CENTOGENE
THE RARE DISEASE COMPANY

Promo Code ›
(if applicable) _____

CentoGenome® - Whole Genome Sequencing

› Number of samples

☐ **Solo**

☐ **Trio**

☐ **Trio FAST** (TAT <12 business days)

☐ **Trio Plus**

› Solo implies analysis of index patient only; we recommend Trio analysis for enhanced diagnostic accuracy.
› Trio implies analysis of index patient along with the parents.
› All Trio samples have to be received simultaneously to start testing, else each sample from the same family will be charged as Solo.
› Trio Plus implies additional family member sequencing beyond Trio

› Sequence analysis data exchange

Please fill this segment only when bioinformatics data alone is required.

☐ **Bioinformatics** (Extended)

☐ **Bioinformatics with annotated and filtered variant report** (Variants)

› Filtered variant report as Excel table
› Variants file are only available when no medical reporting is requested
☐ Optional available files: fastq, bam, vcf*

Reporting

Please fill this segment only when full medical interpretation and reporting is required.

☐ **Medical report** (Advanced)*

› Comprehensive clinical diagnostic report of clinically relevant findings
› Bioinformatic analysis and validation of the sequencing results by Sanger sequencing
☐ Optional available files: fastq, bam, vcf*

☐ **Research report**
(optional, only if medical report does not show clinically relevant findings)

› The research report will include potential disease-causing variants in candidate genes for which there is not yet sufficient published evidence.

*Raw data (fastq and bam files) **is available only for a limited time** and must be downloaded from the server **within 1 month** after the customer is informed of the completion of the analysis or after the final clinical diagnostic report has been issued.

› Additional testing

☐ **STAT** (rush fee for non-prenatal samples at additional cost)
☐ **with Mitochondrial Genome Analysis**
☐ **Prenatal**** ☐ Maternal Cell Contamination

› This reduces the TAT to 15 business days instead of 20

**Only offered with medical report (advanced package) and with Trio/Trio plus analysis. Additional fee apply. Prenatal testing is currently not offered in the US.

CentoGenome® Somatic

› **Raw data only** as fastq file

☐ **Basic (90x tumor/30x normal)**

For Somatic Mutation Analysis Only

1. Year of tissue fixation .....
2. Tumor grading stage .....
3. Tumor content (%) .....
4. Tissue of origin .....

Minimum Sample Requirements

Purified **DNA** (2 µg with min. 50ng/µl)
EDTA Blood (1 ml)
CentoCard® (1pc, 10 fully saturated dried blood spots)

› To add clinical or additional information please use page 3
› Pages 1-6 are mandatory
› All test results are supported by CentoMD®
*List prices include 10% for the use of CentoMD®

CLIA #99D2049715
CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS
ISO 15189 CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS

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› Patient information

Last Name _____

First Name _____

Date of Birth MM DD YYYY

Sex ☐ Male ☐ Female

Street _____

ZIP Code/Town _____

Country _____

Your Reference Number _____

Sample Collection Date MM DD YYYY

› Physician or Laboratory (Reporting Address)

Name of Physician _____

Clinic _____

Department _____

Street _____

ZIP Code/Town _____

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 report recipient

Name of Physician _____

Clinic _____

Department _____

Street _____

ZIP Code/Town _____

Country _____

Phone _____ Fax _____

E-mail _____

If an genome test is cancelled after receipt of the sample, but prior to analysis set-up, CENTOGENE charges a processing fee and will send a cancellation report. Once testing is initiated, the full price of the analysis will be charged.

› Additional family information

DO NOT LABEL WITH THE INDEX PATIENT´S NAME.

› Father ☐ Asymptomatic ☐ Symptomatic (attach summary of finding)

Last Name _____

First name _____

Date of Birth MM DD YYYY ☐ Not available

Date of collection MM DD YYYY

› Mother ☐ Asymptomatic ☐ Symptomatic (attach summary of finding)

Last Name _____

First name _____

Date of Birth MM DD YYYY ☐ Not available

Date of collection MM DD YYYY

› Additional family member ☐ Asymptomatic ☐ Symptomatic (attach summary of finding)

Last Name _____

First name _____

Date of Birth MM DD YYYY ☐ Not available

Date of collection MM DD YYYY

› Billing

CENTOGENE Quotation No. _____

Invoice to ☐ Patient ☐ Clinic/Insurance
Please attach Authorization/Referral

Name _____

Department _____

Street _____

ZIP Code/Town _____

Country _____

VAT No. _____

Phone _____ Fax _____

E-mail _____

› In Case of Direct Billing to the Patient

I authorize the physician to request this analysis/these analyses and I am informed about the resulting costs (and possibly applicable German 19% VAT). I herewith undertake to be liable for the payment of any invoice related to this diagnostics and I declare that the address given above is the correct billing address.

Place, Date _____

Signature of Patient/Guardian ✗ _____

› I herewith confirm the correctness of the above given information.

Place, Date _____

Signature of Patient/Guardian ✗ _____

› The Terms & Conditions of CENTOGENE AG, which are available on www.centogene.com, apply to your order.
Your specific order will be invoiced at the specific prices as listed on www.centogene.com at the time of receipt of your order.

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MANDATORY

Please provide detailed clinical information

Patient name .....

☐ Age of manifestation .....

☐ Unaffected

Family history:

A. Consanguinity ☐ YES ☐ NO

B. Affected siblings ☐ YES ☐ NO

Pedigree

Clinical information

Please tick the appropriate phenotype(s) ☑

A. NEUROLOGY

1. Behavioral abnormality
- 1.1 Autism
- 1.2 Attention deficit disorder
- 1.3 Psychiatric diseases

2. Brain imaging
- 2.1 Abnormal cortical gyration
- 2.2 Abnormal myelination
- 2.3 Agenesis of corpus callosum
- 2.4 Brain atrophy
- 2.5 Cerebellar hypoplasia
- 2.6 Heterotopia
- 2.7 Holoprosencephaly
- 2.8 Hydrocephalus
- 2.9 Leukodystrophy
- 2.10 Lissencephaly

3. Developmental delay
- 3.1 Delayed language dev.
- 3.2 Delayed motor dev.
- 3.3 Developmental regression
- 3.4 Intellectual disability

4. Movement abnormality
- 4.1 Ataxia
- 4.2 Chorea
- 4.3 Dystonia
- 4.4 Parkinsonism

5. Neuromuscular abnormality
- 5.1 Hyperreflexia
- 5.2 Muscle hypertonia
- 5.3 Muscle hypotonia
- 5.4 Spasticity

6. Seizures
- 6.1 Febrile seizures
- 6.2 Focal seizures
- 6.3 Generalized seizures

7. Others
- 7.1 Craniosynostosis
- 7.2 Dementia
- 7.3 Encephalopathy
- 7.4 Headache
- 7.5 Macrocephaly
- 7.6 Microcephaly
- 7.7 Migraine
- 7.8 Stroke

B. METABOLISM
1. Abnormal creatine kinase
2. Decreased plasma carnitine
3. Hyperalaninemia
4. Hypoglycemia
5. Increased CSF lactate
6. Increased serum pyruvate
7. Ketosis
8. Lactic acidosis
9. Organic aciduria

C. EYE
1. Blepharospasm
2. Cataract
3. Coloboma
4. Glaucoma
5. Microphthalmos
6. Nystagmus
7. Ophthalmoplegia
8. Optic atrophy
9. Ptosis
10. Retinitis pigmentosa
11. Retinoblastoma
12. Strabismus
13. Visual impairment

D. MOUTH, THROAT AND EAR
1. Abnormality of dental color
2. Cleft lip / palate
3. Conductive hearing impair.
4. External ear malformation
5. Hypodontia
6. Sensoneural hearing impair.

E. SKIN, INTEGUMENT AND SKELETAL

1. Skeletal
- 1.1 Abnormal limb morphology
- 1.2 Abnormal vertebral column
- 1.3 Abnormality of the skeletal system
- 1.4 Joint hypermobility
- 1.5 Multiple joint contractures
- 1.6 Polydactyly
- 1.7 Scoliosis
- 1.8 Syndactyly
- 1.9 Talipes equinovarus

2. Skin and integument
- 2.1 Abnormal hair
- 2.2 Abnormal nail
- 2.3 Abnormal skin pigmentation
- 2.4 Hyperextensible skin
- 2.5 Ichthyosis

F. CARDIOVASCULAR
1. Angioedema
2. Aortic dilatation
3. Arrhythmia
4. Atrial septal defect
5. Coarctation of aorta
6. Dilated cardiomyopathy
7. Hypertension
8. Hypertrophic cardiomyopathy
9. Hypotension
10. Lymphedema
11. Malf. of heart and great vessels
12. Myocardial infarction
13. Stroke
14. Tetralogy of Fallot
15. Vasculitis
16. Ventricular septal defect

G. GASTROINTESTINAL, GENITOURINARY, ENDOCRINE

1. Gastrointestinal
- 1.1 Aganglionic megacolon
- 1.2 Constipation
- 1.3 Diarrhea
- 1.4 Gastroschisis
- 1.5 Hepatic failure
- 1.6 Hepatomegaly
- 1.7 High hepatic transaminases
- 1.8 Obesity
- 1.9 Pyloric stenosis
- 1.10 Vomiting

2. Genitourinary
- 2.1 Abnormal renal morphology
- 2.2 Abnormal urinary system
- 2.3 Hydronephrosis
- 2.4 Renal agenesis
- 2.5 Renal cyst
- 2.6 Renal tubular dysfunction

3. Endocrine
- 3.1 Diabetes mellitus
- 3.2 Hyperparathyroidism
- 3.3 Hyperthyroidism
- 3.4 Hypoparathyroidism
- 3.5 Hypothyroidism

H. REPRODUCTION
1. Abnormal external genitalia
2. Abnormal internal genitalia
3. Hypogonadism
4. Hypospadias
5. Infertility

I. ONCOLOGY
1. Adenomatous colonic polyposis
2. Breast carcinoma
3. Colorectal carcinoma
4. Leukemia
5. Myelofibrosis
6. Neoplasm of the lung
7. Neoplasm of the skin
8. Paraganglioma
9. Pheochromocytoma

J. HEMATOLOGY AND IMMUNOLOGY
1. Abnormal hemoglobin
2. Abnormality of coagulation
3. Anemia
4. Immunodeficiency
5. Neutropenia
6. Pancytopenia
7. Splenomegaly
8. Thrombocytopenia

K. PRENATAL AND DEVELOPMENT
1. Abnormal facial shape
2. Failure to thrive
3. Hemihypertrophy
4. Hydrops fetalis
5. IUGR
6. Oligohydramnios
7. Overgrowth
8. Polyhydramnios
9. Premature birth
10. Short stature
11. Tall stature

What is a Whole Genome Sequencing test?
A new form of genetic testing called Whole Genome Sequencing (WGS) provides the most comprehensive collection of an individual's genetic variation by determining the complete chromosomal DNA sequence as well as the full mitochondrial DNA sequence. Whereas most genetic tests focus on a single gene or on a set number of predetermined genes, WGS tests examine the complete genetic code at once.

Test Reports
When a genome sequence is analyzed, it is compared to the reference human genome. While there are always certain variations, depending upon the individual and the data available, CENTOGENE reports only disease causing mutations which can be found by comparing data with medical databases and looking for scientific links. If your WGS test reveals any potentially disruptive variations or problems which may be related to your medical condition, this would be reported to your physician.

Incidental findings
We report incidental findings according to the ACMG guidelines (Green et al. 2013, GenMed 15:565) and include variants of uncertain significance but with strong in silico prediction in the class of expected pathogenicity (EP). If incidental findings are requested, we actively check the ACMG listed genes for reportable variants. In case of Trioanalyses, incidental findings are only analysed for the index patient. Carrier information of the parents for identified incidental findings of the index can be requested with a new consent of the parents. Findings will be issued on individual reports. Incidental findings are not reported for fetal samples or samples from deceased persons.

Accuracy of reported findings
Our diagnostic NGS sequencing workflow has achieved an outstanding level of precision and accuracy. CENTOGENE's evaluation of hundreds of performed Sanger confirmations showed a 100% accuracy of high quality NGS called variants. We can therefore now completely rely on standalone NGS sequencing for these high quality variants. All variants which do not fulfill the quality parameters established for 100% accuracy are confirmed by Sanger sequencing.

Use of parental samples in the testing process of WGS
Biological parental samples are mandatory to enable the interpretation of the final results in WGS testing. In Trio analysis WGS testing and bioinformatic analyses on parental samples is done in parallel to the analysis of the index patient. We can check the parents´ material (based on the genome sequencing data) only with regard to the patient´s condition.
Parental samples are not included in the price for the examination of the index patient sample. CENTOGENE issues a medical report for the index case that includes indirectly some information of the parents. Report of incidental findings in the index patient will be done following ACMG guidelines and after informed consent will be properly fulfilled.

Technical limitations
Since WGS testing cannot analyze all genes in the human genome, it is not always possible to detect all mutations with WGS methods. Some genes cannot be examined because of various technical reasons.
The raw filtered variant may include secondary findings and variants that may be potential sequencing artefacts.

Additional information
The cumulative results of WGS testing on many samples may be published in the medical literature. These publications will not include any information that will identify you personally.

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Information part of consent form for conducting genetic analyses

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:

- Controller and responsible entity for the processing of your personal data is CENTOGENE AG, Am Strande 7, 18055 Rostock, represented by the Executive Board members as can be found on our website (https://www.centogene.com/about-centogene/team/executive-board.html). You can reach our data protection officer under the same address with the addition "Attn: Data Protection Officer" or by email 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 the following rights regarding personal data relating to you, 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 we process personal data please visit our Data Protection Statement under www.centogene.com/data-protection.

Declaration of consent

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 AG, Am Strande 7, 18055 Rostock, Germany, (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 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 am aware that I can withdraw my consent with effect for the future in full or in part at any time and that I have the right not to know the results of the genetic analyses as described in the preceding written explanation.

By ticking the relevant "YES/NO" boxes below, I give my additional consent or consent on behalf of the patient for whom I am the legal guardian to:

OPTIONAL

Reporting of incidental findings
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.

☐ YES
☐ NO

Further storage and use of my Personal (Health) Data and the sample
I understand that 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 stores (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 uses this data and the remaining samples for the purpose of internal 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 ownership in the sample is then transferred to CENTOGENE. Both will then remain in CENTOGENE's archives for use by CENTOGENE without restrictions.
- I agree that CENTOGENE may at any time process my anonymized or pseudonymized Personal (Health) Data, e.g. 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. Access to such pseudonymised or anonymised data might be granted to external physicians, scientists and (pharmaceutical) companies for research and development purposes.
- I understand that I will not receive any compensation for the use of my Personal (Health) Data or sample by CENTOGENE.
- I understand that data in CENTOGENE's databases – once anonymized - cannot be destroyed upon request as it is unidentifiable and untraceable.

☐ YES
☐ NO

If the undersigning is the legal guardian of the Patient, he/she herewith to confirms to provide the above consent declarations not for himself/herself but on behalf of the respective patient.

Date	Name of Patient	Signature of Patient /Legal Guardian

I hereby confirm that the consent as shown above has been declared by the patient or (as the case may be) his/her parent or legal guardian and that I have his/her signature on file if it is not shown above. I confirm that the patient is capable of giving this consent (alternatively that the 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

CENTOGENE AG
Am Strande 7
18055 Rostock, Germany

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