BostonGene Test requisition form

Email: clientservices@bostongene.com
Fax: +1 (857) 557-6273, Phone: +1 (781) 552-3131

1. PATIENT INFORMATION

First name | Last name | Patient MRN

DOB MM / DD / YYYY | Sex ☐ M ☐ F | Ethnicity | Phone | Email

Street address | City | State | Postal code

2. TREATING PHYSICIAN INFORMATION

First name | Last name | NPI | Email

Medical center | Phone | Fax

Street address | City | State | Postal code

3. BILLING INFORMATION (please select payment option and attach front and back copies of the insurance card)

☐ **Medicare** see section #10 ☐ ABN attached if required | Medicare policy ID | Patient status at time of collection ☐ Outpatient ☐ Non-hospital/Office ☐ Hospital inpatient - **date of discharge** MM / DD / YYYY **OR** ☐ Not yet discharged

☐ **Other insurance** | Insurance provider | Policy holder name | Policy holder DOB MM / DD / YYYY

Policy # | Group # | Prior authorization #

☐ **Self-pay** | Contact name | Phone | Email

☐ **Facility** ☐ Same as treating physician | Facility name | Street address

City | State | Postal code

4. CLINICAL INFORMATION (required for payer coverage determination)

ICD-10 code | Stage | Diagnosis

Disease status Select all that apply ☐ Recurrent ☐ Relapsed ☐ Refractory ☐ Advanced (stages III / IV) ☐ Metastatic ☐ None

Are you aware if the patient previously tested with a similar CGP (Comprehensive Genomic Profiling) test for the same cancer genetic content that resulted in a successful not failed report?

Please note that progression after targeted therapy or recurrence is possible evidence of clonal evolution and different genetic content
See section #10 for Medicare coverage criteria

☐ Yes ☐ No

Has the patient previously received hematopoietic stem cell transplantation (HSCT/BMT/UCBT)? ☐ Yes* *Due to method limitations, orders for patients after HSCT will be not accepted ☐ No

Current line of therapy Optional

PLEASE ATTACH THE PHYSICIAN NOTE OR CLINICAL HISTORY SUMMARY

5. TEST INFORMATION

☑ **BostonGene Tumor Portrait™**
FFPE (tumor) + Whole blood / Saliva / Buccal swab (normal)

Tumor + normal tissue based CGP test. The report combines results of DNA and RNA analysis.

Optional add-on tests:

IHC testing
FFPE block OR 1 FFPE unstained slide per marker

☐ dMMR IHC (MLH1, MSH2, MSH6, PMS2)
☐ PD-L1 IHC (22C3)

6. SPECIMEN INFORMATION (for more information about specimen types see section #11)

Tumor

☑ FFPE tissue* | Pathology lab name | ☐ Pathology lab is **NOT** part of the treatment team

Case # | Date of collection Performed or scheduled for MM / DD / YYYY | ☐ Specific FFPE block required | Block #

*Microdissection is performed if needed based on FFPE sample quality.

Normal

☐ Saliva ☐ Buccal swab ☐ Whole blood* *Blood as a "normal" sample is not accepted in case of heme cancers | Date of collection MM / DD / YYYY | Send to patient ☐ Buccal swab / Saliva kit ☐ Mobile phlebotomy

7. TREATING PHYSICIAN SIGNATURE

By signing this form, I affirm that this test is medically necessary and that I am authorized to order this test. I also confirm that I have obtained the patient's (or the patient's authorized representative's) written consent in accordance with applicable law to allow BostonGene **(a)** to perform the test and retain results, specimens, and clinical information generated from the test; **(b)** to release accompanying medical information to BostonGene; **(c)** to remit test results to me or my organization as the ordering provider and patient's treating clinician, and to the patient's payer as needed for reimbursement purposes; **(d)** to pursue any and all necessary appeals of full or partial payment on behalf of the patient with respect to services provided by BostonGene as authorized by the patient's assignment of benefits and right to payment for services; and **(e)** to de-identify the test results, specimens, and clinical information and use, disclose, and retain such de-identified test results, specimens, and clinical information for future unspecified research. I will maintain a copy of the written consent and will make it available to BostonGene upon request.

Physician signature | Printed name | Date MM / DD / YYYY

8. FORM COMPLETED BY

Full name | Email

Additional report recipients (optional)

Full name | Email

PLEASE OBTAIN PATIENT CONSENT ON THE BACK PAGE OF THE FORM

9. CHECKLIST

Required supporting documents:

- ☐ Front/back copy of insurance card
- ☐ Relevant lab results
- ☐ Treating physician progress note
- ☐ Pathology/cytology report

Additional documents, optional:

- ☐ Radiology reports, radiation therapy notes, DICOM images
- ☐ Radiology/operative reports
- ☐ Historical progress reports
- ☐ BostonGene financial assistance program application form
- ☐ Prior molecular test reports
- ☐ ABN

10. MEDICARE COVERAGE SUMMARY

Test	Conditions for Medicare coverage	Coverage criteria
BostonGene Tumor Portrait™ test	Covered by Medicare for all solid tumors when all coverage criteria is met. Advanced Beneficiary Notice (ABN) is required if the patient does not meet the coverage criteria or if the test is not ordered by a treating physician. ABN is also required for all tests ordered for hematological diseases.	**1)** Patient has been diagnosed with a solid malignant neoplasm; **AND 2)** Patient has either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer (only requires one of these to be met); **AND 3)** Patient has not been previously tested with a CGP test for the same cancer genetic content. (Progression after targeted therapy or recurrence can be associated with significant changes of the molecular profile and therefore can be considered as potential indications for repeat testing.); **AND 4)** Patient has decided to seek further cancer treatment.

11. SAMPLE REQUIREMENTS

FFPE	For NGS: 1 FFPE block (resections, core-needle biopsies, cell-blocks) **OR** 10 unstained slides (positively charged and unbaked at 4 µm thick) + 1 H&E slide. The number of cells required is 40,000 tumor cells per specimen and the specimen must have tumor content > 20% AND a tissue area > 5 mm^2. Ship via FedEx.
	For IHC: 1 FFPE unstained slide (positively charged and unbaked at 4 µm thick) per marker for PD-L1, and + 4 unstained slides for dMMR OR 1 FFPE block. The number of cells required is 100 viable tumor cells. Ship via FedEx.
FFPE bone marrow	We only accept bone samples that are decalcified in EDTA. Ship via FedEx.
Whole blood	Collect 5-10 mL in the provided blood collection tubes. Ship overnight via FedEx.
Saliva	Collect 2 mL of saliva using the provided kit. Patient should not eat, drink, smoke or chew gum before giving sample. Ship via FedEx.
Buccal swab	Collect buccal swab using the provided kit. Patient should not eat, drink, smoke or chew gum before giving sample. Ship via FedEx.
Special cases	
Blood transfusion	Blood is not accepted as a "normal" specimen if the patient has undergone a systematic blood transfusion. In this case, buccal swab or saliva is recommended as a "normal" sample.
Hematopoietic stem cell transplantation (HSCT / BMT / UCBT)	Samples are not accepted from patients who had hematopoietic stem cell transplantation.
Heme cancers	Blood is not accepted as a "normal" specimen if the patient has hematologic cancer. In this case, buccal swab or saliva is recommended as a "normal" sample.
Other	Fresh samples collected within 48 hours and frozen samples can be received as a "tumor" sample in certain circumstances. Extracted DNA and RNA are acceptable sample submission types and must be extracted in a CLIA laboratory.

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 the pharmacologic 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 [1]

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 [2]

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 [3]

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.

Patient consent

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.

Patient signature	Printed name	Date MM / DD / YYYY

***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.