowed by law. Base10 will release the results of my testing to my ordering health care provider, to the RD assigned to me (for nutrigenomic testing only) and to other third parties as required by state and local law and/or as specifically authorized by me in writing. By providing my consent, acknowledge and agree that Base10 may communicate with me about my collection kit, test order, results, account details and other related logistics and procedures. If my employer has provided or paid for (in whole or in part) my tests, I acknowledge and agree that my de-identified results may be provided to my employer or its designee (such as a health plan administrator or pharmacy benefits manager) singly or aggregated with other de-identified results as a data analytics resource. “De-identified” means that personal identifiers associated with my genetic information will be removed.
- I understand and acknowledge that Base10 will not return any remaining sample to me or to any health care provider unless requested in writing by an authorized health care professional. By signing this consent, I permit Base10 to maintain my sample and to use it in an anonymous fashion for research/development or for quality assurance purposes. If I am a New York resident, my sample will be destroyed within 60 days after Base10’s affiliated laboratory receives the sample or upon completion of all tests, if later. If I am a resident of a state other than New York, my sample will be destroyed in compliance with my state’s laws and regulations. I understand that Base10 is under no obligation to retain my sample for longer than 60 days unless specifically required by law. I understand that my specimen will only be used for genetic testing as permitted by this consent, and that it will not be used in any identifiable fashion for research purposes without my consent. I also understand that Base10 and its affiliated laboratories store my genetic sequencing and related data as required by applicable laws and regulations, and that Base10 may use this data to conduct subsequent testing or analysis in the event that I consent to any new product or service offering. Based upon Base10’s review of medical literature and/or changes in technology, Base10 may recommend additional analysis to confirm or expand the results provided to me from the testing. Such recommendations will require an updated test order and consent from me.
- By signing this consent, I permit Base10 and its affiliated laboratories to de-identify my health information, including, but not limited to, my sequenced genetic information, and to use such de-identified information in any manner permitted by law. De-identified health information is health information that has been stripped of any information that can be used to identify me.
- My clicking below, I acknowledge my voluntary participation in this/these test(s) and provide my consent for Base10 Genetics, Inc. to perform the test(s). My clicking below also provides my consent for my test results to be reported and released to the health care provider ordering the test(s) and, as applicable, to the RD assigned to me. I have read this entire document and have been given the opportunity to ask and have all of my questions answered about the applicable test(s). I represent that I am at least 18 years old.