

Patient Consent for Molecular Profiling – New York

分子谱分析患者同意书 - 纽约



Please read carefully and discuss with your physician.

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

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

请仔细阅读并与您的医生进行讨论。

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

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

Molecular profiling from Caris Life Sciences® (Caris) assesses cancer markers found in your tumor to help your health care team develop a treatment plan that is specific to you. As part of your testing, your 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.

检测目的、样本收集和检测结果

Caris Life Sciences® (Caris) 的分子谱分析评估您的肿瘤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，您的肿瘤样本将被送往 Caris 进行分析（您的样本以及从您的样本中提取的 DNA 和 RNA），从而生成基因组信息。Caris 会将您的检测结果报告给为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。

Benefits, Risks, and Limitations of Genomic Testing

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 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.

基因组检测的益处、风险和局限性

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。

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分子谱分析患者同意书 - 纽约 (第 2 页)



Confidentiality, Sample/Data Retention, Use, and Sharing

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 takes patient confidentiality seriously and has in place policies and procedures to restrict access to samples, health data, test results and genetic information obtained from samples. 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. These uses may include additional genetic testing on your sample(s), genetic information, and other health data, including for future research purposes. Unless you opt-out on the following page, Caris may also use your information to identify and contact your physician about clinical trials or other research opportunities (including general information about research findings and information about research tests on your sample(s), genetic information, and other health data that may benefit you or your family members), and your samples and data will be stored indefinitely for as long as they are useful for the purposes described in this form. 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.

保密、样本/数据保留、使用和共享

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。Caris 将对患者信息严格保密，并制定政策和规程以限制接触样本和查阅健康数据、检测结果以及从样本中获得的遗传信息。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。这些使用可能包括对您的样本、遗传信息及其他健康数据进行额外的基因检测（包括用于未来研究之目的）。除非您在下一页选择退出，否则，Caris 还可能使用您的信息来识别和联系您的医生，告知临床试验或其他研究机会（包括有关研究发现的一般信息，有关您样本的研究检测信息、遗传信息以及可能使您或您家人获益的其他健康数据）。只要您的样本和数据对本同意书所述目的有用，则将无限期保存。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。

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分子谱分析患者同意书 - 纽约 (第 3 页)



PATIENT CONSENT / 患者同意书

By signing below:

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 health data as described in this form, including to contact me about potential research opportunities for which I may be eligible, general information about research findings, and information about research tests on my sample that may benefit me or my family members. I understand that the potential benefits of such contact may include learning about research opportunities that I may be interested in and that may help advance science.

I understand that the potential risks of agreeing to be contacted include learning additional information about my condition or new information about other conditions I or my family members may have or be at risk of developing. I understand that, other than the testing authorized in this consent (including any future genetic testing on my sample for the purposes described in this form), no genetic tests will be performed on my sample. 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 or anonymized 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.

在下面签名, 即表明:

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, 并且如本同意书所述收集、使用、保留、维护和披露我的样本、基因组信息和健康数据, 包括就我可能有资格参加的潜在研究机会、有关研究发现的一般信息, 以及有关我的样本的研究检测信息 (这些信息可能使我或我的家人受益) 与我联系。我明白, 这种联系的潜在益处可能包括获知我可能有意向参与的以及可能有助于推动科学进步的研究机会。我明白, 同意接受联系的潜在风险包括了解有关我病情的其他信息, 或有关我或我家人可能罹患其他病症或有患病风险的新信息。我明白, 除了本同意书中授权的检测 (包括出于本同意书所述目的对我的样本进行的任何未来基因检测) 外, 不会对我的样本进行基因检测。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) 任何已去识别化或匿名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。

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分子谱分析患者同意书 - 纽约 (第 4 页)



By checking this box, I **DO NOT** authorize Caris to retain my sample(s) indefinitely for the purposes described in this form. I understand that my sample(s) will be destroyed at the end of the testing process or not more than 60 days after collection.

勾选此框, 表示我**不同意**授权 Caris 出于本同意书所述目的无限期保留我的样本。我明白, 我的样本将在检测流程结束时或采集后 60 天内销毁。

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: _____