Patient information

Surname, first name(s) (patient):

Date of birth:

Street | Postcode

City | Country | 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. K. Hörtnagel (Head)
Dr. med. D. Wahl
Dr. Univ. Verona M. Cohen
Prof. Dr. med J.-U. Walther
Dr. med. C. Siegel
Dr. med. A. Schossig
Dr. med. L. Peterson (In training)

Test material

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

Sampling date | Time

Is this a repeat test? ☐ Yes ☐ No

Please note: Blood samples should be stored at **room temperature** until pick-up. Samples should arrive in the lab within 72 hrs of sampling.
Incorrectly labeled or incomplete samples will be rejected.

Important note: Since NIPT is subject to the regulations of the German Genetic Diagnostics Act (GenDG), this order form is only valid in conjunction with a signed **declaration of consent** (see reverse) and **genetic counseling.**

Reporting: exclusively to the responsible physician in accordance with GenDG. **Informed consent on the reverse**

Test options

Basic option

Trisomies 13, 18, 21 € 169.03

Additional options

☐ **Sex chromosomal aberrations** + € 49.25
(only possible in singleton pregnancy)
☐ **Microdeletion[1] del22q11.2** + € 49.25
☐ **Microdeletions[1] del1p36, del17p11.2, del4p16.3** + € 49.25

Gender determination[2]

☐ **Yes** + € 10.05 ☐ **No**

Billing in accordance with fee scale for physicians

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 blood sample 4 weeks after the vanishing event) ☐ 2 fetuses → ☐ Monochorionic ☐ Dichorionic

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

☐ ICSI pregnancy

Test indication

☐ Personal situation ☐ Abnormal ultrasound ☐ Maternal age (≥ 35 years): ☐☐ years

☐ Medical history
☐ Genetically inferred increased aneuploidy risk (i.e., parental Robertsonian translocation involving chromosome 21 or 13)
☐ Previous pregnancy/spontaneous abortion caused by chromosomal aberration

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

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

Possible results of the VERACITY test

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

Inconspicuous: there is a high probability of **NO** aberration of chromosomes 21, 18, 13, a gonosomal aberration, 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 cannot be excluded. For statistical reasons, 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-Hirschhornsyndrome)] 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 communicated afer the 12+0 week of pregnancy post conception (in accordance with GenDG).

* VERACITY **is not suitable** for **twin** and **vanishing twin** pregnancies resulting from **egg donation** or by use of a **surrogate mother**. Egg donation and surrogacy are not permitted in Germany.

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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, sex chromocomal aberrations, selected microdeletions (DiGeorge, 1p36 deletion, Smith-Magenis, Wolf-Hirschhorn) and fetal gender. The test requires a venous blood sample from the pregnant woman (2 x 10 ml).

VERACITY can be used at the earliest in the 10th week of pregnancy for singleton and twin pregnancies and in pregnancies resulting from in vitro fertilization (IVF). 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 the detection of sex chromosomal aberrations.** Patients with a confirmed malignancy and recipients of 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 male twin. 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 (e.g., 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 genetic counseling before and after the test, including giving advice regarding the need for additional invasive prenatal genetic testing. It is strongly recommended that a positive result is confirmed by amniocentesis.

Samples 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 processed for quality assurance by the test developer NIPD Genetics (Nicosia, Cyprus). It is also possible that not all of the sample material is necessary for the analysis. As MVZ Martinsried GmbH uses anonymized surplus sample material for quality improvement and/or ongoing research efforts, an option is available below for you to grant permission for your sample to be used in this way. This means that upon completion of the test, all personal information and details are removed, and the sample and test results are anonymized. No personal information will be associated with studies or publications. Genetic data that must be uploaded to 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, purpose, scope, possibilities, significance and limitations of the VERACITY test by the responsible physician in accordance with German GenDG and 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 until 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 sample after the analysis is performed, without claiming storage,
- consent to my sample 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.

Name of the patient (in block letters)

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