



Medical Genetics Center



Patient Information

**INFORMATION ON
GENETIC ANALYSIS IN
ACCORDANCE WITH THE GERMAN
GENETIC DIAGNOSTICS ACT
(GENDIAGNOSTIKGESETZ, OR GENDG)**



Dear Patient,

Your doctor works together with MGZ – Medical Genetics Center in Munich, Germany. Clinicians and scientists worldwide have been taking advantage of our laboratory services for 18 years by sending us samples for genetic analysis. Our medical and scientific experts are available to work with your doctor to develop strategies for testing which are most likely to yield informative results for you and your family. The interpretation of test results is personally handled by the medical doctors and scientists at MGZ most knowledgeable about the clinical manifestations of the disease of interest and/or specializing in that particular scientific field. In writing our test reports, we focus on the clinical information provided for each patient so that we may include information and recommendations regarding differential diagnostics.


This brochure was created to help you and your doctor or healthcare provider discuss the information that you should understand prior to consenting to any genetic testing. Please read this information on genetic analysis carefully and discuss any questions you may have with your doctor.

■ ABOUT GENETIC ANALYSIS

- ▶ Chromosomes, the carriers of genetic material, using chromosome and/or molecular cytogenetic analysis, and/or
- ▶ DNA, the genetic material itself, using molecular genetic and/or microarray analysis.

Testing detects genetic characteristics which may be responsible for causing the disease or disorder affecting you and/or your family.

The scope of genetic testing varies and depends on the clinical question being posed. Nowadays it is possible to analyze not only individual genes but multiple or even all genes simultaneously using [next-generation sequencing \(NGS\) technology](#).



Normally, the only sample material required for genetic testing is a blood sample. If in your particular case another type of sample material is required, you will be informed of the specific risks involved in providing that sample.

■ UNDERSTANDING YOUR RESULTS

- ▶ Should a disease-causing feature (pathogenic variant) be detected, test results are usually highly certain.
- ▶ Should no pathogenic variant be detected, other disease-causing genetic variants may be present which cannot yet be detected using the available test methods.
- ▶ Sometimes genetic variants are detected that have as yet no clear clinical significance (variants of uncertain significance, or VUS). These are indicated in the test results and will be discussed with you at that time.
- ▶ A comprehensive clarification of all possible (epi-)genetic causative factors is not possible.
- ▶ It is also not possible to exclude every risk of disease for you or your family (including your children) using genetic analysis.

■ LEGAL FRAMEWORK

Genetic testing in Germany is subject to the German Genetic Diagnostics Act (Gendiagnostikgesetz, or GenDG), the fundamental principle of which is informed autonomy. You must give your consent to genetic testing and have not only a right to be informed of test results but also a right not to know the results of genetic testing.

Due to legal requirements in Germany as well as the complexity of genetic analysis, test reports are sent to your requesting doctor or licensed healthcare professional who can then discuss the results and their significance with you. Tests reports may also be released to any other healthcare professionals, as indicated on the test request form.

■ COOPERATING LABORATORIES

MGZ offers a variety of genetic analyses. However, in rare instances, the test request and sample material may be forwarded – after consultation with your doctor – to one of our cooperating laboratories.

You may indicate whether or not you consent to the forwarding of your personal information and sample material to another lab (if necessary) on the informed consent form, if you decide to proceed with genetic testing.

■ STORAGE AND USAGE OF DATA AND SAMPLE MATERIAL

The GenDG requires MGZ to destroy your sample material after the completion of genetic testing and to keep your genetic test results on file for 10 years.

However, it may be advantageous to keep both your data and your sample for a longer period of time. This could be important e.g. for the counseling of family members, additional testing, and/or the verification of test results, and enables internal laboratory quality assurance.

Furthermore, your sample could also help contribute to the continued development of diagnostic methods in the field of medical genetics and to the development of therapies for inherited diseases. For this, we would utilize your personal information and/or genetic material only within the context of the clinical symptoms or phenotype and only in encrypted (pseudonymous) form, thereby preserving your right to privacy.

You may indicate whether or not you would like your personal information and sample material to be stored and used in this way on the informed consent form, if you decide to proceed with genetic testing.

■ INCIDENTAL FINDINGS

In principle, every medical test may reveal results which have no direct link to the disease in question but which nevertheless could have medically relevant or therapeutic consequences for you and/or your family (so-called "incidental findings"). These findings may also have legal consequences with regard to an insurance policy, disability benefits, or nursing care (pre-contractual duty of disclosure).

In accordance with international recommendations, MGZ reports any incidental findings which according to current scientific knowledge may be of therapeutic consequence to you and/or your family (based on the guidelines of the American College of Medical Genetics and Genomics, or ACMG).

You may indicate whether or not you would like to be informed of such findings on the informed consent form, if you decide to proceed with genetic testing.

■ CANCELLATION POLICY

Even if you consent to testing now, you may revoke your consent in whole or in part at any time in the future, no questions asked.

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CONTACT



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