BCM-MEDICAL GENETICS LABORATORIES
WHOLE GENOME LABORATORY

PHONE: 1-800-411-GENE | FAX: 713-798-2787 | www.bcmgeneticlabs.org

SHIP TO: Medical Genetics Laboratories
Baylor College of Medicine
2450 Holcombe, Grand Blvd. -Receiving Dock
Houston, TX 77021-2024
Phone: 713-798-6555

CANCER EXOME SEQUENCING - TUMOR SAMPLE FORM

PATIENT INFORMATION

NAME: _____ (LAST NAME) _____ (FIRST NAME) ____ (MI)

DATE OF BIRTH: ____ / ____ / ____ (MM / DD / YY)

GENDER (Please select one): ☐ FEMALE ☐ MALE ☐ UNKNOWN

MEDICAL RECORD #: _____

ACCESSION #: _____

HOSPITAL #: _____

ETHNIC BACKGROUND (Select all that apply):

- ☐ AFRICAN AMERICAN
- ☐ ASIAN
- ☐ ASHKENAZIC JEWISH
- ☐ EUROPEAN CAUCASIAN
- ☐ HISPANIC
- ☐ NATIVE AMERICAN INDIAN
- ☐ OTHER JEWISH
- ☐ OTHER (Please specify): _____

REPORTING INFORMATION

PHYSICIAN: _____

INSTITUTION: _____

PHONE: _____ FAX: _____

EMAIL (INTERNATIONAL CLIENT REQUIREMENT): _____

ADDITIONAL PROFESSIONAL REPORT RECIPIENTS

NAME: _____

PHONE: _____ FAX: _____

NAME: _____

PHONE: _____ FAX: _____

SAMPLE INFORMATION

PLEASE SELECT FROM THE GROUPS LISTED BELOW

1) SOLID TUMOR SAMPLE:

☐ 9610 - Tissue (Fresh Frozen) - Ship Frozen — DATE OF COLLECTION: ____ / ____ / ____

☐ 9615 - Please check if additional tumor sample is being submitted (additional fees will apply) — DATE OF COLLECTION: ____ / ____ / ____

ACCESSION #: _____

2) HEMATOLOGIC TUMOR SAMPLE:

☐ 9610 - Bone Marrow: 5 cc in EDTA (purple-top) — DATE OF COLLECTION: ____ / ____ / ____

☐ 9610 - Leukemic Blood: 5 cc in EDTA (purple-top) — DATE OF COLLECTION: ____ / ____ / ____

☐ 9610 - Extracted DNA: 6 micrograms — DATE OF COLLECTION: ____ / ____ / ____

☐ 9615 - Please check if additional tumor sample is being submitted (additional fees will apply) — DATE OF COLLECTION: ____ / ____ / ____

ACCESSION #: _____

PLEASE FILL OUT CANCER EXOME SEQUENCING - NORMAL/NON TUMOR SAMPLE INFORMATION ON PAGE 2.
PAGE 2 MUST ACCOMPANY NORMAL/NONTUMOR SAMPLE

☐ NORMAL/NONTUMOR SAMPLE INCLUDED WITH TUMOR SAMPLE

☐ NORMAL/NONTUMOR SAMPLE WILL BE SENT SEPARATELY

PATHOLOGY REPORT MUST BE INCLUDED WITH TUMOR SAMPLE

TEST WILL NOT BE PERFORMED UNTIL BOTH TUMOR AND NORMAL SAMPLES HAVE BEEN RECEIVED

Additional Tests to Cancer Exome Sequencing (For Tumor Sample Only)

☐ 9705 Cancer Gene Mutation Panel V. 2 - if selected, this test will be ordered in addition to the CES test

☐ 9715 Leukemia Mutation Panel - if selected, this test will be ordered in addition to the CES test

☐ 9510 BCM 400K CGH/SNP Array - if selected, this test will be ordered in addition to the CES test

Reporting:
Turnaround time is 15 weeks after financial responsibility has been verified and both normal/nontumor and tumor samples have been received to obtain a final report for cancer exome. If other tests are requested along with cancer exome sequencing, these tests will be reported independently according to each test's established turnaround time (available at www.cancergeneticslab.org). For more details regarding the reporting system please visit our website or call.

LAST UPDATED: 8/14/2014

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CANCER EXOME SEQUENCING - NORMAL/NONTUMOR SAMPLE FORM

PATIENT INFORMATION

NAME: _____ (LAST NAME) _____ (FIRST NAME) ___ (MI)

DATE OF BIRTH: ____ / ____ / ____ (MM / DD / YY)

GENDER (Please select one):
- ☐ FEMALE
- ☐ MALE
- ☐ UNKNOWN

ETHNIC BACKGROUND (Select all that apply):
- ☐ AFRICAN AMERICAN
- ☐ ASIAN
- ☐ ASHKENAZIC JEWISH
- ☐ EUROPEAN CAUCASIAN
- ☐ HISPANIC
- ☐ NATIVE AMERICAN INDIAN
- ☐ OTHER JEWISH
- ☐ OTHER (Please specify): _____

MEDICAL RECORD #: _____

ACCESSION #: _____

HOSPITAL #: _____

CONSENT DATE: _____

PHYSICAN CONTACT INFORMATION

PHYSICIAN: _____

INSTITUTION: _____

PHONE: _____ *FAX: _____

REPORTS WILL BE ISSUED TO REFERRALS SPECIFIED ON PAGE 1.

SAMPLE INFORMATION

THIS REQUISITION IS FOR NORMAL/NONTUMOR SAMPLE ONLY.
FOR TUMOR SAMPLES, PLEASE FILL OUT CANCER EXOME SEQUENCING - TUMOR SAMPLE INFORMATION ON PAGE 1.

IF TUMOR SAMPLE IS FRESH FROZEN TISSUE:

☐ 9611 - PERIPHERAL BLOOD: 5 cc in EDTA (purple-top)

DATE OF COLLECTION: ____ / ____ / ____ (MM / DD / YY) TIME OF COLLECTION: _____

☐ 9611 - Extracted DNA: 6 micrograms

DATE OF COLLECTION: ____ / ____ / ____ (MM / DD / YY) TIME OF COLLECTION: _____

IF TUMOR SAMPLE IS BONE MARROW OR LEUKEMIC BLOOD:

☐ 9611 - SKIN BIOPSY: 3 mm skin punch biopsy in tissue culture media

DATE OF COLLECTION: ____ / ____ / ____ (MM / DD / YY) TIME OF COLLECTION: _____

☐ 9611 - SKIN FIBROBLAST CULTURE: 2 T25 Flasks

DATE OF COLLECTION: ____ / ____ / ____ (MM / DD / YY) TIME OF COLLECTION: _____

THIS FORM IS TO BE FILLED OUT WHEN NORMAL/NONTUMOR SAMPLE IS COLLECTED.

A REPORT WILL NOT BE ISSUED FOR THIS FORM.

TEST WILL NOT BE PERFORMED UNTIL BOTH TUMOR AND NORMAL/NONTUMOR SAMPLES HAVE BEEN RECEIVED.

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CANCER EXOME SEQUENCING FORM

NAME: _____ (LAST NAME) _____ (FIRST NAME) ___ (MI) DATE OF BIRTH: ___ / ___ / ___ (MM / DD / YY) GENDER (Please select one): ☐ FEMALE ☐ MALE ☐ UNKNOWN

REQUIRED - INDICATION FOR STUDY

Please provide the following clinical information regarding the patient to be tested. Please also submit a clinical summary and pedigree if available. This information is needed to facilitate interpretation of whole exome sequencing results. If the laboratory requires additional information, please indicate the health care provider to be contacted:

NAME: _____ PHONE/PAGER #: _____

TUMOR TYPE

TO AVOID DELAY IN SAMPLE PROCESSING, PROVIDE AN ACCURATE LIST OF INDICATIONS (MUST CHECK ONE OR MORE ITEMS BELOW)

- ☐ BREAST CANCER
- ☐ COLORECTAL CANCER
- ☐ LUNG CANCER
- ☐ OVARIAN CANCER
- ☐ PROSTATE CANCER
- ☐ RENAL CANCER
- ☐ ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)
- ☐ ACUTE MYELOID LEUKEMIA (AML)
- ☐ CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)
- ☐ CHRONIC MYELOGENOUS LEUKEMIA (CML)
- ☐ MYELODYSPLASTIC SYNDROME (MDS)
- ☐ MYELOPROLIFERATIVE DISORDER (MPD)
- ☐ PLASMA CELL NEOPLASMS - includes Multiple Myeloma (MM)
- ☐ OTHER (Please specify): _____

ADDITIONAL TUMOR INFORMATION

	COMMENTS
☐ Metastatic neoplasm, refractory to treatment	
☐ Recurrent metastatic neoplasm	
☐ Malignant neoplasm, unclassified	
☐ Primary neoplasm, uncertain treatment	
☐ Other	

TRANSPLANT/TRANSFUSION (RECENT) HISTORY*

TRANSFUSION				DATE	COMMENTS (e.g., white blood cells, platelets, etc.)
☐	Yes	☐	No		
☐	Yes	☐	No		

*If patient has had a whole blood transfusion within 30 days, or has had a bone marrow transplant at anytime, you must contact us prior to submitting a sample.

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CANCER EXOME SEQUENCING FORM

NAME: _____ (LAST NAME) _____ (FIRST NAME) ___ (MI) DATE OF BIRTH: ___ / ___ / ___ (MM / DD / YY) GENDER (Please select one): ☐ FEMALE ☐ MALE ☐ UNKNOWN

PRIOR THERAPIES (chemotherapy, radiation, and/or targeted)

☐ NO PRIOR THERAPY

Therapy	Best Response	Notes
	☐ Progression ☐ Partial Response ☐ Complete Response	
	☐ Progression ☐ Partial Response ☐ Complete Response	
	☐ Progression ☐ Partial Response ☐ Complete Response	

FAMILY HISTORY

Family History of Cancer: ☐ YES ☐ NO

If yes, please provide detailed information on affected family members and/or a pedigree.

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CANCER EXOME SEQUENCING FORM

INFORMATION AND CONSENT FOR TESTING

Your physician has advised you (or your child) to undergo the genetic test called the Cancer Exome Sequencing test (abbreviated CES). The purpose of this document is to provide information about the test. This information is meant to be used as a supplement to your discussion with a health care professional. If you agree to have the CES test, you will be asked to sign the last page of this document, indicating that you understand the information provided and wish to have testing. You will be given a copy of this document for your records.

Description of the Cancer Exome Sequencing Test

The Cancer Exome Sequencing test is a highly complex test that is newly developed for the identification of changes in an individual's tumor DNA that are believed to be causative or related to the tumor's behavior or it's response to therapeutic agents. The exome refers to the portion of the human genome that contains functionally important sequences of DNA that direct the body to make proteins essential for the body to function properly. These regions of DNA are referred to as exons. It is known that most of the errors that occur in DNA sequences that then lead to altered functions in cancer cells are located in the exons. In contrast to current sequencing tests that analyze one gene or small groups of related genes at a time, the Cancer Exome Sequencing test will analyze the important regions of tens of thousands of genes at the same time. Therefore, sequencing of the exome is thought to be an efficient method of analyzing a patient's tumor DNA to discover the underlying genetic cause of tumor behavior or response to therapy. However, it is possible that even if the CES identifies the underlying genetic changes in the tumor, this information may not help in predicting prognosis or change medical management or treatment of disease.

Indications for Testing

The decision to undergo the Cancer Exome Sequencing test is made by you and your physician. In general, the test is used when your physician would like to have information about genetic changes in the tumor that might explain the degree of aggressiveness of a tumor or the likelihood of the tumor to respond to targeted therapeutic agents. The test requires either a sample of tumor tissue (fresh or frozen) and 5-10 cc (about 1-2 teaspoons) of whole blood (as a source of normal DNA) OR 3-5 cc leukemic blood (about 1 teaspoon) and a skin biopsy (as a source of normal DNA).

Test Reporting

In the Cancer Exome Sequencing test, the tumor exome sequence is compared to your normal tissue exome sequence, in order to identify variations or differences unique to the tumor. Many of these variations are expected to be found. We will categorize these variations using a classification system based on currently available information in the medical literature and in scientific databases that indicates the likelihood that the information about mutations in the tumor can be used for medical management. For genes that are known to be the cause of hereditary cancer syndromes (inherited gene mutation that increases the likelihood of developing cancer over a person's lifetime), the normal (germline) sequence will be compared to a reference sequence. Based on currently available information in the medical literature and in scientific databases, we will decide whether any of these variations are predicted to be causative or related to your cancer or associated with an increase chance to develop cancer. Only somatic mutations (those present only in the tumor) with established and potential clinical utility, as well as cancer susceptibility germline variants, are confirmed by a second sequencing method. The CES test results will be reported to your physician in approximately 15 weeks from when all necessary samples and paperwork have been received.

Constitutional (inherited) exome interpretation. In discussion with your physician, an additional report can be ordered for up to 6 months after the Cancer Exome Sequencing report is received, for no additional charge. Instructions for ordering the constitutional (inherited) exome interpretation will be found in the report for the Cancer Exome Sequencing test. This report will summarize findings in your normal genome and will contain information on genes and diseases that have clear and immediate medical significance to your health or the health of family members, whether or not they relate to cancer or other current symptoms. Carrier status for autosomal recessive conditions will include disorders recommended for reproductive screening by professional societies such as ACMG or ACOG (such as cystic fibrosis and Tay-Sachs disease). In addition, carrier status for severe, early-onset conditions will be reported only for those genes that have testing available in a clinical lab. Variants in genes involved in drug metabolism will also be reported. This report may contain information on diseases and genes that do not relate to the current cancer type or to cancer susceptibility, or may develop many years from now, or do not have any known link to disease, according to current knowledge.

Because medical information continues to advance, it is important to know that the interpretation of the variants is based on information available at the time of testing and may change in the future. If new symptoms or concerns arise later your data can be reanalyzed for an additional charge.

Report Exclusions

The CES report will not include genetic variations in your normal tissue DNA that is not associated with a hereditary cancer syndrome. The constitutional (inherited) exome report (must be ordered separately once the CES report is received) will not include findings in genes causing adult onset dementia syndromes or other adult onset neurological conditions for which there is presently no prevention or cure. Heterozygous unclassified variants associated with recessive disorders will not be reported unless a deleterious mutation or a second unclassified variant in the same gene is also detected.

Potential Risks and Discomforts

(1) It is possible that your tumor could have a mutation in a gene included in the CES test, but the CES test was unable to detect the mutation. Therefore, it is possible that the tumor has a mutation that could modify medical management, but that the test did not detect the condition.
(2) The CES test does not analyze 100% of the genes in the human genome. There are some genes that cannot be included in the test due to technical reasons.

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CANCER EXOME SEQUENCING FORM

Potential Risks and Discomforts (continued)

(3) Results may be unclear or indicate the need for further testing on other family members.

(4) If you sign the consent form, but you no longer wish to have your sample tested by CES, you can contact your doctor to cancel the test. If testing is complete, but you have not received your results yet, you can inform your doctor that you no longer wish to receive the results. However, if you withdraw consent for testing after 5 p.m. the next business day from the day of sample receipt by the laboratory, you will be charged for the full cost of the test.

(5) The cumulative results of CES testing on many samples may be published in the medical literature. These publications will not include any information that will identify you personally.

I hereby authorize the BCM Cancer Genetics and Whole Genome Sequencing Laboratories to conduct genetic testing for myself (or my child) for the Cancer Exome Sequencing test (CES) as recommended by my physician. (PLEASE INITIAL) _____

Signature: _____ Date: _____

Printed Name: _____

Patient Name: _____ Relationship to Patient: _____

Physician's/Counselor's Signature: _____ Date: _____

* For a list of genes and conditions associated with inherited cancer syndromes, please visit www.cancergeneticslab.org.

REQUIRED: NEW YORK STATE PHYSICIAN SIGNATURE OF CONSENT

I certify that the patient specified above and/or their legal guardian has been informed of the benefits, risks, and limitations of the laboratory test(s) requested. I have answered this person's questions. I have obtained informed consent from the patient or their legal guardian for this testing.

Physician's Printed Name:_____Signature:_____ Date (MM/DD/YY):_____

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CANCER EXOME SEQUENCING FORM

BILLING INFORMATION

IMPORTANT NOTICE: ONE OF THE THREE FOLLOWING BILLING OPTIONS MUST BE INDICATED BELOW.
PLEASE FORWARD ALL BILLING QUESTIONS TO: MEDGENBILLING@BCM.EDU

PATIENT INFORMATION

PATIENT NAME (LAST,FIRST, MI): _____ PATIENT DATE OF BIRTH (MM/DD/YY): _____

ADDRESS: _____ CITY, STATE, ZIP: _____

PHONE: _____ EMAIL: _____

☐ PAYMENT OPTION 1 - INSTITUTION

BCM-MEDICAL GENETICS LABORATORIES CAN ONLY RUN THIS TEST IF THE INSTITUTION ACCEPTS FINANCIAL RESPONSIBILITY FOR THE FULL PRICE OF THE TEST. PLEASE SIGN AND DATE BELOW THAT YOU ARE AN AGENT OF THE ORDERING INSTITUTION AND CAN ORDER GENETIC TESTING ON ITS BEHALF. TESTING WILL NOT BEGIN WITHOUT THIS SIGNATURE.

PRINTED NAME: _____ SIGNATURE: _____ DATE (MM/YY): _____

INSTITUTION NAME: _____ INSTITUTION CODE: _____

CONTACT NAME: _____ EMAIL (REQUIRED): _____

BILLING ADDRESS: _____ CITY, STATE, ZIP: _____

PHONE: _____ FAX: _____

☐ PAYMENT OPTION 2 - SELF-PAY (PAYMENT MUST ACCOMPANY SAMPLE)

☐ CREDIT CARD (PLEASE SELECT ONE): ◯ AMEX ◯ DISCOVER ◯ MC ◯ VISA

VALID CARD #: _____ EXPIRATION DATE (MM/YY): _____ CVC CODE: _____

CARDHOLDER PRINTED NAME: _____ CARDHOLDER SIGNATURE: _____

☐ CHECK/MONEY ORDER

☐ PAYMENT OPTION 3 - INSURANCE

PROVIDE A LEGIBLE PHOTOCOPY OF THE FRONT & BACK OF THE INSURANCE CARD OR HMO/MEDICAID HMO AUTHORIZATION/REFERRAL.

INSURED MEMBER'S INFORMATION

MEMBER NAME (Last, First, MI): _____ MEMBER DATE OF BIRTH (MM/DD/YY): _____ GENDER: ◯ FEMALE ◯ MALE

MEMBER POLICY #: _____ MEMBER SS #: _____ MEMBER GROUP #: _____

INSURANCE CO. NAME: _____ PHONE: _____

INSURANCE CO. ADDRESS: _____ CITY, STATE, ZIP: _____

ORDERING PROVIDER: _____

ICD9 Diagnosis Code(s) - must be provided or insurance cannot be filed: _____

INSURANCE FINANCIAL POLICY: I UNDERSTAND THAT INSURANCE IS FILED TO BCM-MEDICAL GENETICS LABORATORIES' CONTRACTED CARRIERS AS A CLIENT SERVICE COURTESY. I AM AWARE THAT I AM RESPONSIBLE FOR NON-COVERED SERVICES, DEDUCTIBLES, CO-INSURANCE, CONTRACT EXCLUSIONS, NON-AUTHORIZED SERVICES AND REMAINING BALANCES AFTER INSURANCE REIMBURSEMENT. I AUTHORIZE BCM-MEDICAL GENETICS LABORATORIES TO FURNISH ANY MEDICAL INFORMATION REQUESTED ON MYSELF, OR MY COVERED DEPENDENTS. IN CONSIDERATION OF SERVICES RENDERED, I TRANSFER AND ASSIGN ANY BENEFITS OF INSURANCE TO BCM-MEDICAL GENETICS LABORATORIES.

☐ I have read and agree to all sections of the insurance financial policy above - TESTING WILL NOT BEGIN WITHOUT THIS SIGNATURE

PRINTED NAME: _____ SIGNATURE: _____ DATE (MM/YY): _____

LAST UPDATED: 8/14/2014