 Genetic Tests – Patient Informed Consent Form

Before you choose to have your specimen(s)/clinical samples for genomic test at ACT Genomics Co. Ltd. (Hereafter referred to as “ACT Genomics”. This includes its affiliated companies in Hong Kong, Taiwan, and Thailand.), please read this form and make sure you fully understand the purpose, procedures, limitations and risks involved in doing this test. If you have any questions, please consult your referring doctor prior to signing this consent form.

# **Testing Purpose**

ACT Genomics’ cancer genetic testing service is used to detect specific gene mutations related to cancer. This information can be used to assist physicians in determining the clinical treatment for cancer or potential participation in clinical trials.

# **Testing Procedure**

Upon the determination made by your doctor, ACT Genomics will arrange the transportation of your clinical samples (formalin-fixed paraffin-embedded specimens, peripheral blood, or cerebrospinal fluid, etc.) obtained through surgery or other sampling methods. After receiving your clinical samples by ACT Genomics Laboratory (Hereafter referred to as the “Lab”) located in Hong Kong, Taipei, Taiwan or Bangkok, Thailand and confirm that your clinical samples meeting the testing acceptance criteria of the Lab, the Lab will conduct the test and prepare the test report based on the testing service (further described below) you and your doctor selected. The report will then be provided to the commissioned healthcare institution.

1. Next-generation sequencing (NGS) testing services utilize next-generation sequencing and nucleic acid testing to sequence specific cancer-related genetic mutations within the specimen and generate the genomic mutation data. Subsequently, a comparison will be made with a large medical database to generate a testing report based on the sequencing results.
2. Droplet Digital Polymerase Chain Reaction (ddPCR) testing or immunohistochemistry staining will be used to detect specific genes, and the obtained test results will be used to generate a testing report.

# **Limitations and Risks of Testing Technology**

1. If the clinical samples do not meet the acceptance criteria for testing, the test will not be conducted. Such clinical samples will be assessed by the referring physician or your doctor to determine whether either reacquire a qualified clinical sample or terminate the testing.
2. Next-generation sequencing testing, ddPCR testing, immunohistochemistry staining and other testing technologies still have their limitations, and the accuracy of these tests is not 100%.
3. The scope of testing primarily focuses on gene mutations. Due to limitations in testing technology and variations in tumor genes among individual clinical samples, even if testing personnel have diligently followed standard operating procedures, it is still possible that no mutation abnormalities will be found in specific genes tested, or this may result in the inability to provide some test results. Examples of such situations include copy number variations (CNV), microsatellite instability (MSI), tumor mutation burden (TMB), and others.
4. The mutation status found in the test results may: a. has no corresponding drugs in the current medical databases; b. be in clinical trial stages; or c. be the same as the treatment drugs you are currently or previously receiving.

# **Testing Report and Specimen Explanation**

1. The information related to cancer gene mutations and treatment outcomes continuously evolve with ongoing medical research. Your medical team will integrate clinical data such as blood and imaging, which may lead to varying interpretations of the drugs matched to the testing results. The testing results are intended for reference by healthcare professionals only and do not replace the independent professional medical judgment of healthcare professionals. They should not be considered as a diagnosis or medical treatment advice for any individual.
2. Due to the need for medical terminology and literature verification, **the test report is presented in English** for the convenience of healthcare institutions as a reference.
3. In compliance with the applicable laws, the test report will be provided to your doctor or the commissioned healthcare institution. If you need to obtain the test report, please submit the request to your doctor or the commissioned healthcare institution.
4. Genetic test may reveal information related to genetics. For clinical interpretation of any test results, it is advised that you should consult with your doctor to assist in evaluating subsequent health management considerations.
5. ACT Genomics will retain the test results for 7 years or a longer term required by applicable laws for the purpose of further serving you or discussing with your doctor.
6. ACT Genomics will retain any remaining clinical samples for up to 6 months after the completion of the test report. To the maximum extent permitted by applicable laws, the clinical samples will be retained in a de-identified manner for medical analysis. However, if you select otherwise in the following “**Certificate of Medical Necessity/Content”** or request ACT Genomics to destruct the remaining clinic samples, ACT Genomics will destruct the remaining clinic samples as instructed.

Your privacy and personal information will be kept confidential in accordance with the applicable laws.

# **Certificate of Medical Necessity/Content:**

* I, or my legal representative, have discussed with the Ordering Physician stated herein and am willing to undergo the selected test (stated below) and assume any related risks. I hereby give consent to the medical institution that collected the sample, pathology report, and medication records, among other medical information, providing them to ACT Genomics to conduct the test and analyze the results. I also understand that ACT Genomics will, following applicable laws or regulations, provide the test results to the Referring Healthcare Institutions stated below:

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| Referring Healthcare Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Hospital, Clinic) |
| Ordering Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Selected Test (e.g., ACTOnco® Pro**)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

* I, or my legal representative, have thoroughly read and fully understood the contents of this Genetic Test Patient Informed Consent Form (“Consent Form”). **I hereby consent to the terms of this Consent Form,** and I agree that ACT Genomics may collect, process, and utilize my personal data following the terms specified in this Consent Form.
* **I acknowledge that ACT Genomics will only commence genetic testing after payment has been completed.**

**Optional Fields for the Test Subject:**

Any of the following items which I have not checked or checked both “Agree” and “Disagree” shall be considered as disagree.

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| --- | --- |
| □Agree □Disagree | When a biopharmaceutical company is researching and developing new drugs/treatment methods related to my testing results, ACT Genomics is allowed to provide information to the referring physician. The referring physician will then assess whether these new drugs/treatment methods may be beneficial for my future treatment. |
| □Agree □Disagree | In compliance with personal data protection laws and relevant regulations, ACT Genomics, after removing information that can directly or indirectly identify my identity from genetic information and test results, may utilize such de-identified data, for example, to establish a database or for queries or research purposes by ACT Genomics or other institutions or companies. |
| □Agree □Disagree | ACT Genomics may use my prognosis tracking information for medical research and analysis purposes. |
| □Agree □Disagree | In compliance with personal data protection laws and relevant regulations, ACT Genomics may retain and use my remaining clinical samples in a de-identified manner for research or medical analysis purposes. |

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| Patient's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | National ID/Passport ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Patient's Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Contact Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Emergency Contact Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Relationship to the Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Patient/Representative Signature：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Relationship to the Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signature Date: \_\_\_\_\_\_\_\_\_\_\_\_\_(YYYY/MM/DD) |