

Pharmacogenomics Test – Information Document

Medical Corporation ISEIKAI / SOPHIA Complete Medical Checkup Center (hereafter referred to as “our hospital”) provides pharmacogenomics testing services related to drug responsiveness (hereafter referred to as “this test”).

Before undergoing this test, please carefully read and fully understand the following information, and provide your consent.

1. Purpose and Scope of This Test

1. This test analyzes genetic sequence information related to individual drug responsiveness, with the aim of estimating:
 - *Drug efficacy* (how well a drug works)
 - *Risk of adverse drug reactions*
 - *Predisposition to drug allergies*
 2. This test is for the purpose of providing information through genetic analysis and its interpretation (estimation of predispositions). It is **not** a medical act intended for diagnosis or treatment. Therefore, the information provided by this test does not replace a physician’s diagnosis or prescription. If you are currently receiving or have previously received medical care, your physician’s judgment takes precedence.
 3. This test does **not** target cancer genomes, and is therefore different from cancer genome profiling tests.
 4. This test is not used for forensic purposes (e.g., paternity or kinship testing) or the diagnosis of genetic disorders (such as single-gene diseases).
 5. You will be asked about the medications you are currently taking. Please bring accurate information, such as your medication handbook.
 6. General interpretations of the results will be explained by our staff. However, for information regarding your current prescriptions, please consult your primary physician. Upon request, we can refer you to a physician at ISEIKAI International General Hospital.
 7. Do not adjust, discontinue, or change the dosage of your medications on your own based on the test results. Our hospital is not responsible for any harm caused by self-adjustment without consulting your physician.
 8. This test is intended solely to examine genetic predisposition to drug responsiveness. It must not be used for any other purpose, and we cannot guarantee its reliability if applied outside its intended use.
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2. Application for the Test

1. The application is complete when you consent to the contents of this document, sign the consent form, and pay the designated fee.
2. For minors, consent must be obtained from a parent or legal guardian. If the subject is a junior high school graduate or 16 years or older, their own consent will also be obtained, provided they are deemed capable of understanding. For minors under 16, the test will be explained in age-appropriate terms to ensure understanding and agreement.
3. If the subject is elderly, ill, or otherwise incapable of giving informed consent, consent will be obtained from a spouse, adult child, parent, adult sibling or grandchild, grandparent, cohabiting relative, a person considered equivalent to a close relative, or a legal guardian. In such cases, the applicant will sign the consent form.

4. Applications will not be accepted in the following cases:
 - Missing information on the consent form
 - Applications that do not meet the requirements in (2) or (3)
 5. Before the results are provided, the applicant may withdraw their application in writing. However, the test fee is non-refundable.
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3. Genetic Analysis Conducted in This Test

1. A 5 mL blood sample will be collected. If re-testing is necessary, an additional 5 mL sample may be collected at no extra cost.
 2. DNA will be extracted from the blood, and only the genetic regions related to drug responsiveness will be analyzed. This test does not detect predispositions or risks for diseases unrelated to drug responsiveness.
 3. The test analyzes:
 - *Single nucleotide polymorphisms (SNPs)*: differences in DNA base sequences
 - *Copy number variations (CNVs)*: structural variations in the genome
 4. The latest technologies will be used, and interpretations will reference established medical evidence and international guidelines, with emphasis on genetic traits common among Japanese and East Asian populations.
 - Unknown or clinically uncertain genetic variants cannot be interpreted at the time of testing.
 - Future advances in technology, new drugs, and medical discoveries may change the interpretation of results.
 5. Examples of medications requiring caution will be provided, focusing on those used at ISEIKAI International General Hospital. For other medications, please consult our staff directly.
 6. Test results are usually available within **8–12 weeks** after blood collection. Delays may occur due to laboratory operations, holidays, or major disasters.
 7. In the event of a major disaster or social/economic disruptions, the test may be discontinued before results are available. In such cases, the test fee will be fully refunded.
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4. What This Test Reveals

1. The test identifies genetic features related to drug response, allowing estimation of how your body metabolizes and responds to medications. For example:
 - Reduced enzymatic activity may increase the risk of adverse drug reactions.
 - If a drug requires activation by a particular enzyme, reduced enzymatic activity may lower its effectiveness.
 - Genetic testing may also indicate predisposition to drug allergies.
2. Results will be explained in our hospital's *Genomic Consultation on Drug Responsiveness and Drug Allergy Predisposition*, reporting the key gene types and their estimated functions.
 - Please note that results are not absolute or unchanging. They indicate higher risks based on current science but do not guarantee that adverse drug reactions or allergies will occur.
3. Because this test is based on Japanese and East Asian research, results may not be accurate for individuals of other ethnic backgrounds.
4. For more detailed information, you may visit our consultation service. Genetic counselors are available for concerns about genetic information. For concerns about current medications, please consult your physician.

5. If you previously took this test and wish to receive updated interpretations based on the latest knowledge, you may do so through our consultation service.
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5. Handling of Specimens

1. All specimens are anonymized using identification numbers or codes, in compliance with the Act on the Protection of Personal Information, the Genomic Medicine Act, and ISEIKAI's privacy policies.
 2. Blood samples are stored only for the period necessary for testing and are disposed of properly afterward. Blood or DNA samples cannot be returned to you.
 3. If you consent to research use, extracted DNA may be stored for future research. Otherwise, it will be discarded.
 4. For non-Japanese nationals, all DNA and blood samples will be discarded after the results are reported.
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6. Storage and Management of Personal Information

1. Personal genetic and personal information is managed appropriately under relevant laws and ISEIKAI's privacy policy.
 2. The information obtained is stored in electronic medical records at ISEIKAI International General Hospital and affiliated facilities, and used to ensure safe and appropriate drug therapy.
 3. Records already used in medical care at ISEIKAI facilities cannot be deleted.
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7. Use of Information

1. Genetic information obtained from this test will be anonymized and used for quality control.
 2. If you consent, anonymized genetic information may also be used in pharmacogenomics research, along with anonymized personal information (e.g., health history, medical records, ethnicity). Research aims to improve the test and contribute to the future of medicine.
 3. When research results are presented externally (e.g., at academic conferences or in publications), all personal information will be removed and only anonymized data will be used.
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8. Revisions to This Consent Form

Our hospital may revise the contents of this consent form. Any important changes will be published on the ISEIKAI International General Hospital website.

9. Governing Law and Jurisdiction

1. This consent form is governed by Japanese law.

2. In the event of disputes between the subject and our hospital, the Osaka Summary Court or the Osaka District Court will have exclusive jurisdiction as the court of first instance.

10. Contact Information

If you have any questions or concerns about this test, please contact us at the number provided.

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