

Patient Consent for Molecular Profiling – New York

Konsantman Pasyan pou Pwofilaj Molekilè – New York



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 LAN

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.

Objektif Tès la, Kòlèk Echantiyon, epi Rezilta yo

Profilaj molekilè nan Caris Life Sciences® (Caris) evalye makè kansè ki prezan nan timè w la pou ede ekip swen sante w la devlope yon plan tretman ki pou ou preziman. Nan kad tès ou a, yo pral voye 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 e 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.

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.

Avantaj, Risk, ak Limit Tès Jenomik la

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 la; (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 sitiyasyon. Ou ka ale sou 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.

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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.

Konfidansyalite, Konsèvasyon, Itilizasyon e Pataj Echantiyon/Done

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 pran konfidansyalite pasyan yo oserye epi li gen politik ak pwosedi an plas pou mete limit nan aksè nan echantiyon, done sou sante, rezilta tès ak enfòmasyon jenetik yo jwenn apati echantiyon 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. Itilizasyon sa yo ka gen ladan tès jenetik siplemantè sou echantiyon w(yo), enfòmasyon jenetik, ak lòt done sou sante, sa gen ladan pou fè rechèch alavni. Sòf si w chwazi pou w refize nan paj ki annapre a, Caris ka itilize enfòmasyon w yo tou pou idantifye e kontakte doktè w konsènan esè klinik oswa lòt okazyon pou rechèch (sa gen ladan enfòmasyon jeneral sou rezilta rechèch ak enfòmasyon sou tès rechèch sou echantiyon w(yo), enfòmasyon jenetik, e lòt done sou sante ki ka benefisye oumenm oswa manm fanmi w), epi echantiyon w ak done w yo pral konsève san yon peryòd tan fiks pandan tout tan yo itil pou rezon yo ki dekri nan fòm sa a. Caris pral de-idantifye oswa anonimise 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 òganizasyon ki pa pou fè pwofi, antite komèsyal oswa gouvènmantral tèlke 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.

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PATIENT CONSENT / KONSANTMAN PASYAN AN

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.

Lè m siyen anba a:

Mwen rekonèt ke mwen te li epi mwen konprann enfòmasyon yo bay nan fòm sa a, mwen te pale avèk doktè m sou fyabilite rezilta tès pozitif oswa negatif yo ansanm ak sou nivo sètitud ke yon rezilta tès pozitif pou yon maladi oswa yon pwoblèm medikal sèvi pou predi maladi oswa pwoblèm sa, epi mwen te gen okazyon pou poze kesyon, epi te yo reponn yo ak yon fason ki satisfè m. Mwen aksepte volontèman pou Caris fè tès la ansanm ak lòlèk, itilizasyon, konsèvasyon, mentnans, ak komunikasyon echantiyon mwen an(yo), enfòmasyon jenomik, e lòt done sou sante jan li dekri nan fòm sa a, sa gen ladan kontakte m pou opòtinite rechèch potansyèl mwen ka kalifye pou yo, pou enfòmasyon jeneral sou rezilta rechèch yo, epi pou enfòmasyon sou tès rechèch sou echantiyon m lan ki ka benefisye mwenmenm oswa manm fanmi m. Mwen konprann benefis potansyèl nan kontak sa ka gen ladan aprann opòtinite pou rechèch ki ka enterese m epi ki ka ede fè lasyans avanse. Mwen konprann risk ki ka genyen nan aksepte pou yo kontakte m gen ladan aprann enfòmasyon anplis sou eta m oswa aprann nouvo enfòmasyon sou lòt pwoblèm mwenmenm oswa manm fanmi m ka genyen oswa riske devlope. Mwen konprann, apa tès ki otorize nan konsantman sa a (ansanm ak nenpòt tès jenetik alavni sou echantiyon m pou rezon ki dekri nan fòm sa a), yo pa pral fè okenn tès jenetik sou echantiyon m lan. Mwen konprann epi mwen otorize Caris resevwa peman pou tès la, mwen otorize Caris aji nan non m konsènan detèminasyon, refi e/oswa nenpòt apèl ki nesèsè anrapò ak kouvèti sèvis Caris bay yo, epi mwen sede bay Cari tout benefis asirans sante ak ranbousman nan kad plan asirans sante m (sa gen ladan Medicare ak Medicaid)s. Sizoka m pa gen asirans sante, mwen konprann Caris Billing pral kontakte m pou pale sou opsyon pou èd finansye yo, epi m konprann si m pa kalifye, y ap voye ban m yon bòdwo pou tès la. Mwen otorize Caris ak lòt payè deyò yo kominike nenpòt nan enfòmasyon sou sante pwoteje m nan bi pou rezoud reklamasyon ak/oswa apèl mwen. Mwen konprann mwen gendwa kontakte Caris nenpòt lè pou m revoke konsantman mwen bay pou konsèvasyon echantiyon mwen an (echantiyon mwen yo), enfòmasyon jenomik, e lòt done sou sante m yo. Sepandan, anilasyon mwen an pa p gen okenn efè sou sa ki annapre la yo: (i) nenpòt echantiyon (yo), enfòmasyon jenomik, e lòt done sou sante ki te de-identifye oswa rann anonim epi yo pa ka rekonekte yo ak mwen fasilman; (ii) nenpòt itilizasyon oswa pataj echantiyon(yo), enfòmasyon jenomik, ak lòt done sou sante ki te deja fèt, oswa (iii) nan limit Caris dwe konsève echantiyon(yo), enfòmasyon jenomik, e lòt done sou sante pou l konfòme l ak lwa aplikab la. Mwen aksepte epi m otorize Caris (ak ajan li yo, kontraktè li yo e lòt moun k ap aji nan non li) pou yo fè apèl oswa voye mesaj tèks ban mwen, ansanm ak sa ki itilize yon vwa atifisyèl oswa ki anrejistre davans, oswa ki fèt apati nenpòt kalite sistèm telefòn ki konpoze nimewo otomatikman oswa lòt sistèm otomatik pou plasman apèl oswa pou voye tèks, bay nenpòt nan nimewo mwen oswa doktè m nan non m bay Caris. Si m ap siyen nan non pasyan an, mwen sètifye anplis ke m gen otorite legal pou bay konsantman nan non pasyan an.

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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.

Lè m tcheke ti kare sa a, mwen **PA** otorize Caris konsève echantiyon mwen(yo) san yon peryòd tan fiks pou rezon ki dekri nan fòm sa a. Mwen konprann echantiyon mwen(yo) pral detwi nan fen pwosesis tès la oswa pa plis pase 60 jou apre kòlèk la.

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 Reprizantan Legal Pasyan an: _____ Dat: _____