MEDICOVER GENETICS

VERACITY® new generation NIPT

ORDER FORM

AFFIX BARCODE LABEL

PATIENT INFORMATION / [LOCAL LANGUAGE]

First Name / [local language]

Last Name / [local language]

Date of Birth (DD/MM/YYYY) / [local language]

ID / [local language]

Telephone Number / [local language]

E-mail Address / [local language]

Address / [local language]

City / [local language]

Post Code / [local language]

Country / [local language]

REFERRAL INFORMATION / [LOCAL LANGUAGE]

Clinic Name / [local language]

Telephone Number / [local language]

Fax / [local language]

E-mail / [local language]

Clinic ID / [local language]

Address / [local language]

Referring Clinician [local language]

City / [local language]

Post Code / [local language]

Country / [local language]

CLINICAL AND TEST DETAILS

REQUESTED TEST / [ADD LOCAL LANGUAGE]
TICK ONLY ONE BOX BELOW

FOR SINGLETON PREGNANCIES / [ADD LOCAL LANGUAGE]

- ☐ VERACITY BASIC: TRISOMIES 13, 18, 21
- ☐ VERACITY PLUS: TRISOMIES 13, 18, 21; ANEUPLOIDIES X,Y
- ☐ VERACITY PREMIUM: TRISOMIES 13, 18, 21; ANEUPLOIDIES X,Y; MICRODELETIONS (del22q11.2, del1p36, del17p11.2, del4p16.3)

FOR TWIN/VANISHED TWIN PREGNANCIES / [ADD LOCAL LANGUAGE]

- ☐ VERACITY BASIC: TRISOMIES 13, 18, 21
- ☐ VERACITY PREMIUM: TRISOMIES 13, 18, 21; MICRODELETIONS (del22q11.2, del1p36, del17p11.2, del4p16.3)

GENDER INFORMATION* / [ADD LOCAL LANGUAGE] ☐ YES / [LOCAL LANGUAGE] ☐ NO / [LOCAL LANGUAGE]

*Gender information can only be communicated after the 12+0 week of pregnancy post conception (in accordance with GenDG).

CLINICAL INFORMATION / [ADD LOCAL LANGUAGE]
COMPLETE ALL SECTIONS BELOW

MATERNAL INFORMATION / [ADD LOCAL LANGUAGE]

GESTATIONAL AGE (WEEK + DAY) / [ADD LOCAL LANGUAGE]

WEIGHT (KG) / [ADD LOCAL LANGUAGE]

HEIGHT (CM) / [ADD LOCAL LANGUAGE]

NUMBER OF FETUSES / [ADD LOCAL LANGUAGE]

- ☐ 1 FETUS / [ADD LOCAL LANGUAGE]
- ☐ 1 FETUS – VANISHED TWIN / [ADD LOCAL LANGUAGE] Collect 4 weeks after the vanishing event
- ☐ 2 FETUSES MONOCHORIONIC TWIN / [ADD LOCAL LANGUAGE]
- ☐ DICHORIONIC TWIN / [ADD LOCAL LANGUAGE]

TEST INFORMATION / [ADD LOCAL LANGUAGE]

REDRAW TEST: / [ADD LOCAL LANGUAGE] ☐ YES / [LOCAL] ☐ NO / [LOCAL]

COLLECTION DATE (DD/MM/YY): / [ADD LOCAL LANGUAGE]

IVF INFORMATION / [ADD LOCAL LANGUAGE]

IVF PREGNANCY: / [ADD LOCAL LANGUAGE] ☐ YES / [LOCAL] ☐ NO / [LOCAL]

IF IVF, EGG USED: / [ADD LOCAL LANGUAGE] ☐ SELF / [LOCAL] ☐ DONOR / [LOCAL]

SURROGATE: / [ADD LOCAL LANGUAGE] ☐ YES / [LOCAL] ☐ NO / [LOCAL]

AGE AT EGG RETRIEVAL / [ADD LOCAL LANGUAGE]

TEST INDICATIONS / [ADD LOCAL LANGUAGE]
TICK APPROPRIATE BOX & ADD COMMENTS

- ☐ PRIOR PREGNANCY RISK / [ADD LOCAL LANGUAGE]
- ☐ ABNORMAL ULTRASOUND / [ADD LOCAL LANGUAGE]
- ☐ ADVANCED MATERNAL AGE / [ADD LOCAL LANGUAGE]
- ☐ SERUM SCREEN RISK / [ADD LOCAL LANGUAGE]

T21 RISK SCORE: 1IN / [ADD LOCAL LANGUAGE]

T18 RISK SCORE: 1IN / [ADD LOCAL LANGUAGE]

T13 RISK SCORE: 1IN / [ADD LOCAL LANGUAGE]

- ☐ FAMILY HISTORY / [ADD LOCAL LANGUAGE]
- ☐ OTHER / [ADD LOCAL LANGUAGE]

CLINICIAN COMMENTS / [ADD LOCAL LANGUAGE]

PATIENT CONSENT

By placing my signature signing below I hereby:

1. **Declare that I have had the opportunity to receive counseling from referring clinician on the VERACITY test and to discuss with the clinician all aspects of the VERACITY test and this form including the benefits, risks and limitations of the VERACITY test, as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.**
2. **Authorize my referring clinician to collect the necessary blood samples, and to submit this form and transport the samples to MVZ Martinsried GmbH laboratories for the purposes of conducting the tests requested with this form.**
3. **Authorize MVZ Martinsried GmbH to use any part of or the entirety of the blood sample for the purposes of conducting the tests requested with this form.**
4. **Authorize MVZ Martinsried GmbH to communicate the results of the test to my referring clinician.**
5. **Confirm that all the information on this form is true to the best of my knowledge.**

Your test results and any unused biological material can help MVZ Martinsried GmbH improve and further develop the quality, accuracy and effectiveness of diagnosis and help us expand the scope of genetic testing. For this reason, MVZ Martinsried GmbH would like to use your anonymized, de-identified (i.e. after removing all the personal information from which you can be identified) test results and unused biological material.

☐ *For the above scope, I consent to the inclusion of my test results in MVZ Martinsried GmbH database, the coding, storing and using of biological material*

PATIENT SIGNATURE

DATE

CLINICIAN ATTESTATION

I hereby certify and undertake that:

1. **The patient has been informed that the test will only test for the disorder(s) requested with on this form and has been duly and thoroughly counseled about the test and has received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the VERACITY test.**
2. **I have answered all the patient's queries about the VERACITY test.**
3. **This form has been completed according to the wishes and instructions of the patients.**
4. **I have obtained the patient's informed consent and have attested their signature.**

CLINICIAN SIGNATURE

DATE

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Accreditation: DIN EN ISO 15189
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MVZ Martinsried GmbH
Lochhamer Str. 29
82152 Martinsried

MEDICOVER GENETICS

INFORMATION PART OF CONSENT FORM

AFFIX BARCODE LABEL

PATIENT INFORMATION / [ADD TRANSLATION IN LOCAL LANGUAGE]

First Name / [Add translation in local language]

Last Name / [Add translation in local language]

Date of Birth (DD/MM/YYYY) / [Add translation in local language]

Gender (male/female/other - specify karyotype) / [Add translation in local language]

Telephone Number (country code & number) / [Add translation in local language]

E-mail Address / [Add translation in local language]

I understand I will be tested for: / [Add translation in local language]

VERACITY TEST: VERACITY is a Non-Invasive Prenatal Test (NIPT) which can be taken by pregnant women during or after the 10th week of pregnancy to screen for certain genetic conditions in the developing fetus before birth. VERACITY tests for the presence of an extra chromosome – a genetic condition called trisomy – in chromosomes 13, 18 and 21. VERACITY also offers additional testing for changes in the number of X and Y chromosomes (sex chromosome aneuploidies), and sub-chromosomal deletions (loss of a part of a chromosome). VERACITY can also provide fetal sex information, if you opt to know.

SAMPLE COLLECTION: Your healthcare provider will take a blood sample from your arm, following standard phlebotomy practices, and send it to MVZ Martinsried GmbH laboratories for analysis. The blood draw does not pose any serious physical harm to you or the fetus. Additional sample may be needed if there is a shipping delay, breakage of the sample collection tubes, sample degradation or contamination, or if the sample has been submitted incorrectly.

TESTING PROCESS: Genetic material (DNA) from the developing fetus's placenta is present in the pregnant woman's blood. With the help of specialized equipment and software, VERACITY uses an innovative, patented technology called 'Target Capture Enrichment Technology' to isolate the fetal DNA, and calculate whether there is an increased risk of the fetus having an aneuploidy or a microdeletion. If the quantity of the fetus's DNA (cffDNA) in the blood sample is too low for accurate analysis, redraw samples will be requested. Although rare, there is always a chance that a result will not be obtained due to lack of genetic material.

INTERPRETING NIPT RESULTS: The healthcare provider ordering this test is responsible to understand the specific uses and limitations of the test, communicate this information to you and answer any questions you may have. VERACITY only tests and reports on the tests selected on the information form. The VERACITY test does not test for other conditions such as triploidy (3 copies of all chromosomes), mosaicism (some cells having the normal number of chromosomes and others having an abnormal number), partial trisomy, or translocation (wrong rearrangement of chromosomes). The test will not identify all deletions associated with each microdeletion syndrome. A negative result is reported as VERY LOW RISK for the specific condition and indicates that the possibility of the fetus having that condition is very low. A positive result is reported as VERY HIGH RISK for the specific condition and indicates that there is an increased possibility of the fetus having the specified condition. A VERY HIGH RISK result in twin pregnancies indicates very high risk of at least one fetus having the specified condition. The result of this test does not eliminate the possibility that other genetic conditions might be present, nor does it guarantee a healthy baby. As VERACITY is a screening test, a positive result should always be confirmed with a diagnostic test such as amniocentesis. Results, possible next steps and clinical management should always be considered in the context of other clinical criteria and should be fully discussed with your healthcare provider.

ELIGIBILITY CRITERIA:

- Singleton or twin pregnancies are eligible after 10th week of gestation.
- Twin pregnancies in which loss of 1 fetus occurred (vanished twin) are eligible for testing after the 10th week of gestation and 4 weeks after the vanishing event.
- Patients with malignancies or history of malignancies, with bone marrow or organ transplant, or with recent transfusion, are not eligible for the test.
- Twin or vanished twin IVF pregnancies conceived using a donor egg are not eligible for the test.
- Twin pregnancies and vanished twin pregnancies are not eligible for testing for sex chromosome aneuploidies.

By my signature, I hereby certify that:

1. I have been informed of the nature and purpose of the genetic test.
2. I have been informed of the benefits and limitations of the genetic test by _____ (name of physician).
3. I have received clear answers to my questions in relation to the genetic test.
4. I have received a copy of this form.
5. I agree to provide a sample for the above mentioned genetic test.

Completed by: ☐ **Patient**

First Name

Last Name

Date of Completion

Signature

I have explained the risks and benefits of the test as well as alternative test methods to the patient. I have answered all the questions from the patient.

Name of the ordering physician

First Name

Last Name

Signature of the Ordering Physician

Date of Signature