

Patient Consent for Molecular Profiling – US

分子谱分析患者同意书 – 美国



Please read carefully and discuss with your physician.

请仔细阅读并与您的医生进行讨论。

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

如有疑问，请发送电子邮件至 CarisConsents@CarisLS.com，或拨打 (888) 979-8669 联系 Caris。

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

请将填妥的同意书通过电子邮件发送至 CarisConsents@CarisLS.com，或传真至 866-479-4925。

TEST INFORMATION

检测信息

Test Purpose, Sample Collection, and Results

检测目的、样本收集和检测结果

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) 的分子谱分析评估您的肿瘤或血液中发现的癌症标志物，以帮助您的医疗保健团队制定适合您的治疗计划。作为检测的一部分，您的血液样本和/或肿瘤样本将被送往 Caris，Caris 将对您的样本以及从您的样本中提取的 DNA 和 RNA 进行分析，生成基因组信息。Caris 会将您的检测结果报告给您安排检测的医生，以及您的治疗团队要求的其他医务人员。检测结果可能表明您的样本中存在（或不存在）所检测的标志物，并可能发现您癌症的其他特征。您的检测结果可从您的医生处获取，或根据法律要求以书面请求的形式向 Caris 索取。

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:

对于血液分子谱分析 (Caris Assure)，您和您的医生都有机会选择不接收遗传性（来自您的家人）基因信息的报告。您的医生可能在给您安排检测的订单上已选择不接收此报告。如果您不想接收遗传性基因信息的报告，请勾选以下方框：

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

我选择不接收（不想接收）遗传性癌症易感基因检测的报告。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:

仅限血液分子谱分析：除非您或您的医生选择不接收遗传性基因信息的报告，否则 Caris Assure 将包括遗传性（来自您的家人）基因信息的报告，该报告能够提供有关您的癌症是否由遗传 DNA 变异引起以及您罹患其他类型癌症的风险的信息。这些结果可能会揭示有关您或您家人的其他非预期信息，并且您的检测结果可能会对您的家人产生影响。在某些情况下，您的医生可能会建议进一步检测，以明确这些结果。在同意参加检测之前，您最好进行遗传咨询。如果您提供血液样本进行检测，并且您或您的医生未选择不接收遗传性基因信息报告，您的生殖系/遗传性检测结果可能包括：

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.

*阳性：*阳性结果可能表明您携带、易患或患有本次检测的特定疾病或不良状况。如果您的结果为阳性，您最好与您的医生或遗传咨询师作进一步沟通。您或您的家人可能会经由您的医生转诊去进行额外检测或确证性检测。

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

即使勾选此框，仍可能报告某些与癌症易感性无关的药物基因组学结果。

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.

阴性: 阴性结果表明, 在进行的检测中未发现致病变异。然而, 阴性结果并不能保证您和您的家人没有遗传性疾病或其他病况, 未来可能获得的额外信息有可能会影响对您检测结果的解释。但是, Caris 在向您的医生提供检测结果后, 没有义务更新、重新查看或在之后重新评估该检测结果。

Benefits, Risks, and Limitations of Genomic Testing 基因组检测的益处、风险和局限性

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.

这项检测的益处可能包括: (i) 可获得更多信息, 以便为自己和家人作出医疗保健决策; 以及 (ii) 可获得入组研究的潜在机会。检测风险可能包括: (i) 对检测的焦虑; (ii) 提供组织或血液样本时的轻度不适; (iii) 基于您的检测结果的歧视行为 (虽然某些联邦和州法律提供了一些针对基因歧视的保护, 但这些法律并非适用于所有情况。您可以访问 www.genome.gov/10002328, 了解有关《反基因歧视法》的信息, 这是一项保护基因信息的联邦法律); 以及 (iv) 由于未经授权访问您的个人信息而丧失保密性 (Caris 实施了合理的保护措施来保护您的个人信息, 但无法保证这些信息的保密性)。局限性: Caris 不保证或担保其基因组检测可检测出所有基因组突变和某种不良状况的所有携带者。与检测目的无关的基因变异可能不会随您的检测结果一起报告。

Confidentiality, Sample/Data Retention, Use, and Sharing

保密、样本/数据保留、使用和共享

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.

适用法律规定, 您有权对您的样本、基因组信息和其他健康数据进行保密处理。为您安排检测的医生及其工作人员和下属, 以及您的医生要求的第三方可能会获得您的样本和检测结果。Caris 工作人员和为 Caris 工作的其他人员可能会接收您的样本、进行检测或有权查阅您的健康数据和检测结果。在法律允许的情况下, Caris 可能会出于监管合规目的、报销目的、质量保证或改进、运营活动、验证试验、研究、产品开发或出版需求, 在内部储存、使用, 或向第三方披露您的样本、基因组信息和其他健康数据。Caris 还可能使用您的信息来识别和联系您的医生, 告知有关临床试验或其他研究机会的信息。您的样本和数据将无限期储存。Caris 将在法律要求的范围内, 对样本、基因组信息和其他健康数据进行去识别化或匿名化处理。可能接收您的样本、基因组信息和其他健康数据的第三方可能包括非营利、商业或政府实体, 如学术研究人员、大学、医院、实验室以及生命科学、保险、制药等公司。如果因这些活动产生了任何形式的商品或补偿, 即使是使用了您的样本、基因组信息和其他健康数据, 也不会与您或您的家人分享收益。您可以通过访问 www.CarisLifeSciences.com/privacy-us 了解更多关于 Caris 隐私政策的信息, 包括关于在美国境内外如何对去识别化样本、基因组信息和其他健康数据进行商业使用和共享的信息。

Patient Consent for Molecular Profiling – US (Page 2)

分子谱分析患者同意书 – 美国（第 2 页）



PATIENT CONSENT

患者同意书

By signing below:

在下面签名，即表明：

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.

我确认，我已阅读并理解本同意书中提供的信息，与我的医生讨论了阳性或阴性检测结果的可靠性以及某种疾病或不良状况的阳性检测结果作为该疾病或不良状况的预测因子的确定性水平，并有机会提出问题且得到了令我满意的回答。我自愿同意 Caris 进行这项检测，并如本同意书所述收集、使用、保留、维护和披露我的样本、基因组信息和其他健康数据，包括就我可能有资格参加的潜在研究机会与我联系。我了解并授权 Caris 获得检测费用，并授权 Caris 代表我处理与 Caris 提供的服务覆盖内容有关的裁定、驳回和/或任何必要的上诉，并且我将自己的医疗保险计划（包括 Medicare 和 Medicaid）下的所有医疗保险福利和报销金额转让给 Caris。如果没有保险，我明白 Caris 收费部门将与我联系，讨论财务援助选项，并且我明白如果我不符合援助资格，我将收到该检测的账单。我授权 Caris 和第三方付款人为解决我的索赔和/或上诉而发布我的任何受保护健康信息。我明白，我可以随时联系 Caris 撤销我对保留我的样本、基因组信息和其他健康数据的同意。但是，我的撤销不会对以下情形产生任何影响：(i) 任何已去识别化且无法轻易追溯到我的样本、基因组信息和其他健康数据；(ii) 任何已发生的对样本、基因组信息和其他健康数据的使用或共享，或 (iii) Caris 依据适用法律必须保留的样本、基因组信息和其他健康数据。我同意并授权 Caris（及其代理、承包商和代表其行事的其他方）通过我或我的医生提供给 Caris 的任何号码，给我打电话或发送短信，包括涉及预先录制或虚拟语音的内容，或使用任何类型的自动电话拨号系统或其他自动拨打电话或发送短信的系统拨打或发送的电话或短信。如果我代表患者签字，我进一步证明，我拥有代表患者同意的法定权限。

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: _____
患者或患者法定代表人的签名：_____ 日期：_____