

Sample information form

*All field must be filled

* Sample ID _____

Basic information

* Package (Please select only one package from below)

- ☐ OncoPress Key (188 genes, FFPE) ☐ OncoPress Key (188 genes, ctDNA)
- ☐ OncoPress Premium (1021 genes, FFPE) ☐ OncoPress Premium (1021 genes, ctDNA)
- ☐ OncoPress Premium (1021 genes, FFPE) + OncoPress Monitoring (ctDNA, MRD) 1 time
- ☐ OncoPress Premium (1021 genes, FFPE) + OncoPress Monitoring (ctDNA, MRD) 5 times
- ☐ OncoPress Monitoring (ctDNA, MRD)

Hospital/Clinic information

* Hospital/Clinic name: _____ * Doctor name: _____

Medical license: _____ Submission department: _____

* Email address: _____ * Telephone: _____

Patient information

* Patient name: _____ (In Capital) Gender: ☐ Male ☐ Female

* Date of birth (DD/MM/YYYY): _____ Telephone: _____

* ID card/Passport No. _____

Diagnosis and Patient History

* Cancer type: _____

* Stage of cancer: ☐ I ☐ II ☐ III ☐ IV Others: _____ * Pathological sub-type: _____

* Treatment history: ☐ Chemotherapy ☐ Radiotherapy ☐ Surgery ☐ Targeted therapy ☐ Others: _____

Last treatment date: _____ (DD/MM/YYYY)

* History of blood transfusion: ☐ No ☐ Yes, Transfusion date _____ (DD/MM/YYYY)

* Attachment: Please provide the following information ☐ Copy of recent pathology/cytology

☐ Test results from FISH, IHC or other molecular diagnostic assays (eg. ER, PR, EGFR, HER2, BRCA, KRAS, etc.)

Specimen information

* ☐ FFPE Tissue: _____ slides Block ID./Slide ID. _____

* Collection position: _____ * Collection date (DD/MM/YYYY): _____

* ☐ Blood sample : _____ mL _____ tube(s) * Collection date (DD/MM/YYYY): _____

For BKG laboratory use

Sample information – Peripheral blood

* ☐ Streck Cell-Free DNA BCT tube: _____ mL * Collection date (DD/MM/YYYY): _____

Sample information – DNA extract from peripheral blood

* ctDNA concentration: _____ (ng/μL) * ctDNA volume: _____ μL * Collection date (DD/MM/YYYY): _____

* gDNA concentration: _____ (ng/μL) * gDNA volume: _____ μL * Collection date (DD/MM/YYYY): _____

Information confirmation

Service contents

Oncology therapy-related gene detection: Based on the Next Generation technology, through the detection of gene mutations related to tumor drugs in samples such as blood and tumor tissues, comprehensive tumor molecular typing information can be obtained to assist clinicians in formulating individualized drug regimens.

Personalized Molecular Residual Disease (MRD) Assay is a personalized, hybridization capture, and NGS-based liquid biopsy test designed for MRD detection and surveillance in solid tumor patients. Based on the detection results from tissue by 1021 genes Assay, this assay selects the clonal mutations through patented algorithm to design personalized probes, which combines with core probes to form a personalized MRD detection panel. Personalized Molecular Residual Disease (MRD) Assay provides a reference for the accurate whole-course management of patients with solid tumor through the detection of peripheral blood ctDNA mutation in early, locally advanced or advanced patient.

1. Limitations of gene variation detection

(i) Oncology therapy-related gene detection only targets DNA-level variations in specific gene regions (including point mutations, small fragment indels, copy number variations, and fusion genes), and does not involve detection on protein and RNA levels.

(ii) Tumors are heterogeneous, so the mutations detected by small tumor tissue may not fully reflect Sequencing all the mutations in the lesion.

(iii) Circulating tumor DNA in plasma originates from cells at the lesion site and is released into the blood. Not all mutations of diseased cells are released into the blood, so the detectable mutations in plasma may not fully reflect all mutations at the lesion site.

(iv) Some patients do not have specific gene mutations corresponding to targeted drugs, so not all patients can find corresponding targeted drugs or identify drug resistance mechanisms through this test.

(v) Genetic variations outside the detection range and/or non-genetic variation factors such as drug-drug interactions may affect clinical phenotypes such as drug effects.

(vi) This test is mainly used to assist clinical decision-making. The test results are only for reference by clinicians and do not represent clinical decision-making opinions.

2. Potential risks

(i) If the type of unconventional sample submitted for inspection, or the sample is not collected, stored or transported correctly, the accuracy of the test result may be affected, and the institution shall not be responsible.

(ii) If the sample is lost due to irresistible factors (such as broken blood collection tubes, natural disasters, etc.), or fails to pass the quality control standards during the testing process, you need to cooperate with the company to collect samples again.

(iii) During the testing process or after knowing the test results, you may experience different degrees of mental stress and burden, and this company shall not be responsible.

(iv) In order to continue to provide the most optimized testing services, the company will update the testing platform from time to time. Before and after the platform switching, there may be inconsistencies in the detection sites, but this does not affect the judgment of the detection significance of the samples.

Informed consent of the testee

- (i) Patient agrees to authorize the company to obtain the personal information and related materials that I fill in the sample information form and provide during the testing process and agrees to authorize the company to analyze and process the sample testing data during the testing process to deliver the testing results to me.
- (ii) Patient agrees to authorize the company to store or destroy the provided personal information and related materials, sample testing data and remaining samples in accordance with the requirements of laws, regulations, or policies after the test.
- (iii) After anonymity the identity information, Patient allows the company to process the remaining samples and data or use it for further scientific research, technology development or clinical research. The company can obtain the intellectual property rights involved in the research results and allow testing agencies to get in touch with me when necessary.
- (iv) Patient's specimen and genetic data will be proceeded at Beijing Geneplus Technology Co. Ltd. and/or referral laboratories. An adequate degree of protection is afforded to the transferred personal data, or that the transfer is otherwise permitted in accordance with the applicable data protection law.
- (v) Patient and physician confirm that the information and relevant materials provided are true, accurate and complete.

Medical personnel statement

- (i) I confirm that the patient/testee has been duly informed of the specific purpose of this genetics test, its risk, and its limitations.
- (ii) I have clearly explained that the heterogeneity of the sample and other uncontrollable technical reasons, the subject should understand that the test may give false-positive or false-negative results.
- (ii) I confirmed that the patient/testee has been informed that the test will provide result for the conditions indicated on this form and we/I will ensure that the test result will be interpreted to the patient in an appropriate setting with accompanying genetic counseling.
- (iii) I have answered all the patient/testee's questions regarding this test.
- (iv) I reviewed the confirmation statement with the patient/testee and obtained the patient/testee's signed consent on the request and confirmation statement from conducting genetic analysis.
- (v) I confirmed that we/I carry out our duties in accordance with all applicable laws, rules and professional standards/ The location that is used in the performance of our duties also complies with all applicable laws.
- (vi) I understand the test description and I have read and accepted the test disclaimer as outlined in overleaf.

I have carefully read and fully understood all the contents of this form for oncology gene detection, fully understood the service content, detection limitations and potential risks of this gene detection, and my concerns have been answered in detail. Therefore, I fully voluntarily and cautiously sign this application form and agree to participate in the oncology gene detection project and promise that the information provided is true and effective.

* Marked items are required, to ensure the smooth running of the test and the accuracy of the report, please be sure to fill in the information

* ☐ I consent for OncoPress service

* Applicant signature: _____

* Physician signature: _____

Date: _____

Date: _____