Invitae Genetic Health Screen Information & Self-Pay Consent Form

Name:
Birthday: sex:
ID:
Patient record No:

Panel	Invitae Genetic Health Screen
Specimen types	3ml whole blood- purple-top EDTA tube (***Blood can be kept at room temperature**)
Gene List (DNA: 163 genes)	ABCD1, ACTA2, ACTC1, ACTN2, ACVRL1, APC, APOB, ATM, ATP7B, AXIN2, BAG3, BAP1, BARD1, BMPR1A, BMPR2, BRCA1, BRCA2, BRIP1, BTD, CACNA1C, CACNA1S, CALM1, CALM2, CALM3, CASQ2, CAV1, CAV3, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2, COL3A1, COL5A1, COL5A2, CRYAB, CSRP3, DES, DICER1, DMD, DSC2, DSG2, DSP, EGFR, EMD, ENG, EPCAM, F2, F5, F9, F11, FBN1, FH, FHL1, FLCN, FLNC, G6PD, GAA, GCH1, GDF2, GLA, GREM1, HAMP, HCN4, HFE, HJV, HMBS, HNF1A, HNF1B, HOXB13, JUP, KCNE1, KCNH2, KCNJ2, KCNQ1, KIT, LAMP2, LDLR, LDLRAP1, LMNA, LZTR1, MAX, MEFV, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, MYBPC3, MYH11, MYH7, MYL2, MYL3, MYLK, NF1, NF2, NTHL1, OTC, PALB2, PCSK9, PDGFRA, PKP2, PLN, PMS2, POLD1, POLE, POT1, PRKAG2, PRKAR1A, PRKG1, PROC, PROS1, PTCH1, PTEN, RAD51C, RAD51D, RB1, RBM20, RET, RPE65, RYR1, RYR2, SCN5A, SDHA, SDHAF2, SDHB, SDHC, SDHD, SERPINA1, SERPINC1, SGCD, SLC40A1, SMAD3, SMAD4, SMAD9, SMARCA4, SMARCB1, STK11, TCAP, TFR2, TGFB2, TGFB3, TGFBR1, TGFBR2, TMEM127, TMEM43, TNNC1, TNNI3, TNNT2, TP53, TPM1, TRDN, TSC1, TSC2, TTN, TTR, VCL, VHL, WT1

A. Purpose

Your blood sample will be sent to a testing laboratory in the United States: Labcorp Genetics, Inc. Laboratory (1400 16th Street, San Francisco, California 94103, USA). This laboratory is accredited by the College of American Pathologists (CAP), a group that checks that laboratories meet high quality standards, and your test is run to those standards. The test can reliably show whether or not you carry certain inherited gene changes (differences in your DNA that can be passed down in families). This helps you and your doctor understand whether you may be at risk, so you can take the right steps. To learn more, see https://www.invitae.com/en/

B. Information about the test

- **Test description：**
  This test is intended for use to screen individuals for hereditary conditions, allowing individuals to be more proactive about their health, which, if detected early, may have effective medical interventions and preventive measures. Conditions tested include, but are not limited to: (1) cancers (2) cardiovascular diseases (3) metabolic diseases.
- **Cost:** This is an out-of-pocket testing, not covered by national health insurance, with a fee of NT$28,000 per person.
- **What we collect:** We take a 3 ml sample of your blood (about half a teaspoon). You do not need to fast (go without food) beforehand.
- **Who this test is for：**
  1. General public, as a self-paid health check item.
  2. Individuals with habitual smoking, alcohol consumption, high stress, staying up late, being overweight, or lack of regular exercise.

3. People who prioritize their health.
4. Individuals seeking to prevent potential health problems by identifying their genetic risk factors.

C. Procedure

After you decide to have the **Invitae Genetic Health Screen**, we will arrange a time to collect your blood. Your sample is then sent to the testing laboratory, Labcorp Genetics, Inc. Laboratory, to look for inherited gene changes. When the testing is done, our hospital receives a report with your results and what they may mean for your risk.

You can then go over the results with your doctor or another health professional, together with other information such as your medical history and other tests. Based on the results, they can give you advice suited to you and help you make a health plan that fits your needs.

D. Sequencing methodology

This test uses a modern method called next-generation sequencing (NGS) to read the DNA in your blood and look for changes. The laboratory then double-checks any changes using other well-established methods, such as Sanger sequencing, aCGH, MLPA, and PacBio sequencing. It chooses the method that best suits each kind of change. Together, these methods let the laboratory reliably tell whether or not you carry an inherited gene change.

NGS has four main steps: preparing the DNA sample (library preparation), making many copies of it (library amplification), reading the DNA letters (sequencing reaction), and analyzing the data (data analysis). Together these steps produce your full DNA sequence, which is then compared with a reference database to find any gene changes.

E. Potential Risks and Benefits

- **Benefits:**

  Labcorp Genetics, Inc. Laboratory is accredited by CAP. Its **Invitae Genetic Health Screen** helps doctors and patients understand health risks and plan effective ways to help prevent disease.

- **Potential Risks:**

  1. This test is very accurate and gives the correct result more than 99% of the time (known technically as sensitivity and specificity). But in a small number of cases, the result can still be wrong. A "false negative" means the test misses a gene change that is really there. This could make you think you have no risk, so you might skip future check-ups or prevention steps, which could actually raise your risk. A "false positive" means the test shows a gene change that is not really there. This could make you think you are at risk and lead to extra tests or treatment you do not need.

     Because of limits in the testing technology and natural differences between samples, a gene change can sometimes be missed even when staff follow all the correct procedures. To guard against this, Labcorp Genetics re-checks results and has had its accuracy reviewed and published in respected scientific journals. To help avoid wrong results, the laboratory's procedures and internal quality checks are accredited by CAP at every step: collecting the sample, verifying data, extracting DNA, running the NGS test, doing extra confirmation, analyzing and interpreting the data, and releasing the report. This helps prevent testing errors.
  2. Having blood drawn from your arm may cause some pain, bruising, or dizziness, and, in rare cases, an infection. To help prevent bruising, press firmly on the spot for at least 5

minutes after the draw. If a bruise still forms, a warm compress can ease it. If you feel dizzy, sit still or lie down flat until it passes. If the spot becomes infected, go to a hospital for care right away.

3. If your sample does not meet the quality needed for testing, or if a report cannot be produced because of events beyond the hospital's control (such as a natural disaster), the hospital will arrange either a new sample or a refund, following its usual policies.
4. In rare cases, a small part of the result cannot be read accurately, because of your individual body chemistry or other unknown reasons, and the laboratory issues a "Qualified Report" (a report with limited results). Because the main testing has been done and usable results were given, a refund is not normally provided. To protect your interests, the hospital will offer one free repeat sample and test within one year to try to get a complete result. Even so, repeating the test may not solve the problem.

F. Alternative options

This test uses NGS, which produces a large amount of DNA information quickly in a single test. Another option is Sanger sequencing, an older method that came before NGS. Laboratories differ quite a lot in how they analyze specific genes. For example, they differ in how thoroughly they confirm changes, whether they read non-coding DNA, and which techniques they use to find large rearrangements in the DNA (such as aCGH, quantitative PCR, or PacBio). Overall, NGS is currently the fastest and most accurate method available.

G. Specimen Handling

- Labcorp Genetics, Inc. Laboratory uses and shares your protected health information (your private medical details) only for "treatment, payment, and healthcare operations," as allowed under the U.S. Health Insurance Portability and Accountability Act (HIPAA), a privacy law that protects your medical information.
- After the laboratory receives your sample, it keeps the sample for 30 days. Once your results are released, any leftover sample is thrown away and destroyed following the rules for biohazardous (biologically contaminated) waste. If testing takes longer than 30 days, the sample is kept until the report is ready (up to 60 days), or for as long as the laboratory's policy and regulations require. Under the rules for CLIA-certified laboratories (laboratories that meet U.S. quality standards), some samples may be kept longer than 60 days after your name and identifying details are removed, for purposes such as improving laboratory processes and quality.
- To keep your sample safe and in good condition while it is collected and shipped, our hospital follows the collection instructions from Almar Biotech Co., Ltd. The sample is packed according to the required storage and shipping rules and sent internationally to Labcorp Genetics, Inc. Laboratory.

H. Limitations

Studies show this test is more than 99% accurate at finding several kinds of DNA change: single-letter changes, small insertions or deletions shorter than 15 DNA letters (base pairs), and missing or extra copies of a gene section (an exon). It can also find insertions and deletions larger than 15 letters but smaller than a whole exon, though it may be slightly less sensitive for these. For nearly all the exons it targets, the test can tell whether an exon is present in the normal number of copies.

In rare situations, the test cannot check the copy number of a single exon. This can happen because of the nature of that DNA sequence or lower data quality in that spot. Some kinds of

change may also be missed. These include structural rearrangements, meaning pieces of DNA that are flipped, swapped, or moved (for example, inversions, gene conversion events, or translocations). They also include changes hidden in complex stretches of DNA (for example, short tandem repeats or segmental duplications).

Also, some details about a gene change cannot always be worked out fully. Examples include whether it is present in only some of your cells (mosaicism), which parent it came from (phasing), or exactly where it sits in the DNA (mapping ambiguity). Unless stated otherwise, this test does not cover changes in the promoter, non-coding exons, or other non-coding regions (parts of the DNA that do not code for proteins). In very rare cases, the DNA tested may not match the DNA you were born with. This can happen with a blood cancer, a bone-marrow transplant, a blood transfusion, chimerism (having two sets of DNA), a laboratory artifact, or contamination by the mother's cells.

For each gene, the test usually reads the important regions: the coding exons (the parts that carry instructions for making proteins), 10 to 20 DNA letters of the neighboring intron on each side, and some selected non-coding changes. On average, each DNA position in the reportable range is read about 350 times (350x depth), which supports accurate results. Unless stated otherwise (learn more at https://www.invitae.com/en/), every targeted region is read at least 50 times (>=50x depth) or checked with extra analysis. The DNA is compared with a standard reference sequence (GRCh37), and any changes are interpreted against one medically relevant version of the gene (a transcript). The test focuses on the coding sequence of these genes, 20 DNA letters of the neighboring introns, and other regions known to cause disease when the test was designed. If you have any questions about your report, please talk to a specialist doctor.

I. Informed Consent and Patient Confidentiality

Because your sample must be sent to Labcorp Genetics, Inc. Laboratory for the **Invitae Genetic Health Screen**, the hospital will share the personal information on this form with two companies: Almar Biotech Co., Ltd. (Labcorp's distributor in Taiwan) and Labcorp Genetics, Inc. Laboratory. This is done under Taiwan's Personal Data Protection Act (Taiwan's law that protects your personal data). We will respect your rights and use your information only for this purpose, only as far as needed, and in good faith.

I understand that, under the Personal Data Protection Act and other rules, my signature here is my formal agreement that the hospital may collect, process, and use my personal information.

I confirm that my doctor, or the person who runs this test, has explained the purpose and benefits of the **Invitae Genetic Health Screen** to me, and has given me the following information:

J. General Information about the Invitae Genetic Health Screen：

1. I understand that my **Invitae Genetic Health Screen** report will become part of my medical record. My doctor and Labcorp Genetics, Inc. Laboratory will also keep it, as the law requires. My results may be shared with people or organizations allowed to see my medical records. These include the doctors and nurses caring for me, staff at Labcorp Genetics, Inc. Laboratory, my current and future insurance companies, anyone authorized by law or a court order, and anyone I (or my authorized representative) specifically permit. Without my written permission, no one else may obtain or keep my **Invitae Genetic Health Screen** results.
2. Labcorp Genetics, Inc. Laboratory will retain the results for customer service consultation, discussion with the doctor who issued the medical order, and/or for the purpose of diagnosis

or treatment as outlined in this consent form, with applicable fees, as necessary.

3. The information on this form will be used only once. After your test request is complete, the form will be kept for seven years. While applying for and shipping your blood sample to Labcorp Genetics, Inc. Laboratory, Almar Biotech Co., Ltd. may handle your personal information, including: your Chinese name, English name, ID number, medical record number, gender, date of birth, and whether you have had an organ transplant. Under the Personal Data Protection Act, you may ask Almar Biotech Co., Ltd. and Labcorp Genetics, Inc. Laboratory to: (1) let you see or review your data; (2) give you a copy; (3) add to or correct it; (4) stop collecting, processing, or using it; or (5) delete it. However, they may refuse if they need the information to carry out their official duties or business.
4. I understand that, apart from what its normal business requires, Labcorp Genetics, Inc. Laboratory does not share de-identified data or samples (with your identifying details removed) with academic researchers, companies, or other genetic testing laboratories, and does not use them for research or commercial purposes.
5. Someone has asked me whether I have any questions about the **Invitae Genetic Health Screen**, or whether I want a fuller explanation of the risks and benefits. I have received enough explanation.

I understand and agree to have the self-paid genetic test listed on the first page. I authorize Koo Foundation Sun Yat-Sen Cancer Center to send my sample to Labcorp Genetics, Inc. Laboratory, which is accredited by CAP and CLIA, for testing, and I authorize the laboratory to release the report. The laboratory is responsible for the quality of the testing and the accuracy of the report, and it strictly follows personal-data and privacy protection laws. It will not use my sample or related data for any purpose other than those needed to register, record, and carry out this test, or for its own internal quality checks.

*** Please read carefully before signing. This consent form must be fully completed and signed by you or your parent/guardian or legally authorized representative. ***

Signature of Doctor：_____ Date of Signature：_____

Signature of Consent Person (Patient/Agent)：_____

Patient's English Name (Last , First)：_____ Phone：_____

Date of Signature：_____

*** If the person signing the consent form is not the Patient, please fill in the following information**：

Relationship to patient：_____ ID number or Passport Number：_____