

Patient Consent for Molecular Profiling – US

患者分子分析同意書 - 美國



Please read carefully and discuss with your physician.

請仔細閱讀並與您的醫師討論。

If you have questions, please contact Caris at CarisConsents@CarisLS.com or (888) 979-8669.

如果您有疑問，請聯絡 Caris，電子郵箱：CarisConsents@CarisLS.com 或電話：(888) 979-8669。

Email completed form to CarisConsents@CarisLS.com, or fax to 866-479-4925.

以電子郵件將填妥的表單寄送至：CarisConsents@CarisLS.com，或傳真發送至：866-479-4925。

TEST INFORMATION

檢測資訊

Test Purpose, Sample Collection, and Results

檢測目的、檢體採集和結果

Molecular profiling from Caris Life Sciences® (Caris) assesses cancer markers found in your tumor or blood to help your health care team develop a treatment plan that is specific to you. As part of your testing, your blood sample(s) and/or tumor sample(s) will be sent to Caris, where your sample, and DNA and RNA extracted from your sample, will be analyzed, producing genomic information. Caris will report your test results to the physician who ordered your test and to other health care providers requested by your treatment team. Test results may indicate that the markers being tested for are or are not present in your sample and may identify other characteristics of your cancer. Your test results are available from your physician, or from Caris upon written request as allowed by law.

Caris Life Sciences® (Caris) 的分子分析會評估存在於您腫瘤或血液中的癌症標記，以協助醫療團隊制定專屬於您的治療計畫。作為您檢測的一部分，會將您的血液檢體和/或腫瘤檢體送往 Caris，並於該處分析您的檢體，及從您檢體中萃取出氧核糖核酸 (deoxyribonucleic acid, DNA) 和核糖核酸 (ribonucleic acid, RNA)，以產生基因體資訊。Caris 會將您的檢測結果報告給為您開立檢測的醫師，以及您的治療團隊要求的其他健康照護提供者。檢測結果可能顯示所檢測的標記是否存在於您的檢體中，且可能找出您癌症的其他特性。您的檢測結果可向醫師取得，或在法律允許的情況下，經書面要求向 Caris 取得。

For blood-based profiling (Caris Assure), you and your doctor each have the opportunity to opt-out from receiving reports of heritable (from your family) genetic information. Your doctor may have opted-out of this reporting as part of your test order. If you would like to opt-out of heritable reporting of genetic information, please check the following box:

對於血液分析 (Caris Assure)，您和醫師都有機會選擇不收到遺傳（來自您的家人）基因資訊報告。醫師可能已在您的檢測單中選擇不收到此報告。如果您想選擇不收到基因資訊的遺傳報告，請勾選以下方格：

I opt-out (do not want to receive) reporting of heritable genetic testing for cancer predisposition.¹

我選擇不接收（不想接收）癌症易發體質遺傳基因檢測報告。¹

Blood Profiling Only: Unless you or your physician have opted-out of receiving reports of heritable genetic information, Caris Assure includes reporting of heritable (from your family) genetic information, which can provide information about whether your cancer is driven by an inherited DNA variant and your risk of developing other types of cancer. These results may reveal additional information about you or your family that is unexpected, and your testing results may have implications for your family members. In some cases, your physician may recommend further testing to clarify those results. You may wish to obtain genetic counseling before consenting to the test. If you provide a blood sample for your test, and you or your physician have not opted-out of receiving reports of heritable genetic information, your germline/ hereditary test results may include:

僅限血液分析：除非您或醫師選擇不收到遺傳基因資訊報告，否則 Caris Assure 包括遺傳（來自您的家人）基因資訊報告，其中可提供關於您的癌症是否由遺傳性 DNA 變異驅動、以及您罹患其他類型癌症之風險的資訊。這些結果可能會揭露有關您或您家人的非預期額外資訊，且您的檢測結果可能對您的家人有影響。在某些情況下，您的醫師可能會建議進行進一步檢測，以釐清這些結果。在同意進行檢測之前，建議您可尋求遺傳諮詢。若您提供血液檢體進行檢測，且您或醫師尚未選擇不收到遺傳基因資訊報告，則您的生殖細胞/遺傳檢測結果可能包括：

Positive: A positive result may indicate that you are a carrier of, predisposed to, or have the specific disease or condition being tested for. If you receive a positive result, you may wish to talk to your physician or a genetic counselor. You or your family members may be referred by your physician for additional or confirmatory testing.

陽性：陽性結果可能表示您是所特定檢測疾病或病症的帶原者、容易罹患該疾病或病症，或患有該疾病或病症。如果您的檢測結果為陽性，建議您可與醫師或遺傳諮詢師討論。醫師可能會將您或您的家人轉介至進行額外或確認性檢測。

¹ Certain pharmacogenomic results that are not associated with cancer predisposition may be reported even if this box is checked.

即使勾選此方格，仍可能報告與癌症易發體質無關的特定藥物基因體學結果。

Negative: A negative result indicates that no disease-causing variant was identified in the test performed. However, a negative result does not guarantee that you and your family are free from genetic disorders or other medical conditions, and additional information may become available in the future that could impact the interpretation of your test results. However, Caris is not obligated to update, revisit or later re-evaluate the results of the tests after those results have been made available to your physician.

*陰性：*陰性結果表示在執行的檢測中未發現致病變異。然而，陰性結果並不保證您和您的家人沒有遺傳疾病或其他醫療狀況，且未來可能取得也許會影響您檢測結果判讀的額外資訊。然而，Caris 並無義務在將檢測結果提供給您的醫師後，更新、重新檢閱或之後重新評估檢測結果。

Benefits, Risks, and Limitations of Genomic Testing

基因體檢測的益處、風險和限制

Benefits of the test may include: (i) more information to make healthcare decisions for yourself and your family members; and (ii) potential enrollment in research studies. Risks of the test may include: (i) anxiety about the testing; (ii) mild discomfort when providing your tissue or blood sample; (iii) discrimination based on your test results (while certain federal and state laws provide some protections against genetic discrimination, these laws do not apply in all situations. You can visit www.genome.gov/10002328 for information about the Genetic Nondiscrimination Act, a federal law that protects genetic information); and (iv) loss of confidentiality due to unauthorized access to your personal information (Caris implements reasonable safeguards to protect your personal information but cannot guarantee the confidentiality of this information). Limitations: Caris makes no guarantee or warranty that its genomic test(s) detect all genomic mutations and all carriers of a condition. Genetic variation that are not associated with the purpose of testing may not be reported with your test results.

檢測的益處可能包括：(1) 取得更多資訊，用於為您自己和您的家人做出健康照護決定；以及 (2) 可能納入研究試驗。檢測的風險可能包括：(1) 對檢測的焦慮；(2) 提供組織或血液檢體時輕微不適；(3) 基於您的檢測結果而受到歧視（雖然某些聯邦和州法律提供一些防止基因歧視的保護，但這些法律並未適用於所有情況。您可以造訪 www.genome.gov/10002328，以瞭解有關反基因歧視法的資訊，這是保護基因資訊的聯邦法律）；以及 (4) 因未經授權存取您的個人資訊而喪失機密性（Caris 採取合理保護措施來保護您的個人資訊，但無法保證此資訊的機密性）。限制：Caris 不保證或擔保其基因體檢測可偵測所有基因體突變和所有病症的帶原者。可能不會連同您的檢測結果報告與檢測目的無關的基因突變。

Confidentiality, Sample/Data Retention, Use, and Sharing

機密性、檢體／資料保留、使用和分享

You have the right to confidential treatment of your sample(s), genomic information, and other health data in accordance with applicable law. The physician who ordered your test, their staff and affiliates, and third parties as your physician requests may have access to your sample and test results. Caris personnel and others working for Caris may receive your sample, perform testing or have access to your health data and test results. Caris may store, use, and disclose your sample(s), genomic information, and other health data, both internally and to third parties, as permitted by law for regulatory compliance purposes, reimbursement purposes, quality assurance or improvement, operational activities, validation studies, research, product development, or in publications. Caris may also use your information to identify and contact your physician about clinical trials or other research opportunities. Your samples and data will be stored indefinitely. Caris will de-identify or anonymize the sample(s), genomic information, and other health data to the extent required by law. Third parties that may receive your sample(s), genomic information, and other health data may include non-profit, commercial, or governmental entities such as academic researchers, universities, hospitals, laboratories, and life science, insurance, pharmaceutical, and other companies. If these activities result in commercial products or compensation of any sort, proceeds will not be shared with you or your family, even if your sample(s), genomic information, and other health data are used. You can learn more about Caris's privacy practices, including information about how de-identified sample(s), genomic information, and other health data may be commercially used and shared in or out of the United States, by visiting www.CarisLifeSciences.com/privacy-us.

您有權根據適用法律對自己的檢體、基因體資訊和其他健康資料進行保密處理。為您開立檢測的醫師、其工作人員和附屬公司，以及按醫師要求的第三方，可能可以取得您的檢體和檢測結果。Caris 人員和為 Caris 工作的其他人員可能會收到您的檢體、進行檢測，或取得您的健康資料和檢測結果。在法律允許下，Caris 可能會基於法規遵從目的、補償目的、品質保證或改善、營運活動、驗證試驗、研究、產品開發或出版物中，而儲存、使用和揭露您的檢體、基因體資訊和其他健康資料，包括在內部和由第三方進行。Caris 也可能使用您的資訊，以找出臨床試驗或其他研究機會，並就它們與您的醫師聯絡。您的檢體和資料將無限期儲存。Caris 將在法律要求的範圍內，將檢體、基因體資訊和其他健康資料去識別化或匿名化。可收到您檢體、基因體資訊和其他健康資料的第三方可能包括非營利、商業或政府實體，例如學術研究人員、大學、醫院、實驗室，以及生命科學、保險、製藥和其他公司。如果這些活動導致商業產品或任何形式的補償，將不會與您或您的家人分享收益，即使使用了您的檢體、基因體資訊和其他健康資料。您可以造訪 www.CarisLifeSciences.com/privacy-us，以進一步瞭解 Caris 的隱私實務，包括有關去識別化檢體、基因體資訊和其他健康資料可能如何在美國或境外進行商業使用和分享的資訊。

Patient Consent for Molecular Profiling – US(Page 2)

患者分子分析同意書 - 美國 (第 2 頁)



PATIENT CONSENT 患者同意書

By signing below: 透過在下方簽名：

I acknowledge that I have read and understand the information provided in this form, discussed the reliability of positive or negative test results and the level of certainty that a positive test result for a disease or condition serves as a predictor of such disease or condition with my physician, and received an opportunity to ask questions, which have been answered to my satisfaction. I voluntarily consent to performance of the test by Caris and to the collection, use, retention, maintenance, and disclosure of my sample(s), genomic information, and other health data as described in this form, including to contact me about potential research opportunities for which I may be eligible. I understand and authorize Caris to obtain payment for testing, authorize Caris to act on my behalf regarding the determination, denial and/or any necessary appeal relating to coverage of the services provided by Caris, and I assign all health insurance benefits and reimbursement under my health insurance plan (including Medicare and Medicaid) to Caris. In the event that I do not have insurance, I understand Caris Billing will reach out to me to discuss financial assistance options, and I understand if I do not qualify, I will be invoiced for the test. I authorize Caris and third-party payors to release any of my protected health information for the purpose of resolving my claim and/or appeal. I understand that I may contact Caris at any time to revoke my consent to the retention of my sample(s), genomic information, and other health data. However, my revocation will not have any effect on the following: (i) any sample(s), genomic information, and other health data that has been de-identified and cannot be readily traced back to me; (ii) any use or sharing of sample(s), genomic information, and other health data that has already occurred, or (iii) to the extent Caris must retain the sample(s), genomic information, and other health data to comply with applicable law. I consent and authorize Caris (and its agents, contractors and others acting on its behalf) to place calls or send text messages to me, including those involving a pre-recorded or artificial voice, or placed using any kind of automatic telephone dialing system or other automated system for placing calls or sending texts, to any of the numbers I or my physician provide to Caris. If I am signing on behalf of the patient, I further certify that I have legal authority to consent on behalf of the patient.

我確認，我已閱讀並瞭解本同意書所提供的資訊，與醫師討論陽性或陰性檢測結果的可靠性，及以疾病或病症陽性檢測結果作為此類疾病或病症預測因子的確定性程度，已有機會提出問題，且已獲得滿意答覆。我自願同意由 Caris 進行檢測，以及收集、使用、保存、維護和揭露我的檢體、基因體資訊，以及本同意書所述的其他健康資料，包括就我可能符合資格的潛在研究機會聯絡我。我瞭解並授權 Caris 取得檢測費用、授權 Caris 代表我處理有關 Caris 所提供服務之判定、拒絕和/或任何必要上訴，且我把我健康保險計畫（包括 Medicare 和 Medicaid）下的所有健康保險福利和補償轉讓給 Caris。若我未投保，我瞭解 Caris Billing 將聯繫我，討論財務協助選項；且我瞭解，若我不符合資格，將收到此檢測的帳單。我授權 Caris 和第三方付款者基於解決我索賠和/或上訴之目的，釋出我的任何受保護的健康資訊。我瞭解，我可隨時聯絡 Caris，以撤回對於保存我檢體、基因體資訊，和其他健康資料的同意。然而，我撤回同意將不會對下列項目造成任何影響：(1) 任何已去識別化且無法輕易追溯至我身分的檢體、基因體資訊和其他健康資料；(2) 任何對已使用或分享之檢體、基因體資訊和其他健康資料，或 (3) 基於 Caris 遵守適用法律所需的範圍，而保留檢體、基因體資訊和其他健康資料。我同意並授權 Caris（及其代理人、承包商和其他代表其行事的人員）打電話給我或發送文字簡訊給我，包括涉及預先錄音或人工語音者，或使用任何類型的自動電話撥號系統，或使用其他可撥打電話或發送文字的自動系統，來撥打我或我的醫師提供給 Caris 的任何號碼。如果我代表患者簽署，我進一步證明，我具有代表患者同意的法律授權。

Patient Name (print): _____ Date of Birth: _____ Date: _____
患者姓名（正楷）：_____ 出生日期：_____ 日期：_____

Signature of Patient or Patient's Legal Representative: _____ Date: _____
患者或患者法定代理人簽名：_____ 日期：_____