Veritas a LetsGetChecked company | my Newborn

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* ◯ Cord blood		◯ No ◯ Yes

PATIENT INFORMATION (CHILD)

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): _____

Relevant clinical information *	**Disease(s) and age(s) of onset** (if applicable)
◯ No ◯ Yes, specify: _____	
Bone marrow/peripheral stem cell recipient/recent blood transfusion *	**Previous genetic testing/Results**
◯ No ◯ Yes, specify: _____	

PRENATAL/NEWBORN HEALTH HISTORY *

Were there any abnormal prenatal testing results during the pregnancy? (Check all that apply)

- □ Abnormal ultrasound
- □ Fetal AFP analysis
- □ Noninvasive prenatal testing (NIPT)
- □ Fetal chromosome analysis
- □ Fetal chromosomal microarray
- □ Maternal serum screening (1st trimester screening, AFP, quadruple screen, etc.)
- □ None
- □ Not sure

Has the child had routine state newborn screening?

- □ Yes, what were the results? _____
- □ No
- □ Unsure

FAMILY HEALTH HISTORY *

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

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, 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 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 the **myNewborn** test, which utilizes whole exome sequencing (WES) analysis on the child's genetic material (termed DNA). This test will sequence or "read" certain regions of the DNA, and variants (changes) in the newborn's 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 have an impact on the child's health. If I have concerns about a disease in myself, the child, and/or my family, I am aware that I should discuss appropriate medical and/or genetic testing options with my child's healthcare provider.

I understand that the myNewborn test is a genetic screening test designed for healthy children and it should not be used to diagnose a known or suspected heritable condition or disease in the child. **myNewborn** is a multi-gene screening panel test which screens for childhood onset diseases. Children with these conditions may benefit significantly from early diagnosis and intervention. The diseases included on this test have a high likelihood of presenting with signs and symptoms in early childhood (typically before the age of 10 years). The disease risks will differ from gene to gene. Medical management recommendations will depend on the gene in which the variant(s) was/were identified. The results may or may not have immediate implications for the child's health.

I request and permit Veritas Intercontinental to analyze the 407 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 the DNA, subject to the limitations described below.
- Next-generation sequencing (NGS) technology is utilized to sequence my child's 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 **myNewborn** 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:

- This test will only report on variants in the 407 genes included on **myNewborn** screening panel as requested on the test requisition form by the 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 childhood onset diseases, 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 only interpreting variants that are present in public databases (e.g. ClinVar) with the exception of novel variants detected in the genes of the panel that are predicted to severely impact the protein.
- Benign, likely benign and variants of uncertain significance (VUS or VOUS) will not be reported.
- Carrier status for recessive disorders will not be reported.
- A report will be provided to the ordering physician. Variants classified as likely disease causing or disease causing (likely pathogenic or pathogenic) will be included.
- A DNA sample from one or both of the biological parents may be requested to help interpret the gene sequencing results of the child (proband). If parental samples are requested, then targeted testing will be utilized; these samples will only be studied for a variant(s) previously identified in the proband. No independent interpretation of the parental results will be performed and as such, no separate reports will be issued. Biological parents agree to be recontacted by Veritas if DNA samples are needed.
- 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 the test report to other individuals/healthcare providers if they have my written permission (Veritas Protected Health Information form).
- The test report may become part of the newborn's medical record.

4. Possible outcomes:

- **Positive Result:** A positive result indicates that a pathogenic or likely pathogenic variant(s) has been identified. 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 the child 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 the healthcare provider to evaluate if changes to the child medical care are indicated.
- **Negative Result:** A negative test result indicates that no pathogenic or likely pathogenic variant has been identified. A negative report does not rule out the possibility of developing disease 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 the child and his/her family in order to accurately interpret the genetic data. Veritas will use all available health information provided by the ordering healthcare provider(s), including medical records and family history, in order to interpret the child's results.
- Veritas may need to contact the 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 the test results may help the child and the health care providers make more informed choices about the child's health care. I may learn the child has one or more genetic variants that predispose to certain conditions for which prevention and/or treatment strategies are available. Thus knowing this information may help the child and the family receive necessary medical care.

7. Risks of testing:

Unperceived risks:

- Medical information about the newborn and the family may be needed to accurately interpret the genetic data. However, if the clinical information provided to Veritas by the ordering provider is inaccurate, I understand it may lead to misinterpretation or misdiagnosis.
- It is possible the test results may reveal information about the child or his/her relatives that I would rather not know. For example, I may learn information about predispositions to disease, including ones for which limited treatment or cure is available. I understand that I should talk to the physician or genetic counselor prior to genetic testing, so that I am fully aware of the types of information I may learn.
- The test results may impact health or future reproductive decisions for the child and 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 the clinical reasons for testing.
- Potential Side Effects of Sample Collection: There are no known significant adverse effects from saliva collection. 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 of the child. I am aware that this test may identify variants known or highly suspected of causing serious medical disease, which may lead to recommended medical follow-up for the child. I acknowledge that the cost of any clinical confirmation and subsequent medical follow-up of the child will be my sole responsibility. I understand that all variants considered clinically relevant in the report should be confirmed with secondary testing before changes to the child's 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 the risk. Lifestyle choices and environmental exposures often contribute equal or greater risks to health. In the same way, not having a genetic risk factor does not guarantee that the child will not develop health conditions.

9. Genetic counseling:

- Genetic counseling should be considered before and after this test. The results may prompt additional testing or physician consultation(s). The ordering healthcare provider will make the final interpretation about what the results of the report mean for the child 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:

- The test results may have implications for the child's blood relatives (parents, siblings, etc.). I understand I should speak with the genetic counselor, physician, or other licensed healthcare professional about whether I should share the newborn screening 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 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.

12. Informed Consent for genetic testing:

I understand that if I, ...

[NAME, LAST NAME, ID NUMBER/PASSPORT]**, sign this Informed Consent, I am doing so on behalf of the child identified in the Requisition Form of which this Informed Consent is a part, and I confirm that I am such child's parent or legal guardian, with the legal authority to sign and provide this Informed Consent with respect to such child. I have been informed about the characteristics, benefits, risks and limitations of performing the genetic test myNewborn, and I state that:**

I request **myNewborn** test voluntarily and will discuss the results and appropriate medical management with my child's healthcare provider.

I specifically accept that my child's sample and personal data will be used by Veritas and its service providers to sequence my child's DNA, in order to perform the genetic test I requested.

I authorize Veritas to use internally my child's sample, my child's genetic information, my child's personal data and my child's 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 child's 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 child's sample, the data provided and my child's genetic information to perform the test requested and to use my child's data internally to improve the service and for quality assessment. Veritas may use portions of my child's 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 child's 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 child's ordering physician to provide this information

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 child's 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 child's 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 child's 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 child's 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.

* Mandatory field

Where we refer to 'your data', 'your information' or 'your rights' throughout the below Data Protection Information, this relates to both you and your child, where applicable.

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 INFORMATION (CHILD)

First Name *

Last Name *

FATHER'S SIGNATURE

First Name *

Last Name *

ID Number

Date (DD/MM/YYYY)

Signature *

MOTHER'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 *

Where we refer to 'your data', 'your information' or 'your rights' throughout the below Data Protection Information, this relates to both you and your child, where applicable.

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.