Health insurance company or carrier

Last name, first name and adress of insured person

DOB

Health insurance No. | Insured No. | Status

Facility No. | Doctor No. | Date

Responsible doctor (Stamp)

PrenaTest®

WM-3050-EN-008

Mandate reference for SEPA direct debit mandate:

Attach barcode label or enter barcode number

Send the original together with the blood sample in the return box.

To be completed by the doctor

Information on the pregnancy

Date of blood draw (DD/MM/YYYY)

☐ Repeat blood sample (if 1st analysis is failed)

Week of pregnancy: + p.m. (at least week 9+0 to 32+1 p.m.)

☐ **Patient is receiving low-molecular-weight heparin (LMWH)**

☐ **Singleton pregnancy**

Body height: cm

☐ **Twin pregnancy** Monochorionic: ☐ **Yes** ☐ **No**

Weight prior to pregnancy: kg

Reason for the genetic examination

☐ Age 35 years and over at the time of the birth

☐ Prior pregnancy with fetal aneuploidy

☐ Increased risk of aneuploidy based on screening methods for prenatal risk determination

☐ Ultrasound anomalies of the fetus

☐ Hereditary risk of fetal aneuploidy

☐ Other medical reasons/additional pregnancy info (e.g. vanishing twin)

Results report (Multiple languages may be selected) ☐ **German** ☐ **English** ☐ **French** ☐ **Italian** ☐ **Dutch** ☐ **Turkish**

Requirement according to the German Genetic Diagnostics Act

I confirm that the abovementioned patient received human genetic counseling and explanations in accordance with the German Genetic Diagnostics Act. The patient's written consent for the selected genetic testing (PrenaTest® test option 1, 2 or 3) is available. I hereby confirm the order for genetic analysis using the PrenaTest® by LifeCodexx AG in accordance with section 7 of the German Genetic Diagnostics Act. The blood sample comes from the patient named on this form, provided that the barcode numbers on the blood sample test tube and on the form agree or the patient can be clearly identified by name and date of birth on the test tube and form. **Note:** If less than 3 mL of plasma can be obtained from each of the two blood samples, the plasma from the two blood samples will be combined in order to be able to perform a PrenaTest® analysis. If this total quantity is insufficient, a new blood sample will be requested.

Place, Date

Signature of the responsible doctor

✗

Order to perform the PrenaTest®

Prices include VAT and shipping / * According to the GenDG, notification by the doctor starting at pregnancy week 14+0 since LMP

☐ **Test option 1** EUR 199

Determination of fetal trisomy 21
for singleton pregnancy, incl. gender determination on request

Gender determination* desired ☐ Yes ☐ No

☐ **Test option 2** EUR 269

Determination of fetal trisomies 21, 18 and 13
for singleton or twin pregnancy, incl. gender determination on request

Gender determination* desired ☐ Yes ☐ No

☐ **Test option 3** EUR 299

Determination of fetal trisomies 21, 18, 13 and gonosomal aneuploidies
for singleton pregnancy, incl. gender determination on request

Gender determination* desired ☐ Yes ☐ No

Written agreement on self-pay service

I would like to have the PrenaTest® performed through my responsible doctor as a private patient. The request was not made at the initiative of my doctor. The service I am requesting is not a component of care provided by statutory health insurance doctors. I will pay for the PrenaTest® myself. I am responsible for clarifying whether costs will be reimbursed on a case-by-case basis by my health insurance company. **My signature provided herewith is independent of an agreement regarding cost reimbursement by my health insurance company.**

To be completed by the patient

SEPA direct debit mandate – Creditor ID: DE 35ZZZ00000415178

Only fill out if you have a German bank account! If not, transfer the payment in advance to LifeCodexx AG, IBAN DE83 2073 0017 7000 0034 50, Swift-BIC HYVEDEMME17, UniCredit (HypoVereinsbank). I/we hereby revocably authorize LifeCodexx AG to collect the amount to be paid by me/us according to the test option selected above following report of results to the responsible doctor. If my full address is on hand, I will receive an invoice after receipt of payment. Even if I waive communication of the investigation results, I am obligated to pay for the services rendered. I have taken note of the General Terms and Conditions.

First and last name of the account holder

IBAN/account no. BIC/bank sort code

Credit institution | Place, Date | Signature of the patient/authorized account user ✗

Consent to perform the PrenaTest®

With my signature, I hereby give my consent to have the PrenaTest® performed. I received human genetic counseling and explanations from my responsible doctor in accordance with the German Genetic Diagnostics Act (GenDG). I have taken note of the General Terms and Conditions (see reverse).

Collected data/results not identified by name may be used for scientific purposes and published in anonymized form in professional journals. ☐ Yes ☐ No

Surplus examination material that is not identified by name may be stored for purposes of quality assurance, scientific research, and the development of new diagnostic options. ☐ Yes ☐ No

Consent

☐ **I hereby agree** that my personal data (name, address, telephone number, e-mail address, date of birth, insurance number, insured status, pregnancy information) and my blood sample are collected by the responsible physician and transmitted to LifeCodexx AG for the implementation of the PrenaTest®. Furthermore I agree that LifeCodexx AG collects, processes and uses my personal data and my blood sample exclusively within the scope of the contractual relationship for the implementation of the PrenaTest®. After completion of the PrenaTest®, LifeCodexx AG will destroy my blood sample immediately, unless I have consented to a longer storage. I can withdraw my consent to the responsible physician at any time. In that case the processing of the already collected personal data remains lawful.

Telephone number of the patient

E-Mail address of the patient

I have taken note of the General Terms and Conditions and of the Notes on Data Protection (see reverse).

Place, Date | Signature of the patient ✗

LifeCodexx AG Line-Eid-Strasse 3 | 78467 Konstanz | Germany | telephone +49 (0) 7531-9769460 | fax +49 (0) 7531-9769480 | info@lifecodexx.com | www.lifecodexx.com
Chief Executive Officer: Dr. Michael Lutz | Freiburg im Breisgau District Court | Commercial registry 701989 | Registered office: Konstanz | VAT ID no. DE 258862614

General Terms and Conditions of LifeCodexx AG

§ 1 General Information

1. The following general terms and conditions exclusively apply to the delivery and sale of the products and the services of LifeCodexx AG.
2. LifeCodexx AG does not accept any terms and conditions of the other contracting party contrary to or deviating from our own, unless we have expressly agreed to their applicability in writing. The general terms and conditions of LifeCodexx AG also apply even if we provide services without conditions, despite knowledge of contradictory terms and conditions of the contractual partner which deviate from our own.
3. All agreements made between LifeCodexx AG and the contractual partner for the purpose of fulfilling this contract must be made in writing in this contract.

§ 2 Offers and Conclusions

1. In general, the requirement for a valid conclusion of contract in accordance with § 2 between LifeCodexx AG and the contractual partner is a simultaneous identical order of a genetic examination at LifeCodexx AG performed by a physician qualified in accordance with national law (called ‚responsible physician' in the following) (in Germany this is § 7 German Genetic Diagnostics Act (GenDG)).
2. A contract is concluded by the performance of the service. If information is missing, which is necessary for the orderly analysis of the blood sample, the responsible physician is notified and requested to subsequently deliver within a given period. If no subsequent delivery follows within the given period, the responsible physician will be notified that the performance of the service may be delayed due to missing information relevant for the analysis. If no subsequent delivery of the missing information follows by the time the test results come in, LifeCodexx AG reserves the right not to provide the test result. The obligation to pay of the contractual partner remains unaffected by this.
3. The contractual partner explicitly acknowledges that the test results determined by the provision of the service by LifeCodexx AG, in accordance with the provisions of the German Genetic Diagnostics Act (GenDG) will be directly reported only to the responsible physicians appointed by the contractual partner of LifeCodexx AG or their appointed representatives.

§ 3 Prices and Payment Terms

1. All prices are in Euro and when directly billed to the patient inclusive of the legally valid German VAT.
2. The order of the performance of the service initiates the obligation to pay.
3. If the contractual partner has a bank account at a German or Austrian credit institution, payment will be made via a SEPA direct debit mandate. The payment to be made will be withdrawn after the test result has been sent to the responsible physician, however, no earlier than five days after the order was placed. The contractual partner may demand reimbursement of the debited amount within eight weeks starting from the debit date. The respective terms and conditions of the bank of the contractual partner shall apply. If the bank account indicated does not have the necessary covering funds, the credit institution in charge of the account has no obligation to honour the payment. The contractual partner's obligation to pay LifeCodexx AG remains unaffected. If the contractual partner is not account owner of the specified bank account from which the payment is to be drawn on maturity, either the account owner shall authorize the payment with his/her signature, or the contractual partner hereby confirms automatically with her signature on the PrenaTest® order form that she has a valid bank mandate of the specified account in the due amount. The payment obligation of the contractual partner towards LifeCodexx AG remains, even if she is not account owner of the specified bank account or does not have valid bank mandate.
4. The contractual partner will automatically receive an invoice after payment has been received, provided that LifeCodexx AG has the contract partner's complete address.
5. Changes to the contract after the contract has been signed are excluded. In rare cases the determination of the gender is not possible. Nevertheless, the contractual partner is obliged to pay the full price.
6. In the case of revocation of the consent to the genetic examination the contractual partner is obligated to pay LifeCodexx AG for the provided service to the following amount:
   – Fifty per cent of the total amount before the analysis was started.
   – One hundred per cent of the total amount after the analysis was started.
7. In case of revocation of the consent to the genetic examination by the contractual the responsible physician must inform LifeCodexx AG about this in text form. The date of the receipt stamp applies.
8. If the evaluation of the analysis of the sample does not lead to a usable result, the payment obligation becomes null and void for the contractual partner.

§ 4 Service of LifeCodexx AG

1. The object of the contract is the performance of the PrenaTest®, a non-invasive prenatal diagnostic examination method for singleton and twin pregnancies, which enables the responsible physician to make a statement regarding the most frequent fetal autosomal chromosomal disorders with a blood sample of a pregnant patient, who has a risk for chromosomal disorders of the unborn child.
2. PrenaTest® is a progressive, non-invasive test method with a high validity, which is currently called ‚not completely diagnostic' (in accordance with the statements of relevant specialised associations such as ISPD, BVNP, DGGG, GfH, ACOG, etc.). In accordance with the Genetic Diagnostics Commission (GEKO) guidelines concerning the requirements for the performance of prenatal risk evaluation as well as the measures necessary for quality assurance in this context pursuant to § 23 para. 2 no. 5 GenDG" the PrenaTest® is a prenatal genetic analysis for the exclusion or the determination of a numeric chromosomal disorder (§ 3 no. 1a GenDG).
3. The bioinformatic analysis software PrenaTest® DAP.plus used in the context of the PrenaTest® has successfully completed the conformity assessment procedure necessary for the CE marking to determine fetal trisomy 21, 18 and 13 as well as gonosomal aneuploidy and has proven its effectiveness in accordance with the in-vitro directive of the European Union. The PrenaTest® determines the fetal trisomies 21, 18 and 13, gonosomal aneuploidy and the 22q11.2 microdeletion in the unborn child. Current data on the performance qualification of the PrenaTest® are available at www.lifecodexx.com. LifeCodexx AG notes that a validity of 100% (so-called ‚sensitivity' and ‚specificity') in the use of the PrenaTest® at the practice cannot be expected. In general, no statements regarding structural chromosomal changes, mosaics or polyploidy can be made with the PrenaTest®. Gonosomal aneuploidy can only be determined in the case of single pregnancies.
4. Depending on the selected test option, the transmission of the results to the responsible physician is usually made within two to six business days after the receipt of the sample and successful quality control. The contractual partner and the responsible physician are immediately informed about any delays in the performance of the service.
5. The provision of the service by LifeCodexx AG assumes the timely and orderly fulfilment of the contractual partner's obligations and the provided identical order of a genetic examination by the responsible physician in accordance with § 2 of these general terms and conditions.

§ 5 Joint and Several Liability

1. LifeCodexx AG is exclusively liable for the fulfilment of the obligations arising from this contract, the functionality and validity of the PrenaTest® described in § 4 nos. 1 to 3 and the technically correct performance of the offered PrenaTest®.
2. Force majeure, operating disorders, strikes or other forms of work stoppage at LifeCodexx AG or its suppliers for which LifeCodexx AG is not responsible frees LifeCodexx AG from the obligation to deliver for the duration of the disturbance and its effects.

§ 6 Genetic Examinations

1. LifeCodexx AG commits itself to comply with the requirements of §§ 12, 13 GenDG. The results of the PrenaTest® analysis are thoroughly documented and archived or, on the contractual partner's request, completely destroyed.
2. The contractual partner agrees that LifeCodexx AG will inform the responsible physician about the content in the case of direct communication between the contractual partner and LifeCodexx AG.

§ 7 Place of Fulfilment and Jurisdiction and Applicable Law

1. Unless otherwise specified in the order, the place of business of LifeCodexx AG shall be the place of performance.
2. Pursuant to legal regulations, the place of jurisdiction is the contractual partner's place of residence.

Notes on Data Protection

1. Hereinafter we inform you about the collection of personal data in business relations. Personal data means any information relating to you as an identifiable natural person, e.g. name, address, e-mail address and payment details.
2. Responsible processor pursuant to Art. 4 para. 7 General Data Protection Regulation (GDPR) is LifeCodexx AG, Line-Eid-Straße 3, 78467 Konstanz, Germany.
3. In order to provide the contractual services, personal data is collected, stored and, if necessary, passed on to third parties. Therefore the collection, storage and transmission are carried out for the purpose of fulfilling contractual or pre-contractual obligations and on the basis of Art. 6 para. 1 sentence 1 lit. b GDPR.
   If we ask for giving your consent to processing personal data, we obtain the consent for data processing on the legal basis of Art. 6 para. 1 lit. a GDPR.
   Failure to provide this information may result in that the contract cannot be concluded. A processing of personal data only takes place if you have given your prior consent or if permitted by law.
4. We maintain up-to-date technical measures to ensure the protection of personal data. These are adapted to the current state of the art.
5. You have the right to request information concerning the personal data stored with us at any time (Art. 15 GDPR). This also applies to the purpose of storage and the recipients or categories of recipients to whom the personal data is transmitted. In addition, you have the right to request correction and/or deletion and/or restriction of the data processing under the conditions of Art. 16 GDPR, Art. 17 GDPR and Art. 18. GDPR. Under the conditions of Art. 20 GDPR you can request a data transfer at any time.
6. If the purpose of storage has been omitted, personal data will be deleted or blocked immediately. A longer storage may take place if required by the European or national legislators, by EU regulations, laws or other regulations to which the controller is subject. Unless there is a need for further storage in order to conclude or fulfill a contract, blocking or deletion of the personal data takes place if a storage period prescribed by the mentioned standards expires.
7. All requests for information or objections to data processing should be directed by e-mail to our data protection officer at [Datenschutz@lifecodexx.com] or to the address mentioned above (2). For further information, please refer to the full text of the GDPR available on the internet at http://eur-lex.europa.eu/eli/reg/2016/679 and our privacy statement, which is available on the internet at http://www.lifecodexx.com. Moreover you have the opportunity to complain to the responsible supervisory authority about data protection matters.

LifeCodexx AG
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Chief Executive Officer: Dr. Michael Lutz
Freiburg im Breisgau District Court, Commercial registry 701989
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