

CARRIER SCREENING

INFORMED CONSENT

I request and give permission for Fulgent Genetics to test my sample for the Mount Sinai Services Expanded Carrier Screen.

Genetic screening is completely voluntary. I am aware that there are other screens available and that I have the choice not to have my sample tested.

I understand the following:

RISKS:

1. Screening can be performed on a blood sample or cheek (buccal) swab. There are risks associated with each sample type:
 - Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection.
 - The cheek swab can result in minimal bleeding if done too forceful.
2. I may need to give additional samples if the sample given does not contain enough DNA, is damaged in shipment or is missing information.
3. I may learn information about myself and/or family members that is not related to the medical issue for which this screen is ordered. This information may include:
 - Genetic risks for diseases that may develop later in life.
 - Disorders that do not have a current treatment.
 - The discovery of previously unknown information about family relationships, such as nonpaternity (someone who is not the biological father), or adoption.

Having this information may cause anxiety, guilt and psychological stress, which may lead to changes pertaining to self-image and expectations of self and of others, familial stress related to identification of other at-risk family members, difficulties obtaining life and/or disability insurance.

LIMITATIONS:

1. Genetic screening is complex and although the lab takes precaution, errors may occur. You and/or your doctor/genetic counsellor will be notified if there is an error with the screen.
2. The technical process of this screen has been validated by Fulgent Genetics. This screening test has not been approved by the U.S. Food and Drug Administration (FDA).
3. FDA approval is currently not needed for clinical use of this screen. Fulgent Genetics is authorized under Clinical Laboratory Improvement Amendments (CLIA)* and The College of American Pathologists (CAP)* to perform this screen.
4. Interpretation of screening results depends on the accuracy of the patient's clinical findings and/or family medical history and that any reported family relationships are true biological relationships. An error of a clinical diagnosis in the patient or family member can lead to an incorrect interpretation of the results.
5. As medical knowledge advances and new discoveries are made, the interpretation of results may change.
6. The interpretation of results are specific only for the screen ordered. This screen will not detect all variants in any evaluated

gene. Your referring doctor/genetic counsellor may suggest if more/ other testing is necessary in addition to this screen.

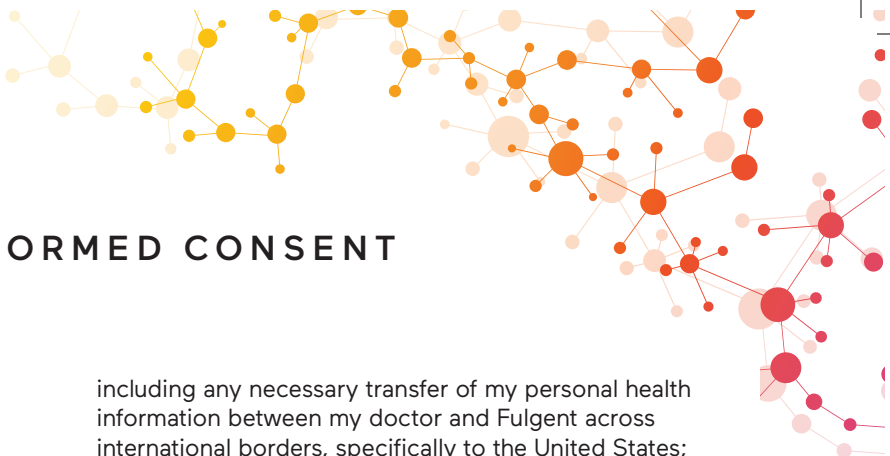
REPORTING:

1. Results will be reported to the ordering doctor/genetic counsellor and Mount Sinai Services for Genetic Counselling. Results are confidential and will only be released to other parties with my written consent.
2. Results should be interpreted by a healthcare professional (doctor/genetic counsellor) in the context of the patient's clinical findings and/or family medical history. All lab raw data are confidential and will not be released unless a separate consent is completed.
3. I understand that if the test result is **positive** it means that I may be a carrier of a condition because a disease-causing or likely disease-causing variant was identified. If the test result is **negative** it means that my risk to be a carrier for the disorder screened is reduced but not zero. This does not rule out any disease-causing variants in areas not covered by the screen and regions too low to reliably assess. It also does not rule out variants that are of the sort not queried by this screen. If the test result is **failed** it means there was not enough DNA submitted to perform the screen. I will need to provide another DNA sample.
4. The interpretation of the results will be based on the lab's current information at the time of analysis.

SAMPLE STORAGE/RETENTION:

1. The Fulgent lab will not return the remaining sample to individuals or doctors. Samples will be retained in the lab in accordance with the lab's specimen retention policy:
 - **Whole Blood:** Any blood specimen remaining after extraction of DNA will be retained for a period of 90 days after issuance of the final test result. At that time, blood samples will be discarded.
 - **Cheek (buccal) swabs:** Kept for a period of 90 days after issuing the final screen result.
 - **DNA Samples:** DNA samples remaining after testing will be kept for a minimum of 2 years after issuing the final screen result. DNA samples may be kept for longer periods of time in case of situations where any future screening is added on. Any further screening will only be performed with the consent of the referring patient.
 - **Unacceptable Specimens:** All unacceptable specimen types may be destroyed after 14 days of receipt, unless the return of the specimen is requested by the authorizing provider.
 - Genetic material and the raw data will be used for the patient's clinical purposes and will not be stored, used or sold for research.

*CLIA & CAP are lab accreditation granting organizations.



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ACKNOWLEDGMENT OF CONSENT:

By signing this Informed Consent, I agree that I have read and understand the information, and that I have had the opportunity to have any additional questions answered by a doctor or genetics professional to my satisfaction. With my signature below, I give my consent or consent on behalf of the patient for whom I am legal guardian to Fulgent and Mount Sinai Services to:

1. Perform the genetic analysis as ordered by my doctor;
2. Collect and process my personal health information and sample as required to conduct the genetic analysis,

including any necessary transfer of my personal health information between my doctor and Fulgent across international borders, specifically to the United States;

3. Perform the analysis on the obtained sample and to store it at Fulgent, in accordance with Fulgent’s specimen retention policy;
4. Inform my doctor and Mount Sinai Services Genetic Counsellor about the results of the genetic analysis;
5. Provide upon request to me or my doctor the raw data of the genetic analysis.

I am aware that I can withdraw my consent at any time by contacting privacy@fulgentgenetics.com and that I can decide not to receive the results of the genetic analysis as described in this Consent Form, as long as Fulgent is notified prior to releasing.

My signature below acknowledges the voluntary participation of myself/the patient in this screen but in no way releases the laboratory and staff from their professional and ethical responsibilities.

PATIENT SIGNATURE	DATE (MM/DD/YYYY)	PATIENT PRINTED NAME	DOB: (MM/DD/YYYY)
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Doctor/Counsellor Statement: I have fully informed the patient about the nature, purpose, capabilities, and limitations of and alternatives to the ordered screen, and answered any patient questions to their satisfaction.

DOCTOR/COUNSELLOR SIGNATURE	DOCTOR/COUNSELLOR PRINTED NAME	DATE (MM/DD/YYYY)
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By signing below, the partner is agreeing to a merged couple report. Merged couple reports can only be produced for patients and partners that have ordered the same genetic screen.

Partner Information (if applicable)

PARTNER SIGNATURE	PARTNER PRINTED NAME	DATE (MM/DD/YYYY)
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MSS is associated with Sinai Health System. Net proceeds from the program will be reinvested to support patient care and research at Sinai Health. Sinai Health has been involved in the validation of the medical content of the document and other program support. MSS takes responsibility for its overall content.

Compensation may be provided to physicians or associated parties for test kits ordered as a result of their consultation, subject to applicable law and standards of practice.

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