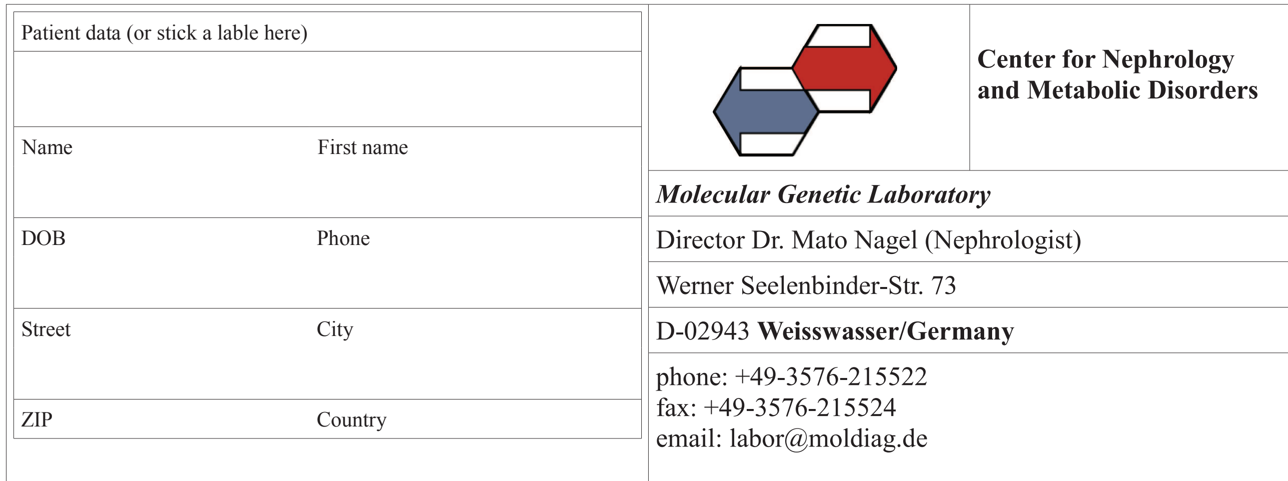


Patient data (or stick a lable here)	
Name	First name
DOB	Phone
Street	City
ZIP	Country

Center for Nephrology and Metabolic Disorders

Molecular Genetic Laboratory

Director Dr. Mato Nagel (Nephrologist)

Werner Seelenbinder-Str. 73

D-02943 **Weisswasser/Germany**

phone: +49-3576-215522
fax: +49-3576-215524
email: labor@moldiag.de

Consent and Information Form

According to German law this is requiered from January 2nd, 2010.

I give my consent to have my sample sent to Laboratory for Molecular Diagnostics at the Center for Nephrology and Metabolic Disorders (Moldiag) for DNA testing for the above-designated genetic condition.

I have discussed the principles, the benefits and the risks of this testing with a physician/genetic counselor, and I have had my questions answered.

I understand the following benefits, risks and limitations:

1. While DNA testing is a valuable diagnostic tool, it may not always give a definite answer about the genetic status of an individual. More specific information will be reported to me with the results of the test.
2. This DNA test is specific only for the condition named above.
3. While mutation and/or linkage analysis often gives precise information, there are several possible sources of error. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, incorrect paternity identification, and sample contamination.
4. The test is complex, may not be FDA approved, and may use some reagents produced for research purposes only. There is always a possibility that a diagnostic error may occur. In addition, the laboratory may have difficulties analyzing my sample and a second sample may be requested.
5. The test may reveal previously unrecognized biological relationships, such as nonpaternity. DNA tests also may reveal a genetic condition in another family member.
6. After the DNA testing of my sample is completed, it may be used anonymously for medical research. Please circle here: Yes No Refusal to permit use of my sample for research will not affect this test procedure. **I am free to withdraw this consent at any time without prejudice to future care. I can withdraw my consent by calling the laboratory director.**
7. There will be a fee for this DNA testing___________(initial).
8. DNA testing may involve emotional stress and may result in discrimination (insurance or work-related). The results of this testing will be treated in the standard medically confidential manner. We are obligated to release test results to your insurance provider if the provider asks for them in order to pay for the test.

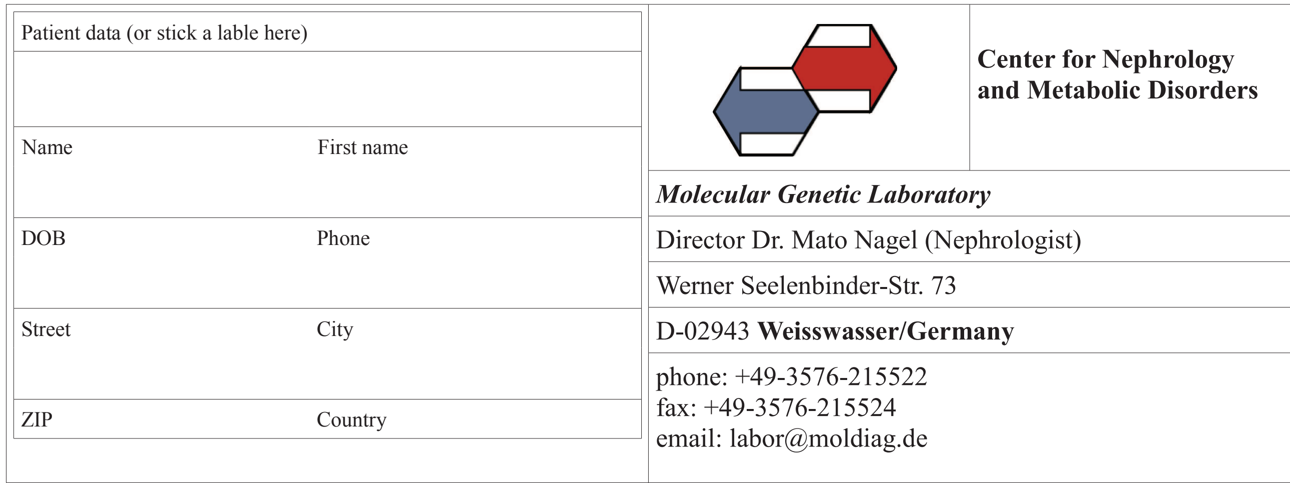
9. Follow-up genetic counseling is available.
10. I agree that my sample anonymously can be further used for biomedical research. (strike out this point if not acceptable)
11. According to German law samples and summary reports have to be destroyed after 10 years. I agree that my sample and data can be can be kept for further use, so my family can profit from it. (strike out this point if not acceptable)

I can decide not to receive the results of the test, but I will still have to pay for the test. In the event of physical injury resulting from this procedure the Moldiag is not able to offer financial compensation or to absorb the cost of medical treatment. However, necessary facilities, emergency treatment and professional services will be available just as they are to the community generally.

Date

Signature of Patient or Legal Guardian

Name	Signature



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Molecular Genetic Laboratory

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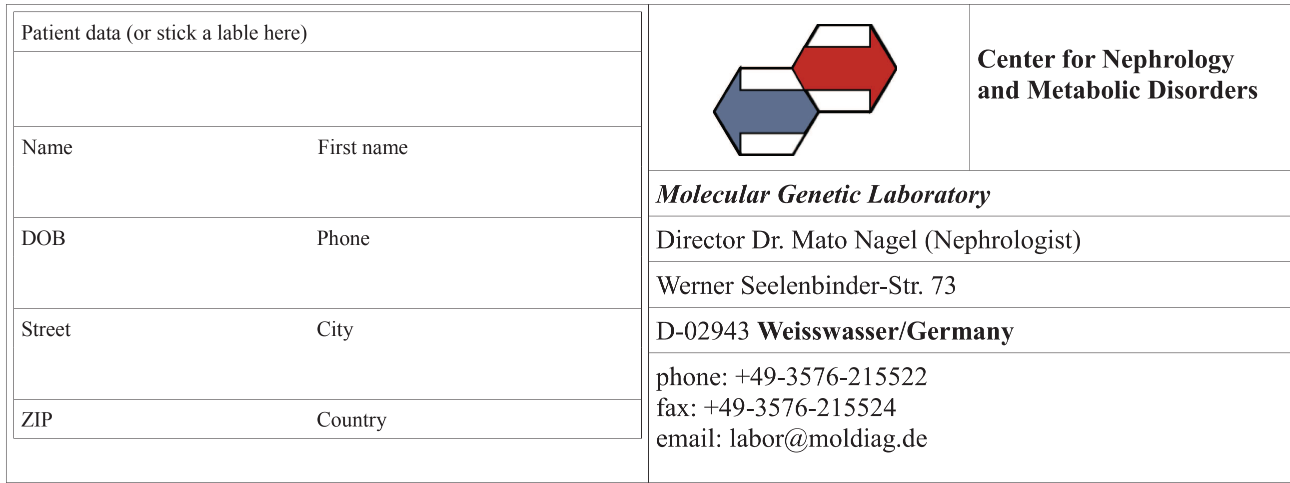
Clinical Survey Form

Clinical data
Alternatively or additionally Any attached documents clinical reports, diagnostic findings including histomorphology related to the disease are warmly welcome.

Clinical consequences of the test	
Therapeutic	□ Initiation of a specific therapy (please specify) □ Avoidance of cumbersome therapy (please specify) □ Transplantation related issues (please specify) □ Other (please specify)
Diagnostic	□ Improvement of diagnostic precision in otherwise uncertain cases (please specify) □ Avoidance of cumbersome diagnostic procedures (please specify) □ Family screening (please specify) □ Other (please specify)
Family counseling	□ Family planning □ Prenatale Diagnostik □ Other (please specify)
Other	

Family history	
X-liked recessive	□ true x-linked (male->female->male transmission) □ probably x-linked (affected males and a- or oligosymptomatic females)
autosomal recessive	□ typical (consanguinity) □ typical (parents healthy and two or more children symptomatic) □ probably
autosomal dominant	□ typical (male->male transmission) □ probably
uncertain	□ a single patient in an otherwise healthy family □ no family data
Other	

Additional samples	
Sample / Patient identification	Family relation
Sample / Patient identification	Family relation
Sample / Patient identification	Family relation
Sample / Patient identification	Family relation
Sample / Patient identification	Family relation
Alternatively or additionally You are invited to attach a pedigree.	



Patient data (or stick a lable here)		Center for Nephrology and Metabolic Disorders
		Molecular Genetic Laboratory
Name	First name	Director Dr. Mato Nagel (Nephrologist)
DOB	Phone	Werner Seelenbinder-Str. 73
Street	City	D-02943 **Weisswasser/Germany**
ZIP	Country	phone: +49-3576-215522 fax: +49-3576-215524 email: labor@moldiag.de

Diagnostic Order Form

Order text (diagnoses, genes, or methods)

Who should receive the summary report?
Name of physician, First name
Clinic, Department
Street, Building, Room
ZIP code, City
E-mail, Phone, Fax
Please provide email or fax and check below if notifications should be sent.

Additional patient data
Patient identification
Sex
Race
Known infectious diseases

Sample data		
Sample identification		
Type of specimen	◻ Purified DNA by (kit or method) ◻ Blood with EDTA anticoagulant (please specify if other) ◻ Blood without anticoagulant ◻ Buccal swabs/ saliva (please specify) ◻ Biopsy material (please give details) ◻ Purified RNA by (kit or method) ◻ Other	
DNA concentration		Sampling date

Who should receive a copy of the summary report?
Name, First name
Clinic, Department
Street, Building, Room
ZIP code, City
E-mail, Phone, Fax
Please provide email or fax and check below if notifications should be sent.

Who should receive the invoice?
Name of clerk in charge, First name
Department
Street, Building, Room
ZIP code, City
E-mail, Phone, Fax
Reference
Please provide patient identification and clinic or any other information that you want to be put on the invoice for reference.

Checklist	
obligatory	◻ Patient has given written consent ◻ Genetic counseling can be assured ◻ Pro forma invoice included
optional	◻ Clinical survey form attached ◻ Yes, I want notification of sample arrival to the email or fax given above ◻ Yes, I want notification of summary report dispatched to the email or fax given above ◻ Yes, I want a provisional summary report sent to the email or fax given above