

# BAYLOR MIRACA GENETICS LABORATORIES

PHONE: 800-411-GENE | FAX: 713-798-2787 | www.bmgil.com

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

## ADULT SCREENING EXOME SEQUENCING (ASE) REQUISITION (TEST CODE: 1605)

PATIENT INFORMATION		SAMPLE INFORMATION	
NAME: _____ <small>LAST NAME FIRST NAME MI</small>	DATE OF COLLECTION: ____ / ____ / ____ <small>MM DD YY</small>	HOSPITAL#: _____ ACCESSION#: _____	
DATE OF BIRTH: ____ / ____ / ____ <small>MM DD YY</small>	GENDER (Please select one): <input type="checkbox"/> FEMALE <input type="checkbox"/> MALE <input type="checkbox"/> UNKNOWN	SAMPLE TYPE (Please select one): <input type="checkbox"/> BLOOD <input type="checkbox"/> EXTRACTED DNA <input type="checkbox"/> FIBROBLAST	ETHNIC BACKGROUND (Select all that apply): <input type="checkbox"/> AFRICAN AMERICAN <input type="checkbox"/> ASIAN <input type="checkbox"/> ASHKENAZIC JEWISH <input type="checkbox"/> EUROPEAN CAUCASIAN <input type="checkbox"/> HISPANIC <input type="checkbox"/> NATIVE AMERICAN INDIAN <input type="checkbox"/> OTHER JEWISH <input type="checkbox"/> OTHER (Please specify): _____
-OR- PLACE PATIENT STICKER HERE			

### PATIENT MEDICAL INFORMATION

Please indicate if this patient has a known or suspected chronic medical diagnosis:  YES  NO  
If yes, please describe: \_\_\_\_\_

Please indicate if there is a family history of known or suspected chronic medical diagnosis:  YES  NO If yes, please attach detailed family history

Please list medications this patient takes on a regular basis: \_\_\_\_\_

REPORTING INFORMATION	ADDITIONAL PROFESSIONAL REPORT RECIPIENTS
PHYSICIAN: _____	NAME: _____
INSTITUTION: _____	PHONE: _____ FAX: _____
PHONE: _____ FAX: _____	NAME: _____
EMAIL (INTERNATIONAL CLIENT REQUIREMENT): _____	PHONE: _____ FAX: _____

**Reporting:**  
Turnaround time is 15 weeks after financial responsibility has been verified.

**Biological Parental Samples Are Optional:**  
Biological parental samples may be submitted to facilitate interpretation of ASE results. Blood samples from the parents may accompany the proband's sample (preferred) or may be sent together at another time. Preferably, patient and parental samples should be shipped together, but if not, they should be shipped within one month of the submission of the patient's sample. These studies are limited to the biological parents of the proband, other family members cannot be substituted without approval from the lab. Testing done on the parental samples is at no additional charge. Please review ASE consent "Request for Biological Parental Samples" section for more information and the final page for signature authorization.

**BIOLOGICAL PARENTS SAMPLES** are optional. Send 10 cc EDTA. Be sure to label parental samples with full name and date of birth - DO NOT LABEL WITH PATIENT'S NAME.

1505: **MOTHER** (FULL NAME): \_\_\_\_\_ DOB: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
LAST NAME FIRST NAME MM DD YY

ASYMPTOMATIC  MEDICAL PROBLEMS (attach summary of findings)

SAMPLE TYPE:  BLOOD  SALIVA DATE OF COLLECTION: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  NOT AVAILABLE  TO BE SENT LATER\*

1505: **FATHER** (FULL NAME): \_\_\_\_\_ DOB: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
LAST NAME FIRST NAME MM DD YY

ASYMPTOMATIC  MEDICAL PROBLEMS (attach summary of findings)

SAMPLE TYPE:  BLOOD  SALIVA DATE OF COLLECTION: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  NOT AVAILABLE  TO BE SENT LATER\*

\*If parental samples are to be sent later, please include copy of this requisition form with those samples. Those samples must be received within 3 weeks after the proband sample is received.

## ADULT SCREENING EXOME SEQUENCING (ASE) REQUISITION (TEST CODE: 1605)

### INFORMATION AND CONSENT FOR TESTING

Under the guidance of your physician, you are electing to undergo the genetic test called the Adult Screening Exome Sequencing test (ASE). The purpose of this document is to provide information about the test. This information is meant to be used as a supplement to your genetic counseling with a health care professional. If you agree to have the ASE 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 Adult Screening Exome Sequencing (ASE) Test

The Adult Screening Exome Sequencing test is a highly complex test that is newly developed for the identification of changes in an individual's DNA that are causative or related to a significant medical concern. This test is used for healthy individuals with no significant, active or past medical problems (examples such as developmental or neurologic problem, heart disease that they were born with, or cancer diagnoses) who are seeking information about their future risk of developing a genetic disorder. It is important to note that even if the ASE test identifies an underlying genetic disorder in you, this information may not help in predicting prognosis or change medical management or treatment of disease.

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 genetic disorders 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 Adult Screening 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 individual's DNA to discover the genetic cause of diseases or disabilities.

#### Indications for Testing

The decision to undergo the Adult Screening Exome Sequencing test is made by you and your physician. This test is used for healthy individuals over the age of 18 years with no significant active or past medical problems who are seeking information about their future risk of developing a genetic disorder. The ASE test is not appropriate for individuals who are suspected of having a genetic disorder or who have a strong family history of a genetic disorder. Individuals with significant medical histories should consider the Whole Exome Sequencing test (test code 1500). The ASE test requires 5-10 cc (about 1-2 teaspoon) of whole blood. You should expect that results of the ASE test will be sent to your physician in 15 weeks.

#### Test Reporting

When your exome sequence is compared to a normal reference sequence, many variations or differences are expected to be found. Based on currently available information in the medical literature and in scientific databases, we will decide whether any of these variations are known or predicted to be causative of a medical condition. The ASE test results will be reported to your physician.

The report will contain results in three different areas.

- (1) Your health: information on genes and diseases that have clear medical significance to your health or the health of family members. Examples of possible findings include mutations in genes that significantly increase or risk of cancer or genes that may cause heart disease or neurologic disease, including dementia syndromes.
- (2) Your reproductive health: information on genes and diseases that you are at-risk of passing to your offspring. This is known as carrier status for autosomal recessive conditions or X-linked conditions, examples of which include disorders recommended for reproductive screening by professional societies such as ACMG or ACOG (such as sickle cell, cystic fibrosis and Tay-Sachs disease). Carriers of these conditions are usually without symptoms of the condition, but are at-risk of passing the condition to offspring.
- (3) Your risk of altered drug metabolism. Variants in genes involved in drug metabolism will also be reported. The genes to be reported in this category are CYP2C9 and VKORC1 (warfarin metabolism) and CYP2C19 (plavix metabolism).

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 one year after the ASE report is issued.

#### Request for Biological Parental Samples

Biological parental samples are requested, if available, to facilitate interpretation of ASE test results. ASE will NOT be performed on the parental samples. The parental samples will be tested by other targeted methods for mutations and/or variants in genes that are highly likely to be causative of disease to confirm mode of inheritance, de novo status, etc. These studies will be performed at no additional charge. A separate parental report will not be issued. The laboratory will decide which mutations/variants will need parental studies based on the following criteria.

- Using Sanger sequencing parental samples will be tested to determine inheritance in the proband for genes related to a genetic disorder. Parental samples will not be run for genes with autosomal recessive inheritance pattern that only have one sequencing change identified. We will not study parents samples for medically actionable or carrier status mutations. If desired, these mutations may be studied in relatives for a fee.

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### INFORMATION AND CONSENT FOR TESTING (cont.)

#### Test Limitations and Potential Risks and Discomforts

- (1) It is possible that you could have a mutation in a gene included in the ASE test, but the ASE test was unable to detect the mutation. Therefore, it is possible that you may be affected with one of the conditions tested by ASE sequencing, but the test did not detect the condition. The ASE test will only include results with clear interpretations according to medical information that exists at the time of testing.
- (2) The ASE 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.
- (3) Results may be unclear or indicate the need for further testing on other family members, usually parents. It is possible, that additional information may come to light during these studies regarding family relationships. For example, data may suggest that family relationships are not as reported, such as non-paternity (the father of the individual is not the biological father).
- (4) If you sign the consent form, but you no longer wish to have your sample tested by ASE sequencing, 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 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 ASE testing on many samples may be published in the medical literature. These publications will not include any information that will identify you personally.
- (6) There is a small risk of bruising and bleeding at the puncture site where you give the blood sample.
- (7) Due to the fact that many different genes and conditions are being analyzed, there is a risk that you will learn genetic information about yourself or your family that was unexpected and may cause anxiety for you and possibly your family members. This information might relate to diseases with symptoms that may develop in the future in yourself or other family members as well as conditions that have no current treatment. If you have concerns about learning this type of information, please tell your doctor.

I hereby authorize Baylor Miraca Genetics Laboratories to conduct genetic testing for myself for the Adult Screening Exome Sequencing test (ASE) as recommended by my physician. (PLEASE INITIAL) \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Physician's/Counselor's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

#### Parental Testing Authorization

I hereby authorize Baylor Miraca Genetics Laboratories to conduct genetic testing for myself for the purposes of clarifying results for the Adult Screening Exome Sequencing test (ASE) that is being performed on my son or daughter's blood sample as recommended by their physician. I understand that my sample will not be subjected to ASE sequencing, but will be subjected to targeted testing methodologies (Sanger sequencing). A separate report of these data will not be issued.

Mother Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Father Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

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### 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

**BAYLOR MIRACA 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 BAYLOR MIRACA 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 BAYLOR MIRACA 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 BAYLOR MIRACA 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): \_\_\_\_\_