

INFORMATION ABOUT THE CONSENT FORM FOR GENETIC ANALYSIS

AGIOMIX requires a signed consent form from the patient in order to be legally able to conduct a genetic analysis. Please ensure that this signed consent form accompanies the sample(s) that are sent to us for testing.

Greetings,

You (or a person in your legal custody) have been recommended a genetic analysis for by your physician to clarify the diagnosis/symptoms stated in the section “declaration of consent” below. To ensure that you have understood the terms and conditions for the test, we have provided information about the testing process and potential results below.

The purpose of the genetic test is to identify the cause of a suspected disease in you or your family with the help of analysis of your genetic material (DNA-Deoxyribonucleic Acid). Any change within the DNA, a ‘mutation’ as we call it, could help explain the disease you or members of your family are experiencing.

What would the genetic analysis help identify?

- A single gene/variant responsible for a specific, suspected genetic disease, or
- Multiple genes (gene panels, whole exome or genome sequencing) in parallel.

The sample type that is required to perform the genetic analysis has been stated in the TRF (Test Requisition Form). Usually, blood, or purified DNA, and sometimes tissue is used. Saliva or buccal swab can also be used in some cases.

What will I know from the genetic analysis?

A genetic analysis can have either of the following outcomes:

- The disease-causing DNA variant is identified, thus confirming the diagnosis. This would allow appropriate medical management by your physician (if available).
- A DNA variant is identified but currently, there is not enough scientific and medical information to determine if this is a disease-causing variant or not. This is where your physician will discuss better options for you regarding the diagnosis and management.
- No specific finding is identified that can explain the symptoms. This can be due to the current limitations in scientific or medical knowledge and technology.

It is important to understand that despite a negative result, genetic analyses are not exhaustive and that it is therefore not possible to exclude risks for all possible genetic diseases for you and your family members (especially your children).

To avoid any psychological stress for you and your family, it is always recommended to discuss the results with your responsible physician.

What are ‘incidental findings’?

When genetic analysis involving a large number of genes (such as whole exome or genome sequencing is carried out) there may be some results which can identify DNA variants that are not directly related to the actual reason for your testing. These are called incidental findings. Such findings could still be of medical importance as they may provide information about a risk for potentially serious, unavoidable or non-treatable genetic diseases, which may not be known at the current time. As per CAP/ACMG standards (College of American Pathologists/ American College of Medical Genetics), incidental findings are to be reported during reporting. However, you can choose to receive or not receive information about incidental findings in the consent declaration below.

Why are family relationship findings important for genetic testing?

In cases where several family members are tested, the correct interpretation of the results depends on the provided relationships between family members being accurate. If the genetic analysis reveals a possibility that there is inconsistency in the provided relationships, AGIOMIX will not inform you, unless in exceptional cases where this information is absolutely necessary for the completion and correct medical interpretation of the requested analysis.

What will happen to my health data, sample and test results?

The sample and provided data including health data will be used for the requested analysis. It will be stored and processed in accordance with your consent declaration along with the test results as specified by CAP and United Arab Emirates (UAE) standards.

What if I decide not to have my DNA analyzed in the future?

You have the choice to withdraw your consent to the analysis if you decide not to have your DNA analyzed in the future. This can be done at any time in full or in part and you need not provide any reason for it. In case of withdrawal of consent, an email can be sent on inquiries@aqiomix.com to request the same.

What if I decide not to have the test done anymore or not have the results?

You have the right not to be informed about test results (right not to know) and to stop the testing processes at any time up to being given the results and to request the destruction of all analysis results. An email can be sent to inquiries@aqiomix.com in order to request the same.

INFORMATION ABOUT THE CONSENT FORM FOR GENETIC ANALYSIS (Continued...)

What do the terms Pseudonymization and Anonymization mean?

Pseudonymization means processing your personal data in a way that the personal data can no longer be attributed to your person without a certain identifier. This is kept separately and protected only by AGIOMIX. "Anonymization" would help render your data anonymous. This then does not allow your identification from the anonymous data at all anymore.

Data protection information for patient and physician:

In the following information below, we want to inform you about the processing of personal data during and after the performance of the genetic analysis. "Personal data" is understood to mean all information which relates to an identified or identifiable natural person. To all such collected and processed personal data, the following applies:

- The controller and entity responsible for the processing of your personal data is AGIOMIX FZ LLC, PO Box 478847 Dubai, Dubai Science Park, United Arab Emirates. You can reach AGIOMIX's concerned personnel under each of the addresses above with the addition "Attn: Data Protection query" or by email at inquiries@agiomix.com
- Patient: By virtue of this consent form and through your physician, we collect the following data about you (in each case insofar as provided): personal details (including name and address), family relations, age/date of birth, gender, ethnicity, nationality, insurance information, symptoms and other medical information, disease, the study material / sample with identifiable genetic data, the genetic analysis results and findings. All your collected data will be stored for as long as indicated in the consent declaration. The data will be processed and stored – partially also in data operated by service providers under our control and instructions - for the performance of the genetic analysis requested and for informing your physician of the results of such analysis, in each case on the basis of the consent provided. In case you have consented accordingly, such data will also be stored and processed for those further purposes as specified in the consent declaration
- Physician: All your collected data will be processed to communicate with you about the tests and the results, as well as for invoicing, for as long as we keep identifiable data about your patients. This takes place on the basis of legal provisions allowing to process personal data for the purpose of performing a contract and for customer relation management reasons because we have a respective legitimate interest. We use data processors, which have been carefully selected and are subject to our instructions and to regular monitoring. Disclosures to data processors may result in such data being processed and stored in countries outside of the UAE. For each such transmission of data to a third country it is safeguarded that either an adequate level of protection or reasonable guarantees exists; e.g. by concluding a data processing agreement containing CAP standard data protection clauses as per CAP and UAE standards

You (Patient and Physician) do have certain rights under UAE laws towards the AGIOMIX FZ LLC, PO Box 478847 Dubai, Dubai Science Park, United Arab Emirates under the laws of the United Arab Emirates. You (Patient and Physician) have the right to be provided with information about you and to have easy access to the personal data we store about you. You can exercise this right at any time, e.g. through an email to inquiries@agiomix.com

For a more detailed and regularly updated information about how AGIOMIX processes personal data please visit AGIOMIX website: www.agiomix.com

Under UAE laws, we have the following obligations while storing and processing your health-related information:

- To keep your health-related information safe and confidential and not to allow it to be circulated unless under the permitted conditions.
- To keep your health -related information secure from being corrupted, amended, deleted or added to without proper authorizations.
- To restrict access to your health-related information only to individuals and entities on a need to know basis.
- Not to publish your health-related information without complying with the legal requirements.

UAE laws require that we may disclose patients' health-related information under the following circumstances:

- To insurance companies, or other entities that fund health services, but only for purposes of obtaining approvals, reviews or to check on financial dues.
- For scientific research purposes, provided we do not disclose the identities of patients and while always complying with the ethics and rules of scientific research.
- To alarm against epidemics or to take preventive measurements that protects the health of the public.
- By an order from a judicial authority
- By an order from health authorities in UAE

By signing this declaration of consent, I acknowledge that I have received, read and understood the preceding written explanation about genetic analyses.

I also received appropriate explanations (from my physician) regarding the genetic basis, the purpose, scope, type and significance of the planned genetic analysis and achievable results, possibilities of prevention/treatment of the possible disease as well as with regard to risks associated with collecting the sample required for the genetic analysis and the knowledge of the results of the genetic analysis. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic analysis.

With my signature below I give my consent or consent on behalf of the patient for whom I am the legal guardian:

MANDATORY

- (1) **to the genetic analysis by AGIOMIX FZ LLC, PO Box 478847 Dubai, Dubai Science Park, United Arab Emirates for the disease stated above, (2) to the collection, storing and processing by my physician, AGIOMIX, its employees, affiliates, officers, and sub-contractors of my "Personal (Health) Data" (meaning in particular and in each case insofar as provided: personal details (including name and address), family relations, age/date of birth, gender, ethnicity, nationality, insurance information, symptoms and other medical information, disease, the study material/sample with identifiable genetic data, the genetic analysis results and findings) as far as required to conduct the genetic analysis including any necessary transfers of my Personal (Health) Data between physician, AGIOMIX and its entities or sub-contractors across national borders (3) to the analysis of the obtained data and its storage for 25 years at AGIOMIX together with my patient file to be able to verify results of the analysis if need be, (4) to add to my patient file or to files of family members and to use for the above purposes – if applicable – Personal (Health) Data on me or members of my family insofar as they have consented, (5) Analysis of data might be carried out by subcontractor outside the UAE where data will be destroyed after the analysis within 72 hours. (6) to inform me or my physician or – if AGIOMIX has been instructed by a laboratory acting on behalf of my physician – such laboratory about the results of the genetic analysis, (7) to provide upon request to me, my physician or – as the case may be – the requesting laboratory, the raw data of the genetic analysis; and (8) to destroy the obtained samples as per the policies of AGIOMIX that are in place at the time of the destruction (9) Data to be stored for 25 years.**
- (2) I also agree that AGIOMIX shares my personal data – but only to the extent absolutely necessary in each case – with further parties, particularly to (i) acquire the necessary blood sample for testing (phlebotomy service), (ii) organize a health insurance review and possible insurance payment through a billing service provider and if selected by me, to (iii) invoice the costs of the genetic testing towards my health insurance carrier, health plan or other third party provider (jointly "Insurance") and in this regard to provide my Insurance with my Personal (Health) Data including - if necessary and requested - the results of the ordered genetic testing.

Reporting of incidental findings (additional optional consent)

Whole exome sequencing (WES) and whole genome sequencing (WGS) tests analyze numerous different genes at the same time. It is therefore possible that a genetic variant found in the genetic analysis is possibly not related to the cause for ordering the testing. These findings, known as incidental findings, can provide information unrelated to your reported clinical symptoms, but can be of medical value for your treatment in the future.

I understand the significance of such incidental findings and consent to AGIOMIX reporting DNA variants of the specified classes or types in certain genes in accordance with the "ACMG Recommendations for Reporting of Incidental Findings". I understand that AGIOMIX, using its own discretion, may refrain from reporting the recommended incidental findings or additionally also report (other) non-ACMG recommended incidental findings, in each case because of additional scientific and medical information available in AGIOMIX'S databases.

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DATE

NAME OF PATIENT UNDERGOING THE TEST

SIGNATURE OF PATIENT/LEGAL GUARDIAN

OPTIONAL

Further storage and use of my Personal (Health) Data and the sample (additional optional consent My Personal (Health) Data and (remaining) sample may help in further research, development and improvement of diagnostic methods and possibly therapeutic solutions. Such measures may in the future also enable and support medical advice and guidance to me and my family members, e.g. related to the diagnosis and treatment of a potential genetic disease.

- I agree that AGIOMIX may store (1) the Personal (Health) Data I provided and information on affected family members - if they consented - and the results of the genetic analysis and (2) my sample (including original and processed sample) for a period of 25 years and use this data and the remaining samples for the purpose of research, improvement, development and validation of analysis procedures and related product and service developments.
- I agree that after a period of 25 years my Personal (Health) Data and (remaining) sample are anonymized and both will then remain in AGIOMIX's archives for use by AGIOMIX without restrictions.
- I agree that AGIOMIX may at any time use and process my Personal (Health) Data without direct identifiers (e.g., name, street address) and place such information into its databases and datasets concerning genetic diseases, for the purpose of scientific and commercial research and to facilitate and contribute to the diagnosis of genetic changes and diseases of other patients. I further agree that AGIOMIX may share my Personal (Health) Data without direct identifiers with external physicians, scientists and commercial companies (e.g., pharmaceutical companies) for research and development purpose. I understand that I have the right to withdraw from any research and I can do so by contacting AGIOMIX authorities for the exclusion of my sample from the study.

I understand that my treatment, payment for treatment, health insurance enrolment or eligibility for benefits will not be affected if I do not authorize this further storage and use of my Personal (Health) Data. I understand that I will not receive any compensation for the use of my Personal (Health) Data or sample by AGIOMIX and that I may revoke this permission at any time by sending a written request to AGIOMIX at PO Box 478847 Dubai, Dubai Science Park, United Arab Emirates, except to the extent action has been taken in reliance on my permission. I also understand that data in AGIOMIX's databases – once anonymized - cannot be destroyed upon request as it is unidentifiable and untraceable. I understand that I have the right to withdraw from any research and I can do so by contacting AGIOMIX authorities for the exclusion of my sample from the study. I understand that once my Personal (Health) Data has been disclosed, privacy laws may no longer apply or protect the information from further disclosure. If I do not revoke this authorization, it will expire 25 years from the date I sign below.

I confirm the above consent to the further storage and use of my Personal (Health) Data and the sample or confirm on behalf of the Patient (as the case may be).

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DATE

NAME OF PATIENT UNDERGOING THE TEST

SIGNATURE OF PATIENT/LEGAL GUARDIAN

I hereby confirm that the consent(s) as shown above have been declared by the patient or (as the case may be) his/her parent or legal guardian and that I have his/her signatures on file if there are not shown above. I confirm that the patient is capable of giving these consents (alternatively that consent was given by a legal guardian of the patient), that all questions of the patient have been answered, that the patient had the necessary time to consider his/her decision and that the patient until now has not exercised his/her right not to know the results of the genetic analyses. I understand that the patient may request to have his/her genetic analyses results eliminated at any time and that I shall forward such requests to AGIOMIX without undue delay. I agree that my own personal data is stored in AGIOMIX's databases for organizational and invoicing purposes.

OPTIONAL

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DATE

NAME OF CLINICIAN

SIGNATURE OF CLINICIAN