VERACITY®
new generation NIPT

AFFIX
BARCODE LABEL – SIF
HERE

SAMPLE INFORMATION FORM

Please complete sections below in English.

PATIENT INFORMATION

FIRST NAME	LAST NAME
DATE OF BIRTH	ID
PHONE NUMBER	EMAIL
ADDRESS	
CITY / POST CODE / COUNTRY	

REFERRAL INFORMATION

CLINIC NAME	CLINIC ID
REFERRING HEALTHCARE PROVIDER	
PHONE NUMBER	FAX
EMAIL	
ADDRESS	
CITY / POST CODE / COUNTRY	

CLINICAL AND TEST DETAILS

REQUESTED TEST
TICK ONLY ONE BOX BELOW

FOR SINGLETON PREGNANCIES

- ☐ **CORE:** TRISOMIES 13, 18, 21 ☐ PRESENCE OF Y
- ☐ **PLUS:** TRISOMIES 13, 18, 21; ANEUPLOIDIES X,Y; PRESENCE OF Y
- ☐ **ADVANCED:** TRISOMIES 13, 18, 21; ANEUPLOIDIES X,Y; MICRODELETIONS; PRESENCE OF Y

FOR TWIN/VANISHED TWIN PREGNANCIES

- ☐ **CORE:** TRISOMIES 13, 18, 21 ☐ PRESENCE OF Y
- ☐ **ADVANCED:** TRISOMIES 13, 18, 21; MICRODELETIONS; PRESENCE OF Y

TEST INDICATIONS
TICK APPROPRIATE BOX & ADD COMMENTS

- ☐ PRIOR PREGNANCY RISK
- ☐ ABNORMAL ULTRASOUND
- ☐ ADVANCED MATERNAL AGE
- ☐ SERUM SCREEN RISK

T21 RISK SCORE:	1 IN
T18 RISK SCORE:	1 IN
T13 RISK SCORE:	1 IN

- ☐ FAMILY HISTORY
- ☐ OTHER

CLINICAL INFORMATION
COMPLETE ALL SECTIONS BELOW

MATERNAL INFORMATION

GESTATIONAL AGE (WEEK + DAY)
WEIGHT (KG)
HEIGHT (CM)

TEST INFORMATION

COLLECTION DATE (DD/MM/YY) _____

REDRAW TEST ☐ YES ☐ NO

NUMBER OF FETUSES

- ☐ 1 FETUS
- ☐ 1 FETUS – VANISHED TWIN
  Collect 4 weeks after the vanishing event
- ☐ 2 FETUSES – MONOCHORIONIC TWIN
- ☐ 2 FETUSES – DICHORIONIC TWIN

IVF INFORMATION

IVF PREGNANCY	☐ YES	☐ NO
IF IVF, EGG USED	☐ SELF	☐ DONOR
SURROGATE	☐ YES	☐ NO

AGE AT EGG RETRIEVAL (In cases of IVF) _____

HEALTHCARE PROVIDER COMMENTS

FOR LABORATORY USE ONLY
F-OPR-01/01-V24-EN

ORDER NUMBER	LAB ID NUMBER	KIT LOT NUMBER
COMMENTS	DATE & TIME OF RECEIPT (DD/MM/YY HH:MM)	RECEIVED BY

MEDICOVER GENETICS
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CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS
Clinical Laboratory Improvement Amendments
LRQA CERTIFIED ISO 13485 UKAS
ISO 9001
IQNET
CONFIDENTIAL

VERACITY
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PATIENT CONSENT

By placing my signature signing below I hereby:

1. Confirm that I have read, or have had read to me, the Patient Informed Consent which is attached to this page and that I understand it.
2. Declare that I have had the opportunity to receive counseling from referring healthcare provider on the VERACITY test and to discuss with the healthcare provider 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.
3. Authorize my referring healthcare provider to collect the necessary blood sample, and to submit this form and transport the sample to Medicover Genetics laboratories for the purposes of conducting the tests requested with this form.
4. Authorize Medicover Genetics to use any part of or the entirety of the blood sample for the purposes of conducting the tests requested with this form.
5. Authorize Medicover Genetics to communicate the results of the test to my referring healthcare provider.
6. 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 Medicover Genetics improve and further develop the quality, accuracy and effectiveness of the analysis and help us expand the scope of genetic testing. For this reason, Medicover Genetics 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 Medicover Genetics' database, the coding, storing and using of biological material.

PATIENT SIGNATURE	DATE

HEALTHCARE PROVIDER ATTESTATION

I hereby certify and undertake that:

1. The patient has been informed that the test will only test for the disorder(s) requested 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 patient.
4. I have obtained the patient's informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE	DATE

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VERACITY
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PATIENT INFORMED CONSENT

VERACITY TEST: VERACITY is a Non-Invasive Prenatal Test (NIPT) which can be performed during or after the 9th 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 microdeletions (loss of a part of a chromosome). VERACITY can also provide fetal sex information, if you opt to know.

CONDITIONS TESTED BY VERACITY

	CONDITIONS	SIGNIFICANCE
Autosomal Chromosome Aneuploidies	Trisomy 13 - Patau syndrome	Life-threatening, high fetal mortality rate, reduced lifespan
	Trisomy 18 - Edwards syndrome	
	Trisomy 21 - Down syndrome	Mild to severe, with intellectual and physical disabilities, heart defects
Sex Chromosome Aneuploidies	Monosomy X - Turner syndrome, XO	Fertility problems. Mild to severe learning difficulties & behavioral problems. Moderate to distinctive appearances
	Triple X syndrome, XXX	
	Klinefelter syndrome, XXY	
	Jacobs syndrome, XYY	
	XXYY syndrome	
Microdeletions	DiGeorge syndrome, 22q11.2 deletion	Several organs affected, mild to severe learning disabilities & behavioral problems. Distinctive appearances
	1p36 deletion	
	Smith-Magenis syndrome, 17p11.2 deletion	
	Wolf-Hirschhorn syndrome, 4p deletion	
	Prader-Willi and Angelman, 15q11.2-q13	
	Cri-du-chat, 5p	

SAMPLE COLLECTION: Your healthcare provider will take a blood sample from your arm, following standard phlebotomy practices, and send it to Medicover Genetics 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 tube, 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 results are communicated within 4-7 working days from sample receipt directly to your healthcare provider. Your healthcare provider is responsible to understand the specific uses and limitations of the test, communicate this information to you and answer any questions you may have. The healthcare provider is also responsible for counselling before and after the test, discussing possible next steps and clinical management including the provision of advice regarding the need for additional prenatal genetic testing. 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:

1. Singleton or twin pregnancies are eligible on or after the 9th week of pregnancy.
2. Twin pregnancies in which loss of 1 fetus occurred (vanished twin) are eligible for testing on or after the 9th week of pregnancy and 4 weeks after the vanishing event.
3. Patients with malignancies or history of malignancies, with bone marrow or organ transplant, or with recent transfusion, are not eligible for the test.
4. Twin or vanished twin IVF pregnancies conceived using a donor egg are not eligible for the test.
5. Twin pregnancies and vanished twin pregnancies are not eligible for testing for sex chromosome aneuploidies.

Consult with your healthcare provider to determine if VERACITY is appropriate for you. Please see table below for eligibility.

	Trisomies 13, 18, 21	Aneuploidies X, Y	Microdeletions	Presence of Y
Singleton	✓	✓	✓	✓
Twin / Vanishing Twin	✓		✓	✓
IVF Pregnancy (Self Egg Used)				
Singleton	✓	✓	✓	✓
Twin / Vanishing Twin	✓		✓	✓
IVF Pregnancy (Donor Egg Used or Surrogate)				
Singleton	✓	✓	✓	✓

DISCLOSURE: Medicover Genetics is a fully accredited state of the art genetic testing laboratory. All necessary measures are taken to perform the testing reliably and under strict standards. 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 VERACITY test is highly accurate, however, there is a small possibility for false positive and false negative results due to technical and biological reasons. A rare phenomenon that can cause discordant NIPT results includes Confined Placenta Mosaicism (the DNA of the placenta is different than that of the baby). Other reasons for discordance may include other types of mosaicism, maternal 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 on full region deletions and may be unable to detect smaller deletions. This test has been validated for the detection of full-region deletions associated with Prader–Willi syndrome (PWS) and Angelman syndrome (AS). It has not been validated for other molecular mechanisms underlying PWS/AS, such as uniparental disomy (UPD) or methylation abnormalities. In addition, this test has been validated for the detection of terminal deletions larger than 4Mb within the 5p critical region associated with Cri-du-chat syndrome.

QUALITY IMPROVEMENT: Please choose the relevant option on the consent form to grant us permission to anonymously use your remaining sample to improve the quality, accuracy and effectiveness of VERACITY.

Please make sure you read and understand the information on this document before signing it, and complete all relevant information accurately as incorrect information can lead to inaccurate test results. Please discuss any questions you may have with your healthcare provider. For additional information please visit our website at ***www.medicover-genetics.com****.*

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PATIENT PRIVACY SUMMARY

This privacy notice provides a summary of how Medicover Genetics Limited collects and processes your personal data with this form. It is important that you read this privacy notice together with our full privacy policy which contains more detailed information about our data processing. A copy is available online at www.medicover-genetics.com.

1. Important information and who we are

Medicover Genetics is responsible for processing the personal data collected on this form.

We have appointed a data protection officer (DPO). If you have any questions about this privacy notice or our data protection practices, please contact the DPO.

CONTACT DETAILS

Full name of legal entity: Medicover Genetics Limited (HE 418406)

Email address: dpo.cy@medicover.com

Postal address: 31 Neas Engomis Street, 2409 Engomi, Nicosia, Cyprus

Telephone number: + (357) 22266888

2. The data we collect about you

We collect, use, store and transfer personal data about you as follows:

- Identity Data.
- Contact Data.
- Sensitive data.

3. How we use your personal data

We will only use your personal data for the purpose for which we collected it. This includes the following:

- To register you as a new customer.
- To conduct the selected test and to process and deliver your results.
- To manage your relationship with us and to provide customer support, where applicable.
- To contact you or your referring healthcare provider on your results.
- To invoice the referring healthcare provider.

4. How we share your personal data

We share your personal data with your referring healthcare provider, so we can communicate the results of your test to them.

Medicover Genetics stores personal information on its database which is hosted by cloud service providers.

5. International transfers

We do not transfer, store or process your personal data outside the European Economic Area unless you or your referring healthcare provider are located outside the EEA.

6. Your legal rights

Under certain circumstances, you have rights under data protection laws in relation to your personal data including the right to receive a copy of the personal data we hold about you, the right to erasure ('right to be forgotten'), the right to restriction of processing and the right to make a complaint at any time to the Office of the Commissioner for Personal Data Protection.

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