Informed consent for BostonGene tests

Your healthcare provider wishes to order laboratory test(s) offered by BostonGene (a "Test" or the "Tests"), including BostonGene’s Tumor Portrait™ test. The test reports provide information for your healthcare provider to review. Decisions regarding your care and treatment, including therapy selection, are solely based on the independent medical judgment of your doctor. If you have any questions or need additional information, please consult your doctor before signing. There is no guarantee that a test report will reveal clinically relevant information or affect your healthcare provider’s decision-making. There is a possibility of testing errors, and analysis of nucleic acids can be affected by multiple factors including, but not limited to, specimen collection and storage processes. The lack of detection of a specific genomic alteration does not definitively rule out the possibility that the patient carries said alteration. Detection of an alteration does not necessarily indicate effectiveness (or lack thereof) of any particular therapy or therapeutic regimen. Some test results may show one or more “actionable” genomic alterations, which means that there may be FDA-approved therapies available for targeting a specific disease subtype, certain clinical trials may be available to you, or genetic information that may impact your ongoing health care management. BostonGene is not obligated to re-evaluate a test report based on new medical knowledge that emerge after those results have been sent to your healthcare provider.

By signing below, you consent to the transfer of your tissue samples and the disclosure of your protected health information (“PHI”) for treatment purposes to BostonGene. Submitting your sample for testing is voluntary and you may choose not to have your sample tested. Your personal information will be stored and protected in compliance with applicable U.S. and state laws. 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. However, it is your responsibility to consider the possible impact of your genetic test results as they relate to insurance rates and your ability to obtain disability and/or life insurance and employment. The federal Genetic Information Nondiscrimination Act (GINA) provides some protections against genetic discrimination.

Use and retention of de-identified leftover specimens, results, and clinical information for research purposes

BostonGene may remove personally identifiable information from your test results, specimens, and clinical information in accordance with applicable law, and use and store it indefinitely for de-identified research and development purposes. Although the results of research involving your de-identified test results, specimens, and clinical information may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research. You may withdraw your consent to use your test results, specimens, and clinical 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 de-identified or used, it cannot be destroyed or retrieved. You may request the destruction of your specimens or the deletion of your information by sending an email to clientservices@bostongene.com. If you do not want to allow your de-identified sample or information to be used or stored for research, please check the box at the bottom of this form. Checking the box 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 that are not related to the reason for the test, known as secondary findings. Many secondary findings are not related to cancer. BostonGene will not report secondary findings not related to cancer if you opt out and check the box below. If you consent, you may receive information beneficial to you or your family, although you may also receive information regarding your or your family’s risk for certain diseases and conditions. Some secondary findings are related to cancer. BostonGene will therefore provide secondary findings related to cancer even if you do not opt in and consent to receive secondary findings because these findings may describe your or your family’s risk for certain cancers and may be beneficial for you and your family. BostonGene strongly recommends that you seek additional consultation from your doctor or a genetic counselor regarding any secondary results you receive because secondary results are not related to the reason that the ordering physician authorized this test. For a list of medical geneticists and counselors who may be available in your area, please visit the National Society of Genetic Counselors website at nsgc.org.

Future contact

Your healthcare provider or BostonGene may also 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* you confirm that you have read this consent form, that your physician has reviewed with you the purpose, benefits, and limitations of genomic/transcriptomic testing, and that, unless indicated otherwise below, you consent to: a) the release of your specimens and clinical information to BostonGene for testing; b) the retention and use of your de-identified specimens, test results, and clinical information for as long as deemed useful for research and development purposes, which may be indefinite; c) to receive secondary findings; and d) future contact regarding ongoing research.

☐ 1 Check this box if you do not consent to the research and development use of your de-identified samples and data as described in the relevant section above.
☐ 2 Check this box if you do not consent to receiving secondary findings that are not related to cancer.
☐ 3 Check this box if you do not consent to receiving future contact regarding ongoing research.

* MINNESOTA RESIDENTS ONLY: By signing above, you consent to the retention of your de-identified samples, DNA/RNA, and genetic/clinical information for up to 30 years unless you indicate otherwise above.

ALASKA, DELAWARE, NEVADA, NEW MEXICO, AND NEW YORK RESIDENTS ONLY: By signing above, you consent to the retention of your de-identified samples, DNA/RNA, and genetic/clinical information unless you indicate otherwise above, in which case your samples will be destroyed within 60 days after collection or upon completion of the genetic tests for which they were collected. By signing above, you also consent to future contact unless you indicate otherwise above.