

# Patient Consent for Molecular Profiling – US

## Konsantman Pasyan pou Pwofilaj Molekilè – Etazini



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.**

Tanpri li ak anpil atansyon epi pale sou sa avèk doktè w.

Si w gen kesyon, tanpri kontakte Caris nan CarisConsents@CarisLS.com oswa (888) 979-8669.

**Voye fòm ou fin ranpli a pa imèl bay CarisConsents@CarisLS.com, oswa fakse l bay 866-479-4925.**

### TEST INFORMATION / ENFÔMASYON SOU TÈS LA

#### Test Purpose, Sample Collection, and Results

#### Objektif Tès la, Kòlèksyon Echantiyon, epi Rezilta yo

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.

Profilaj molekilè nan Caris Life Sciences® (Caris) evalye makè kansè ki prezan nan timè w la oswa nan san w pou ede ekip swen sante w la devlope yon plan tretman ki pou ou prezizeman. Nan kad tès ou a, yo pral voye echantiyon san w(yo) ak/oswa echantiyon timè w(yo) bay Caris, kote yo pral analize echantiyon w lan, ansanm ak ADN e ARN ki ekstrè nan echantiyon w lan, pou pwodui enfòmasyon jenomik. Caris ap rapòte rezilta tès ou a bay doktè ki te preskri tès ou a epi bay lòt founisè swen sante ekip tretman w lan te mande. Rezilta tès yo gendwa endike makè y ap teste yo prezan oswa yo pa prezan nan echantiyon w lan epi yo gendwa idantifye lòt karakteristik kansè w la. Rezilta tès ou yo disponib nan men doktè w, oswa nan Caris sou demann alekri jan lalwa pèmèt sa.

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:

Pou pwofilaj ki baze sou san (Caris Assure), oumenm ak doktè w, nou chak gen posiblite pou refize resevwa rapò sou enfòmasyon jenetik ereditè (ki soti nan fanmi w). Doktè w ka chwazi pou pa patisipe nan rapò sa a nan kad demann tès ou a. Si w ta renmen refize rapò enfòmasyon jenetik ereditè yo, tanpri fè yon tchèk nan ti kare ki annapre la a:

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

Mwen refize (mwen pa vle resevwa) rapò sou tès jenetik ereditè pou tandans pou gen kansè.<sup>1</sup>

**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:

**Etid pwofil san sèlman: Sòf si oumenm oswa doktè ou te refize resevwa rapò sou enfòmasyon jenetik ereditè,** Caris Assure gen nan rapò sou enfòmasyon jenetik ereditè (ki soti nan fanmi w), ki ka bay enfòmasyon sou si kansè ou a se akòz yon varyant ADN ereditè epi risk ou pou w devlope lòt tip kansè. Rezilta sa yo gendwa revele enfòmasyon anplis sanzatann sou ou oswa sou fanmi w, epi rezilta tès ou yo gendwa gen enplikasyon pou manm fanmi w. Nan kèk ka, doktè w ka rekòmande plis tès pou klarifye rezilta sa yo. Ou gendwa vle jwenn konsèy jenetik anvan ou dakò pou tès la. Si ou bay yon echantiyon san pou tès ou a, epi oumenm oswa doktè ou pa te refize resevwa rapò enfòmasyon jenetik ereditè, rezilta tès liye jèminal/ereditè w la ka gen nan li:

*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.

*Pozitif:* Yon rezilta pozitif gendwa endike ou se yon pòtè, ou predispoze pou, oswa ou gen maladi espesifik oswa twoub sante yo te fè tès pou li a. Si ou resevwa yon rezilta pozitif, ou ta dwe pale avèk doktè w oswa yon konseye jenetik. Doktè w gendwa refere w oswa refere manm fanmi w pou fè tès siplemantè oswa tès pou konfimasyon.

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*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.

*Negatif:* Yon rezilta negatif endike pa gen okenn varyant ki lakòz maladi yo te idantifye nan tès ki fèt la. Sepandan, yon rezilta negatif pa garanti ou menm ak fanmi w pa gen pwoblèm jenetik oswa lòt twoub medikal, epi plis enfòmasyon gendwa vin disponib alavni ki ta ka afekte entèpretasyon rezilta tès ou yo. Sepandan, Caris pa oblije mete ajou, revize oswa re-evalye pita rezilta tès yo apre rezilta sa yo te disponib pou doktè w.

### Benefits, Risks, and Limitations of Genomic Testing Avantaj, Risk, ak Limit Tès Jenomik la

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](http://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.

Avantaj tès la ka gen ladan: (i) plis enfòmasyon pou pran desizyon sou swen sante pou tèt ou ak pou manm fanmi w; (ii) posiblite pou enskripsyon nan etid rechèch. Risk tès la ka gen ladan: (i) enkyetid konsènan tès la; (ii) malèz lejè lè w bay echantiyon tisi w oswa san w; (iii) diskriminasyon ki baze sou rezilta tès ou yo (byenke sèten lwa federal ak lwa Eta a bay kèk pwoteksyon kont diskriminasyon jenetik, lwa sa yo pa aplike nan tout sityasyon. Ou ka ale sou [www.genome.gov/10002328](http://www.genome.gov/10002328) pou jwenn enfòmasyon sou Lwa sou Nondiskriminasyon Jenetik, yon lwa federal ki pwoteje enfòmasyon jenetik yo); epi (iv) pèt konfidansyalite akòz aksè san otorizasyon nan enfòmasyon pèsònèl ou (Caris aplike pwoteksyon rezonab pou pwoteje enfòmasyon pèsònèl ou men li pa ka garanti konfidansyalite enfòmasyon sa yo). Limit yo: Caris pa bay okenn garanti ni asirans tès jenomik li(yo) ap detekte tout mitasyon jenomik e tout moun ki pòtè yon pwoblèm sante. Varyasyon jenetik ki pa asosye ak objektif tès la pa ka rapòte avèk rezilta tès ou yo.

### Confidentiality, Sample/Data Retention, Use, and Sharing Konfidansyalite, Konsèvasyon, Itilizasyon e Pataj Echantiyon/Done

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](http://www.CarisLifeSciences.com/privacy-us).

Ou gen dwa ak yon tretman konfidansyèl echantiyon ou(yo), enfòmasyon jenomik, e lòt done sou sante dapre lalwa ki aplikab. Doktè ki te preskri tès ou a, estaf ak afilye li yo, ansanm ak tyès pati, jan doktè w mande, ka gen aksè ak echantiyon ou e rezilta tès ou yo. Caris ak lòt moun k ap travay pou Caris gendwa resevwa echantiyon ou an, fè tès oswa gen aksè ak done sou sante w ak rezilta tès ou yo. Caris gendwa estoke, itilize, epi kominike echantiyon ou(yo), enfòmasyon jenomik, e lòt done sou sante, ni anndan ni bay tyès pati, jan lalwa otorize, pou rezon konfòmite reglemantè, rezon ranbousman, asirans kalite oswa amelyorasyon, aktivite operasyonèl, etid validasyon, rechèch, devlopman pwodui, oswa nan piblikasyon. Caris kapab itilize enfòmasyon w yo tou pou idantifye epi kontakte doktè w konsènan esè klinik oswa lòt okazyon pou rechèch. Yo pral estoke ak done w yo san yon peryòd tan fiks. Caris pral de-idantifye oswa anonimize echantiyon an(yo), enfòmasyon jenomik yo, ansanm ak lòt done sou sante nan mezi lalwa egzijè. Tyès pati ki ka resevwa echantiyon w(yo), enfòmasyon jenomik, e lòt done sou sante yo ka gen ladan

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òganizasyon ki pa pou fè pwofi, antite komèsyal oswa gouvènmanal tankou chèchè inivèsite, inivèsite, lopital, laboratwa, epi konpayi syans lavi, asirans, famasetik, e lòt konpayi. Si aktivite sa yo abouti nan pwodui komèsyal oswa nenpòt jan de konpansasyon, benefis yo p ap pataje avèk ou ni fanmi w, menm si yo itilize echantiyon ou(yo), enfòmasyon jenomik ou, e lòt done sou sante w. Ou ka aprann plis sou pratik konfidansyalite Caris yo, ansanm ak enfòmasyon sou fason yo ka itilize echantiyon ki de-idantifye(yo), enfòmasyon jenomik, e lòt done sou sante yo sou plan komèsyal epi pataje yo andedan oswa deyò Etazini lè w vizite [www.CarisLifeSciences.com/privacy-us](http://www.CarisLifeSciences.com/privacy-us).

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

<sup>1</sup> Yo gendwa rapòte sèten rezilta famakojenomik ki pa asosye avèk tandans pou gen kansè menm si kaz sa a tcheke.

### PATIENT CONSENT / CONSENTEMENT DU PATIENT

#### By signing below: En signant ci-dessous :

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.

Je reconnais avoir lu et compris les renseignements fournis dans ce formulaire, avoir discuté de la fiabilité des résultats positifs ou négatifs du test et du niveau de certitude qu'un résultat positif pour une maladie ou une affection serve de prédicteur d'une telle maladie ou affection avec mon médecin, et avoir eu l'occasion de poser des questions auxquelles j'ai obtenu des réponses satisfaisantes. Je consens volontairement à la réalisation du test par Caris et à la collecte, à l'utilisation, à la conservation et à la divulgation de mon ou mes échantillon(s), de mes renseignements génomiques et d'autres données sur la santé comme décrit dans ce formulaire, y compris pour communiquer avec moi au sujet des possibilités de recherche auxquelles je pourrais être admissible. Je comprends et j'autorise Caris à obtenir un paiement pour le test, j'autorise Caris à agir en mon nom concernant la détermination, le refus et/ou tout appel nécessaire concernant la couverture des services fournis par Caris, et je cède toutes les prestations d'assurance maladie et le remboursement en vertu de mon régime d'assurance maladie (y compris Medicare et Medicaid) à Caris. Si je n'ai pas d'assurance, je comprends que le service de facturation de Caris communiquera avec moi pour discuter des options d'aide financière et je comprends que si je ne suis pas admissible, le test me sera facturé. J'autorise Caris et les tiers payeurs à divulguer tout renseignement sur la santé protégé dans le but de résoudre ma réclamation et/ou mon appel. Je comprends que je peux communiquer avec Caris en tout temps pour révoquer mon consentement à la conservation de mon ou mes échantillon(s), de mes renseignements génomiques et d'autres données sur la santé. Toutefois, ma révocation n'aura aucun effet sur les éléments suivants : (i) tous les échantillons, renseignements génomiques et toutes les autres données sur la santé qui ont déjà été anonymisés et qui ne peuvent pas être facilement retracés jusqu'à moi; (ii) toute utilisation ou divulgation d'échantillon(s), de renseignements génomiques et d'autres données sur la

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santé qui a déjà eu lieu ou (iii) dans la mesure où Caris doit conserver le ou les échantillon(s), renseignements génomiques et d'autres données sur la santé conformément à la procédure légale en vigueur. Je consens à ce que Caris (et ses agents, sous-traitants et autres personnes agissant en son nom) m'envoie des appels ou des messages textes, y compris ceux utilisant une voix préenregistrée ou artificielle, ou qu'il utilise tout type de système de composition téléphonique automatique ou autre système automatisé pour passer des appels ou envoyer des messages textes, à tout numéro que je fournis (ou mon médecin fournit) à Caris. Si je signe au nom du patient, je certifie également que j'ai l'autorité légale de consentir au nom du patient.

Patient Name (print): \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Date: \_\_\_\_\_

Non Pasyan (lèt detache): \_\_\_\_\_ Dat Nesans: \_\_\_\_\_ Dat: \_\_\_\_\_

Signature of Patient or Patient's Legal Representative: \_\_\_\_\_ Date: \_\_\_\_\_

Siyati Pasyan an oswa Repezantan Legal Pasyan an: \_\_\_\_\_ Dat: \_\_\_\_\_