Diagnostics and Data Protection — Information Sheet

Your physician recommends a genetic and/or biochemical analysis ("**Analysis**") to be performed by CENTOGENE for you/the person for whom you are the custodian or legal guardian ("**You**"). CENTOGENE only performs the Analysis; it is the sole responsibility of the treating physician ("**Physician**") to interpret the result(s) of such Analysis and to inform You of such results. Your Physician will collect Your sample as is required for the Analysis which will either be biological material or raw DNA sequencing data ("**Sample**").

For operational (technical and cost-efficiency) reasons, in some cases, CENTOGENE will sequence a larger part of Your genome although Your Physician has ordered a targeted Analysis. In any case, the report that is provided to the Physician will only contain the results of the ordered Analysis. However, if raw data results are requested by the Physician, these may contain more data than ordered, analyzed, and reported by CENTOGENE, possibly including relevant variants of the DNA.

Family Relationship Findings

If several family members are tested, accurate interpretation of the results depends on the information provided concerning familial relationships. If the Analysis reveals that reported familial relationships are not identical with biological relationships, we will not report such findings.

Secondary, Incidental and Carriership Findings – Only Relevant for Genetic Analysis

Secondary, Incidental and/or Carriership Findings will only be reported if You have given Your (optional) consent by ticking "Yes".

When performing genetic analysis, it is possible that a pathogenic variant discovered unintentionally is not related to the cause of the investigated disease but is still considered medically relevant due to its clear and immediate medical significance to Your health or the health of family members. In this regard the following findings may occur:

(1) The American College of Medical Genetics ("**ACMG**") has published guidelines for the reporting of findings, which are known as "**Secondary Findings**" to be found at www.acmg.net. These recommendations form the basis for CENTOGENE's reporting of Secondary Findings.

(2) CENTOGENE may decide to report further non-ACMG recommended findings, which are called "**Incidental Findings**" and include disease causing variants, apparently not related to the phenotype, with potential clinical actionability.

(3) If requested and available, CENTOGENE will report on "**Carriership Findings**", which include mainly findings indicating carrier status for recessive disorders and/or variants that may impact health and disease ("**Predictive Variants**"), provided these variants have been subject to CENTOGENE's prior evaluation.

Interpretation of the variants/carrier status is based on information available at the time of the Analysis and may change in the future as medical knowledge advances. We are unable to guarantee that the Analysis will find all medical conditions for which a pathogenic or likely pathogenic variant might exist.

Reanalysis

Diseases, genes, and variants are subject to ongoing scientific research, thus it may be beneficial to re-evaluate Your Sample ("**Reanalysis**"), when new findings have been discovered. Hence, if related to Your health status, CENTOGENE may review Your Sample for clinically relevant variants, whereas only the raw DNA sequencing data will be subject to a Reanalysis. If different ("novel") results are found than in the original report, CENTOGENE sends an updated report to Your Physician. You can also actively request a Reanalysis of the Sample in the absence of new clinical information (whereas it is recommended to wait at least one year from the original Analysis) or any time when the phenotype has changed.

Data Protection Notice

CENTOGENE GmbH, Am Strande 7, 18055 Rostock, Germany ("**CENTOGENE**", "**we**" or "**us**") acts as the responsible controller for the processing of Your personal data under the General Data Protection Regulation ("**GDPR**"). "**Personal data**" means any information relating to an identified or identifiable natural person. If You have any questions on CENTOGENE's data processing or want to make use of Your data protection rights, You can contact our data protection officer directly at the address above with the addition: Attn: Data Protection Officer, or via email at dataprivacy@centogene.com.

Data Processing and Legal Basis

We regularly collect the following data: personal data, including first name, last name, address, date of birth, gender, family relations, ethnicity, nationality, insurance information, patient code number (CGXXXXXXXX), disease, symptoms, and other medical information, including image material if provided together with Your Sample. Your Sample is analyzed using state-of-the-art scientific methods and the extracted data is processed with the collected data in our databank. We then provide the results containing biochemical, genetic and health data to Your Physician. The legal basis for the processing of Your personal data is Your consent (Art. 6 para. 1 a); Art. 9 para. 2 a) GDPR). Additional legal bases may apply when we process (e.g., store) Your data due to statutory storage periods under applicable law or perform other necessary processing, such as required under the Medical Association's Professional Code of Conduct, the Medical Device Regulation (MDR, Regulation (EU) 2017/745) or In Vitro Diagnostic Regulation (IVDR, Regulation (EU) 2017/746), when we use Your (de-facto anonymized) data for scientific research purposes (Art. 6 para. 1 h), Art. 9 para. 2 j) GDPR, Art. 89 GDPR and § 27 BDSG) or when the processing is necessary for the purposes of medical diagnosis or treatment (Art. 9 para. 2 h) GDPR).

Further Data Protection Information

You can find further data protection information, incl. information regarding data storage, data recipients, international data transfers and Your data protection rights under the following link: centogene.com/data-protection-notice-for-patients/.

Disclaimer: Please note that genetic and/or biochemical analyses are not definitive. Due to limitations in technology and/or incomplete medical knowledge, some disease-causing variants may not be detected. Therefore, it is not possible to completely exclude all risks for all possible genetic diseases. Moreover, in some cases, the Analysis may indicate a genetic abnormality when You are actually unaffected (false positive) or may indicate no genetic abnormality when You are actually affected (false negative).

IN CASE OF THE UNDERLYING CAUSE OF A FALSE-POSITIVE OR FALSE-NEGATIVE FINDING COULD NOT BE IDENTIFIED BY CENTOGENE, CENTOGENE SHALL NOT BE RESPONSIBLE FOR THE INCOMPLETE, POTENTIALLY MISLEADING OR INCORRECT RESULT OF AN ANALYSIS.

Diagnostics — Informed Consent Form

Suspected Disease / Requested Test (to be completed by the treating Physician)

With my signature below, I confirm or confirm on behalf of the person for whom I am the custodian or legal guardian (hereinafter, "I", "me", "my") that I have received and read the preceding written explanation about the Analysis. I have been adequately informed regarding the purpose, scope, type and significance of such Analysis, possible results and possible risks by the responsible Physician.

Consent to the Analysis and Related Data Processing

By signing this Informed Consent Form, I consent or consent on behalf of the person for whom I am the custodian or legal guardian

(1) to an Analysis of my Sample by CENTOGENE GmbH, Am Strande 7, 18055 Rostock, Germany ("CENTOGENE") for a possible diagnosis of the disease specified above; (2) to the processing of my personal data to perform such Analysis, as specified in the Information Sheet; (3) to provide the results of the Analysis to the treating Physician; (4) to provide the results of the Analysis to health care professionals, who are involved in my medical counseling and/or clinical care (additional report recipients), if so requested by the treating Physician; (5) to provide the results of the Analysis to the requesting laboratory, as documented on the request form; (6) to provide raw DNA sequencing data of the Analysis, upon request, to the treating Physician and/or the requesting laboratory; and (7) to store the personal data and the Sample for up to 10 years after CENTOGENE has reported the last result and to anonymize the personal data.

Furthermore — if the data recipients are located in a so-called third country outside the European Economic Area, where GDPR provisions do not always apply — I consent to the transfer of my personal data to this third country, in particular (1) to provide the results of the Analysis and the raw data to the treating Physician and/or the requesting laboratory; and (2) to provide the results of the Analysis to the health care professionals who are involved in my medical counseling and/or clinical care. I acknowledge that such third country may not provide a level of data protection equivalent to the GDPR and may grant fewer or less enforceable data protection rights and no independent data protection supervisory authority to assist in exercising these rights.

Optional Consent for Reporting of Secondary, Incidental and/or Carriership Findings

(Relevant for genetic analyses that have these reporting options)

I consent that CENTOGENE may

(1) report the ACMG recommended Secondary Findings	◯ YES	◯ NO
(2) report Incidental Findings (as defined above)	◯ YES	◯ NO
(3) report Carriership Findings and Predictive Variants (as defined above)	◯ YES	◯ NO

Not ticking a box is treated as a "No". I am aware that CENTOGENE — at its own discretion — may refrain from reporting the Secondary, Incidental and/or Carriership Findings.

Optional Research Consent to Further use of the Sample and Personal Data

I understand that my Sample and personal data may enable CENTOGENE to develop and improve diagnostic methods and therapeutic solutions for genetic diseases in general. I acknowledge that neither I or the person for whom I am the custodian or legal guardian will receive any compensation for the donation of the Sample and use of personal data. In the following, not ticking a box is treated as a "No".

(1) I consent to the usage of my Sample and personal data by CENTOGENE for scientific (including commercial) research, which focuses on the cause, early detection and/or treatment of rare diseases in general. I acknowledge that the Sample and data will be used in the interest of the greatest possible benefit to the general public for research which aims to improve the prevention, detection and treatment of rare diseases. Such includes but is not limited to disease areas such as metabolic disorders, neurodegenerative disorders, cardiac disorders and malformations as well as to diseases and genetic relationships that are still unknown today. As in any research on rare diseases — particularly due to the latest findings in genetic diagnostics — it is usually not possible to predict in detail which research questions and matters will be addressed in the future. Therefore, the specific research purpose cannot be detailed herein, and the Sample and data may also be used for medical research projects that cannot be foreseen today.		
(2) I consent that CENTOGENE shares my biochemical, genetic, and health data, including the results of the Analysis — solely in de-facto anonymized form — with external doctors, scientific institutions, and/or (pharmaceutical) companies for their own scientific (including commercial) research. I acknowledge that "de-facto anonymized" means that the data available at CENTOGENE is altered in such a way, including redaction and removal of any pseudonyms, that re-identification of me as a person for any further recipient of the data is practically impossible. However, the confidentiality risks described in the Information Sheet persist.	◯ YES	◯ NO
(3) I consent that CENTOGENE stores my Sample and personal data for 20 years after the last result has been reported and I hereby donate and transfer ownership of my Sample to CENTOGENE for further scientific (including commercial) research, which focuses on the cause, early detection and/or treatment of rare diseases in general. I acknowledge that after 20 years — once the identifying data was deleted — the Sample will become anonymized and will remain in CENTOGENE's archive — in anonymized form — for such scientific (including commercial) research. In anonymized form means, that CENTOGENE cannot identify me as a person from such Sample anymore.		

I am aware that the consent(s) is/are voluntary and valid until such time as I choose to withdraw consent. The consent with regard to (1) the Analysis and the optional consent for Secondary, Incidental and/or Carriership Findings can be withdrawn until such has been performed; and (2) the processing of the personal data can be withdrawn at any time. Furthermore, the destruction of the Sample can be requested as long as it has not yet been anonymized; in each case with effect for the future. Until the moment the results of the Analysis have been provided to me, I understand that I have the right (1) not to be informed about such results (so called right not to know); and (2) to request the destruction of all such results. To withdraw the consent and/or to exercise the rights, I may contact CENTOGENE's data protection officer.

Date	Name and date of birth (DD.MM.YYYY) of the Patient	Signature of the Patient, and/or custodian/legal guardian

Notice to the Treating Physician
The applicable law requires informed consent from your patient to be able to perform a genetic and / or biochemical analysis. Please ask your patient to sign the informed consent form. Alternatively, please confirm with your signature that the patient has consented accordingly and that you have such consent on file. Subsequently, please send the completed and signed informed consent form together with the information sheet and Sample(s) to CENTOGENE.

Physician's Confirmation

I acknowledge that (1) the consent as shown above has been declared by the patient and/or the patient's custodian/legal guardian, (2) I have the patient's and/or custodian's/legal guardian's signature on file if it is not shown above, and (3) the patient and/or custodian/legal guardian until now has/have not exercised the right not to be informed of genetic testing results. I understand that (1) the patient and/or custodian/legal guardian may exercise any of its rights specified in the Information Sheet and (2) I shall forward such requests to CENTOGENE without undue delay.

Date	Name of the treating Physician	Signature of the treating Physician