Patient Information

Surname, first name(s) (patient):

Date of birth:

Date

CENTER FOR HUMAN GENETICS AND LABORATORY DIAGNOSTICS
Dr. Klein, Dr. Rost and Colleagues
Lochhamer Str. 29 - 82152 Martinsried - GERMANY

SIF - Barcode

VERACITY®

Genetic Counseling
Dr. med. Imma Rost (Head)
Dr. med. K. Hörtnagel
Dr. med. D. Wahl
Dr. Univ. Verona M. Cohen
Prof. Dr. med J.-U. Walther
Dr. med. L. Peterson
Dr. med. F. Maier

Specimen

2 x 10 ml venous blood (BCT tubes are provided)

Sampling date | Time

Is this a repeat test? ☐ Yes ☐ No

Please note: Specimens should be stored at room temperature until collection. Specimens should arrive in the lab within 72 hrs of sampling.
Incorrectly labelled or incomplete specimens will be rejected.

General Information: VERACITY is a genetic test that - if carried out in Germany - is subject to the German Genetic Diagnostics Act (GenDG). This order form is only valid in combination with **genetic counseling** and a signed **Informed Consent** (see reverse side).
Payment Information: Our payment policy requires **prepayment** of the analysis fee by electronic money transfer.
Reporting: exclusively to the responsible physician in accordance with GenDG. **Informed consent on the reverse**

Test options

Singleton pregnancies

☐ Trisomies 13, 18, 21	229,00 €
☐ Trisomies 13, 18, 21 + aneuploidies X, Y	269,00 €
☐ Trisomies 13, 18, 21 + aneuploidies X, Y + microdeletions (del22q11.2, del1p36, del17p11.2, del4p16.3) [1)]	299,00 €

Twin/vanishing twin pregnancies

☐ Trisomies 13, 18, 21	229,00 €
☐ Trisomies 13, 18, 21 + microdeletions (see above.) [1)]	299,00 €

Gender Information (optional) [2]

☐ **Yes** ☐ **No**

Sender information (or practice stamp)

Clinic

Street

Postcode, city, country

Phone/fax/email

Resposible physican/medical person

Clinical information and test indication (Mandatory fields: incomplete forms and analysis requests cannot be processed!)

Gestational age (week + day): ☐☐ + ☐ Body weight (before pregnancy): ☐☐☐ kg Height: ☐.☐☐ m

☐ Medication with heparin derivatives during pregnancy

Fetal information

☐ 1 fetus ☐ 1 fetus + vanished twin (collect 4 weeks after the vanishing event) ☐ 2 fetuses → ☐ Monochorionic ☐ Dichorionic

☐ IVF pregnancy ☐ Transfer of single embryo or number of embryos: ___ ☐ Egg donation used* Age at egg retrieval: ☐☐
☐ ICSI pregnancy

Test indication

☐ Increased risk prior to pregnancy ☐ Abnormal ultrasound ☐ Maternal age (≥ 35 years): ☐☐ years Other: _____
☐ Medical history
☐ Genetically inferred increased aneuploidy risk (i.e. parental Robertsonian translocation involving chromosome 21 or 13)
☐ Previous pregnancies/spontaneous abortions caused by chromosomal aberrations

☐ Conspicuous first-trimester screening (FTS)
☐ Singleton pregnancy ☐ Twin pregnancy
Ultrasound findings: _____
Risk calculation: ☐ FMF UK ☐ FMF Deutschland

Trisomy 21: 1: ☐☐☐☐ Trisomy 18: 1: ☐☐☐☐ Trisomy 13: 1: ☐☐☐☐

Possible results of the VERACITY-Tests

Conspicuous: high probability of an aberration of chromosome 21, 18, 13, X or Y or of DiGeorge, 1p36, Smith-Magenis or Wolf-Hirschhorn microdeletion syndrome. The result should be confirmed by invasive prenatal diagnostics (i. e. amniocentesis).

Inconspicuous: high probability of **NO** aberration of chromosomes 21, 18, 13, X or Y or of DiGeorge, 1p36, Smith-Magenis or Wolf-Hirschhorn microdeletion syndrome.

Limitations of the VERACITY test: the test covers only chromosomes 21, 18, 13 and, if requested, the X and Y chromosomes and the microdeletion regions of DiGeorge, 1p36, Smith-Magenis and Wolf-Hirschhorn. The test is not currently validated for the detection of triploidies or mosaics. In some rare cases the results cannot be interpreted and the analysis has to be repeated. In very rare cases, the phenomenon of a vanishing twin can lead to a false result. Invasive prenatal diagnostics is recommended to confirm questionable or clearly pathological results. **False negative** and **false positive** results can not be excluded. Statistically, low risk pregnancies have a low positive predictive value.

1) Screening for microdeletions [del22q11.2 (e.g. DiGeorge syndrome), del1p36, del17p11.2 (Smith-Magenis syndrome), del4p16.3 (Wolf-Hirschhorn-syndrome)] not currently recommended by experts. The investigation of sex chromosome aberrations only recommended after in-depth consultation (Kozlowski P. et al, Ultraschall in Med, 40:176-193, 2019).

2) Gender information can only be communcated afer the 12+0 week of pregnancy post conception (in accordance with GenDG).

* The test is **not applicable** in **twin** and **vanishing twin** pregnancies resulting from **egg donation** or by use of a **surrogate mother**. In contrast to embryo donation, commercial egg donations and surrogacy are not permitted in Germany.

CENTER FOR HUMAN GENETICS AND LABORATORY DIAGNOSTICS
Dr. Klein, Dr. Rost and Colleagues
Lochhamer Str. 29 - 82152 Martinsried - GERMANY

VERACITY®

Patient informed consent

VERACITY is a **N**on-**I**nvasive **P**renatal **T**est (NIPT) for the detection of trisomies of 13, 18, 21, and, upon request, XY anomalies, selected microdeletions (DiGeorge, 1p36 deletion, Smith-Magenis, Wolf-Hirschhorn) and fetal gender. The test requires a venous blood sample from the pregnant woman (2x10ml).

VERACITY is available for singleton and twin pregnancies, including *in-vitro* fertilization (IVF) pregnancies, of at least 10 weeks gestation. Twin pregnancies in which loss of one fetus occurred (vanished twin) are eligible for testing after the 10th week of gestation and 4 weeks after the vanishing event. Information relating to the number of fetuses and IVF status is mandatory and affects testing. **Twin pregnancies and vanishing twin pregnancies are not eligible for X and Y aneuploidy detection**. Patients with confirmed malignancy or a history of malignancy and patients with bone marrow or organ transplants are not eligible for the test. In cases of insufficient fetal DNA in the maternal blood (low fetal fraction), blood sampling may be performed at a later date during the pregnancy and the test repeated (recommended time of the least 3 weeks after initial blood sample).

The VERACITY non-invasive prenatal test is not intended or validated for the detection of mosaicism, triploidy, partial trisomy or translocations. A positive result for twin pregnancies indicates a high risk of at least one affected fetus. In twin pregnancies, detection of Y chromosomal DNA, indicates the presence of at least one Y chromosome. Although this test is highly accurate, there is still a possibility of false positive and false negative results. This can have technical and/or biological causes (eg. confined placental mosaicism (CPM) or other types of mosaicism, maternal constitutional or somatic chromosomal abnormalities, residual cfDNA from a vanished twin or other rare molecular events). The test will **not** identify **all** deletions associated with each microdeletion syndrome. This test has been validated for deletions mapped over the whole length of the typical genomic deletion area and may be unable to detect smaller and cryptic deletions. **The VERACITY test is not diagnostic, rather it is a screening test and results should be considered in the context of other clinical criteria**. The referring physician is responsible for counseling before and after the test, including the provision of advice regarding the need for additional prenatal invasive genetic testing. It is recommended that a positive result is confirmed by amniocentesis.

Specimens collected will be used for the purposes of performing the VERACITY test as requested by this order form. No additional clinical testing will be performed by **MVZ Martinsried** GmbH, unless specifically requested. If necessary, samples can be analyzed for quality assurance/method optimization in the accredited laboratory of the VERACITY test developer (NIPD GENETICS PUBLIC COMPANY LTD in Nicosia, Cyprus). It is also possible that some sample will be leftover after the analysis. As MVZ Martinsried GmbH requires samples and test data for quality improvement and/or ongoing research efforts, an option is available below to grant permission for the specimen to be used in this way. This means that upon completion of the test, all personal information and details are removed, and the specimen and test results are anonymized. No personal information will be associated with studies or publications. Genetic data located on the cloud server in Germany will not be labeled with patient name or the respective date of birth.

Declaration of consent to perform the VERACITY test according to the German GenDG

The German GenDG (paragraph 10) requires the **patient** to be fully informed, give written informed consent and in the case of prenatal testing receive detailed genetic counseling.

Please read this information carefully and delete any statements you do not agree with.

I agree/confirm that I

- was informed about the nature, chances, risks, limitations and significance of the VERACITY test by the **responsible physician** in accordance with German GenDG that I have understood and that there was adequate time to ask questions,
- understand that the test is not a diagnostic test (such as a chromosomal analysis) but a statistical procedure with a risk calculation,
- cannot receive fetal gender information before the end of the 12th week of pregnancy in accordance with GenDG paragraph 15/1,
- give my permission for blood sampling required for the analysis, and for the VERACITY test to be performed,
- give my permission to analyze data on a cloud server located in Germany,
- consent to the storage of my specimen after the analysis is performed, without claiming storage,
- consent to my specimen being utilized anonymously for scientific purposes and quality management.

Moreover, I was informed that

- I can stop the analysis at any time, asking for the elimination of all results,
- I can withdraw my informed consent in total or in part at any time without any reason,
- I have to pay for the costs of the analysis that were generated until my withdrawal,
- I have the right not to know the results of the analysis (right not to know),
- the genetic analysis and possible findings are focused on the medical indications given above and no statements are made about other diseases,
- an inconspicuous result does not completely exclude a chromosomal abnormality.

_____ ✗ _____

Place, date — Patient's signature

Disclosure and genetic counseling for VERACITY test according to the German GenDG

I agree/confirm that

- the pregnant woman was informed about the VERACITY test according to German GenDG (paragraph 9)
- the pregnant woman received genetic counseling according to German GenDG (paragraph 10)

_____ ✗ _____

Place, date — Responsible physician's signature and stamp

Credit card information - to be completed by the patient

Type of card: ☐ Mastercard ☐ Visa ☐ American Express

Owner of the card _____

Credit card number _____ Security code _____ Expiration date _____

Amount authorized: ☐ € 229.00 ☐ € 269.00 ☐ € 299.00 (according to requested test)

_____ ✗ _____

Place, date — Signature (owner of the card)