Once Upon a Time UTSW NGS Lab
Comprehensive Pan-Cancer Next Generation Sequencing

ORDER INSTRUCTIONS

1. Email/fax/mail completed advanced beneficiary notice/waiver of liability, consent (available on web site) and requisition to UTSW Next Generation Sequencing Clinical Lab.
2. Await pre-authorization determination, which UTSW will communicate to ordering physician.
3. Call UTSW to request specimen collection kit.
4. Obtain previously collected tumor tissue blocks and slides (if applicable). UTSW can facilitate retrieval.
5. When kit arrives, follow specimen collection and return shipping instructions (see page 2).
6. Reports can be emailed/faxed/mailed.

NOTE: Documents can be returned with specimen collection kit. Testing will NOT proceed without completed and signed documents.

UTSW Next Generation Sequencing Clinical Lab.
Room EB3.302
BioCenter at Southwestern Medical District
2330 Inwood Road
Dallas, Texas 75390
214-648-0924 (phone)
214-648-0952 (fax)
gene.diagnostics@UTSouthwestern.edu
http://www.utsouthwestern.edu/sites/genomics-molecular-pathology/

CLIA #: 45D0861764
CAP #: 2664213
CLIA Director: Ravi Sarode, M.D.

Once Upon a Time NGS lab Next Generation Sequencing
UTSouthwestern Medical Center

PATIENT INFORMATION

Name: (Last, First, Middle)

Date of Birth: (mm/dd/yyyy) | Sex: | ID / MR#:

Order Date: (mm/dd/yyyy) | Order Time: ☐ AM ☐ PM

ORDERING PHYSICIAN INFORMATION

Ordering Physician Name: (Last, First) | NPI:

Ordering Physician Phone: | Ordering Physician Fax:

Ordering Physician E-mail: | Ordering Physician Signature:

Facility/Client:

☐ Children's Medical Center of Dallas ☐ Dallas VA Medical Center ☐ Simmons Cancer Center ☐ Other:_____
☐ Clements University Hospital ☐ Parkland Health and Hospital System ☐ Zale Lipshy Hospital Address:_____

Bill to: ☐ Facility/Client ☐ Patient/3rd party Account #: _____

PRIMARY INSURANCE INFORMATION:

NOTE: The below fields refer to the insured/responsible party of the patient.

Relationship to patient:
☐ Self
☐ Spouse
☐ Dependent
☐ Other:_____

Name: (Last, First, Middle) | Date of Birth: (mm/dd/yyyy) | Sex:

Address: (street, city, state, zip) | Phone:

Insurance Co. Name: | Member ID #: | Group #:

Insurance Co. Address: | Insurance Co. Phone:

☐ Medicare ☐ HMO ☐ Other: _____
☐ Medicaid ☐ PPO

Preauthorization/precertification #: _____
Obtained by: _____
Date: (mm/dd/yyyy) _____

SECONDARY INSURANCE INFORMATION:

Insurance Co. Name: | Member ID #: | Group #:

Insurance Co. Address: | Insurance Co. Phone:

Please attach copies of the patient's identification card AND insured/responsible party's insurance card(s).

TUMOR TISSUE

Next Generation Sequencing Panel
☐ Heme
☐ Solid Tumor

Collection Status
☐ Tumor collected prior to day of order placement
☐ Tumor collected on day of order placement
☐ Tumor to be collected at future date

Tumor Specimen #:

ICD-10-CM: _____
Clinical Stage: _____
Treatment Status: _____

Tumor Collection Date: (mm/dd/yyyy) (including anticipated future date) ____/____/_____
Tumor Collection Time: (if known) _____ ☐ AM ☐ PM
Tissue:
☐ Blood (must collect FRESH)
☐ Bone Marrow (may collect fresh; if collected previously, please provide Tumor Specimen # above)
☐ Other: _____

Was specimen/will specimen be collected at above facility/client?
☐ Yes ☐ No
If no, provide name, address and phone of institution at which specimen was/will be collected:
_____
_____

GERMLINE TISSUE

If patient has leukemia, lymphoma or myelodysplastic syndrome, collect saliva.
If patient has oral cancer or oral dysplasia, collect peripheral blood.
If patient has neither of the above, collect blood or saliva.

Germline Collection Date: (mm/dd/yyyy) (including anticipated future date) _____/_____/_____
Germline Collection Time: (if known) _____ ☐ AM ☐ PM
Tissue: ☐ Blood ☐ Saliva

UTSW LAB USE ONLY

UTSW MRN:_____ UTSW Order # (Epic):_____ UTSW Accession # (Illumina):_____
Specimens Received (Specify #): Blocks:_____ Slides:_____ Lavender-Top Tubes:_____ Saliva Tubes: _____
Received by:_____ Date Received: (mm/dd/yyyy) ____/____/_____ Time Received: _____ ☐ AM ☐ PM

214-648-0924 (phone)
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gene.diagnostics@UTSouthwestern.edu
http://utsouthwestern.edu/sites/genomics-molecular-pathology/

Once Upon a Time NGS lab Next Generation Sequencing UTSouthwestern Medical Center

UTSouthwestern Medical Center

SPECIMEN COLLECTION INSTRUCTIONS

1. Tumor tissue
   -Formalin-fixed, paraffin-embedded tissue (minimum of 10,000 tumor cells accounting for at least 20% of all cells in block or on slide). Send block OR 10 unstained sections cut at 10 microns thickness PLUS 1 H+E-stained section (for biopsy specimens) OR 5 unstained sections cut at 10 microns thickness PLUS 1 H+E-stained section (for non-biopsy specimens). Send block/slides at ambient temperature. Also provide copy of pathology report.
   -Fresh blood or bone marrow. Draw at least 1 mL in lavender-top/K2-EDTA tube (NOT green-top/heparin) and send on cold pack by overnight delivery. Lab will NOT split this collection for other tests.

2. Germline tissue
   -Submit either peripheral blood (solid tumors; at least 1 ml in lavender-top tube sent on cold pack by overnight delivery) or saliva (hematopoietic or non-oropharyngeal solid tumors) collected in UTSW-supplied ORAgene kit. Collection instructions located at https://www.dnagenotek.com/ROW/support/collection-instructions/oragene-dna/OG-500andOG-600.html. Send saliva at ambient temperature.

Note
   -Blood/bone marrow must be sent on cold pack. Block/slides/saliva must be sent at ambient temperature. Specimens NOT accepted on Sundays or holidays.

Questions: Call 214-648-0924 or email gene.diagnostics@UTSouthwestern.edu

RETURN SHIPPING INSTRUCTIONS

1. Specimen collection kit contains all materials needed for return shipping.

2. Secure cap(s) on tube(s).

3. Place blood/bone marrow tube in biohazard bag, then seal biohazard bag and place it on chilled cold pack in insulated, leak-proof bag. Seal insulated, leak-proof bag. DO NOT FREEZE. DO NOT SHIP ON ICE.

4. Place saliva tube back in ORAgene package. Seal ORAGene package with stickers, then wrap with two layers of bubble wrap. Secure bubble wrap with stickers. Place wrapped ORAgene package in biohazard bag and seal bag.

5. Place block/slides in biohazard bag and seal bag. Slides must be in plastic slide holders. Wrap biohazard bag with two layers of bubble wrap. Secure bubble wrap with stickers. (Block will be returned after testing has been completed.)

6. Place all materials back in box. Place UTSW-supplied, prepaid, pre-addressed, return shipping label on box over original shipping label. Seal box via adhesive strip on inside of lid.

Note
   -Blood/bone marrow must be sent on cold pack. Block/slides/saliva must be sent at ambient temperature. Specimens NOT accepted on Sundays or holidays.

Questions: Call 214-648-0924 or email gene.diagnostics@UTSouthwestern.edu

FREQUENTLY ASKED QUESTIONS

Located on FAQs page of http://www.utsouthwestern.edu/sites/genomics-molecular-pathology/

UTSouthwestern
Medical Center

Comprehensive Pan-Cancer Next Generation Sequencing

Pt. Name:_____

Address:_____

_____

City State Zip

MRN: _____

DOB: _____ SEX: _____

The purpose of this molecular genetic test is to ascertain if my tumor carries any mutation(s) which could be a target for drug therapy or predict outcome. This test will include analysis of a comprehensive and regularly reviewed collection of genes that have been associated with the diagnosis, treatment, or progression of cancer.

Reporting Genetic Test Results: The blood, body fluid, or tissue specimen is used for isolation of DNA and RNA for genetic testing. Due to the complexity and the implications of the test results, these results will be reported through your designated physician(s) and their medical team. However, while UTSW providers check results frequently, you may see results in your MyChart account before your designated physician(s) and their medical team has seen them. Additionally, the test results could be released to all who, by law, may have access to such data. Genetic information found from this test will remain in your electronic medical record.

Genes included on this test may be associated with several different types of cancers. The results of this genetic test may or may not have implications for your medical management and available therapeutics based on your genetic testing result may change over time. Identification of a mutation does not imply additional care will be covered by health insurance. Genetic data is used in conjunction with other medical testing to formulate your best treatment plan.

For optimal interpretation of tumor DNA sequence, we will also determine your germline (inherited) DNA sequence. If a mutation found in the tumor is also found in your germline it could have consequences for you and your family members (parents, siblings, children) and could indicate a heritable cancer risk. Please keep in mind that germline DNA sequencing might reveal an underlying genetic risk for a non-tumor disorder in you or your family, but this information may not help in predicting prognosis or change medical management or the treatment of this disease. Further testing of you or your reproductive partner may be recommended based on the results of this test.

Additional specimens: This molecular genetic test may require an additional blood, body fluid, or tissue sample to obtain accurate results.

Genetic Information Protection: There are federal laws in place that prohibit health insurers and employers from discriminating based on genetic information (the Genetic Information Nondiscrimination Act (GINA) of 2008 (Public Law 110-233)). There are currently no laws that prohibit life insurance, long-term care, or disability insurance companies from discriminating based on genetic information.

The results of genetic testing are considered “Protected Health Information” (PHI) as described in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191). Release of test results is limited to authorized personnel, such as the ordering physician, and to other parties as required by law.

Technical Limitations: While this test is designed to identify many mutations in the genes analyzed, it is still possible that there are mutations that this testing technology is unable to detect. In addition, there may be other genes associated with cancer susceptibility that are not included in this analysis or that are not known at this time. Due to the complexity of genetic alterations, the results of the sequencing may not be clear or may require further testing later to confirm or understand the genetic changes. Due to updates in medical knowledge, your physicians may wish to order a reanalysis of your prior test or a new test. If so, a new, updated or amended report will be issued to the ordering physician, unless you opt out of this.

Use of specimens for research: After testing is completed, your blood, body fluid, tissue specimen(s), or DNA sequence may be disposed of or retained indefinitely for medical research, test validation, publication, and/or education by UTSW, as long as your privacy is maintained, without further written consent from you. No compensation will be given nor will funds be forthcoming due to any invention(s) resulting from research and development. You may refuse to submit your specimen for research and may withdraw your consent at any time by contacting the laboratory medical director. Your refusal to consent to medical research will not affect your results.

____I consent to the use of my DNA/RNA sample for research purposes.

____I DO NOT consent to the use of my DNA/RNA sample for research purposes.

Financial responsibility: If the test is canceled before any processing, there will be no charge. If the test is canceled midway during test processing/preparation, the patient will be charged the cost associated with the completed technical work and further testing will stop. If the test is canceled after the DNA sequencing has begun, the patient will be charged the full cost of the test.

I have read or have had read to me all the above statements and understand the information regarding molecular genetics testing and have had the opportunity to ask questions I might have about the testing, the procedure, the risks, and the alternatives prior to my informed consent. I agree to have the molecular genetic testing.

Patient Signature *(or Parent/Guardian if patient is a minor)*

Patient Name *(Print)*

Name and Relationship *(Parent/Guardian if patient is a minor)*

Date/Time(AM/PM)

Interpreter Signature (or Language Line Interpreter ID#)

Interpreter Name (Print)

Date/Time (AM/PM)

FORM # PCNGSGP (05/17) (Rev. 12/01/2022)

CLIN CONS

UTSouthwestern Medical Center

Secuenciación de Nueva Generación del panel completo de cáncer

Comprehensive Pan-Cancer Next Generation Sequencing

Nombre del paciente: _____

Dirección: _____

_____

Ciudad Estado Código postal

N.º de expediente médico: _____

Fecha de nacimiento: _____ Sexo: _____

El objetivo de esta prueba genética molecular es determinar si en el tumor hay mutaciones que pueden ser un objetivo para el tratamiento con medicamentos o para predecir los resultados. La prueba incluirá el análisis de un conjunto completo de genes que se evalúa de manera habitual y que se ha asociado con el diagnóstico, el tratamiento o la progresión del cáncer.

Cómo informar de los resultados de las pruebas genéticas: Las muestras de sangre, fluidos corporales o tejidos se utilizan para el aislamiento del ADN y el ARN para las pruebas genéticas. Debido a la complejidad y a las implicaciones de los resultados de las pruebas, estos se informarán mediante los médicos designados y su equipo médico. Sin embargo, aunque los proveedores de UTSW verifican los resultados con frecuencia, es posible que vea los resultados en su cuenta de MyChart antes de que los vean sus médicos designados y su equipo médico. Además, los resultados de la prueba podrían revelarse a todas las personas que legalmente puedan tener acceso a estos datos. La información genética obtenida en la prueba se incluirá en su expediente médico electrónico.

Los genes incluidos en esta prueba pueden estar asociados a diversos tipos de cáncer. Los resultados de esta prueba genética pueden o no tener implicaciones para su tratamiento médico, y las terapias disponibles según el resultado de las pruebas genéticas pueden cambiar con el tiempo. La identificación de una mutación no implica que el seguro médico cubra atención adicional. Los datos genéticos se usan con otras pruebas médicas para diseñar el mejor plan de tratamiento para usted.

Para la interpretación óptima de las secuencias de ADN tumoral, también determinaremos las secuencias de ADN de la línea germinal (hereditarias). Si una mutación identificada en el tumor también se descubre en la línea germinal, podría haber consecuencias para usted y sus familiares (padres, hermanos e hijos) y podría indicar riesgo de cáncer hereditario. Tenga en cuenta que en la secuenciación de ADN de la línea germinal podría identificarse un riesgo genético subyacente de que usted o sus familiares desarrollen un trastorno no tumoral, pero es posible que esta información no sea útil para determinar el pronóstico, o para cambiar el tratamiento médico de esta enfermedad. Pueden recomendarle que usted o su pareja se hagan otras pruebas en función de los resultados de esta prueba.

Muestras adicionales: Para esta prueba genética molecular puede ser necesaria otra muestra de sangre, fluidos corporales o tejido para obtener resultados precisos.

Protección de la información genética: Hay leyes federales vigentes que prohíben que las compañías de seguros médicos y los empleadores discriminen según la información genética (la Ley de No Discriminación por Información Genética [GINA] de 2008 [Ley Pública 110-233]). En la actualidad, no hay leyes que prohíban que las compañías de seguros de vida, de atención de largo plazo o por discapacidad discriminen según la información genética.

Los resultados de las pruebas genéticas se consideran “información médica protegida” (PHI) según se establece en la Ley de Portabilidad y Responsabilidad del Seguro Médico (HIPAA) de 1996 (Ley Pública 104-191). Los resultados de la prueba solo se revelarán al personal autorizado, como el médico que la pidió, y a otras partes según lo exija la ley.

Limitaciones técnicas: Aunque esta prueba está diseñada para identificar muchas mutaciones en los genes que se analizan, sigue siendo posible que haya mutaciones que la tecnología de estas pruebas no pueda detectar. Además, puede haber otros genes asociados con la predisposición al cáncer que no se incluyen en el análisis o que no se han identificado hasta este momento. Debido a la complejidad de las alteraciones genéticas, es posible que los resultados de la secuenciación no sean claros o que se necesiten otras pruebas en el futuro para confirmar o entender los cambios genéticos. Debido a las actualizaciones de los conocimientos médicos, es posible que sus médicos quieran que se repita el análisis de su prueba anterior o que se haga una prueba nueva. En ese caso, se entregará un informe nuevo, actualizado o modificado al médico que pidió la prueba, a menos que usted no esté de acuerdo.

Uso de muestras para investigaciones: Después de que se hagan las pruebas, UTSW puede desechar o conservar durante un tiempo indeterminado sus muestras de sangre, fluidos corporales o tejidos, o su secuencia de ADN para fines de investigación médica, validación de la prueba, publicación o educación, siempre que se mantenga su privacidad, sin que sea necesario que usted dé otro consentimiento por escrito. No se dará ninguna compensación ni se obtendrán fondos por las invenciones resultantes de la investigación y el desarrollo. Puede negarse a enviar sus muestras para la investigación y puede retirar su consentimiento en cualquier momento comunicándose con el director médico del laboratorio. Su denegación a dar su consentimiento para las investigaciones médicas no afectará a sus resultados.

____Doy mi consentimiento para que se use mi muestra de ADN/ARN para la investigación.

____NO doy mi consentimiento para que se use mi muestra de ADN/ARN para la investigación.

Responsabilidad económica: Si la prueba se cancela antes de que se procesen las muestras, no habrá cargos. Si la prueba se cancela a mitad de su procesamiento/preparación, se le cobrará al paciente el costo asociado con el trabajo técnico que se haya hecho y no se harán más pruebas. Si la prueba se cancela después de que se haya iniciado la secuenciación del ADN, se le cobrará al paciente el costo total de la prueba.

He leído o me han leído todas las declaraciones de arriba, entendí la información sobre las pruebas genéticas moleculares y tuve la oportunidad de hacer las preguntas que podría tener sobre las pruebas, el procedimiento, los riesgos y las alternativas antes de dar mi consentimiento informado. Acepto someterme a las pruebas genéticas moleculares.

Firma del paciente *(o del padre, de la madre o del tutor si el paciente es menor)*	Firma del intérprete (o n.° de identificación del intérprete de Language Line)
Nombre del paciente *(en letra de molde)*	Nombre del intérprete (en letra de molde)
Nombre y relación *(del padre, de la madre o del tutor si el paciente es menor)*	Fecha/hora (a. m./p. m.)
Fecha/hora *(a. m./p. m.)*	

FORM # PCNGSGP (05/17) (Rev. 12/01/2022)

CLIN CONS

Notifier:	***UT Southwestern Medical Center***	**Name:**
	5323 Harry Hines Blvd	**Identification Number:**
	Dallas, TX 75390	

Advance Notice of Non-Covered Services

Items or Services:	Reason Insurance May Not Pay:	Estimated Cost
(1) COMPREHENSIVE PAN-CANCER NEXT GENERATION SEQUENCING [5423418]	This item(s) or service is not covered for your condition.	(1) $2,190.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the items or services listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have.

OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** Your insurance company has informed us that this procedure(s) is **not a covered benefit** of your plan. An estimated price for the non-covered procedure(s) has been established that is due in full prior to your treatment, and this procedure(s) will not be billed to your insurance company.

☐ **OPTION 2.** This procedure(s) may not be a covered benefit of your plan, but you have requested that we submit a claim for these services to your insurance. If your insurance covers any portion of this procedure(s), you are responsible for your normal/regular coinsurance and/or deductibel amounts. If your insurance does not cover any portion of this procedure(s), you are responsible for the full price of any non-covered services. While we may have obtained an authorization from your insurance carrier for this procedure(s), you are responsible for the full price of any non-covered portion of the procedure should it be denied or payment recouped due to an exclusion in coverage determined by your insurance. The payment of your estimated out-of-pocket balance after insurance and any package plan amount is **due in full prior to the procedures being rendered.**

Additional Information: This pricing information include only those services listed above. It does not include additional anesthesia, laboratory, pathology or radiology/imaging services that may be required by the facility or additional procedures that may be performed. Please understand that, in some rare cases, there may be unusual circumstances, unexpected conditions or complications that require additional services to be performed. These additional services may result in additional charges. **These additional charges may or may not be covered by your insurance.** Signing below means that you have received and understand this notice and agree to pay your designated amounts(s) as described within it. You also receive a copy.

Signature:	**Date:**