

\* Mandatory field

PATIENT INFORMATION			
<b>First Name *</b>	<b>Last Name *</b>	<b>Date of birth (DD/MM/YYYY) *</b>	
<b>Address</b>		<b>City</b>	<b>Zip code</b>
<b>Email</b>		<b>Phone</b>	

CLINICAL INFORMATION			
<b>Gestational age *</b> Week _____ Days _____	<b>Estimated on (DD/MM/YYYY) *</b>	<b>Date of collection (DD/MM/YYYY) *</b>	<b>Maternal data *</b> Height _____cm Weight _____kg
<b>Dating method *</b> <input type="radio"/> LMP <input type="radio"/> Date of implantation <input type="radio"/> Ultrasound (CRL) <input type="radio"/> Other (specify) _____		<b>Test indications *</b> <input type="radio"/> Spontaneous termination of pregnancy	
<b>Number of fetuses *</b> <input type="radio"/> 1	<b>IVF pregnancy *</b> <input type="radio"/> No <input type="radio"/> Yes	<b>If IVF, eggs *</b> <input type="radio"/> Self <input type="radio"/> Non-self	
<b>Additional information</b>			

PregnancyLoss
<input checked="" type="checkbox"/> <b>Autosomes and sex chromosomes</b>
<input checked="" type="checkbox"/> <b>Deletions and duplications (CNVs) &gt; 7Mb</b>

ORDERING PHYSICIAN INFORMATION		
<b>First Name *</b>	<b>Last Name *</b>	
<b>Institution &amp; Address *</b>	<b>NPI *</b>	<b>Phone</b>
	<b>Email</b>	

I certify I am authorized under local law to request this test and have explained the patient the test benefits, risks and limitations, obtaining from the patient, or parent/legal guardian if the patient is under the age of 18, her consent. The information provided is consistent with the Veritas Intercontinental Informed Consent form for this test and with the local law.

<b>Physician signature</b>	<b>Date (DD/MM/YYYY)</b>
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## INFORMED CONSENT

### Purpose:

PregnancyLoss is a non-invasive prenatal test that analyses cell-free fetal (placental) DNA in a maternal blood sample in case of spontaneous termination of pregnancy.

The test analyses numerical chromosomal abnormalities in the autosomes and sex chromosomes, as well as CNVs (Copy Number Variants) larger than 7 Mb in all autosomes, that may be related to the spontaneous termination of pregnancy.

Genetic counselling by a physician or specialized genetic counsellor is recommended before requesting the test, to explain the advantages and limitations, as well as to discuss the outcome and possible implications.

### How this test works:

PregnancyLoss analyses the cell-free maternal and fetal DNA present in the mother's peripheral blood by NGS (Next Generation Sequencing) with paired-end (bidirectional) reads. The following bioinformatic analysis allows to determine the proportion of fetal DNA, the amount of DNA from each chromosome and/or from regions larger than 7 Mb to assess the risk of fetal chromosome abnormalities.

The test is performed in the Veritas Intercontinental laboratory located in Europe and it requires a maternal blood sample. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and rarely, infection.

### Test results:

PregnancyLoss determines the risk of fetal chromosomes abnormalities. The results may be consistent with "absence" of abnormalities in the analysed chromosomes or "presence" of abnormality. The abnormalities reported may be: monosomies, trisomies, multiple aneuploidies, partial deletions or duplications greater than 7Mb. Additionally, the percentage of fetal DNA (fetal fraction) is reported.

There is a possibility of receiving an inconclusive result if, for example, the amount of fetal DNA is insufficient to complete the study within the established performance parameters.

The test result is confidential. The result will only be communicated to your physician or another healthcare provider involved in your medical care, unless the communication of this information is required by a competent judicial or administrative body, by law, and/or authorized by applicable legislation.

### Limitations of the test:

PregnancyLoss is a screening test and as such has limitations, including false positive and false negative results. This means that the chromosomal abnormalities being tested for may be present, even if you receive a result consistent with "absence" of abnormalities ("false negative"), or you may receive a result consistent with "presence" of a certain chromosomal abnormality that is not actually present ("false positive"). The test is not designed to detect mosaic aneuploidies, triploidies and translocations. A result compatible with absence of abnormalities does not eliminate the possibility of the fetus to present other genetic alterations not analysed by this test.

Due to the origin of the DNA analysed, there is a possibility that the result does not represent the chromosomal state of the fetus, but chromosomal changes in the placenta (placenta-confined mosaicism), or in the mother (maternal chromosomal abnormalities). This test is not designed to provide information about your health, however, it is possible that in some cases this may occur, for example, in the presence of sex chromosome aneuploidies, or undiagnosed benign or malignant neoplasms. The results should always be interpreted in the context of all available clinical information by a health care professional who can assess all the implications and recommend additional parental tests if necessary.

## INFORMED CONSENT FOR GENETIC TESTING:

I, \_\_\_\_\_  
[NAME, LAST NAME, ID NUMBER/PASSPORT] **have been informed, in my name, or if applicable, in the name of the person who I represent, about the characteristics, benefits, risks and limitations of performing the genetic test PregnancyLoss, and I state that:**

I request **PregnancyLoss** test voluntarily and will discuss the results and appropriate medical management with my healthcare provider. I specifically accept that my sample and personal data will be used by Veritas and its service providers to sequence the DNA, in order to perform the genetic test I requested.

I authorize Veritas to use internally my sample, the genetic information, my personal data and my personal and/or family history provided, to produce the result of the test or service I purchased from Veritas in accordance with the Veritas Privacy Policy and Terms of Service. Likewise, I authorize Veritas to provide the test results to my ordering physician and myself. If my answers to any question necessary or helpful to process my request for test or services are not complete, Veritas may recontact me for an answer.

I authorize Veritas to use my sample, the data provided and the genetic information to perform the test requested and to use the data internally to improve the service and for quality assessment. Veritas may use portions of the de-identified data, that do not permit re-identification, to publish findings in professional journals. Veritas may use anonymized or de-personalized aggregate data for research or scientific publications purposes.

I affirm that I am at least 18 years old and that I am the person requesting the test. I acknowledge that the sample provided belongs to the person for whom this test has been prescribed. I agree that Veritas can release to legal authorities, as it deems appropriate, any identity violation. Veritas reserves the right to cancel the test without refund or return of results if it is determined that I have misrepresented my age or identity when ordering the test.

I have read this document in its entirety and realize I may retain a copy for my records, I have understood the information provided. I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits, risks, and limitations of this screening test. Any question I may had has been solved, and I have been informed about the availability of having genetic counseling before and after testing to help me understand my results.

\* Mandatory field

**We specifically request your consent for the following sections.**

**Yes**  **No** **Recontact for Additional Health Information, to Obtain Feedback and Share Opportunities to Participate in Research.**

I authorize Veritas to send me regular communications with information about advances in the area of genetics.

Veritas may recontact me or my healthcare provider to offer me the opportunity to provide additional health information for the purpose of improving the outcomes of genome or exome sequencing, testing and other genetic sequencing, analysis and tests, or that might be useful to improving how Veritas serves me and others like me with new insights. Veritas may also recontact me directly or via a third-party research service to gather feedback about my experience with Veritas in its efforts to improve its service to me and others like me. Veritas may also recontact me to offer me new opportunities to participate in research.

You can withdraw your consent to processing at any time by e-mailing dpo@veritasint.com.

**Yes**  **No** **Recontact for Marketing and New Product Offers.**

Veritas may recontact me via email or SMS Text Message to provide information about new or other health products and services offered by Veritas and its affiliated companies that may be of interest to me.

You can withdraw your consent to processing at any time by e-mailing dpo@veritasint.com, or by using the opt out functions in any email or SMS text message you receive.

**BASIC DATA PROTECTION INFORMATION**

<b>CONTROLLER</b>	VERITAS INTERCONTINENTAL, S.L. - TAX Number: ES B-88132907
<b>PURPOSE</b>	GENETIC ANALYSIS FOR PATIENTS
<b>LAWFUL BASIS</b>	CONSENT OF THE DATA SUBJECT
<b>RECIPIENTS</b>	NO DATA WILL BE TRANSFERRED TO THIRD PARTIES EXCEPT WHERE IT IS NEEDED TO DELIVER THE PRODUCTS AND SERVICES YOU HAVE REQUESTED.
<b>RIGHTS</b>	ACCESS, RECTIFICATION, OPPOSITION, ERASURE, RESTRICTION AND DATA PORTABILITY
<b>ADDITIONAL INFORMATION</b>	MORE INFO OVERLEAF

I confirm that I have been provided with and have read a copy of the Veritas Intercontinental Data Protection Information.

**PATIENT'S SIGNATURE**

First Name \*

Date (DD/MM/YYYY)

Last Name \*

Signature \*

ID Number

**SIGNATURE OF LEGAL GUARDIAN (IF MINOR OR INCOMPETENT)**

Relationship to the PROBAND \*

First Name \*

Date (DD/MM/YYYY)

Last Name \*

Signature \*

ID Number

**SIGNATURE OF THE PHYSICIAN REQUESTING THE CONSENT**

First Name \*

Date (DD/MM/YYYY)

Last Name \*

Signature \*

ID Number



### DATA PROTECTION INFORMATION

*Deliver to the patient*

<b>CONTROLLER</b>	VERITAS INTERCONTINENTAL, S.L. - TAX Number: ES B-88132907
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#### WHO IS THE CONTROLLER FOR YOUR DATA?

IDENTITY: VERITAS INTERCONTINENTAL, S.L. - TAX Number: ES B-88132907  
 POSTAL ADDRESS: CALLE ORENSE 58, 2º-C-D - 28020 (MADRID) SPAIN  
 PHONE: +34 915 623 675

DATA PROTECTION OFFICER CONTACT: [DPO@VERITASINT.COM](mailto:DPO@VERITASINT.COM)

NOTE THAT YOU CAN REVIEW OUR FULL PRIVACY NOTICE ONLINE AT [WWW.VERITASINT.COM/PRIVACY-POLICY-AND-LEGAL-NOTICE](http://WWW.VERITASINT.COM/PRIVACY-POLICY-AND-LEGAL-NOTICE) OR REQUEST A COPY OF THIS NOTICE FROM THE DATA PROTECTION OFFICER CONTACT DETAILS ABOVE.

#### FOR WHAT PURPOSE DO WE PROCESS YOUR PERSONAL DATA?

- To fill and support your purchases of our products and services, including to process payments and to provide customer assistance.
- Performing health diagnostic testing, genetic sequencing, and providing our health testing and genetic testing services. This includes using personal data to receive, store and analyse your samples, to contact you, and to provide you with your results and, in some instances, relevant treatment options.
- For service improvement and product quality improvement.
- To use anonymized or de-personalized aggregate data for research or scientific publications purposes.

#### HOW LONG DO WE RETAIN YOUR DATA FOR?

Personal data will be stored for as long as the contractual relationship with the patient prevails (unless the patient exercises his/her rights of cancellation, opposition or deletion, and further retention of the data is not needed for any legal reasons, such as to comply with applicable laws or regulatory requirements). Certain personal data related to health and genetics testing will be retained for a minimum period of 5 years in accordance with applicable laws.

#### WHAT IS THE LAWFUL BASIS FOR PROCESSING YOUR DATA?

The legal basis for processing your data is your consent and the contractual relationship.

#### WHICH RECIPIENTS WILL YOUR DATA BE RELEASED TO?

Your data will not be disclosed to third parties, unless legally or contractually obliged to do so. However, we may disclose your data to our suppliers in order to provide the service you have requested (accredited laboratories, carriers, IT service providers).

#### INTERNATIONAL TRANSFERS

Your data may be transferred to our information systems, our service providers (such as laboratories), or other organizations outside of your country of residence where necessary for us to deliver our services. This may include transferring your data (and your sample, depending on the service you are using) to a location in the European Union, United Kingdom or United States. Any international transfers of samples or data are subject to appropriate privacy, security and legal protections.

#### WHAT ARE YOUR RIGHTS WHEN YOU PROVIDE US WITH YOUR DATA?

You may have certain privacy rights depending on your circumstances or residency. To exercise your rights or to submit a question, you can email us at [dpo@veritasint.com](mailto:dpo@veritasint.com).

- Access. You have the right to request a copy of your information that we process as well as further information including (i) the purposes of processing, (ii) categories of information we process, (iii) recipients or categories of recipient to whom the personal information have been or will be disclosed, (iv) where possible, the envisaged period for which the personal data will be stored, or, if not possible, the criteria used to determine that period, (v) where the personal information is not collected from you as the data subject, any available information as to the source of the information, and (vi) existence of automated decision-making, including profiling.
- Correction. If you discover that we hold inaccurate information about you, you have a right to ask us to correct that information.
- Erasure. You have the right to request that we delete your information. We may refuse this request if (a) the information is still necessary for the purposes that we collected or processed it and (b) we still have a legal basis to process it, even after you've withdrawn consent or requested deletion.
- Restriction. You have the right, in some cases, to restrict the processing of your information, such as where you have exercised your right to object and we are reviewing your objection.
- Objection. You have the right to object to us using your information based on our legitimate interests. In such cases, we will cease processing your information unless we have compelling legitimate grounds to continue processing or where it is needed for legal reasons. Where we use your data for direct marketing, you can always object by using the unsubscribe link in such communications, changing your account settings or, if you do not have an account, you can email us at [dpo@veritasint.com](mailto:dpo@veritasint.com).
- Portability. You have the right in some cases to port your information from us to a new data controller by obtaining a copy of your data from us in a common machine readable format.
- Withdraw consent. You can withdraw your consent to processing at any time by e-mailing [dpo@veritasint.com](mailto:dpo@veritasint.com). Withdrawing your consent does not affect processing that has already occurred. Where you withdraw your consent, we will no longer process your information based on your consent. We may process your information if another legal basis applies, for example, if we are legally obligated to store certain records or if your withdrawal of consent was limited to certain processing activities.
- Complain. You have the right to lodge a complaint with the relevant data protection supervisory authority. If you are considering lodging a complaint, we would appreciate the opportunity to try and resolve your issue before you submit your complaint. To learn more about how to make a complaint email us at [dpo@veritasint.com](mailto:dpo@veritasint.com).

#### PERSONAL DATA WE COLLECT

When you use our products and services we collect, receive or otherwise process personal data in several different ways. In many cases, you choose what information to provide. Some information is required in order for us to provide our products and services. We may collect and process the following types of information about you, from the following sources:

- Product, purchase and assistance personal data. We collect information when you purchase or use our products and services, including when you interact with our company or staff. This information may include name, gender, date of birth, contact information (such as billing address, delivery address) and any further information you or any interested party such as an ordering healthcare provider may provide to us in connection with your test.
- Health-related personal data. When you purchase or use our products and services, we will collect, process and potentially generate data concerning health, including by processing samples, test information or any further information we might receive from you or from any interested party involved in the ordering of your test. We will collect and process information relating to your personal health record which may include through the use of questionnaires or forms you or the interested party submit.
- Genetic and genetic-related personal data. Collection of genetic data may include physical samples provided in connection with your use of our products and services (such as a blood sample, saliva sample, or nasal swab). We may also request or generate genetic data, medical history, family history, known familial genetic conditions or mutations where necessary to provide our products and services.