MICHIGAN MEDICINE 病理 Pathology 种系基因检测的申请和同意 Request and Consent to Germline Genetic Testing (Chinese)	MRN: NAME: BIRTHDATE: CSN:

您的医疗保健提供者已经开具了 _____ 遗传基因检测。
（病况名称）

Your healthcare provider has ordered genetic testing for _____.
(Name of condition)

此检测将由以下机构完成：

☐ 密西根医学部遗传学实验室 （CAP#7123231 / CLIA#23D1088637）

☐ _____

This testing will be completed through:

☐ The Michigan Medical Genetics Laboratory (CAP#7123231 / CLIA#23D1088637)

☐ _____

此检测的目的是什么？
What is the purpose of this testing?

该检测的目的是评估是否存在特定染色体异常、基因变异或其他遗传疾病过程，这些可能对您的健康或家庭成员的健康带来风险。此同意书中的“您”一词可指您、您的孩子或您的胎儿。

您的医疗保健提供者认为遗传基因检测可有助于您的医疗保健计划的制定。这可包括治疗、监测或生殖管理选择的改变。本文概述了您决定进行此检测之前应考虑的详细信息。

The purpose of this testing is to evaluate for the presence of a specific chromosomal abnormality, genetic variant, or other genetic disease process that may pose risk to your health, or the health of your family members. For this consent, the term “you” may refer to you, your child, or your fetus.

Your healthcare provider has determined that genetic testing may be helpful in identifying a plan for your medical care. This may include changes in treatment, surveillance, or options for reproductive management. This document outlines the details you should consider before deciding to proceed with this testing.

此检测如何进行的？
How will this testing be performed?

检测将通过您所提供的血液、唾液或其他组织样本来进行的。测试将评估身体遗传指令代码中的变化，称为变异。

Testing will be performed on a blood, saliva, or other tissue sample that you provide. Testing will evaluate for changes, called variants, in the genetic instructional code of the body.

此检测可能出现哪些结果？
What are the possible results from this testing?

阳性 —— 检出基因或染色体变异。这可为您和您的医疗保健提供者针对您的医疗状况提供特定的诊断，或者可显示您将来患上某种特定医疗疾病的风险增加。此结果也可能提示与检测目的无关的健康风险。亦可能识别其他亲属的健康风险，包括子女、兄弟姐妹或父母。

Positive – A variant in a gene or chromosome was identified. This may provide you and your healthcare providers with a specific diagnosis for your health condition or may reveal an increased risk for you to develop a specific health condition in the future. This result could also indicate health risks unrelated to the purpose of testing. Health risks for other relatives, including children, siblings, or parents, may also be identified.

阴性——**未**检出基因或染色体变异，或者仅检出不会导致并发症或疾病风险的良性基因变异。此结果可能不能排除您的医疗状况是因遗传引起的可能性，也不能排除未来患上某种特定疾病的风险。

Negative – A variant in a gene or chromosome was NOT identified or only benign gene variants were identified that do not cause health complications or risk for disease. This result may not eliminate the chance that your health condition is due to a genetic cause and may not eliminate future risk to develop a specific disease.

不确定（意义不明确的变异） - 检出基因变异，但没有足够的信息来确认变异是阳性（致病）还是阴性（良性）。可能会建议进行更多检查以帮助澄清结果。可能需要更多的研究或时间才能澄清其意义。我们鼓励您定期联系我们的诊所以获取任何更新。

Inconclusive (Variant of Uncertain Significance) – A variant in a gene was identified but there is not enough information to determine whether the variant is positive (disease-causing) or negative (benign). More testing may be recommended to help clarify the result. More research or time may be required before the significance can be clarified. We encourage you to contact our clinic periodically for any updates.

此检测的局限性有哪些？
What are the limitations of this testing?

临床认证实验室遵循必要的程序和预防措施，以确保您的结果准确有效。然而，目前的医学知识或检测技术可能存在局限性，从而阻碍某些基因变异的识别。基因检测无法检测所有可能的健康风险。阴性/正常检测结果并不能保证您的健康。
Clinical, certified laboratories follow necessary procedures and precautions to ensure that your results are accurate and valid. However, there may be limitations in current medical knowledge or testing technology that may prevent certain gene variants from being identified. Genetic testing cannot detect all possible health risks. A negative/normal test result does not guarantee your health.

结果的准确性也可能受到样本质量差、运输过程中样本损坏、样本污染、镶嵌或实验室处理错误的限制。在某些情况下，实验室可能会要求提供第二份样本。
The accuracy of results may also be limited by poor sample quality, sample damage during shipment, sample contamination, mosaicism, or laboratory processing error. In some situations, the laboratory may request a second sample.
准确性还取决于您向医疗团队提供的有关您自己和家人的信息，包括病史和生物学关系。
Accuracy is also dependent on the information that you provide to your healthcare team about yourself and your family members including medical history and biological relationships.

此检测有哪些风险？
What are the risks of this testing?
基因检测对身体带来的风险很小。抽血的风险则包括采血部位的瘀青、疼痛和感染。其他样本类型（例如，唾液采集、口腔拭子、皮肤活检、绒毛膜绒毛取样、羊膜穿刺术等）对身体带来的风险则根据样本类型可能有所不同。您的医疗团队已经解释了任何其他对身体带来的风险。

The physical risks of genetic testing are minimal. For blood draws, they include bruising, pain, and infection at the site where the blood was taken. Physical risks for other sample type (e.g., saliva collection, buccal swab, skin biopsy, chorionic villus sampling, amniocentesis, etc.) may vary. Your healthcare team has explained any other physical risks.

基因检测的其他可能风险可能包括不良心理或情绪反应（例如，压力、焦虑、抑郁、愤怒、悲伤）、失去社会支持、对家庭关系的影响和经济风险。基因检测可能会揭示生物学关系的差异（例如，它可能确认您的父母不是您的亲生父母，或者您的父母有血缘关系）。
Additional possible risks from genetic testing may include adverse psychological or emotion reactions (e.g., stress, anxiety, depression, anger, grief), loss of social support, impacts on family relationships, and financial risk. It is possible that genetic testing reveals differences in biological relationships (e.g., it may identify that your mother and father are not your biological parents or that your parents are related by blood).

在进行基因检测之前，您有责任考虑您想要的保险承保范围。美国有一项名为《遗传基因信息非歧视法》（GINA）的联邦法律，禁止健康保险公司和雇主根据您的遗传基因信息做出决定。但是，这些保护措施不适用于人寿保险、残障保险或长期护理保险。有关该法律和现有限制的更多信息，请访问 www.ginahelp.org。

It is your responsibility to consider your desired insurance coverage prior to proceeding with genetic testing. The United States has a federal law called the Genetic Information Non-Discrimination Act (GINA) that prohibits health insurance companies and employers from making decisions based on your genetic information. These protections, however, do not apply to life insurance, disability insurance, or long-term care insurance. For more information on this law and existing limitations, please visit www.ginahelp.org.

如何通知我检测结果？
How will I be informed of the results of my testing?

此检测的结果将被发送回您的医疗保健提供者，并安全地保存在密西根医学部的电子病历中。在医疗保健提供者/团队与您联系之前，您的结果可能已经显示在您的患者门户中。

您的医疗保健提供者将与您一起查阅检测结果，然后根据结果讨论建议可选择的管理方案。

The results from this testing will be forwarded back to your healthcare provider and saved securely in your electronic medical record at Michigan Medicine. Your results may become available to you in your patient portal before you are contacted by your healthcare provider/team.

Your healthcare provider will review the results of the testing with you and will discuss any available management recommendations based on the results.

遗传咨询可以帮助您和您的家人了解、适应并围绕您的遗传基因检测结果做出决定。您的医疗保健提供者可能会建议您在遗传基因检测前、期间或之后进行遗传咨询。您还可以要求您的医生为您转诊至密西根医学部的遗传专科，与专家会面。

Genetic counseling can help you and your family members understand, adapt to, and make decisions surrounding your genetic test results. Your healthcare providers may recommend genetic counseling before, during, or after genetic testing. You can also request that your doctor place a referral for you to meet with a genetics specialist at Michigan Medicine.

会共享我的样本或检测信息（数据）吗？
Can my sample or the information (data) from my testing be shared?

该检测是作为一项临床检测开具的，根据 1996 年《健康保险流通与责任法案》（HIPAA）的规定,其结果将予以保密。其检测结果将成为您密西根医学部电子病历的一部分，您医疗团队的其他成员可能会查看。

This testing is being ordered as a clinical test and results are kept confidential in accordance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The results of your testing will become part of your electronic medical record at Michigan Medicine and may be viewed by other members of your healthcare team.

对于有关数据保护、数据共享、样本存储和保留，以及使用去掉身份识别样本进行研究的政策，商业遗传基因检测实验室可能有其自己的特定规定。您的医疗保健提供者可为您提供网络或印刷资料，以查看承担完成检测的实验室的政策。

Commercial genetic testing laboratories may have specific policies regarding data protection, data sharing, sample storage and retention, and use of deidentified samples for research. Your healthcare provider can provide you with online or printed resources available reviewing the policies for the laboratory used to complete your testing.

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如果您在下面的同意书上签名，则表示您确认同意进行种系基因检测，这项检测可对您的医疗保健提供者管理您的医疗保健有所帮助。本同意书明确允许我们对您的组织样本进行内部检测，或将其和任何所需的临床数据发送给我们分子检测实验室的外部合作伙伴，_____

If you sign the consent document, below, it confirms your agreement to pursue germline genetic testing that may be of help to your healthcare providers in managing your healthcare. This consent specifically gives us your permission to either internally test your tissue sample(s) or send them and any required clinical data to our external molecular testing laboratory partner, _____.

财务责任。 我理解，我将负责支付任何不在我医疗保险承保范围内的检测相关费用，包括未经授权或不在承保范围内的检测。

Financial Responsibility. I understand that I may be responsible for any testing-related fees not covered by my health plan, including non-authorized or non-covered testing.

在签字之前我已经阅读并理解了本表的信息。我接受以上所列出的风险，或与我的医生、遗传咨询师或其他医疗专家已讨论过的风险。

I HAVE READ AND UNDERSTOOD THE INFORMATION ON THIS FORM BEFORE I SIGNED IT. I ACCEPT THE RISKS LISTED ABOVE OR AS DISCUSSED WITH MY DOCTOR, GENETIC COUNSELOR, OR OTHER HEALTH PROFESSIONAL.

_____ **日期：** _____

患者或法定代理人签名（如患者无法签字） （月月/日日/年年年年）

Signature of Patient or Legally Authorized Representative (if patient is unable to sign) (mm/dd/yyyy)

_____

法定代理人姓名（印刷体）（如患者无法签字）

Printed Name of Legally Authorized Representative (if patient is unable to sign)

关系： ☐ 配偶 ☐ 父母 ☐ 近亲 ☐ 法定监护人 ☐ 医疗护理永久代理人 ☐ 其他（请注明）：_____

Relationship: ☐ Spouse ☐ Parent ☐ Next-of-Kin ☐ Legal Guardian ☐ DPOA for Healthcare ☐ Other (specify): _____

_____ _____ _____

获取和解释者（姓名印刷体和签名） 头衔 呼机号/提供者号码

Obtained and Explained by (Printed Name and Signature) Title Pager/Provider No.

日期： _____ **时间:** _____ **上午 / 下午**

（月月/日日/年年年年）

Date: _____ **Time:** _____ **A.M. / P.M.**

(mm/dd/yyyy)