Veritas a LetsGetChecked company | myGenome by Veritas

Requisition Form & Informed Consent

Barcode label *

* Mandatory field

SAMPLE INFORMATION

Have you ordered a test with Veritas previously? *

◯ No ◯ Yes, specify: _____

Sample type *	**Date of collection** (DD/MM/YYYY) *	**Redraw** *
◯ Saliva ◯ Blood ◯ Extracted DNA ____ µg/mL*		◯ No ◯ Yes

PATIENT INFORMATION

First Name (Given Name) *	**Last Name** (Family Name) *	**Date of birth** (DD/MM/YYYY) *
Address		**Biological sex** * ◯ Male ◯ Female
Email		**Phone**

Ethnicity *

◯ White/Caucasian ◯ Hispanic ◯ Ashkenazi Jewish ◯ Black/African American ◯ Asian ◯ Middle Eastern ◯ Other (specify): _____

Previous genetic testing/Results

Bone marrow/peripheral stem cell recipient/recent blood transfusion *	**Additional clinical information**
◯ No ◯ Yes, specify: _____	

ORDERING PHYSICIAN INFORMATION

First Name *	**Last Name** *	
Institution & Address *	**NPI** *	**Phone**
	Email	

PHYSICIAN CONSENT ACKNOWLEDGEMENT

I certify I am a clinician and I am authorized under local law to request this test and have recently reviewed current Veritas documentation regarding this test. I have explained and obtained from the patient an Informed Consent, and that Informed Consent is consistent with the test benefits, risks and limitations and use of patient information set forth in the Veritas Intercontinental *Informed Consent* form for this test and local law.

Physician signature *	**Date** (DD/MM/YYYY)
x	

* *Veritas requires that the extracted DNA sample meets the established quality criteria. Please, consult with the lab before sending this type of sample.*

I understand that:

1. Test purpose:

I acknowledge that Veritas Intercontinental (hereinafter Veritas) will perform **myGenome** test, which utilizes whole genome sequencing (WGS) analysis and interpretation on my genetic material (termed DNA). This test will sequence or "read" my DNA, and variants (changes) in my genetic material will be identified (see Limitations in Section 2). Genetic testing seeks to make correlations between genetic variants in an individual's DNA and the presence of, or risk for, a variety of diseases and traits. These genetic variants may positively or negatively contribute to one's health, or they may have no impact at all.

I understand that Veritas myGenome is a screening test for healthy individuals. It should not be used to diagnose a known or suspected heritable disease in myself or my family. If I have concerns about a disease in myself and/or my family, I am aware that I should discuss appropriate medical and/or genetic testing options with my healthcare provider.

2. Whole genome sequencing information & limitations:

- Whole Genome Sequencing is the process of determining my complete DNA sequence. This process involves looking at both the coding and non-coding regions of my DNA, subject to the limitations described below.
- myGenome test utilizes next generation sequencing technology to sequence my DNA. The data generated from this process is analyzed. Those genetic variants meeting Veritas-specific criteria and included in the test's interpretative product region are evaluated to determine their impact to health. Details of the analysis process are available upon request. Reportable pathogenic and likely pathogenic variants may be confirmed with a second testing method.
- I understand that, due to limits of current technology, there are regions of the genome that are not accessible by sequencing and that certain kinds of variants cannot be detected by myGenome test. These variants include repeat expansions, inversions, deletions, translocations, and large structural rearrangements, which are responsible for some genetic diseases. In addition, the technology utilized may be unable to determine whether variants are located on the same or opposite chromosomes.

3. Interpretation and reporting limitations:

- Identified variants are evaluated based on published guidelines from the American College of Medical Genetics and Genomics (ACMG) (PMID: 25741868).
- I understand that interpretation for a limited subset of genes is included in the myGenome report. The list of genes can be requested by email at info@veritasint.com.
- Veritas Intercontinental is only interpreting variants that are present in public databases (e.g. ClinVar) with the exception of novel variants predicted to severely impact the protein in a limited subset of genes.
- Any diagnostic genetic laboratory may produce false positive or false negative results due to a variety of reasons, including, but not limited to, laboratory errors incurred during any phase of testing or due to unusual circumstances such as recent bone marrow transplantation or blood transfusion, genetic mosaicism, or incorrect reporting of personal or family medical history or familial relationships.
- Genetic testing is a rapidly evolving field, and there is always a chance certain variants reported as pathogenic in medical literature are not included in the public databases used by Veritas. The interpretation provided in your report is based on information available at the time of testing and may change in the future as more information becomes available. For example, there is a chance that future medical advancement may determine a variant currently thought to be pathogenic is benign, or a variant currently thought to be benign is pathogenic.
- A report will be provided to me by my ordering provider. Variants in my DNA determined by Veritas to be pathogenic or likely pathogenic (known or expected to be disease causing) will be reported, accompanied by detailed discussions of these specific findings. Benign variants, likely benign variants, and variants of uncertain significance (VUS) are typically not reported, although occasionally, exceptions may be made. For example, a VUS may be reported if there is enough evidence to warrant consideration of medical follow up.
- The finding of a pathogenic (or likely pathogenic) variant does not mean I have a 100% certainty of developing a disease associated with that variant(s). All positive findings (pathogenic or likely pathogenic variants) should be further discussed with my healthcare provider to evaluate whether confirmation or changes to medical care are indicated.
- myGenome report may also include information on Traits and Ancestry as well as Drug Sensitivities (Pharmacogenomics or PGx).
- I acknowledge that future reinterpretation of my results may be available for an additional fee.
- Veritas will only release a copy of my test report to other individuals/healthcare providers if they have my written permission (Veritas Protected Health Information form).
- My test report may become part of my medical record.

4. Benefits of testing:

- I understand myGenome results may help me and my health care providers make more informed choices about my health care. I may learn I have one or more genetic variants that predispose me to certain conditions for which prevention and/or treatment strategies are available.
- I may learn that myGenome test did not identify any pathogenic or likely pathogenic variants in genes associated with disease or health conditions, and/or that I carry variants in genes which protect against the development of certain diseases. However, this type of result does not eliminate all risk to develop these diseases.
- I may learn I am a carrier for a recessive genetic condition. In most cases this will not have an impact on my own health, but could increase my chance to have a child affected with a genetic disorder if my partner were a carrier for the same disorder. Knowing this information could be useful to me for family planning purposes. If I am identified as a carrier, further screening options for me, my spouse/partner, and other family members may be considered and should be discussed with my genetic counselor or healthcare provider. In this category there are some diseases with high prevalence caused by genetics variants that cannot be detected by NGS and therefore are not included in this test. For this reason, myGenome should not be used as a replacement for a specific carrier testing.
- myGenome test will give me insight regarding my Ancestry. People with similar backgrounds share certain patterns of genetic variations, which is not only interesting but could also provide health-related information.

- I may learn from my Pharmacogenomics report how I may respond to certain medications. Genetic variants may influence my response to drugs and can help my prescribing healthcare providers individualize drug therapy, decrease the chance for adverse drug events, and increase the effectiveness of drugs I am taking now or in the future. This test does not cover HLA genes, which carry important pharmacogenetic information.
- I may learn about selected lifestyle Traits that may be modifiable with lifestyle changes, such as exercise, diet, and nutrition.

5. Risks of testing:

- Unperceived risk: It is possible myGenome results may reveal information about myself or my relatives that I would rather not know. For example, I may learn information about predispositions to disease, including ones for which there is no available treatment or cure. I understand that I should talk to my physician or genetic counselor prior to genetic testing, so that I am fully aware of the type of information I may learn.
- Potential side effects of sample collection: There are no known significant adverse effects from self-collected saliva. When blood is collected as the source of DNA, adverse effects are rare but may include swelling, soreness, bruising, dizziness, fainting, or infection.

6. Medical care:

- I understand that the data, interpretation and overall results reported by Veritas are not a substitute for medical care. I am aware that this screening test may identify variants known or highly suspected of causing serious medical conditions, which may lead to voluntary medical follow-up. I acknowledge that the cost of any clinical confirmation and subsequent medical follow-up will be my sole responsibility. I understand that all variants considered clinically relevant in my report should be confirmed with secondary testing before changes to my healthcare are made.
- I understand that any medical or health decision should consider more than just genetic screening results. A genetic variant can cause or greatly increase the risk of developing specific conditions. However, for many diseases and conditions, genetics contributes only a part of my overall risk. Lifestyle choices and environmental exposures often contribute equal or greater risks to my health. In the same way, not having a genetic risk factor does not guarantee that I will not develop health conditions.
- I understand that my Pharmacogenomics results should be further discussed with my healthcare providers. I should never change my drug regimen except under the guidance of my authorized healthcare providers.
- Traits pertain to characteristics that are heavily influenced by multiple genetic and environmental factors. Some of these characteristics are modifiable with lifestyle changes, such as exercise, diet, and nutrition, while some are inherited predispositions. Because of the complexity of these traits, I will discuss any concerns I have about these findings with my healthcare providers.

7. Genetic counseling:

- Genetic counseling should be considered before and after this test. My results may prompt additional testing or physician consultation(s). My ordering healthcare provider will make the final interpretation about what the results of myGenome report mean for me and provide the appropriate follow up recommendations.
- Veritas Intercontinental provides genetic counseling services that may include an additional fee. For additional information, I may contact Veritas by email genetic.counseling@veritasint.com to request an appointment with one of our genetic counselors.

8. Implications for my family:

- myGenome screening results may have implications for my blood relatives (parents, siblings, children, etc.). I understand I should speak with my genetic counselor, physician, or other licensed healthcare professional about whether I should share my screening results with others.

9. Sample requirement:

- This test requires saliva, whole blood, or extracted DNA from whole blood. If extracted DNA from whole blood is used, Veritas requires that the extracted DNA sample meets the established quality criteria. Please, consult with the lab before sending this type of sample.
- In some cases, an additional sample may be requested if the volume, quality, and/or condition of the initial specimen is not adequate.

10. Raw data:

- An adjunct variant call format (VCF) file will be made available upon request for an additional fee. The VCF file reports all called variants, with no filtering for quality or read depth, such that a fraction of variants in this file are false positive calls. In addition, there is no warranty that the VCF file will work with third party tools. Veritas does not provide the raw genetic sequencing data (BAM File).

11. Informed Consent for genetic testing:

I, ...

[NAME, LAST NAME, ID NUMBER/PASSPORT] **have been informed about the characteristics, benefits, risks and limitations of performing the genetic test myGenome, and I state that:**

I request **myGenome** 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 my DNA, in order to perform the genetic test I requested.

I authorize Veritas to use internally my sample, my 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 my genetic information to perform the test requested and to use my data internally to improve the service and for quality assessment. Veritas may use portions of my 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 authorize Veritas to consult my genetic data in order to inform me regarding changes in the classification of the variants found that could have a clinical impact and to answer possible questions I may have regarding the test. I authorize Veritas to contact me or my ordering physician to provide this information.

* Mandatory field

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.

The information obtained could be relevant for my family members. It is my personal decision to inform them, so they can request a genetic consultation to be informed about their personal risk and their health options for the future, if they wish to do so.

We specifically request your consent for the following sections.

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

By selecting YES, I authorize Veritas to review my genetic data to inform me about the availability of additional reports that I can benefit from, based on updates and advances in the available scientific information. Additional reports may include new discoveries such as genes recognized as having clinically actionable findings, new medications for which pharmacogenomic findings are available, new findings such as additional risk alleles that may be of interest or new genetic traits. I authorize Veritas to recontact me to notify me of the availability of such information. 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	
CONTROLLER	VERITAS INTERCONTINENTAL, S.L. - TAX Number: ES B-88132907
PURPOSE	GENETIC ANALYSIS FOR PATIENTS
LAWFUL BASIS	CONSENT OF THE DATA SUBJECT
RECIPIENTS	NO DATA WILL BE TRANSFERRED TO THIRD PARTIES EXCEPT WHERE IT IS NEEDED TO DELIVER THE PRODUCTS AND SERVICES YOU HAVE REQUESTED.
RIGHTS	ACCESS, RECTIFICATION, OPPOSITION, ERASURE, RESTRICTION AND DATA PORTABILITY
ADDITIONAL INFORMATION	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 *

Last Name *

ID Number

Date (DD/MM/YYYY)

Signature *

SIGNATURE OF THE PHYSICIAN REQUESTING THE CONSENT

First Name *

Last Name *

ID Number

Date (DD/MM/YYYY)

Signature *

DATA PROTECTION INFORMATION	*Deliver to the patient*
CONTROLLER	VERITAS INTERCONTINENTAL, S.L. - TAX Number: ES B-88132907
PURPOSE	GENETIC ANALYSIS FOR PATIENTS
LAWFUL BASIS	CONSENT OF THE DATA SUBJECT
RECIPIENTS	NO DATA WILL BE TRANSFERRED TO THIRD PARTIES EXCEPT WHERE IT IS NEEDED TO DELIVER THE PRODUCTS AND SERVICES YOU HAVE REQUESTED.
RIGHTS	ACCESS, RECTIFICATION, OPPOSITION, ERASURE, RESTRICTION AND DATA PORTABILITY

WHO IS THE CONTROLLER FOR YOUR DATA?

IDENTITY: VERITAS INTERCONTINENTAL, S.L. - TAX Number: ES B-88132907

POSTAL ADDRESS: CALLE ORENSE 58, 2ºC-D - 28020 (MADRID) SPAIN

PHONE: +34 915 623 675

DATA PROTECTION OFFICER CONTACT: DPO@VERITASINT.COM

NOTE THAT YOU CAN REVIEW OUR FULL PRIVACY NOTICE ONLINE AT 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.

- 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.
- 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. 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.

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.