Michigan Medicine 病理 Pathology **申请并同意在 Tempus 实验室进行遗传基因和分子检测** **Request and Consent to Genetic and Molecular Testing at Tempus Laboratories(Chinese)**	MRN: NAME: BIRTHDATE: CSN:

实验室名称，城市和州： LABORATORY NAME, CITY AND STATE: Tempus Labs, Inc. 600 West Chicago Avenue, Suite 775, Chicago, Illinois 60654	要求进行基因检测： GENETIC TESTING REQUESTED FOR: _____ _____ （疾病名称） (name of condition)

您的医疗保健提供者认为对您的肿瘤/癌症进行遗传基因检测可能有助于您未来医疗保健计划的制定。本文概述了您决定进行此测试之前应考虑的详细内容。
Your healthcare provider has determined that genetic testing on your tumor/cancer may be helpful in determining a future plan for your care. This document outlines the details you should consider before making a decision to proceed with this testing.

您可以选择同意您的医疗保健提供者将您现有或预期的肿瘤活检（样本）和相关手术病理报告（以及血液样本和/或其他临床信息，在您的医疗提供者认为适当的某些情况下）发送到名为 Tempus 实验室的外部机构。
You have the option to provide consent for your healthcare provider to send a portion of your existing or anticipated tumor biopsy (a sample) and the associated surgical pathology report (along with a blood specimen and/or additionally clinical information, as deemed appropriate by your provider in some instances) to an outside institution called Tempus Laboratories.

此测试的目的是什么？
该测试的目的是识别肿瘤遗传基因密码的独特变化，称为肿瘤的“分子特征”。肿瘤中这些独特的遗传变化可提供有价值的信息，来帮助您的肿瘤科团队为您的医疗选择最合适的治疗方法。结果还可以表明哪些正在进行的临床试验与您的特定肿瘤完全匹配，以及您是否有资格参加。
What is the purpose of this testing?
The purpose of this testing is to identify unique changes to the genetic code of your tumor, called your tumor's "molecular signature." These unique genetic changes in your tumor may provide valuable information to help your oncology team select the most appropriate treatment for your care. The results could also indicate which active clinical trials are well-matched for your specific tumor and whether you may be eligible for enrollment.

遗传基因检测的局限性有哪些？
准确性 – 准确性受到的限制包括所使用的技术，以及您向医生提供的有关您自己和家人的信息（包括病史和生物学关系）。
实验室处理——所有实验室都有严格的样本处理规定。但在极少数情况下，实验室处理样本时可能会出现问题，从而导致结果不正确。这些问题的例子包括标记错误、污染或对结果的误读。有时测试本身可能无法正常工作。有时实验室可能需要第二个样本才能完成测试。
What are the limitations of genetic testing?
Accuracy – Accuracy is limited by the techniques used and information that you provided to your doctor about yourself and your family members, including medical history and biological relationships.
Laboratory Processing – All laboratories have strict rules for handling samples. In rare cases, though, problems may occur in handling a sample at the laboratory, which may lead to incorrect results. Examples of these problems include mislabeling, contamination, or misinterpretation of findings. Sometimes, the test itself may not work properly. Sometimes, the laboratory may need a second sample in order to complete the test.

我的样本将如何处理，在哪里完成此检测？
您的样本将被去掉身份标识，并用只有密西根医学部知道的代码重新标记，以进一步保护你的隐私，然后运送至位于伊利诺伊州芝加哥的 Tempus 实验室，在那里进行您要求做的临床检测。 Tempus 是一家获得联邦许可的外部基因检测实验室合作伙伴，在严格的监管监督下为密歇根大学提供临床诊断服务。一旦完成您的组织样本测试，剩余未使用的石蜡块部分将被发回密西根医学部病理科，以进行长期存档（至少十年）。您的血液样本，如果作为该测试的一部分收集，将被 Tempus 用于

参考种系分析，剩余未使用的血样则将在两周后丢弃。对您的样本进行检测后所得到的原始分子结果数据和处理后的分子结果报告，将以电子方式传回密西根医学部。此外，您的临床数据和结果数据将由 Tempus 以去掉身份识别的形式保留，以便根据您的医疗机构的要求进行重新检测和/或后续的分析工作，以及 Tempus 内部的分析活动，包括去掉身份识别过程的验证。

What will happen to my samples and where will this testing be done?

Your samples will be de-identified and re-labeled with a code number only known to Michigan Medicine, to further protect your privacy, and shipped to Tempus Laboratories in Chicago, IL, where your requested clinical testing will be performed. Tempus is a federally licensed external genetic testing laboratory partner, which provides clinical diagnostic services to the University of Michigan, under strict regulatory oversight. Once testing on your tissue sample is completed, any unused portion of the paraffin block will be returned to Michigan Medicine for long term archival in the Department of Pathology (at least ten years). Your blood sample, if one is collected as part of this test, will be utilized for reference germline analysis by Tempus, with any unused portion discarded after two weeks. The raw molecular results data and processed molecular results report, as derived from testing of your sample(s), will be electronically transferred back to Michigan Medicine. Additionally, your clinical data and results data will be retained by Tempus in de-identified form to allow for repeated and/or subsequent analysis efforts as requested by your provider and for Tempus's internal analysis activities, including validation of the de-identification process.

谁将接触到采集的样本？

样本将始终由训练有素的诊所工作人员处理，他们将安全地将样本运送到 Tempus 实验室，在那里，经过类似培训和执业许可的实验室工作人员将按照严格和经过验证的规程进行处理和分析。

Who will have access to the sample taken?

The sample will be handled at all times by trained clinic staff, who will securely ship the specimen(s) to Tempus Laboratories, where similarly trained and licensed laboratory staff will carry out processing and analysis, per a strict and validated protocol.

此检测有哪些风险？

检测对身体带来的风险通常很小。对于抽血，它们包括抽血部位的瘀伤、疼痛和感染。如果您的检测程序中除了抽血外还包括其他项目，您的医生已经解释了所涉及的其他身体上的风险。遗传基因检测的其他风险包括侵犯隐私、影响家庭关系，以及保险或就业歧视。联邦和州法律保护隐私，并在一定程度上保护公民免受保险和就业歧视。有关这些保护的更多信息，请参阅 http://www.MiGeneticsConnection.org 的“政策和法律”。

What are the risks of testing?

The physical risks of testing are usually small. For blood draws, they include bruising, pain, and infection at the site where the blood was taken. Your doctor has explained other physical risks involved in your testing procedure if it includes activities in addition to a blood draw. Other risks of genetic testing include breach of privacy, impact on family relationships, and insurance or employment discrimination. Federal and state laws protect privacy and protect citizens from insurance and employment discrimination to some degree. More information on these protections is available under “Policy and Law” at http://www.MiGeneticsConnection.org.

如何通知我的结果？

此测试的结果将转发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，在整体病历的一部分中，仅添加了“需要知道”的访问权限。您的医疗保健提供者将与您一起查阅检测结果，然后根据结果讨论管理方案的选择。

How will I be notified of my results?

The results from this testing will be forwarded back to your healthcare provider and saved securely in your electronic medical record at Michigan Medicine, in a section of the overall medical record with added “need-to-know” access only. Your healthcare provider will review the results of the testing with you and will discuss any available treatment options based on the results.

这个检测还能告诉我什么？

该检测的主要目的是提供您的肿瘤的遗传基因构成信息，以帮助您的医生就未来的癌症治疗做出决定。您肿瘤中的基因变化是*获得性*改变，是您的肿瘤所特有的，随着时间的推移伴随着肿瘤的生长变化而逐渐发展。然而，作为这项检测的一部分，我们也有可能检测到您出生时就有的、在您家族中遗传的基因代码的变化。这些基因变化被称为*种系*变异。一些*种系*基因变

化可提供个体患不同形式癌症的总体风险的信息，并可显示个体已经遗传了的某种*遗传性癌症综合征*。您的医疗保健提供者可能会使用此额外的信息来决定未来的癌症筛查或降低癌症风险的选择。对于其他可能有遗传性癌症综合征遗传风险的家庭成员，这些*种系*的发现也可能对他们的医疗产生影响。

What else can this testing tell me?

The primary purpose of this testing is to provide information on the genetic make-up of your tumor to help your doctor make decisions on your future cancer treatment. The genetic changes in your tumor are *acquired* changes that are unique to your tumor and develop over time as your tumor grows and changes. As part of this testing, however, it is possible that we may also detect changes in the genetic code that you were born with and are inherited in your family. These gene changes are called *germline* variants. Some *germline* gene changes may provide information on an individual's overall risk for different forms of cancer and may indicate that an individual has inherited a *hereditary cancer syndrome*. This additional information may be used by your healthcare providers to make decisions on future cancer screenings or options for cancer risk reduction. These *germline* findings may also have implications for the care of other family members who may also be at risk to inherit the hereditary cancer syndrome identified.

虽然肿瘤检测可以检测到这些*种系*变异，但应该注意的是，这种检测不被认为是评估遗传性癌症综合征的临床级检测。肿瘤检测亦可能遗漏一些遗传性的*种系*基因变化。如果您或您的医疗保健提供者担心您可能遗传了某种遗传性癌症综合征，可通过密西根医学部的癌症遗传学诊所或乳腺和卵巢癌风险评估诊所与癌症遗传专家进行正式咨询（电话：734-647-8902/传真：734-763-7672）。

While these *germline* variants may be identified as part of your tumor testing, it should be noted that this testing is NOT considered a clinical-grade test for evaluation of hereditary cancer syndromes. Some inherited *germline* gene changes may be missed with tumor testing. If you or your healthcare providers are concerned that you may have inherited a hereditary cancer syndrome, formal consultation with a cancer genetic specialist is available at Michigan Medicine through the Cancer Genetics Clinic or the Breast and Ovarian Cancer Risk Evaluation Clinic (ph. 734-647-8902/ fax 734-763-7672).

如果您在下面的同意书上签名，则表示您确认同意由我们为您进行检测，所获取的检测结果可能有助于你的医疗保健提供者为您的癌症选择最佳的治疗方案。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外部合作伙伴——Tempus 实验室。该检测所产生的数据将仅用于临床，用于管理您的恶性肿瘤的特定目的。

If you sign the consent document, below, it confirms your agreement and our commitment to obtain results that may be of help to your healthcare providers in selecting the best treatment for your cancer. 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, Tempus Laboratories. The data that results from this testing will be only used clinically, for the specific purpose of the management of your malignancy.

如果您的样本被发送至 Tempus 实验室，Tempus 实验室可能会要求您的保险公司支付执行这些检测的费用。但是，如果您的保险不涵盖这种类型的肿瘤分子分析，或者您没有保险，在任何情况下都不会直接向您收取 Tempus 检测费用。

If your specimen is forwarded to Tempus Laboratories, your insurance company may be billed by Tempus for performing these tests. However, under no circumstances would you ever be directly billed for testing at Tempus if your insurance does not provide coverage for this type of molecular tumor analysis or if you do not have insurance coverage.

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、护士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 DISCUSSED WITH MY DOCTOR, NURSE, 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)