BostonGene

Consent to Disclosure of Genetic and Related Medical Information and Tissue Specimens to BostonGene for the Performance of BostonGene Tumor Portrait™ Test

ABOUT THE BOSTONGENE TUMOR PORTRAIT™ TEST

The BostonGene Tumor Portrait™ test, based on integrated genomic and transcriptomic analysis, propels precision medicine into daily practice and supports physicians in actualizing personalized therapy for cancer patients. The test uses whole-exome sequencing (WES) and transcriptome sequencing (RNA sequencing or RNAseq) to detect genomic alterations such as single nucleotide variants (CNV), insertions/deletions (Indels), copy number alterations (CNA), tumor mutational burden, microsatellite instability (MSI), fusions, frameshifts, rearrangements, expression levels of more than 20,000 genes. BostonGene-integrated genomic and transcriptomic analysis, in concert with the patient's medical history, provides information regarding the likely benefits of therapies or therapeutic combinations, suitable NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) treatment recommendations and ongoing clinical trials.

The process of DNA and RNA sequencing is not 100% error free. The analysis of nucleic acids by next-generation sequencing (NGS) can be affected by multiple factors and may be influenced by specimen collection and storage processes. The lack of detection of a genomic alteration does not definitively rule out that the patient does not carry this genomic variation. Detection of an alteration does not necessarily indicate pharmacologic effectiveness (or lack thereof) of any therapeutic or therapeutic regimen.

Your physician's interpretation of test results is based in part on currently available information in the medical literature, research, and scientific databases. New information may become available in the future that could impact the interpretation of your results.

The selection of therapies is solely based on the discretion of your treating physician. Decisions regarding your care and treatment must be based on the independent medical judgment of your treating physician, taking into consideration all available information concerning your condition, the U.S. Food and Drug Administration (FDA) prescribing information and medical guidance. Healthcare practitioners are strongly encouraged to collect all available information pertinent to a particular clinical case before making any treatment decisions or initiating any patient-specific management.

The BostonGene Tumor Portrait™ is a CLIA certified Laboratory Developed Test (LDT) that is not subject to review by the FDA.

AUTHORIZATION OF SPECIMEN/MEDICAL INFORMATION RELEASE

By signing this form below you authorize the disclosure of your tissue samples and your personal and medical information related to your clinical care to BostonGene for BostonGene Tumor Portrait™ testing. Submitting your sample for testing is voluntary and you may choose not to have your sample tested.

There are state and federal laws that prohibit discrimination against individuals for the purpose of employment or obtaining health insurance, and prohibit insurers and employers from seeking an individual's genetic information without consent. In accordance with such laws, your healthcare provider will not disclose or interpret your genetic information for use by employers or insurers. However, it is your responsibility to consider the possible impact of genetic test results as they relate to insurance rates and obtaining disability or life insurance and employment. The federal Genetic Information Non-Discrimination Act (GINA) provides some protections against genetic discrimination.

Your personal information will be stored and protected in compliance with U.S. and state privacy laws.

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USE AND RETENTION OF DE-IDENTIFIED TISSUE SPECIMEN, DE-IDENTIFIED GENOMIC/TRANSCRIPTOMIC DATA, DE-IDENTIFIED TEST RESULTS AND DE-IDENTIFIED MEDICAL INFORMATION FOR RESEARCH PURPOSES

Your Healthcare Provider or BostonGene may wish to use your de-identified test results together with de-identified clinical information for research and development purposes. "De-identified" means that your healthcare provider or BostonGene will remove any information that directly identifies or could be used to identify you personally, such as your name, address, or birthdate. However, de-identified information may become personally identifiable if combined with other information.

If you agree, your Healthcare Provider or BostonGene may store and use de-identified leftover specimen materials, de-identified DNA/RNA samples, de-identified test results, as well as de-identified medical information for research and development. This may include sharing your de-identified tissue samples and/or de-identified medical information with other laboratories or private companies for research or commercial collaborations. Although the results of research, including your donated sample and associated information, may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research. Your de-identified specimens, de-identified test results and de-identified medical information will be retained by your healthcare provider or BostonGene and may be shared with third parties as long as deemed useful for research and development purposes, which may be indefinitely.

You may withdraw your consent to use your specimens, results and information for research purposes and/or request the destruction of your specimens or deletion of your information at any time, with the understanding that, to the extent such sample or information has already been used, it cannot be destroyed or retrieved. You may request destruction of your specimens or deletion of your information by sending an e-mail to clientservices@bostongene.com.

Your permission to use your specimens and the information collected from analysis of it for research purposes is optional and completely voluntary. If you do not consent to allow your sample or information to be used or stored for research, it will not adversely affect your medical care or results.

GENOMIC SEQUENCING SECONDARY FINDINGS

The use of your genomic information may reveal one or more findings not related to the reason that the ordering physician authorized this test. Such findings may include incidental or secondary findings identified by the American College of Medical Genetics and Genomics (ACMG). BostonGene will only report secondary findings if you opt-in and consent to receivesecondary findings. If you consent, you may receive information beneficial to you or your family in relation to choices regarding preventive or clinical care, although you may also receive information regarding your or your family's risk for certain diseases and conditions.

You are encouraged to undergo genetic counseling with a geneticist or genetic counselor who can answer your questions and provide information about genetic testing prior to signing this informed consent. For a list of medical geneticists and counselors who may be available in your area, please visit the National Society of Genetic Counselors site at nsgc.org.

FUTURE CONTACT

Your healthcare provider or BostonGene may wish to contact you regarding ongoing research, including findings specific to your disease or genomic data, as well as to obtain information regarding your future medical care.

By signing below I confirm that I have read this consent form, that my physician has reviewed with me the purpose, benefits, and limitations of genomic/transcriptomic testing, and that I consent a) to release of my specimens (e.g. tumor specimen and blood) and medical information to BostonGene for the BostonGene Tumor Portrait™ test, b) to retention and use of my de-identified specimens, de-identified genetic data, de-identified results and de-identified medical information for as long as deemed useful for research purposes, which may be indefinite[1], c) for future contact regarding provision of general information about research findings or about my test results[2].

Printed Name _____ Date _____

Signature _____

☐ Check this box if you don't want to receive secondary findings.

Minnesota residents only: By signing above, you are consenting to the retention of your samples, de-identified DNA/RNA and genetic/medical information for up to 30 years.
New York residents only: By signing above, you are consenting to the retention of your samples, de-identified DNA/RNA and genetic/medical information, otherwise your samples will be destroyed within 60 days after collection or upon completion of the genetic tests for which they were collected.

[1]Several states require express consent to the storage of DNA samples and/or genetic information. Alaska, Minnesota, and New York require such consent regardless of whether the DNA sample and/or genetic information in question is identifiable, de-identified, or anonymous. A number of states including Delaware, Nevada, an New Mexico require such consent if the DNA sample and/or genetic information in question is identifiable, but do not define "identifiable" or address whether de-identified or coded genetic information (as opposed to anonymous information) is considered identifiable under the law. Accordingly, for the purposes of obtaining informed consent, it is generally considered best practice to treat all DNA samples and/or genetic information as identifiable.

[2] Separate opt-in consent to future contact is required in New York.