Patient data

Request for Genetic Analyses

Sender

❑ Hospital ❑ Outpatient Clinic ❑ Physician

Address / Stamp

Phone _____

Fax _____

❑ I confirm that the patient has declared her/his consent to the analyses according to German law in written form.

_____

Signature of the responsible medical professional acc. to GenDG

Invoicing Address (if differing)

_____

_____

_____

Sample data

❑ EDTA blood 5ml

❑ Heparin blood 5ml

❑ Amniotic fluid 15ml

❑ clear ❑ bloody ❑ xanthochromic

❑ Chorionic villi 25ml

❑ DNA, source: _____

❑ Buccal swab

❑ Abortion tissue

❑ Other: _____

> Sampling: Date _____ Time _____

* in case of prenatal molecular genetic diagnostic please extract more sample material and additionally send EDTA-Blood of the mother!

Please be aware that we need the written patient's consent for the investigation or your confirmation that you have the patient's consent.

Analyses _____

Clinical Information _____

Patient Detail

Gender: ❑ female ❑ male ❑ diverse ❑ unkown (e.g. fetus)

Type of analysis: ❑ mutation search ❑ testing for known familial variant(s)

Diagnostic setting: ❑ diagnostic (symptoms present) ❑ predictive (pre-symptomatic) ❑ carrier testing ❑ prenatal

Previous genetic analyses: ❑ no ❑ yes (please specify): _____

Family History

Relatives affected by symptoms: _____

Matching suspected diagnosis: ❑ no ❑ yes (please specify) _____

Genetic analysis in relatives: ❑ no ❑ yes (please specify) _____

Please include family tree:

Sample Arrival (only to be completed by the ZHMA)

Material _____ Route _____ Amount _____ Date _____ Time _____

Address for sending sample (room temperature, no priority mail):

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Genetic Counselling | Molecular Genetics | Paternity Testing

Counselling

I would like to make use of a genetic counselling offer **before** genetic testing: ❑ yes ❑ no

I would like to make use of the genetic counselling offer **after** the results of genetic testing are available: ❑ yes ❑ no

Waiver: I decline the offer of genetic counselling after receipt of the written information about the contents of the counselling. ❑ yes ❑ no

Place, date:	**Patient's signature** or legal representative

Patient Consent

Regarding the disease / disorder / diagnosis

_____

_____

and the planned testing

_____

the genetic background, prophylaxis/prevention/treatment possibilities as well as purpose, nature, scope and information value of a possible genetic diagnosis including the risks attached to the taking of samples and/or the tests have been made sufficiently clear to me and counselling in these matters was adequate.

Reporting

I agree to be informed on findings which at the moment are unclear with respect to a presumed diagnosis, but have based on available information the potential to become diagnostic in the future (Information about variants of unclear significance VUS, class 3 variants). ❑ yes ❑ no

I want to be informed about diagnostic incidental findings which are beyond the initially defined focus of the analysis if they are included in the ACMG list of recommended incidental findings (Green et al. 2013; Genetics in medicine 15:565). The ACMG selection is based on diseases for which a treatment or preventive actions can be defined. ❑ yes ❑ no

In addition to the above mentioned ACMG selection I also want to be informed about incidental findings, not included in the ACMG list. I am aware that for these diseases a treatment option or preventive action is not available yet. (This option is not available for prenatal testing. For minors, only diseases with an onset before the age of 18 will be reported). ❑ yes ❑ no

Data storage and use

I am aware that archiving my personal data and all data regarding the analysis is required by German law for 10 years after completion of the analysis.

In addition to the archiving period of 10 years according to the German law (Gendiagnostikgesetz) I ask SYNLAB to store the data beyond this period. ❑ yes ❑ no

I allow SYNLAB to use all data collected during the analysis including clinical information to be incorporated in the SYNLAB inhouse database to further improve analysis and interpretation of diagnostic assay and variant interpretation. All data will be pseudonymized. ❑ yes ❑ no

I agree to the sharing and use of clinical data, results and generated data for scientific purposes inside or outside the SYNLAB Group. ❑ yes ❑ no

Sample storage

I am aware that in routine procedure my sample will be deleted after completion of the analysis and not available for any further tests.

I ask SYNLAB to archive the collected sample beyond the end of the analysis for its use in eventual further analyses, but also for pseudonymized in house quality controls and contribution to scientific requests from inside or outside the SYNLAB Group. ❑ yes ❑ no

I was advised that I am entitled to withdraw my agreement in whole or in part without giving reasons and without any penalties resulting from this withdrawal. I know that I have the right not to be informed of the examination result(s) (Right not to know). I was advised that I can stop the commenced examination procedure until the communication of the results at any time and that I can demand the destruction of all of my examination material including all components extracted from it. I can as well ask for the deletion of all results and findings obtained so far, if they are not required for legal test documentation.

Place, date:	**Patient's signature** or legal representative

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