



Genetic Diagnostics

Test(s)/Gene(s)/Panel(s): _____

> Analysis Requested

Requested reflexive test (optional, if any) _____

Single Gene Sequencing

- Sequencing (NGS)
- Sequencing (Sanger) if available
- Sequencing + CNVs (with NGS)
- Del/Dup (MLPA or qPCR) if available

Carrier Testing

| | | | |
|-----------------|----------------|---|-------------------------------|
| Gene name _____ | Mutation _____ | Relative tested at CENTOGENE <input type="checkbox"/> yes <input type="checkbox"/> no | |
| _____ | | If yes, CENTOGENE ID _____ | Relationship to patient _____ |

* TAT includes business days

NGS Panel

- Sequencing
- Sequencing + NGS based CNVs
- Del/Dup with MLPA if available

NGS Panel Plus

- Sequencing
- Sequencing + NGS based CNVs
- Del/Dup with MLPA if available

Additional Test Options

- Hotspot Testing
- Repeat Expansion
- Somatic Mutation Analysis
- CentoICU® Platinum (TAT* <15 days)
- CentoICU® FAST (TAT* <10 days)
- CentoArrayCyto® HD (CMA)
- CentoArrayCyto® 750K (CMA)
- NGS Panel Genomic
- CentoMito® Genome
- STAT (Rush fee for non-prenatal samples at additional cost)

> Patient Information

Last Name _____

First Name _____

Date of Birth MM DD YYYY

Sex Male Female

Street _____

Town/State/ZIP _____

Country _____

Phone _____

E-mail _____

Medical Reference Number _____

Sample Collection Date MM DD YYYY

- Arrange for blood draw
- Send sample collection pack to patient
Include family member(s): _____

> Ordering Physician (Reporting Address)

Name of Physician _____

Organization/Institution _____

Point of Contact _____

Street _____

Town/State/ZIP _____

Country _____

Phone _____ Fax _____

E-mail _____

Please note that all diagnostic reports are exclusively available via our online CentoPortal® www.centoportal.com. Additional report recipient(s) can be conveniently added for individual requests via the portal.

> Additional clinical or laboratory contact (optional)

Name _____

Organization/Institution _____

E-mail _____

> For Somatic Mutation Analysis Only

Year of Tissue Fixation _____

Type of Fixation _____

Tumor Grading Stage _____

Tissue of Origin _____

I herewith confirm the correctness of the above given information.

Place, Date _____

Signature of Patient/Guardian _____

CENTOGENE US, LLC

99 Erie St.
Cambridge, MA 02139
USA

> Contact Details

Customer Service

Phone: (+1) 617-580-2102
Fax: (+1) 781-998-1060

customer.support-us@centogene.com
www.centogene.com

> Actual Materials Needed

Blood & DNA requirements:

- ≥ Buccal swab; or
- ≥ 2 µg DNA at a concentration of ≥ 50 ng/µl; or
- ≥ 1ml EDTA Blood; or
- ≥ 1 CentoCard (full 10 spots)



> **Billing**

Direct patient billing

The Patient was informed about the resulting costs and agrees on direct billing. CENTOGENE will send an electronic invoice to the Patient email listed above.

Commercial insurance or third-party billing*

* Please include a copy of the front and back of insurance card

Name /Insurance Company _____

Subscriber name _____

Member ID# _____

Relationship to subscriber _____

Institutional billing

Billing contact name _____

Phone _____ Fax _____

E-Mail _____

Billing address _____

City _____

State _____ Zip Code _____

Patient has been informed and authorizes CENTOGENE to release information concerning testing to his her health insurance and/or an insurance payment consultant in order to process and/or support claims of the Patient for insurance payment. I confirm that I offered pre-test genetic counselling to the Patient if required by his/her insurance.

Date _____

Signature of Physician  _____



CENTOGENE 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).

Dear patient,

Your physician has recommended a genetic analysis for you (or a person in your legal custody) to clarify the diagnosis/symptoms stated in the section "declaration of consent" below. In order to ensure that you have understood the purpose and significance of a genetic analysis, we have provided information about the testing process and potential results below.

The purpose of a genetic analysis is to identify the cause of a suspected disease in you or your family by analyzing your genetic material (DNA) for an abnormal change (variant) that could explain the disease you or members of your family are experiencing.

In a genetic analysis, depending on the case, you can be tested for:

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

The study material that is needed to perform the genetic analysis is stated in the test order form and is typically blood or purified DNA, but may also be tissue, saliva or buccal swab.

Possible results from the genetic analysis:

A genetic analysis can have one of several outcomes:

- A disease-causing DNA variant is identified confirming the diagnosis and allowing appropriate medical management by your physician (if such is available).
- A DNA variant is identified but at this time, there is not enough scientific and medical information to determine if this is a disease-causing variant or not. Your physician will discuss such a result with you and explain what further options are available to you.
- The genetic analysis results in no specific finding 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 genetic analyses – even if the result of a specific analysis is negative – are not exhaustive and that it is therefore not possible to exclude risks for all possible genetic diseases for yourself and your family members (especially your children).

It is possible that the knowledge of the test results may result in psychological stress for you and your family. It is always recommended to discuss the results with your responsible physician.

Incidental findings:

Genetic analyses, particularly those involving a large number of genes such as whole exome or genome sequencing, may identify results that are not directly related to the actual reason for your testing (incidental findings). However, such findings could still be of medical importance for you and your family, as they may provide information about a risk (that you may not be aware of) for potentially serious, unavoidable or non-treatable genetic diseases.

As part of the optional sections of your consent declaration below, you can decide whether or not and under which circumstances you wish to be informed about such incidental findings.

Family relationship findings:

If 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 a discrepancy in the provided relationships, CENTOGENE 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.

Use of the health data, sample and test results:

The sample and provided data including health data will be used for the requested analysis and along with the test results will be stored and processed in accordance with your consent declaration below.

Right of withdrawal:

You can withdraw your consent to the analysis with effect for the future at any time in full or in part without providing a reason.

Right not to know:

You have the right not to be informed about test results (right not to know) and to stop the testing processes that have been started at any time up to being given the results and to request the destruction of all analysis results.

Pseudonymisation and Anonymisation:

Pseudonymisation means the processing of your personal data in a way that the personal data can no longer be attributed to your person without a certain identifier, which is kept separately and protected only by CENTOGENE. "Anonymisation" refers to the process of rendering your data anonymous, which then does not allow your identification from the anonymous data at all anymore.

Data protection information for patient and physician:

In the following 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:

- Joint controllers and responsible entities for the processing of your personal data are CENTOGENE US, LLC, 99 Erie Street, Cambridge, MA 02139, USA, and CENTOGENE AG, Am Strande 7, 18055 Rostock, Germany, (jointly "CENTOGENE") in each case represented by their Executive Board members as can be found on our website (<https://www.centogene.com/about-centogene/team/executive-board.html>). You can reach CENTOGENE's data protection officer under each of the addresses above with the addition "Attn: Data Protection Officer" or by email at dataprivacy@centogene.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 – partially also in data centers 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 in countries outside of the EU (third countries). For each such transmission of data to a third country it is safeguarded that either an adequate level of protection or reasonable guarantees exist; e.g. by concluding a data processing agreement containing EU standard data protection clauses (retrievable at: http://ec.europa.eu/justice/data-protection/international-transfers/transfer/index_en.htm).
- You (Patient and Physician) do have certain rights towards the CENTOGENE US, LLC under the Health Insurance Portability and Accountability Act ("HIPAA") of 1996 as outlined in its notice of privacy practice to be found here: www.centogene.com/hipaa-notice. Insofar as data is partially processed by the CENTOGENE AG in Germany, you (Patient and Physician) do have the following rights regarding personal data relating to you under the European General Data Protection Regulation (GDPR), which you can exercise at any time, e.g. through an email to dataprivacy@centogene.com:
 - Right to be provided with information about and to have access to the personal data stored on you;
 - Right to have the personal data stored on you rectified or erased;
 - Right to obtain restriction of processing your personal data;
 - **Right to object on grounds relating to your particular situation;**
 - Right to data-portability (i.e. receive personal data you provided to us in a structured, commonly used and machine-readable format); and
 - Right to withdraw your consent with effect for the future at any time.
- You have the right to lodge a complaint with a supervisory authority regarding the processing of your personal data.
- You may have further or modified rights under applicable national law, which remain unaffected.
- For a more detailed and regularly updated information about how CENTOGENE AG processes personal data please visit CENTOGENE AG's Data Protection Statement under www.centogene.com/data-protection.



GENETIC ANALYSIS FOR DISEASE:

(filled in by the physician)

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 CENTOGENE US, LLC, 99 Erie Street, Cambridge, MA 02139, USA and/or CENTOGENE AG, Am Strande 7, 18055 Rostock, Germany, (jointly "CENTOGENE") for the disease stated above, (2) to the collection and processing by my physician and CENTOGENE 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 and CENTOGENE and its entities across national borders, (3) to the analysis of the obtained sample and its storage for 10 years at CENTOGENE 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) to inform me or my physician or – if CENTOGENE has been instructed by a laboratory acting on behalf of my physician – such laboratory about the results of the genetic analysis; and (6) to provide upon request to me, my physician or – as the case may be – the requesting laboratory, the raw data of the genetic analysis.

I also agree that CENTOGENE 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 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 CENTOGENE 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 CENTOGENE, 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 CENTOGENE's databases.

OPTIONAL

YES
 NO

| | | |
|------|-----------------|---------------------------------------|
| Date | Name of Patient | Signature of Patient /Legal Guardian* |
|------|-----------------|---------------------------------------|

*Legal Guardian's relationship to the Patient:

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 CENTOGENE 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 20 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 20 years my Personal (Health) Data and (remaining) sample are anonymized and both will then remain in CENTOGENE's archives for use by CENTOGENE without restrictions.
- I agree that CENTOGENE 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 CENTOGENE may share my Personal (Health) Data without direct identifiers with external physicians, scientists and commercial companies (e.g., pharmaceutical companies) for research and development purposes.
- I understand that my treatment, payment for treatment, health insurance enrollment 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 CENTOGENE and that I may revoke this permission at any time by sending a written request to CENTOGENE at 99 Erie Street Cambridge, MA 02139, USA, except to the extent action has been taken in reliance on my permission. I also understand that data in CENTOGENE's databases – once anonymized - cannot be destroyed upon request as it is unidentifiable and untraceable. I understand that once my Personal (Health) Data has been disclosed, U.S. federal privacy laws may no longer apply or protect the information from further disclosure. If I do not revoke this authorization, it will expire 20 years from the date I sign below.

OPTIONAL

YES
 NO

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).

| | | |
|------|-----------------|---------------------------------------|
| Date | Name of Patient | 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 CENTOGENE without undue delay. I agree that my own personal data is stored in CENTOGENE's databases for organizational and invoicing purposes.

| | | |
|------|-------------------|------------------------|
| Date | Name of Physician | Signature of Physician |
|------|-------------------|------------------------|