BAYLOR GENETICS

BAYLOR GENETICS
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

PHONE
1.800.411.4363
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1.800.434.9850

CONNECT

ADULT SCREENING EXOME SEQUENCING (ASE) REQUISITION

PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY)

Address | City | State | Zip | Phone

Accession # | Hospital / Medical Record #

Patient discharged from the hospital/facility: ◯ Yes ◯ No

Biological Sex: ◯ Female ◯ Male ◯ Unknown

Gender identity (if different from above):

REPORTING RECIPIENTS

Ordering Physician | Institution Name

Email (Required for International Clients) | Phone | Fax

ADDITIONAL RECIPIENTS

Name | Email | Fax

Name | Email | Fax

PAYMENT (FILL OUT ONE OF THE OPTIONS BELOW)

◯ **SELF PAYMENT**

☐ Pay With Sample ☐ Bill To Patient

◯ **INSTITUTIONAL BILLING**

Institution Name | Institution Code | Institution Contact Name | Institution Phone | Institution Contact Email

◯ **INSURANCE**

☐ Do Not Perform Test Until Patient is Aware of Out-Of-Pocket Costs (excludes prenatal testing)

REQUIRED ITEMS 1. Copy of the Front/Back of Insurance Card(s) 2. ICD10 Diagnosis Code(s) 3. Name of Ordering Physician 4. Insured Signature of Authorization

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Primary Insurance Co. Name | Primary Insurance Co. Phone

Primary Member Policy # | Primary Member Group #

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Secondary Insurance Co. Name | Secondary Insurance Co. Phone

Secondary Member Policy # | Secondary Member Group #

By signing below, I hereby authorize Baylor Genetics to provide my insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates, as well as any amounts not paid by my insurance carrier for reasons including, but not limited to, non-covered and non-authorized services. I understand that I am responsible for sending Baylor Genetics any and all payments that I receive directly from my insurance company in payment for this test. Please note that Medicare does not cover routine screening tests.

Patient's Printed Name | Patient's Signature | Date (MM / DD / YYYY)

STATEMENT OF MEDICAL NECESSITY (REQUIRED)

This test is medically necessary for the risk assessment, diagnosis, or detection of a disease, illness, impairment, symptom, syndrome, or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein. I confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

Physician's Printed Name | Physician's Signature | Date (MM / DD / YYYY)

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Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Biological Sex

ETHNICITY

- ◯ African American
- ◯ Ashkenazi Jewish
- ◯ East Asian (China, Japan, Korea)
- ◯ Finnish
- ◯ French Canadian
- ◯ Hispanic American
- ◯ Mennonite
- ◯ Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey)
- ◯ Native American
- ◯ Northern European Caucasian (Scandinavian, UK, Germany)
- ◯ Pacific Islander (Philippines, Micronesia, Malaysia, Indonesia)
- ◯ South Asian (India, Pakistan)
- ◯ Southeast Asian (Vietnam, Cambodia, Thailand)
- ◯ Southern European Caucasian (Spain, Italy, Greece)
- ◯ Other (Specify): _____

TESTING OPTION

● 1605 Adult Screening Exome Sequencing (ASE)

SAMPLE

SAMPLE TYPE

- ◯ Blood
- ◯ Buccal Swab
- ◯ Cultured Skin Fibroblast
- ◯ Extracted DNA from _____

Date of Collection (MM / DD / YYYY)

NOTE: Extracted DNA/RNA will only be accepted if the isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

INDICATION FOR TESTING (REQUIRED)

Does patient have a known or suspected chronic medical diagnosis? ☐ Yes ☐ No **If YES, please describe below.**

Does patient have a family history of known or suspected chronic medical diagnosis? ☐ Yes ☐ No **If YES, please attach detailed family history.**

Please list all medications patient takes on a regular basis:

ICD10 Diagnosis Code(s): _____

BIOLOGICAL PARENTS TEST INFORMATION

Reporting: Turnaround time is 12 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. For more information, please review the "Request for Biological Parental Samples" section of the consent and the final page for signature authorization.

Biological parents samples are optional. Send 10 cc blood in an EDTA tube or saliva sample. Be sure to label parental samples with full name and parental date of birth - do not label with patient's name.

MATERNAL INFORMATION

Maternal Last Name | Maternal First Name | MI | Maternal Date of Birth (MM / DD / YYYY)

- ◯ Asymptomatic
- ◯ Symptomatic (Attach summary of findings)

SAMPLE TYPE:
- ◯ Blood
- ◯ Saliva
- ◯ Buccal swab

Date of Collection (MM / DD / YYYY)

- ◯ Not Available
- ◯ To Be Sent Later *

PATERNAL INFORMATION

Paternal Last Name | Paternal First Name | MI | Paternal Date of Birth (MM / DD / YYYY)

- ◯ Asymptomatic
- ◯ Symptomatic (Attach summary of findings)

SAMPLE TYPE:
- ◯ Blood
- ◯ Saliva
- ◯ Buccal swab

Date of Collection (MM / DD / YYYY)

- ◯ Not Available
- ◯ To Be Sent Later *

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

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ADULT SCREENING EXOME SEQUENCING (ASE) REQUISITION

Patient Last Name	Patient First Name	MI	Date of Birth (MM / DD / YYYY)	Biological Sex
			/ /	

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 healthcare 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 an 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 10 weeks.

TESTING 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.

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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ADULT SCREENING EXOME SEQUENCING (ASE) REQUISITION

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Biological Sex

INFORMATION AND CONSENT FOR TESTING

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 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 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) Please tell your doctor because 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.

Initial — I hereby authorize Baylor Genetics to conduct genetic testing for myself for the Adult Screening (ASE) Exome Sequencing test as recommended by my physician.

Signature | Date (MM / DD / YYYY)

Printed Name

Relationship to Proband

Proband Name | Proband Date of Birth (MM / DD / YYYY)

Physician's/Counselor's Signature | Date (MM / DD / YYYY)

Parental Testing Authorization I hereby authorize Baylor Genetics to conduct genetic testing for myself to clarify results for the Adult Screening Exome Sequencing test (ASE) that is being performed on my son or daughter's blood sample as recommended by my and/or 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's Signature | Date (MM / DD / YYYY)

Printed Name | Mother's DOB (MM / DD / YYYY)

Father's Signature | Date (MM / DD / YYYY)

Printed Name | Father's DOB (MM / DD / YYYY)