Veritas INTERCONTINENTAL *The Genome Company*

my CancerRisk

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): _____

Personal medical history relevant to the test * ◯ No ◯ Yes	**Disease(s) and age(s) of onset (if applicable)** *	**Previous genetic testing/Results**
Bone marrow/peripheral stem cell recipient * ◯ No ◯ Yes	**Additional clinical information**	

ORDERING PHYSICIAN INFORMATION

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

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, or parent/legal guardian if the patient is under the age of 18, 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 extracted DNA sample meets the established quality criteria. Please, consult with the lab before sending this type of sample.*

In accordance with what is established in the European General Data Protection Regulation [G.D.P.R. (UE) 2016/679], we inform that in this case Veritas Intercontinental acts as Data Processor, being the Clinic or the ordering Physician the patient's Data Controller.

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Mandatory section

PERSONAL (PATIENT) CANCER HISTORY

Please indicate all relevant personal cancer history

- ☐ Breast cancer
- ☐ Colorectal cancer
- ☐ Kidney cancer
- ☐ Liver cancer
- ☐ Neuro/endocrine cancer
- ☐ Ovarian cancer
- ☐ Pancreatic cancer
- ☐ Skin cancer
- ☐ Stomach cancer
- ☐ Bladder & urinary tract cancer
- ☐ Uterus cancer
- ☐ Testicular cancer
- ☐ Prostate cancer
- ☐ Eye cancer
- ☐ Blood cancer
- ☐ Sarcoma
- ☐ Thyroid cancer
- ☐ Familial non-Hodgkin's lymphoma
- ☐ Head and neck cancer
- ☐ Fallopian tube cancer
- ☐ Primary peritoneal cancer
- ☐ Small intestinal cancer
- ☐ Brain/Central Nervous System cancer
- ☐ Parathyroid cancer
- ☐ Gallbladder cancer
- ☐ Bile duct cancer
- ☐ Gastrointestinal stromal tumor (GIST)
- ☐ Neuroblastoma
- ☐ Other: _____

Genetic Testing
Test Name: _____
Test Date: _____
Result: _____
Notes: _____

Genetic Testing
Test Name: _____
Test Date: _____
Result: _____
Notes: _____

FAMILY CANCER HEALTH HISTORY

Relationship	Maternal	Paternal	Health Condition & diagnosis	Age at diagnosis
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

I understand that:

1. Test purpose:

I acknowledge that Veritas Intercontinental (hereinafter Veritas) will perform the **myCancerRisk** test, which utilizes whole exome sequencing (WES) analysis on my genetic material (termed DNA). This test will sequence or "read" certain regions of my DNA, and variants (changes) in my genetic material may 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. These genetic variants may impact my health. 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.

myCancerRisk is a multi-gene panel test that can help identify individuals at an increased risk to develop certain cancer types. The test can also help identify an underlying genetic cause of cancer for individuals who have a current or past diagnosis. Cancer occurs as a result of variants in the genes responsible for regulating the growth of cells. If an individual has harmful variant(s), these cells may grow uncontrolled, forming a tumor and thus cancer.

The genes included in this test have been reported in association with various cancers, although the cancer type and estimated lifetime risk differs from gene to gene. For some of the genes on the panel, an exact cancer risk may not currently be known. Furthermore, an elevated risk for non-oncological related conditions may be learned, depending on the gene variant(s) identified. Additionally, if a variant is detected in more than one gene, it may be difficult to assess the overall cancer risk. Medical management recommendations will depend on the gene in which the variant(s) was/were identified. Medical guidelines have not been established for all of the genes on this test, therefore, the results may or may not have an established medical management.

I request and permit Veritas Intercontinental to analyze the 40 genes included for the requested test.

2. Whole exome sequencing information & limitations:

- Whole Exome Sequencing (WES) is the process of determining the sequence of the protein coding regions (called exons) in my DNA, subject to the limitations described below.
- Next-generation sequencing (NGS) technology is utilized to sequence my DNA. The data generated from this process is then analyzed for DNA variants. Those genetic variants meeting Veritas-specific criteria and included in the test's interpretative product region are evaluated to determine their impact to health. 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 exome that are not accessible by sequencing and that certain kinds of variants cannot be detected by **myCancerRisk** test. These variants include repeat expansions, inversions, certain 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:

- This test will only report on variants in the 40 genes included on **myCancerRisk** panel as requested on the test requisition form by my ordering provider.
- Variants in genes that are not included on the gene list (called secondary or incidental findings) will not be reported.
- There may be other genes (both known and unknown) related to my indication for testing, not included on this test.
- Identified variants are evaluated based on published guidelines from the American College of Medical Genetics and Genomics (ACMG) (PMID: 25741868).
- Veritas Intercontinental is interpreting both variants that are present in public databases (e.g. ClinVar) and any novel variant detected in the genes of the panel.
- Benign and likely benign variants will not be reported.
- A report will be provided to my ordering physician. Variants classified as likely disease causing or disease causing (likely pathogenic or pathogenic) will be included. Additionally, variants of uncertain significance (VUS or VOUS) will also be reported.
- 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. Because medical information continues to advance, it is important to know that not all disease-associated genes have been identified and the clinical significance of variants in many genes is not well understood at this time. 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.
- Veritas Intercontinental reassesses the current medical literature on a regular basis and will attempt to notify individuals and their ordering physician of any result updates when they are identified. Clinical reclassification of genetic variants is typically a gradual process, though, and occurs as expert consensus is reached, rather than resulting from a single clinical report or publication. Furthermore, despite community efforts supported by Veritas Intercontinental and other groups, no automated alerting system for variant reclassification has yet been universally adopted by clinical genetics laboratories. Due to these and other factors, Veritas Intercontinental cannot guarantee when such reclassification will be reported back to individuals. However, through continuous manual and automated variant (especially VUS) reassessment, Veritas Intercontinental is deeply committed to notifying patients and their physicians in a timely manner for rare instances when a variant's pathogenicity is reclassified. Such re-contact, of course, will also be dependent on available patient and physician contact information provided to Veritas Intercontinental at the time of initial test ordering.
- 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. Possible outcomes:

- **Positive result:** A positive result indicates that a pathogenic or likely pathogenic variant(s) has been identified. This type of result may explain my clinical signs and symptoms and/or family history of disease and provide a genetic diagnosis and/or establish a disease risk. It does not indicate a 100% certainty of developing the disease associated with the identified variant(s). The test result may be able to predict my prognosis, the severity or onset of the identified condition, as well as impact medical management decisions including surveillance and treatment options. All positive findings should be further discussed with my healthcare provider to evaluate whether they can explain my signs and symptoms and/or family history and if changes to my medical care are indicated.
- **Inconclusive Result (Variant of Uncertain Significance): The** finding of a variant(s) of uncertain clinical significance (VUS or VOUS) does not confirm a genetic diagnosis or disease risk. A VUS is a DNA variant whose significance is uncertain, usually because of limited or conflicting published evidence in the medical literature. In the absence of further information, the interpretation of the variant is inconclusive. All inconclusive findings should always be further discussed with my healthcare provider. I acknowledge that the clinical significance of this data is unclear and is subject to further investigation in the course of my medical care. I understand that a VUS may be reclassified to a benign or pathogenic variant in the future.
- **Negative result:** A negative test result indicates that no pathogenic variant, likely pathogenic variant or VUS has been identified. In this case, the test was unable to identify a genetic cause of my clinical signs and symptoms and/or family history of disease. Medical management decisions should be based on my current symptoms and/or family history and further discussed with my healthcare providers. A negative report does not rule out the possibility of developing cancer nor the possibility of a genetic predisposition or diagnosis and additional genetic testing may be indicated now or in the future.

5. Clinical information:

- Veritas may need to have medical information about me and my family in order to accurately interpret my genetic data. Veritas will use all available health information provided by my ordering healthcare provider(s), including medical records and family history, in order to interpret my results.
- Veritas may need to contact my ordering healthcare provider(s) for additional health information if it was not provided on the test requisition form at the time of test order.

6. Benefits of testing:

- I understand my test 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. Thus knowing this information may help me and my family receive necessary medical care.
- 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/ healthcare provider.

7. Risks of testing:

Unperceived risks:

- Medical information about myself and my family may be needed to accurately interpret my genetic data. However, if the clinical information provided to Veritas by my ordering provider is inaccurate, I understand it may lead to misinterpretation or misdiagnosis.
- It is possible my test 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 types of information I may learn.
- My test results may impact health or future reproductive decisions for myself and my family members.
- I may learn about differences in biological family relationships that may not be expected (e.g. non-paternity - the father of the individual is not the biological father or consanguinity - marriage or reproductive partners are blood relatives).
- The test may reveal unexpected findings unrelated to my clinical reasons for testing.
- The test may suggest an uncertain or incorrect genetic cause for my signs and symptoms and/or family history due to test limitations and/or limited scientific knowledge at the time of my testing.
- 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.

8. 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 test may identify variants known or highly suspected of causing serious medical conditions, which may lead to recommended 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 be made on more than just genetic test 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.

* Mandatory field

9. 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 my 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.

10. Implications for my family:

- My test 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 results with others.

11. Sample requirements:

- This test requires saliva, whole blood, or extracted DNA from whole blood. If extracted DNA from whole blood is used, Veritas requires that 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.

12. 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 myCancerRisk, and I state that:**

- I perform the **myCancerRisk** test voluntarily and will discuss the results and appropriate medical management with my healthcare provider.
- 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 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 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.
- My ordering provider will receive a copy of my test results.
- I have read this document in its entirety and realize I may retain a copy for my records.
- 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.
- I give my consent to perform the genetic test in the terms previously explained.

In accordance with what is established in the **European General Data Protection Regulation** [G.D.P.R. (UE) 2016/679], as well as in the applicable local legislation; and as Annex and Complement to your Informed Consent in Data Protection, **we specifically request your consent for the following sections.**

◯ **Yes** ◯ **No** **Authorization for the execution of the test*** 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.

By selecting YES, I specifically accept that my sample will be used by Veritas and, without personal identification, by its collaborating laboratories located in the United Kingdom and in the European Union, to sequence my DNA in order to perform the genetic test I requested.

By selecting YES, 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.

Veritas may use my data internally for quality assessment, in order to improve the service provided. Veritas may use portions of my de-identified data, that do not permit re-identification, to publish findings in professional journals.

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.

If I select NO, Veritas will not be able to provide me with the results of any genetic test or service I have purchased from Veritas, and I will not be able to conduct business with Veritas.

* Mandatory field

◯ **Yes** ◯ **No** **Update reports:** Veritas may contact me to inform me about the availability of additional reports that I can benefit from since I have my DNA sequenced, and to send me information about advances in the area of genetics.

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 the availability of such information.

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

Note: I may withdraw this consent at any time and I may also request Veritas to delete my Data. (Contact info@veritasint.com for more information.)

◯ **Yes** ◯ **No** **Recontact to provide information:** Veritas may contact me to ask for additional health information, offer new products that may be of interest to me, or to request my feedback about my customer experience.

Veritas may recontact me directly or via a 3rd party research service to formally gather the following information:

- Additional information related with health or other information that can be useful to improve the interpretation of genome and/or exome sequencing.
- Information about new health products and services offered by Veritas that can be of my interest.
- Evaluation of my experience as a client to collaborate in the improvement of the experience with Veritas.

I may withdraw this consent at any time by contacting info@veritasint.com.

◯ **Yes** ◯ **No** **Use my data for research:** I authorize Veritas to use my Data, when de-identified, for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

By selecting YES, I permit Veritas to store and use both my sample and my genetic data to be process for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. This purpose is recognized in Article 89 of the General Data Protection Regulation (EU GDPR 2016/679).

If I select NO, Veritas will produce my test results but will not otherwise use my remaining sample to perform or assist in the performance of scientific or historical research.

I do not acquire any property rights of any kind in any research that may be developed even if I consent to share my Data.

Note: Veritas for itself commits, and shall obtain the commitment for any research collaborator, that (1) my Data will not be used without my further consent to re-identify me; and (2) my Data shall not be onward transferred without my further consent. I may withdraw this consent at any time and I may also request Veritas to delete my Data and to instruct any research collaborator to delete my Data by writing to info@veritasint.com.

PATIENT'S SIGNATURE

First Name *

Last Name *

ID Number

Date (DD/MM/YYYY)

Signature *

SIGNATURE OF LEGAL GUARDIAN (IF MINOR OR INCOMPETENT)

Relationship to the PROBAND * _____

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 *

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